

**NIH ETHICS CONCERNS: CONSULTING
ARRANGEMENTS AND OUTSIDE AWARDS**

HEARINGS
BEFORE THE
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED EIGHTH CONGRESS
SECOND SESSION

MAY 12, MAY 18 and JUNE 22, 2004

Serial No. 108-88

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NIH ETHICS CONCERNS: CONSULTING ARRANGEMENTS AND OUTSIDE AWARDS

WEDNESDAY, MAY 12, 2004

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2322, Rayburn House Office Building, Hon. James C. Greenwood (chairman) presiding.

Members present: Representatives Greenwood, Bilirakis, Walden, Ferguson, Barton (ex officio), Deutsch, DeGette, and Allen.

Staff present: Mark Paoletta, majority counsel; Alan Slobodin, majority counsel; Ann Washington, majority counsel; Casey Hemard, majority counsel; Billy Harvard, legislative clerk; David Nelson, minority investigator; and Jessica McNiece, minority research assistant.

Mr. GREENWOOD. Good morning, everyone. This hearing of the Oversight and Investigations Subcommittee will come to order. I apologize for being a few minutes late. The Chair recognizes himself for an opening statement and, welcome to our guests. Thank you for being with us.

For years in America and American political history there was quote "honest graft" described by William Safire as "money made a result of political power without doing anything illegal, no longer considered permissible."

Later as described by Safire the practice "honest graft" became known as the revolving door. Government officials when they retire take jobs with private industry. In an article appearing on December 7, 2003 in the Los Angeles Times detailing the decade long practice of high level scientists at the National Institutes of Health receiving hundreds of thousands of dollars in fees to consult for private drug or biotechnology companies revealed yet a new form of honest graft, what I call the swivel chair. Now the government official does not have to retire, he can take outside consulting jobs with the drug industry as a scientific expert yet still have the privilege of being on the inside of the NIH, the crown jewel of the American biomedical research enterprise.

This swivel chair at NIH is still defended, to some extent, in the name of retention, recruitment and moral, to some extent as an entitlement of the scientific class. The controversial nature of this swivel chair policy at NIH is perceived when one considers its analogy in the context of Congress. I do not believe the American people would tolerate for one moment the notion that Members of Con-

gress could be allowed outside income to consult for private entities doing business before the Congress. In fact, the Congress eliminated the practice of members receiving outside income such as cash gifts for speeches. It took the straightforward approach of raising our salaries and eliminating outside income that raised conflict of interest issues.

Today this subcommittee examines the issue of outside income for NIH scientists posing conflict of interest concerns such as consulting for drug companies or cash gift awards to NIH senior managers from grantee institutions receiving or seeking substantial funds from that official's institute. As we pursue the facts over the nature and extent of these outside income practices one question is worth wondering: If this kind of reform was good enough for the Congress, why is it not good enough for the National Institutes of Health?

As I have noted before as the chairman of the subcommittee, the scandal is often finding out what not what is illegal, but what is legal. Consider NIH's policies on cash awards and outside consulting. Under current policies an NIH Institute director is permitted to accept a cash gift from a grantee or cooperative agreement holder with his institute provide it is presented as a "bona fide award" and meets the minimal criteria for such an award. If a grantee wants to reward or influence an NIH official, it can do so if the cash is called an award as long as there is adequate financial backing for such endeavors.

If a university seeking NIH funds wants to attract reward or influence an NIH official whose salary is paid by taxpayers to give a speech by paying cash to that official for his speech, that is otherwise part of his taxpayer supported official duties. He can do so without running afoul of criminal felony statutes and noncriminal ethics regulations by calling the event a lecture award.

For outside consulting by NIH scientists with drug or biotechnology companies under current policies established by then NIH Director Harold Varmus in 1995, there is no limit on the amount of compensation or the number of hours. On December 7, 2003 the Los Angeles Times revealed that high level NIH scientists, including some institute and center directors, received hundreds of thousands of dollars in compensation for consulting with drug and biotechnology companies. The next day, this committee began its own detailed investigation of these outside consulting arrangements only to discover that high level NIH scientists making higher salaries than that of the Vice President of the United States were not even required to file public financial disclosure reports.

Equally astonishing, this committee learned that prior to our investigation NIH employees were not required to provide the amounts of compensation they were receiving through their drug company consulting, not required to provide it to the public.

Even though the NIH has complied in providing a substantial amount of information in documents in response to the committee's request, as a result of these nondisclosure policies and slow rolling by HHS lawyers, to this day we still lack complete information on the amounts of compensations received by individual NIH scientists in many consulting arrangements over the last 5 years. We have been told that NIH only has the authority to request NIH em-

ployees to voluntarily produce information on past consulting agreements, and many have reportedly not responded.

If NIH scientists are too embarrassed to have these details publicly known, then that reluctance to divulge this information is a message in itself about the propriety of these arrangements. Thus, because of the HHS and NIH inability to respond, I am announcing today that the committee will be sending request letters to drug companies to get the amount data for individual NIH scientists consulting arrangements.

The controversy over outside consulting with drug companies is further underscored when one considers what has happened in the last few years to make working at the NIH more attractive, exciting and important. Many scientific personnel at NIH have boosted their salaries well beyond the caps in the Federal Civil Service System by converting themselves into consultant employees through the widespread use of what are called special compensation authorities under Title 42 of the Public Health Service Act. Not only can annual salaries be boosted by an extra \$50,000 or \$60,000, but under an arcane Office of Government Ethics legal ruling, highly paid Title 42 personnel are exempt from filing public financial disclosure reports, although recently some have been required to be public filers.

Through Federal technology transfer policies, NIH can now pay royalty income to NIH inventors for technologies they have discovered that have been commercialized. Congress has completed the doubling of NIH's budget, vastly enlarging the universe of unique and intellectually enlivened research opportunities at NIH.

Finally, in the post September 11th world, the NIH occupies a key leading role in assisting our bioterrorism defense efforts. But to proponents of outside consulting, notwithstanding all these developments, moral at the NIH will be damaged if the freedom to be put on a drug company's payroll is not preserved, even though we are told very few NIH employees engage in outside consulting.

The committee begins its consideration of these NIH ethics concerns by receiving testimony about the report of the NIH Blue Ribbon panel on conflict of interest policies released last week after 66 days of work. This panel was appointed by the Director of the NIH shortly after the December 2003 Los Angeles Times Article and the beginning of the committee's investigation on outside consulting. The co-chairs of the panel were Dr. Bruce Alberts and Normal Augustine, who will be testifying before us today.

The Blue Ribbon panel assessed the current status of conflict of interest policies with particular attention to outside consulting and made recommendations for improving. The panel states its recommended improvements are "needed to assure the continue deserved public confidence in the work of NIH."

We welcome our very distinguished witnesses from the NIH Blue Ribbon panel. And thank you for your public service and the quick response you delivered to the NIH Director.

By definition and by your description the panel's work was limited by a relatively short timeframe and by limiting yourselves to not investigating specific allegations or reviewing individual cases under investigation. The panel's work was a useful step, but it is

only the first step as the NIH, the Congress and the American public and interested stakeholders sort out the facts and the issues.

In general, the panel recommended that high level employees at the NIH should not engage in consulting activities with pharmaceutical or biotechnology companies, but that some NIH employees should be allowed to consult, but be limited to an amount equal to 50 percent of the employee's annual salary with no one source accounting for more than 25 percent of annual salary.

The panel also called for relaxing restrictions on earnings from outside teaching, writing and speaking engagements.

I look forward to discussing this report with the co-chairs, since I have many questions and I am troubled by some of aspects of the report.

For example, the report maintains that very few NIH employees engage in consulting agreements with drug or biotechnology companies. It also found "an extremely complex set of rules governing conflicts of interest at NIH. These rules are widely misunderstood by some of the very people to whom they are intended to apply, thereby creating uncertainty as to allowable behavior and adversely affecting moral."

If so few NIH employees engage in outside consulting, why allow it in any form replacing one confusing set of rules with another? Why not a blanket prohibition on the swivel chair?

While some of the rules may be confusing, it needs to be acknowledged that some rules are clear. The committee has investing NIH ethics concerns for over a year, along with several other NIH oversight activities. Unlike the Blue Ribbon panel, we have been looking case specific practices. It is clear from the cases we have reviewed that some NIH scientists are either very close to the line or have crossed the line.

We are serious about upholding the highest ethical standards at the NIH, and NIH scientists should not even be close to the line. Yet this has been the persistent problem at NIH for years, not because of confusion but because of a deliberate permissive attitude reflected in some NIH employee comments received by the Blue Ribbon panel.

In a June 1987 letter to HHS David Martin, the Director of the Office of Government Ethics wrote of the ethics program at NIH "My greatest concern, however, relates to the area of outside activities such that there occasionally appears to be a blurring of the distinction between what should be properly authorized as official business and outside activities."

In a November 22, 1991 letter to HHS Secretary Lewis Sullivan the Director of the Office of Government Ethics Steve Potts wrote "I am concerned, however, about the persistent weakness in the NIH outside activity approval system as it relates to scientists and doctors and NIH."

And in December 22, 1991 letter to NIH Director Bernadine Healy Mr. Potts wrote "We believe also that the permissive attitude of NIH toward outside activities has led to certain activities being approved without adequate documentation to support such decisions. Less than 1 percent of over 4,000 requests for approval of outside activities were denied. Moreover," he said, "approx-

mately 40 percent of the 553 requests we received were approved after the activity had already taken place.”

In its 1991 audit OGE reviewers wrote: “The permissive attitude at NIH toward outside activities and its fear that further restrictions of outside activities may hinder recruitment and retention of scientific personnel has also played a major role in the problems and issues we identified.”

One NIH official stated that if OGE is saying that NIH employees who are on the cutting edge of biomedical research are like other Federal employees and should be denied the right to talk about their expertise even though the subject matter is related to agency responsibilities and programs, then NIH does not agree. The official contended that NIH is unique and should be exempt from this restriction.

From its February 1992 report on employee conduct standards, the General Accounting Office found that NIH was one of five out of 11 agencies audited that because of overly permissive policies approved outside activities such as speaking and consulting that it appeared to be violated the standard of conduct prohibiting the use of public office for private gain. Keep in mind, these permissive practices took place under rules on outside consulting that are in some respects more restrictive than what the Blue Ribbon panel is recommending. In November 1995 NIH Director Howard Varmus loosened these consulting restrictions to “strengthen our ability to recruit.”

The Blue Ribbon panel report seems to handle the conflict of interest issues gently and seems almost blithely to accept the retention and recruitment arguments for maintaining some form of outside consulting and compensated scientific activities by NIH scientists. But as I constantly hear on oversight issues from the NIH and the FDA, do not give me anecdotes, give me data. Are there facts or information that back up these arguments about NIH’s ability or inability to retain or recruit? What are the turnover rates of the Title 42 personnel? What have the turnover rates been over the year for NIH scientists? Was NIH less of a research institutions before the November 1995 lifting of consulting restrictions? What have been the benefits to society from the consulting? What new drugs were developed?

Some questions are unanswerable, but are certainly with considering. What new drugs were not developed because the NIH scientists were devoting more energy about the drug company research and not the NIH research?

As Josephine Johnson of the Hastings Center noted in the March 12, 2004 issue of *Science* “If a scientist’s desirably as a consultant stems from her NIH post, can be sure that the advice and time she sells to industry does not already belong to NIH? Nevertheless, given the sometimes six figure sums involved, concerns should persist about whether salaried individuals can give their primary job the effort and attention it deserves while also understanding considerable consulting work given similar consulting arrangements in many of the Nation’s public and private universities the real question of the moment is should we abandon the idea of impartial disinterested science or should NIH be the last stronghold of this ideal?”

I am disappointed by the Blue Ribbon panel's lack of substantive analyses of the issue of bona fide awards. While the panel acknowledges that scientists who receive these awards are frequently required to prepare a lecture as an acceptance speech, it left unexplained the conflict of interest issues arising from the fact that these speeches are required in order to get the cash by a private entity possibly with substantial interests before NIH and are official duty activities of NIH scientists. I believe this matter of what constitutes a bona fide award and the serious conflict of interest issues raised by receipt of cash awards from prohibited sources warranted further consideration and thought by the panel.

In addition, if these awards are so important in raising the visibility of NIH scientists and recognizing the value of NIH research, why does NIH not collect and publish information listing these awards to promote itself and its importance?

We are all eager to hear from the Director of NIH, Dr. Elias Zerhouni. Since the committee has been engaged on these issues over the last year, I have had the pleasure of working with him. I believe Dr. Zerhouni has been a man of good intentions throughout and I hold him in the highest esteem. He has been earnestly attempting to respond to the committee's concerns and to help us to reach a conclusion of this investigation, if for no other reason than to lift the cloud of uncertainty felt by some NIH employees about this probe. When he has been adequately advised by the department, he has taken decisive steps to address the problems, but more needs to be done.

In my discussions with Dr. Zerhouni, I had hoped to complete our investigative work on NIH ethics concerns by the hearings to be held today and on May 18th. Unfortunately, the delays and obstinacy principally at the HHS Office of General Counsel in getting amount data on the individual consulting arrangements will extend this investigation beyond May 18th as we are now forced to pursue this data from the drug companies. As I have learned from experience, the truth will ultimately come out.

This hearing will be Dr. Zerhouni's first public response to the Blue Ribbon panel report and recommendations.

Dr. Zerhouni, I look forward to your testimony and working with you on mutual issues of concern, including the improvement of NIH's ethics program worthy of a great scientific agency with talented and valued employees.

And I now recognize the ranking member, the gentleman from Florida, Mr. Deutsch for an opening statement.

Mr. DEUTSCH. Thank you, Mr. Chairman. With unanimous consent put in Mr. Dingell's statement and Mr. Waxman's statement into the record.

Mr. GREENWOOD. Without objection.

[The prepared statements of Hon. Henry A. Waxman and Hon. John D. Dingell follow:]

PREPARED STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Last December, the Los Angeles Times revealed that a handful of high-ranking NIH scientists had accepted hundreds of thousands of dollars in consulting fees from pharmaceutical companies. The story, and this subcommittee's subsequent investigation, caused NIH to reexamine many of its conflict of interest policies, and

rightfully so. NIH is respected around the world for its scientific leadership and the high quality of its research. Probably the world's greatest biomedical research establishment, NIH's reputation for scientific integrity and independence is unmatched. It is therefore particularly disturbing that NIH scientists should give even the appearance of being influenced by the pharmaceutical industry in their decisions.

I have no doubt that most NIH scientists are carrying out their jobs according to the highest ethical standards. But some of what this subcommittee's investigation has exposed is very troubling. Dozens of NIH scientists have accepted very substantial sums of money from drug companies with few checks on whether those relationships posed conflicts of interest. All public servants must be sensitive to the reality and even the appearance of such conflicts, and an institution of NIH's scientific standing must be especially vigilant. America and the world must feel confident that NIH's research results are not biased by drug company influence. Because if we allow NIH's credibility to be compromised, we have all lost.

I commend Dr. Zerhouni for the steps he has taken to change the ethical rules that guide NIH. And I recognize that the "Blue Ribbon Panel" has made a good faith effort to minimize potential conflicts of interest. But more needs to be done. I am particularly concerned that some potential conflicts of interest will still go undisclosed. Full disclosure is essential for ensuring public confidence in the work of NIH.

I've asked the GAO to analyze the work of the Blue Ribbon panel, and I hope that GAO will be able to provide a roadmap to enhance the Panel's recommendations.

Many argue that if we don't allow NIH scientists to accept large payments from the drug industry, we will lose them to higher paying jobs in industry or academia. I am not ready to accept this conclusion. One heartening finding of the subcommittee's investigation is that the vast majority of NIH scientists are willing to do their jobs without receiving supplemental income from drug companies. Of the thousands of scientists employed by NIH, only a small percentage were found to be receiving money from drug companies. Apparently, the rest of NIH's scientists have found sufficient compensation in their government salaries and the opportunity to work at the world's leading biomedical research facility.

We are justifiably proud of NIH's long tradition of scientific achievement. We've always been able to trust the science that comes out of NIH. This is a legacy we need to defend and protect. Americans need to know that when NIH reaches a conclusion, that conclusion is based on hard evidence and the scientific method. We need to act now to impose appropriate conflict of interest standards so that America and the global scientific community can continue trusting in NIH.

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF MICHIGAN

Mr. Chairman, you are to be congratulated on this investigation into conflicts of interest at the National Institutes of Health (NIH). NIH is a national treasure, the flagship for scientific research into the causes and cures for diseases that have ravaged mankind through the ages and others that have arisen with devastating effect in more recent times. It has been so successful in fulfilling its missions that Congress, on a bipartisan basis, has increased its budget four-fold over the past two decades. Along with the increased funds have come increased tasks.

In general, we have been very careful not to earmark funds for research into specific diseases, trusting the NIH scientists to pursue the most promising research as they see fit. We have also passed legislation to permit private/public partnerships in the hopes of making promising cures available to the American people in an expeditious manner. This makes sense.

Unfortunately, certain scientists have been trusted to determine when their personal financial involvement with drug and biotech companies poses a conflict of interest with their responsibilities to the public. And those scientists have not been subject to rigorous review or full disclosure. Now we see that at least three Administrations have not only tolerated, but encouraged, the acceptance of monies, in some cases extraordinarily large sums, by NIH scientists from private companies with substantial interests in the decisions at NIH. The secret purchase of information and influence must stop.

Mr. Chairman, another activity that must stop is the lack of cooperation with this important inquiry. I agree with you that this investigation has been slow-rolled and stonewalled from its onset a year ago. We have yet to receive all the requested documents and interviews. It is my understanding that the Department of Health and Human Services has refused to supply at least one witness you requested for the hearing next week.

Moreover, the Department has broken with past practice in order to monitor, if not hinder, the inquiry. As you are aware, this Subcommittee has had a long-standing agreement with the Department that it could provide personal counsel to individual employees during staff interviews on particularly sensitive investigations, provided that no information from those interviews would be revealed outside the interview room. That agreement spans three Administrations and control of the Committee by both parties. Two weeks ago we discovered that the attorneys accompanying all department employees to these interviews were reporting back the contents of those interviews, and had informed the employees that they were in the interviews not to represent the individuals but for the purpose of reporting the content of the interviews back to the Department. This came as a surprise to both majority and minority staff and undermines the credibility of our work. I offer you the full support of the minority in whatever steps, including formal process, you may take to acquire the necessary cooperation from the Department.

This investigation is important—both to protect the integrity of the scientific work at NIH, and to protect the credibility of the work of this Subcommittee. Mr. Chairman, you have my thanks and my support as we continue the bipartisan work on this matter.

Mr. DEUTSCH. Thank you.

Thank you, Mr. Chairman, for holding this very important hearing into conflicts of interest at the National Institutes of Health. NIH is truly a critical agency that enjoyed bipartisan support for its work fighting diseases and cripple and kill millions of Americans. Yet it appears that the leadership of NIH may have fallen victim to a disease itself, and that is greed.

It is important to differentiate between the current and former leadership of NIH that have encouraged the option of corruption, the HHS lawyers that have facilitated the payoffs from drug and biotech companies and the thousands of the dedicated scientists that do such brilliant work solely for the benefit of their employers, the American people.

While the full extent of the corruption is unknown largely because of the stonewalling of the Department of HHS, there appears to be only 114 employees out of 17,526 that currently admit to providing consulting services to drug and biotech companies.

Today we hear from a so called Blue Ribbon panel appointed by the Director of NIH Dr. Elias Zerhouni, as well as Dr. Zerhouni himself.

The panel represented by its co-chair today, made 18 recommendations to reform the ethics program at NIH. They issued these recommendations in a 68 page report released last week.

To say that the report constitutes nothing more than an apology for the status quo does it a disservice. It is a report from a panel that blatantly refused to consider the most important facts. The panel apparently felt compelled to base its recommendation on their misplaced need to excuse the inexcusable.

I cite the executive summary, and I am quoting, "The panel did not investigate specific allegations or review individual cases." Nor, apparently, did it do much else except hear testimony from 32 witnesses over 4 days of public hearing, some 28 of which had a direct financial interest in maintaining the status quo. Three others are lawyers that developed or defended the rules that perpetuated the corruption. And finally, the former head of NIH that removed virtually all obstacles to acceptance of gratuities at NIH.

It would appear that the panel had at least some substantial amount of help in drafting this report from HHS General Counsel. Mr. Chairman, that office has facilitated destruction of much of the

legal basis for ethical standards in NIH and it has been largely responsible for the attempt to cover up the extent of the corruption at NIH from this subcommittee. Nonetheless, the panel members are responsible for this public report, and Dr. Zerhouni is the official who will be responsible for cleaning up the corrupt practices at the agency.

Again citing from the report section 5 recommendations page 60, "The panel believes that with careful oversight and monitoring the potential conflicts of interests can be effectively avoided." This is clearly not the case.

I am anxious to hear from the panel representative just how NIH is supposed to effectively monitor and oversee the for profit activities of its thousands of employees. I suggest that the report really proposes is the existing quality control system that might accurately be described as a system of careful twisting of the rules and an overlooking of the consequences.

I submit for the record a summary of what the panel should have had but did not consider, specifically: A spreadsheet prepared by NIH of the employees with current consulting contracts with drug and biotech companies; a series of PowerPoint slides prepared by the subcommittee staff off the information contained in that spreadsheet, and; a series of articles by David Williams from the L.A. Times that explores some of the stories in detail.

Dr. Zerhouni, I have two recommendations for you. If you are indeed serious about restoring the pristine reputation of NIH research, suspend every ethics official in the NIH that has approved a consulting agreement between a drug or biotech company and an NIH employee until real investigations, perhaps from the Office of Inspector General, confirmed that they made a vigorous effort to determine the extent of any potential conflict. Staff review of the documents in our possession today suggests that these ethics officer, by in large, saw their role as facilitating the consulting arrangements rather than protecting the government from conflicts of potential conflict. The NIH's own spreadsheet suggests that their facilitation was a success.

Finally, I would urge you in the strongest possible terms to end the practice today of NIH researchers taking anything of value from a drug a biotech company. The conflict is not defensible short of NIH having supervised each review and every task undertaken, every work product produced, every piece or advice provided the drug company and comparing them against current and former tasks that need to be taken by the Federal Government. Even then it is hard to imagine how the American taxpayer could possibly be assured that the employee on the payroll of a drug or biotech company is always acting in their best interest.

Mr. Chairman, again, I want to thank you for holding this hearing. I look forward to the witnesses.

I yield back any remainder of time.

Mr. GREENWOOD. The Chair thanks the gentleman and notes the presence of the chairman of the full committee, Mr. Barton. And we are pleased to have him here, and he recognized for his opening statement.

Chairman BARTON. Thank you, Mr. Chairman.

I want to commend you for holding this hearing.

I am going to ask unanimous consent that my formal statement be put into the record.

Mr. GREENWOOD. Without objection it will.

Chairman BARTON. I am just going to speak extemporaneously.

The NIH is an important asset to our Nation. As such, we doubled its budget over the last 5 years to I think a little over \$28 billion. There is not a member of this subcommittee or the full committee, or I would even possibly like the House and the Senate, that does not want the NIH to be absolutely totally successful.

I have the privilege to have a private meeting with Mr. Zerhouni, and everything that I know about you personally and the information that we exchanged indicates to me that you really want to do nothing but enhance the reputation of the agency that you head.

Having said that, NIH has not been reauthorized in over 10 years. There are some very controversial issues that your agency deals with, and the Congress has been reluctant to wade into the fray and engage in the policy debates that need to be debated if we are going to reauthorize the Institute.

It is my intention in this Congress to reauthorize the NIH, and I have been working on a bipartisan basis with Ranking Member Dingell, and I think we are going to be able to do that. We want NIH to succeed. But we are also concerned that as our staffs have worked on the policy side and as the oversight investigation staffs have worked together on this side, the administrative side, we have found NIH to be less than cooperative, and that's going to change.

Now, you can go back to your agency and you can tell your directors and all that the administrative officials that they can cooperate, you know, cooperatively or we will make them cooperate coercively, you know. We are going to get the information that this staff has asked for and we are going to share it on a bipartisan basis, and then we are going to see what recommendations, if any, need to be made.

I am very concerned about the fact that there are large honorariums and consulting fees being paid without any internal or external requirements for disclosure. There was a time in the Congress where a Member of Congress could accept an honorarium, I think we were capped at \$2,000 per speech and I think \$30,000 or \$35,000 per year. And those all had to be reported. They could be used for personal use, but they had to be reported and they had to be capped.

Apparently within your agency there are little, if any, controls on that and at least anecdotally there are stories of at least one individual getting a half million dollars. I do not know if that is true or not. But if that is true, at a minimum it needs to be reported and disclosed, and it might need to be banned.

Now the Blue Ribbon panel that Dr. Augustine chaired, I believe, held seven hearings over a 2 or 3 month period and made some recommendations that apparently have not been agreed with. Now, that could be wrong and you may bring that out in testimony. But we have to have transparency. We have to have accountability. And we simply must have the faith of the American people that the research grants that are given at NIH are given because of the merit, not because somebody got a big honorarium or speaking fee.

So, this is not a hearing that is being convened for a witch hunt. Again, we want the NIH to succeed, but we do want to put into place the proper checks and balances to make sure that the full faith and trust of the American people can be placed in the agency.

With that, Mr. Chairman, I would yield back.

[The prepared statement of Hon. Joe Barton follows:]

PREPARED STATEMENT OF HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY
AND COMMERCE

Thank you, Chairman Greenwood for holding this important hearing. The ethics concerns and the lack of public accountability associated with much of the outside consulting fees and cash awards received by NIH scientists is yet another reason the NIH needs to be reauthorized by this Committee.

It has been over a decade since the NIH has been reauthorized. Since that time, the restrictions on outside consulting have been lifted entirely. Rules on public disclosure have been weakened to the point that the Los Angeles Times reported that 94% of NIH's highest paid employees were not required to publicly disclose their consulting incomes. These highly paid employees included some scientists who were paid more than the Vice President of the United States. At the same time restrictions were lifted and public disclosure was minimized, the NIH did not even require the employees to tell the agency the amounts proposed or actually received in order to get the outside consulting approved.

I am well acquainted from my years as Chairman of this Subcommittee with the attitude often found at the NIH: the rules don't apply to us. Now I sense we are hearing a variation on this theme: If the rules do apply to us, they shouldn't. Such permissive attitudes and practices can no longer be tolerated. One can only wonder: if NIH can be so permissive about the most basic ethical rules in the Federal government, what does this say about NIH's ability to manage taxpayer dollars and, most importantly, ensure that taxpayer-supported research gets translated into cures?

The NIH is the premier medical research institution with nearly a \$28 billion appropriation. There must be greater transparency of NIH activities to hold this agency accountable for the taxpayer investments made. It is an enormous agency requiring much constructive oversight and the strong support of this Committee.

Continued public confidence in the work of the NIH must be assured, especially at a time when public-private partnerships should be strengthened. Technology transfer activities of the NIH have helped speed research from the bench to the bedside. These efforts have been successful without the need to place NIH scientists on industry payrolls.

The productive collaborations in clinical research of the Federal government, academia, and industry have recognized the distinct roles that each of these entities is best suited for. These roles should not be blurred.

Chairman Greenwood is to be congratulated for his leadership. In this hearing and others to come, I expect this Subcommittee to reveal the full nature of the problem of the NIH ethics program. This effort should be considered part of the broader work of this Committee to modernize and improve the authority of the NIH.

I especially want to welcome Dr. Elias Zerhouni, the Director of the NIH, and I thank all the witnesses for appearing before the Subcommittee. I look forward to your testimony.

Mr. GREENWOOD. The Chairman thanks the gentleman and recognizes for an opening statement the gentle woman from Colorado, Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman.

And in the interest of time, I would ask unanimous consent to put my entire opening statement in the record.

Mr. GREENWOOD. Without objection it will be put in the record.

Ms. DEGETTE. I just would like to mention one thing that really struck me when I was reading the background materials for today's hearing and also a number of the newspaper articles and other materials about this issue. The Chairman and I had been working for some time on legislation around human subject protection, as you know, Dr. Zerhouni. And what struck me was in previous years

some of the NIH researchers who were on the NIH payroll also had financial interests in drugs that were being provided to people who were in these studies. And this was not disclosed to the individuals in those studies and, in fact, a couple of people died as a result of some of the drugs they were given in the studies.

The reason I bring this up is because I have always assumed, and I think Mr. Greenwood has too, that when we are talking about human subject protection and our legislation, we are sort of talking about some of these renegade researchers. And what struck me was these are NIH researchers. These are researchers, the very top tier researchers in our Nation, and yet they were conducting human subject research without full disclosure to the patients.

I understand since those studies, which were in recent years, the NIH has subsequently instituted a rule that prohibits such conflicts. But that has only been in recent years. And it just strikes me, Mr. Chairman, that a little part of us, a little footnote to this whole investigation is the issue of human subject protection because if this can happen at our flagship institution in this country, think about what is going on everywhere else.

And with that, Mr. Chairman, I will yield back the balance of my time.

[The prepared statement of Hon. Diana DeGette follows:]

PREPARED STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF COLORADO

I want to thank the Chairman for holding this hearing today. Conflicts of interest issues are so important, particularly in the realm of health and science because of the vast research potential that can help mankind and the direct impact on individuals. I am very glad to be here today to try to get at the bottom of what I think is a real scandal.

This issue is of particular interest to me and in fact I have legislation, that I have worked on in cooperation with our esteemed Chairman, that aims to put key protections in place for human research subjects. In working on this bill, one of the things that has become clear is that addressing conflicts of interest issues are crucial; not only is it important to inform patients whenever conflicts of interest exist that could directly affect them, but we need to work towards eliminating such conflicts especially in clinical trials.

I commend Dr. Zerhouni for recognizing that problems exist at the NIH and for convening the Blue Ribbon Panel (BRP) to look into the situation. I think this was an important first step. However, I will be honest and let you know right from the start that I think very serious shortcomings exist within this report and it doesn't give me much confidence that the changes I think need to happen will be made.

Just this morning there was a Los Angeles Times article alleging that although the Blue Ribbon Panel found permissive practices at the NIH, they were not detailed in its final report. I don't understand why the BRP did not consider it important to, at the very least, outline a few examples of the problem. I will be very interested in our witness's explanations as to why they made this choice and how they think they can solve a problem, if the depths of the problem are not illuminated.

This is just one of the reasons that I believe the proposed changes in the BRP report are seriously flawed. Let me cut to the chase about why else the recommendations aren't going to help. Mr. Chairman, unless there is a blanket restriction on outside compensation serious conflicts of interests will continue to exist.

For example, currently honoraria, as such, is not allowed. This ban is essentially meaningless because NIH employees are allowed to receive thousands of dollars in consulting fees, awards that come with significant monetary prizes, etc. So if the BRP recommendations are followed and certain restrictions on consulting fees are instituted for certain employees, but there is no change to regulations regarding receipt of bona fide cash awards, then surely we will see a shift to more and larger cash awards being given to NIH employees from outside companies. The money influx won't change; it will just shift around so that it fits the new rules.

One of the things that struck me in reading the report is the notion that many employees, including senior level scientists are increasingly demoralized by the scru-

tiny and criticism the NIH has received recently in regards to this issue. This is really too bad because these staff members are simply doing what the rules allow them to do. However, I think that there is an implication in the report that somehow it is the media and Congressional condemnation that is the problem, rather than the issue itself. It is not the fault of the scientists that they are under a "cloud of suspicion" as it is characterized in the report, it is the unethical system that has created this situation.

The good news is there is a very easy solution. Clean up the system entirely and the "cloud" and all the investigations and news stories all disappear. It seems crystal clear to me. Remove big money from the equation entirely and the integrity of that great institution that is the National Institute of Health is restored.

Mr. Chairman as you may be aware two Members of this Committee, Mr. Brown and Mr. Waxman wrote ten drug companies in March asking about payments to NIH employees. Only two provided responsive answers, Schering Plough and Abbott Labs.

I ask that both responses be added to the record because they contain several instances of payments that are apparently current but that NIH did not include on its spreadsheets. This may be because the employees did not report the income as required or it may be because the information collection apparatus at NIH failed to include those consulting payments in response to your request.

In either case it is disturbing that an Agency that makes the sanctity of data collection an article of faith seems does not seem to be up to supplying data requested to Congress. Apparently, this Committee should seek information directly from firms in the pharmaceutical and biotech industries since the government agency cannot provide a complete record.

Thank you again for holding this hearing and I look forward to hearing the testimony of our witnesses.

Mr. GREENWOOD. The Chair thanks the gentlelady, and recognizes the gentleman from Oregon, Mr. Walden, for an opening statement.

Mr. WALDEN. Thank you very much, Mr. Chairman.

I have a prepared statement I would like to insert in the record.

And I just want to say, like my other colleagues, I think we are all very supportive of the NIH and the great work that is done by your extraordinary scientists to bring us cures to disease and illness and new research for drugs and other techniques to improve the lives of Americans. And just as NIH is on the cutting edge of research, I think what we are saying is you need to be on the cutting edge of ethics, too. And the problems that have come up are serious and they are ones that need to be addressed. And I know that you have inherited these as you have come on board only recently, and a lot of changes occurred upwards of 10 years ago. But they are now out there and we are going to look at them closely, and we should. Because the research needs to be above question both at NIH and every other institution in America, as well as in journals where they publish medical research, too. We need to know that the information being provided, the research that is being done is above question when it comes to the ethics. And I know you agree on that. So look forward to working with you on this.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Greg Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF OREGON

Chairman Greenwood, thank you for holding this hearing.

I am an enthusiastic advocate for the National Institutes of Health. NIH research yields miraculous breakthroughs that save lives and dramatically improve the quality of life for those with once-untreatable diseases and medical conditions.

I am proud that Congress kept its commitment to doubling the NIH budget. I supported this ambitious endeavor every step of the way.

One thing that we have been abruptly reminded of by recent news accounts is that the questionable actions of a few can tarnish the good, honest work being done by others. Additionally, even the appearance of impropriety and conflict-of-interest can have a devastating affect. Congress and the American taxpayer have invested in NIH, and in a way, we place our hopes and wishes in the hands of NIH researchers. These hopes for a cure and wishes for loved ones to recover from illnesses are more valuable than any cash award or stock option that NIH researchers and staff might receive from extramural consulting agreements.

I applaud NIH Director Zerhouni's initiative in forming a Blue Ribbon Panel on Conflict of Interest Policies. Now that the Blue Ribbon Panel's report has been released the hard work begins. Do the Panel's recommendations go far enough? Will the recommendations truly avert conflicts of interest—both real and perceived? If the answers to these questions are not “yes,” then work remains to be done. The report's recommendations are a good start. I am interested to hear how these recommendations will be put into practice. Finally, I challenge NIH to press forward and continue to find ways to strengthen these policies, so that the hard-earned and well-deserved image of NIH is not tarnished.

Mr. GREENWOOD. The Chair thanks the gentleman, and recognizes the chairman of the Health Subcommittee, the gentleman from Florida, Mr. Bilirakis for an opening statement.

Mr. BILIRAKIS. Thank you. And thank you very much, Mr. Chairman. And, again, my gratitude, too, for you holding this hearing and for all the investigations you all have conducted.

Drs. Zerhouni, Alberts and Augustine, we thank you of course for taking time to be here and for all the work you have done leading up to this hearing.

I had not intended to make an opening statement. I had intended to come in here and just sort of listen to you all before jumping to any conclusions. And I would like to think that I have not jumped to any conclusions.

We hold these hearings to learn, and we certainly should not be prejudging before we listen to you and have an opportunity to ask you questions. But I would say that you have got to know that we are besieged by our constituents and by disease, many many disease-specific groups.

I have chaired the Health Subcommittee for quite a few years. I do not think I knew that there were so many diseases out there. It is just amazing. I sometimes feel, I do not know, like maybe an undertaker or whatever it is and particularly so when the constituents will come in or, as I said before, representatives of disease-specific groups with a child who is ill with a certain disease. And so many comes in, ALS, and whatnot. And what do they ask for? They beg for an increase in research funding at the NIH.

And I have to tell that we formulated a sort of a policy here sometime ago, going back to when the other party was in charge, where you know we did not think that this ivory tower of the Congress should make decisions on how much money should go to research for a specific disease. We do not know. We figured, you know, they might be on the cusp of a real breakthrough in a particular disease and we are we to basically say. And Dr. Zerhouni have discussed this. And who are to basically say that you have got to shift dollars from this to this, or whatever the case may be.

And yet these same people that are already heartbroken after they have sat down and talked to me and other people on this com-

mittee and in this Congress, and they pick up the newspaper and they read some of these things that are taking place.

Now, you know, is it truly a conflict of interest in terms of does it play a part in the decisionmaking in terms of where the dollars go for research, which specific disease and which specific research? I do not know. But I am here to tell you, and I know you are intelligent enough to realize this, that perception and image is really sometimes a hell of a lot more significant than fact. So how much these families feel when they pick up these newspaper articles and read about this stuff and whatnot.

So this is critical. And as Chairman Barton said, you know, we double funded. We made a promise back in the mid-'90's, and I guess there are quite a few promises that we do not fulfill; I think we intend to but we do not. But that is one that fulfilled. And yet I just do not think that the people at NIH are doing their share in terms of fulfilling promises to the sick people of our country regarding their disease and whatnot.

I have often been very concerned and curious, and curious underlined, as to how NIH allocates the funding and whatnot and what criteria they use. And I am not sure that we have ever really gotten a handle on specifically how what criteria you use. But some of these things that are taking place, the consulting fees and the speaking fees and whatnot, playing a part in all that, well whether they are or not, I don't know. But it sure as heck is a perception out there, reasonably so, that that is taking place.

So I hope that you do a good job here this morning trying to explain to us, maybe answer all of these concerns that we have. But not only for ourselves, but also for the sick people out there in America who depend on you so very much. Thank you.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman for his insights.

Prior to introducing our panel, the Chair would ask unanimous consent that this binder be incorporated into the record. It includes several pieces of correspondence from the Department of Health and Human Services, a series of articles from the Los Angeles Times and the Blue Ribbon report is incorporated in here, as are spreadsheets supplied to this subcommittee from the NIH concerning outside consulting agreements. And without objection, that will be incorporated into the record.

[The information referred to appears at the end of the hearing.]

Mr. GREENWOOD. And now I have the privilege to introduce our panel. Thank you for your patience and listening to our opening statements.

And the first of our witnesses is the Honorable Elias Zerhouni. Dr. Zerhouni is the Director of National Institutes of Health. And let me say again and for the record, I think you are the best thing that ever happened to the NIH. I think the skills that you have brought toward reorganizing the NIH, to making its mission clear, the administration of the NIH, your vision are exemplary and I think your commitment to ethics is second to none.

And I regret that—I know that you would have liked to have been spending a lot more time working on the mission of NIH than responding to our requests, and I am sorry for that. We have im-

portant work to do. We are going to get it done. And I am very optimistic when this process is over, we all will be better off for it and so will the NIH, and so will all of the patients, that Mr. Bili-rakis has just referred to.

We also have with us Dr. Bruce Alberts who is President of the National Academy of Science. And we welcome you. We thank you for your service in heading up this Blue Ribbon Commission.

And we also have Dr. Norman Augustine, Ph.D, Co-Chair of the Blue Ribbon Panel on Conflict of Interest Policies for the NIH.

Welcome to all of you.

It is the practice of this committee to take its testimony under oath, and so I need to ask if any of you have any objections to giving your testimony under oath? I see no objections.

I need to advise you that pursuant to the Rules of the House, you are entitled to be represented by counsel. Any of you request to be represented by counsel? I would think not. Okay.

In that instance would you rise and raise your right hands, please.

[Witnesses sworn.]

Mr. GREENWOOD. Okay. You are under oath.

And Dr. Zerhouni, the floor is yours for your opening statement.

TESTIMONY OF HON. ELIAS A. ZERHOUNI, DIRECTOR, NATIONAL INSTITUTES OF HEALTH; BRUCE ALBERTS, PRESIDENT, NATIONAL ACADEMY OF SCIENCE; AND NORMAN AUGUSTINE, CO-CHAIR, BLUE RIBBON PANEL ON CONFLICT OF INTEREST POLICIES

Mr. ZERHOUNI. Thank you very much, Mr. Chairman and members of the subcommittee, ranking member.

I am pleased to have this opportunity to be here and testify about our agency's ethics program. And before I do, I would like to really tell you that my intent and the intent of the agency is to work in parallel with you and your concerns and address them fully. I do not think the American people can afford to have an agency like NIH with any taint, shadow, or cloud over its head. So you have my commitment, and I think you have the commitment of all of NIH to do it as quickly, as effectively as we can within the constraints that you well know are always around a complex agency like the NIH.

So having said that, I believe that NIH has had great success in improving public health thanks to the resources you mentioned provided by the Congress and the President and the talent of our scientists. But without the trust of the American public, there is no progress that will be possible, and we need to address that.

This trust must be sustained. This committee, the subcommittee has raised questions about the NIH ethics process. Your questions must be answered because our public health mission is too important to have it undermined by any real or perceived conflicts of interests.

I want to personally thank you, Mr. Chairman and members of the subcommittee, for helping me in identifying what you perceive as weaknesses in NIH's ethics policies and systems. The Chairman has supported our efforts to review and reform ethics rules and procedures of the agency. Mr. Chairman, I also appreciate very

much your leadership, your fairness and the constructive guidance that you have provided me and NIH throughout this process. We are looking forward to continuing to work with the subcommittee in a process that I agree cannot be finite because this situation evolves, in that the relationship of science, industry, development of new treatments, and new cures is one that is constantly changing and we need to be able to be adaptive to that reality.

First, let me tell you how we internally within the authority of the agency, started to address these issues before the media reports. In July of 2003 as we started looking because of your inquiry into awards. We then immediately realized, I realized and I made the observation that the consistency of our rules across the complex agency were not what they should be. And when I learned of that and evaluated that, we immediately moved to develop a trans-NIH ethics advisory committee that would report directly to me in my own office to review the activities of all high level officials and of all relationships related to industry, biotech, or any relationship that could be construed as influencing a granting decision or a resource allocation decision. That was step one.

Let me give you an example. Because of this panel, we were able then to instruct that all existing consulting relationships with pharmaceutical or biotech firms be stopped and resubmitted to this trans-NIH ethics advisory committee to address this issue of blur that some of you have mentioned and resubmit it to the advisory committee for review and reapproval before they could proceed.

Working through the Department of Health and Human Services, we looked at the issue of disclosure. Chairman Barton raised the issue of a \$500,000 award, I am not clear about what that is. I suspect this is a prize that was given to one of our directors, and I believe that was disclosed publicly. But when you looked at the disclosure levels, you realized that because of Office of Government Ethics rules related to the payment mechanism that we used, that through this mechanism you could have internal disclosure—and let me make sure everybody understands.

We always have internal disclosure of these activities as they occurred. But external disclosure would not occur.

So we immediately asked the HHS and the Office of Government Ethics to close this inadvertent loophole in ethics regulation that does not require public disclosure of financial statements of some of NIH's most senior and highest salaried personnel. OGE approved our request and extended a number of public filers at NIH. As a result, all senior scientific personnel within the jurisdiction of the NIH Director are now required to file. That includes directors of institutes and all their deputies and anyone in charge of a granting program.

This week we submitted a second request to the Office of Government Ethics. Following the Blue Ribbon panel reports, I felt that it was time to move and extend because we heard the recommendation. We are now asking that all policymakers and those who marshal any resource in the public interest be required to file public financial disclosure reports. Our request to the Office of Government Ethics relates to 500 new additional positions that we would like to have disclosed.

As a result of your inquiries, we learned that the majority of NIH scientists who consult for pharmaceutical or biotechnology companies are not required under current rules to disclose the specific amounts and type of compensation. They have to disclose the relationship. But because of the rules that we are under, which are not NIH rules, these are government-wide rules, we could not request, supposedly, that amount. We have changed that in the context of current agreements. I asked that this rule be changed, and we were able to have employees submit these compensation amounts for all current and future consulting arrangements. And I think we submitted all of that information to your committee, subcommittee, Mr. Chairman, in March.

The issue of not being able to provide you all of the information that you needed, frankly, goes beyond my own authority to do. And it relates to the balance between the Privacy Act and the regulations that we can effect. And I think your staff has been well informed of that, and you have my commitment that whatever I can do within the rules and regulations and the advice that I receive, I will do. And this is my promise to you.

Finally, I created a Blue Ribbon panel because I realized, as you did, that in fact these issues were not just of marginal changes or misinterpretation. I believe personally, given my previous experience, that when you see a situation like this it is not just an accident. A system is designed to produce the results that you observe. So I believe right away that what we needed to do was do a system review. And I asked that the Blue Ribbon panel be formed to review existing laws, regulations, policies and procedures under which NIH operates. And I asked the committee to leave no stone unturned. I put no limits on their ability to obtain data, obtain information except that I felt that it was very important, and as I expressed to you Mr. Chairman, it was very important in this situation to state correctly what the problem is and continue in the work of the investigative process of all of the other things that have happened, that I do not think we can have the period of time while we deliberate glaring deficiencies will remain uncorrected.

So that was my goal here, and I think we have made some progress. And I agree with you that we have to look at balancing issues that come from that. I told the Blue Ribbon panel that the principles that we, NIH, myself wanted to apply, and we have been public on that.

No. 1 is transparency. No. 2 is full disclosure, and there is a difference between the two. Full disclosure internally is not fully transparent. Transparency to me relates to the interaction with the public. Full disclosure means do you have the exact content of the relationship well understood by the third component, which is an independent peer review mechanism that understands the science, not just ethics officers who may be well versed in the law of ethics but not well versed in the details of how science gets done.

And fourth, a monitoring process that will allow us to make sure that we are not going to deviate in the future from those principles.

I also have to tell you as NIH Director that although it would be easier, quicker, more satisfying to basically create a blanket prohibition, the reality of science is such that you do need to have interactions between scientists and their colleagues both within

academia and within industry. It is also a public interest, a policy interest of the United States to have translation of these findings be effective. And we have heard that through the many admonishments that Congress has asked our agency to follow. And yet, at the same time, we cannot forget that the primary interest is the public trust.

So we have three interests; public trust first, making sure the translation is effective. But to make that translation effective, you do need the best people that you can recruit. Those three things are very hard to balance, and I want to testify to the fact that we should keep the dialog open. And I am more than happy to provide the data and the information that would enlighten all of us together into what is the best policy framework that we need to develop.

I have reviewed the panel's recommendations. I find them to be constructive and it's a good approach to improve the NIH ethics program. I think that we need to implement the recommendations of the Blue Ribbon panel which improve the trajectory of where we want to be, and do it as diligently as we can either within my authority and if it's not within my own authority, I will work with the department, and the Office of Government Ethics to implement these recommendations as we go forward; modified, obviously, by the process that we're undergoing with you, Mr. Chairman.

In sum, I think these actions have strengthened NIH, the actions we have taken have strengthened NIH's process not to the point of perfection. But let me state here just as in a concluding portion of my testimony, what I think is essentially different about what is being proposed.

One, policy interest No. 1 is public trust. How can we ensure public trust? Well, make sure that no individual who is responsible for program funding decisions and recommendations or professional management of grants or review of grants—we have a very balanced process at NIH with multiple levels of checks and balances. It's very hard for me to see how someone alone can have a granting capability. However, that being said, I think that the recommendation of the Blue Ribbon panel that excludes any and all officials that have those responsibilities from any consulting with not just pharmaceutical and biotech companies, but also paid consulting from academia, is a good recommendation. I think we should implement it and it will preserve, give me, Director of NIH the assurance that there is a layer of government scientists which is completely immune to any potential interference. So that I think is a step that we need to do. This is pretty different than whatever happened before and whatever happens in universities or any other institution. This is an innovative step and I think it's a good step. And I think we need to take that.

I will reaffirm the prohibition against NIH scientists conducting research involving human subjects having financial relationships with any organization whose interest could be effected by their research. We have always used that rule. I am not sure that transgressions occurred. We should look at that. Nonetheless, the principle should be implemented as we speak today and we should be reaffirming this principle making sure it sticks.

I will propose that employees engage in compensated outside activities be prohibited from compensation in the form of stock or other forms of equity ownership. This is a major departure from prior policy. This is a recommendation of the Blue Ribbon panel that does not apply just to employees with responsibilities, but it will apply to every employee of NIH. This is, I think, a major move and I think we should give credit where credit is due, and that is the Blue Ribbon panel giving us a clear recommendation in that regard.

I will set in place policies and procedures which give full consideration of the appropriateness of recusals. I personally believe that recusals should be used only in the most limited circumstances when the employee has an unavoidable conflict, like for example a spouse working for an organization. But recusals that relate to the authority of the employee should be limited to the most extreme exceptions. There may be some, but we have to be very careful.

Principle two is increase transparency. In this case, working with HHS and OGE, as I told you, we have increased the public disclosure requirements. I will aggressively seek additional authorities to require more employees to disclose their outside activities where appropriate, including disclosure of relevant outside relationships and financial holdings in connection with research, publications, speeches, inventions, clinical research. The Blue Ribbon panel has considered this issue.

And let me just state the principle, I think, that we, NIH Director and my own directors, have stated publicly in a testimony in the Senate when asked whether there is any reason why you would not want to disclose an existing outside relationship. My answer to this is there should be no reason. If you cannot disclose that relationship, then you should not have that relationship. That is a clear principle I want to be on the record to tell you that this is what I believe in, this is what my scientists believe in. It is the rules and regulations, complex as they are as pointed out by the Blue Ribbon panel, that prevented this clarity from occurring.

Let me tell you, I am committed to make sure that whatever we need to do we will do, so that in the context of relationships with industry, biotech, any conflicting relationship; and that we find ways of making sure that that relationship is publicly disclosed.

I understand the Privacy Act issues. I understand that people in their outside time on their own time have the right to privacy. But when it comes to activities that are so closely related to their government function, I think we should exclude that from the general government ethics rules under which all agencies of the government are working. So we will look forward to find creative ways of making sure that that principle of full transparency be implemented, however, we need to get there. It may take us some time. We can do what we can do today, but frankly this is a principle that I want to be clear about: increasing the transparency.

There is no doubt also that the rules do prevent, as they stand today, fair, good, honest scientific interchange in the form of writing and teaching and reviewing and conferencing with colleagues. This is something that the Blue Ribbon has looked at. For activities under very limited dollar amounts and other activities, I think as Director of NIH, as a scientific manager, we have to be very careful

to not put that in the same category as drug company business relationships. That's the bread and butter of scientific interactions. I hear your comments, I understand your concerns but I plead with you to be open minded about the academic activities of our scientists. They are important to science.

And last, we will establish effective monitoring and oversight mechanisms. We want to have a central data base that will record all of those activities. One of the issues we found is the disconnect sometimes between the very complex forms. And I have to tell you, the Blue Ribbon panel got an education in the law of ethics about this. If you knew the number of forms and requirements; 520's, 278s, 450s and all of those things, you can see how the employees really become confused. We need to clarify and simplify it and have it in one place so that the recusal, if it ever exists for that individual, is in the same place as the disclosure from that scientist. We want to commit to build probably a paragon, an example, of how you can manage ethics with a transparent fashion by having this central data base and full disclosure.

So I just wanted to convey to you that we want to work with you. I cannot afford, nor can our scientists afford, any sense that we are transparent and not willing to reform as deeply as we need to reform so that this taint that you are worried about, concerned about disappears.

With that, Mr. Chairman, I'm ready to answer any of your questions.

[The prepared statement of Hon. Elias A. Zerhouni follows:]

PREPARED STATEMENT OF ELIAS A. ZERHOUNI, DIRECTOR, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

NIH's mission is to generate new knowledge to improve health. The outcomes of NIH research affect the lives of every American and increasingly people around the world. Medical research leads to new diagnostics, treatments and prevention strategies—and these medical interventions must be founded on the veracity of the data and on the unimpeachable integrity of the individuals who conduct the research and oversee the research enterprise.

Recently Congress has questioned the relationships of some NIH employees with outside organizations. Our public health mission is too important to have it undermined by any real or perceived conflicts of interest. And to this point, I am aggressively developing and implementing new conflict of interest policies, revamping review of activities with outside organizations and working to increase transparency by expanding the number of employees who file internal and public financial disclosure reports.

I want to personally thank Chairman Greenwood and Members of the Subcommittee for helping me to identify potential weaknesses in NIH's ethics policies and systems and for supporting my efforts to review and reform ethics rules and procedures at the Agency. I appreciate both your leadership and the constructive guidance you provided on this very important issue.

New and Ongoing Changes to NIH's Management of Conflict of Interest:

I want to describe actions I have taken in response to concerns about NIH's management of conflict of interest.

I began reviewing ethics rules, policies and practices last July, when this Subcommittee raised questions about NIH employees receiving lecture awards. I believe NIH scientists must remain eligible to receive recognition for their work in the form of legitimate awards. However, NIH scientists should not be accepting awards that are merely a ruse to provide compensation, and we will develop a system to increase uniformity and track the determinations of NIH's senior ethics officials as to whether an award can be accepted by NIH employees.

On November 20, 2003, I wrote to all senior managers at NIH advising them to exercise great prudence in entering into any arrangement that could reflect poorly

on NIH or could create the appearance of conflict, *even in cases where the arrangements are permitted by law* (emphasis added).

In the same memorandum, I announced the creation of the new NIH Ethics Advisory Committee (NEAC) in the Office of the Director to provide independent peer review of activities involving outside organizations. The NEAC, which conducted its first meeting on January 20, advises the NIH Deputy Ethics Counselor (DEC) on conflicts of interest and helps to ensure that activities involving acceptance of compensation from outside sources receive uniform oversight at the NIH. NEAC reviews applications for proposed activities with outside organizations that stand the greatest chance of posing risks to NIH's objectivity, or appearances thereof, including, where an award is valued at \$2,500 or more; where total income from an activity with an outside organization exceeds \$10,000 or is unknown; where outside compensation is in the form of equity; where the activity involves a drug or biotech company; or where the activity involves senior NIH leaders (e.g., scientific and clinical directors).

Co-chaired by the NIH Deputy Ethics Counselor (DEC) and Deputy Director for Intramural Research, the NEAC consists of ten rotating members and two ex-officio ethics advisors, all of whom are full-time federal employees. The rotating members are nominated by IC Directors and appointed by the Co-chairs. Membership represents the categories of employees submitting proposals to the NEAC, including IC Directors and Deputy Directors, Scientific Directors, Clinical Directors, Extramural Directors, OD Senior staff, and others.

During the centralized NIH review, committee members review each proposed activity to help assess whether it creates an actual or apparent a conflict of interest. The committee reviews the proposals based on criteria set forth in the Standards of Ethical Conduct for Employees of the Executive Branch promulgated by the U.S. Office of Government Ethics (OGE) and the supplemental Department of Health and Human Services (HHS) regulations.

To ensure oversight of activities that had already been approved prior to the creation of NEAC, we also instructed that all existing consulting relationships with pharmaceutical or biotechnology firms be stopped and resubmitted to NEAC for its review and input, before they could be reapproved, if appropriate, by the NIH DEC.

The Inspector General of the Department of Health and Human Services and the General Accounting Office also initiated their own, separate reviews of ethics processes at NIH. In addition, OGE accelerated its regularly scheduled review of the NIH ethics program. We welcome these inquiries and are cooperating with the various reviewers.

On January 12, 2004, at my request, Dr. Raynard Kington, the Deputy Director of NIH, was appointed to be the new Deputy Ethics Counselor for the Agency. Commensurate with his appointment, the role of the NIH DEC has been expanded beyond the staff of my office and the Institute and Center Directors to include Institute and Center Deputy Directors, Scientific Directors, Clinical Directors and Extramural Program Directors.

Regarding the important issue of public disclosure, working through the Department of Health and Human Services, I asked that the Office of Government Ethics grant approvals to require increased public disclosure of financial statements of some of NIH's most senior and highest-salaried personnel. OGE approved the request on February 6, and as a result, all senior scientific personnel within the jurisdiction of the NIH DEC are now required to file public financial disclosure statements. Although many of these individuals were already filing public financial disclosure forms, they will now be required to do so. Recently, a second request was submitted to OGE to require additional high-level personnel at NIH to file public financial disclosure reports.

In addition, because the majority of NIH employees who file financial disclosure forms are required to use the OGE-450 financial disclosure form, which does not request the amounts of compensation paid by outside organizations, and because the approval process focuses on the nature of the activity and the identity of the outside organization rather than the compensation paid, the amounts paid to NIH employees in connection with their activities with outside organizations has in many cases not been collected or reported either internally or externally. I requested that the Department ask OGE to revisit this approach and, as a result, NIH employees are now required to submit these compensation amounts for all current and future consulting arrangements in their request for approval of activities with outside organizations. Furthermore, to the extent that additional NIH employees will be required to file public financial disclosure forms, these amounts will be collected and reported on such forms.

As part of our internal policy review, we are also asking employees to disclose compensation amounts for expired activities with outside organizations. I personally

believe we should know those amounts, and so I requested that the Department work with OGE to find a way, consistent with the Privacy Act, which places limits on collection of identifiable information by the federal government, to ask for these amounts. The Department was successful in doing so, and so we have been able to ask employees for these dollar amounts. We have carefully considered, including internal discussions with legal counsel and others, to what extent we can and should order that employees must provide this information instead of voluntarily requesting it. After such consideration, it is our understanding that asking for this information on a voluntary basis is the most appropriate and prudent way to proceed. We have also been cooperative in providing this information we have collected for our internal policy review to the Subcommittee where it has asked for the information.

The Blue Ribbon Panel:

Finally, I created the Blue Ribbon Panel on Conflict of Interest Policies to review existing laws, regulations, policies, and procedures under which NIH operates regarding real and apparent financial conflicts of interest where compensation is received by employees. I also charged the Panel with reviewing public financial disclosure rules and procedures. The panel began its review on March 1 and made its recommendations to the standing Advisory Committee to the NIH Director May 6. The recommendations were adopted by the Advisory Committee and submitted to me on the same day.

The Blue Ribbon Panel operated with extraordinary speed. Norm Augustine and Bruce Alberts, the panel's co-chairs, as well as all the panel members, served with distinction and performed a great public service. They deserve gratitude and respect, and I thank them for their extraordinary efforts. Dr. Alberts and Mr. Augustine are here to testify and answer your questions.

In reviewing the Panel's report, I was impressed with the degree to which they looked closely at both NIH policies and its procedures. The Panel also explored regulations of other Agencies and the rules, regulations, and laws set in place by the HHS, the Office of Government Ethics (OGD), and the Congress. And in making recommendations, they did as I asked—they did not limit themselves to what was in my authority to change—rather I asked them to make any and all recommendations that would improve NIH's management of conflict of interest. I told them that where I did not have the authority to implement change, I would seek the help of HHS and OGE.

I have reviewed all of the Panel's recommendations and plan to move ahead as appropriate.

In sum, these actions have already significantly strengthened NIH's internal oversight of ethics matters and continue to do so in the future.

Next steps: Principles and Policies

After nine months of review and listening to the concerns of the public, and after examining the recommendations of the Blue Ribbon Panel, I want to unveil my plans for further improving NIH's ethics program. My plans are based on four main principles:

- 1) Enhance public trust in NIH by preventing conflicts of interest through the restriction of financial relationships employees may have with outside organizations;
- 2) Increase levels of transparency in the NIH ethics program by requiring much more internal as well as public disclosure of the details of financial relationships employees have with outside organizations, including consulting arrangements and awards;
- 3) Balance NIH's ability to recruit and retain the best scientific expertise while expediting the translation of research advances;
- 4) Establish effective monitoring and oversight of employee activities.

I will seek to implement actions in response to these principles, as appropriate, through administrative actions, and supplemental regulations.

Principle One: Enhance Public Trust

- I will seek to prohibit NIH senior management and NIH extramural employees who are responsible for program funding decisions and recommendations, and professional staff managing grants and contracts and publication review from consulting with pharmaceutical or biotechnology companies or from paid consulting for academia, except in the case of the clinical practice of medicine.
- I will reaffirm the prohibition against NIH scientists participating in research involving human subjects where the scientist has a personal or imputed financial interest in an organization whose interests would be directly and predictably affected by his research, except in those exceptional cases where the interest is

not so substantial as to be deemed likely to affect the integrity of the employee's services to the Government or is otherwise subject to regulatory exemptions.

- I will propose that employees engaged in compensated activities with outside organizations be, in future, prohibited from compensation in the form of stock or other forms of equity ownership in the companies for whom they are working.
- I will set into place policies and procedures to fully consider the extent to which the recusals necessitated by an approved activities with outside organizations have an effect on the ability of senior scientific managers and decision makers to conduct their government work. NIH will clarify the use of recusals that are required because of financial relationships with outside organizations. We will require a uniform policy for informing relevant personnel of who is recused and establish a new process for monitoring recusals.

Principle Two: Increase Transparency

- NIH, working with HHS and OGE, has already increased the number of senior managers who must publicly disclose their compensated activities with outside organizations and the amounts received. These are interim steps. I will aggressively seek additional authorities to require more employees to disclose their activities with outside organizations, where appropriate, including disclosure of relevant relationships and financial holdings in connection with research publications, speeches, inventions, and clinical research. As I have said previously, public disclosure and transparency will be the cornerstone of the NIH ethics program.
- I will ask NIH employees to voluntarily disclose all relevant relationships with outside organizations and financial holdings in their work products, such as publications, speeches, and invention disclosures. And I will seek changes to regulations to make such disclosures a requirement.

Principle Three: Recruit and Retain Best Scientific Expertise While Expediting Translation of Research Advances

- I will propose that regulations allow NIH scientists to receive compensation for teaching, speaking or writing about their research, but only if the information is shared in a public forum and has already appeared in published literature.
- NIH will continue to allow certain types of consulting arrangements, teaching and lecturing opportunities, receipt of bona fide awards, and collaborations with the private sector, but only under clear, rigorous rules meant to eliminate real and appearances of conflict of interest. Consulting, collaborating and teaching must continue in order to expedite the translation of research advances, but only under clear guidelines.

Principle Four: Establish Effective Monitoring and Oversight Mechanisms

- I will seek to limit the amount of time spent on consulting and the amount of compensation received annually. The limits proposed by the Blue Ribbon Panel will be considered as the draft regulation is developed.
- NIH will improve its ability to manage and track approved activities with outside organizations by increasing the accountability of managers, creating a centralized data base, centralizing review of senior managers and scientists, conducting random audits of files pertaining to activities with outside organizations, and continuing the rigorous peer review conducted by the NEAC.
- NIH will develop and implement a new, more understandable method of training employees on ethics rules, and we will establish a web site that displays rules in plain language, updates employees on regulatory trends and changes and discusses—anononymously—ongoing cases as examples of best practices or unacceptable practices.

Much of the discussion about ethics policies and procedures at NIH has been unnecessarily negative. NIH employees have great integrity. In retrospect, the policies and rules could have been even stricter, their implementation could have been more efficient and oversight could have been more rigorous. But for better or worse, this was the system NIH employees had to negotiate.

As we move forward, all of us, the NIH leadership, HHS, OGE, and the Congress, will have to strike a careful balance between maintaining public trust in NIH and allowing appropriate interactions between NIH scientists, industry, academia and all elements of the research community.

Collaborations with the non-governmental research community are vital, not only for understanding and advancing science, but for translating our knowledge into actual medical practice and treatment. We should be more transparent, more vigilant about oversight, and we need to tighten the rules. But it would be a mistake to ban all compensated activities with outside organizations. Such an action would be bad

for science, unfair to the employees, and ultimately hinder our efforts to improve the nation's health.

Mr. GREENWOOD. Thank you very much, Dr. Zerhouni.

Dr. Alberts, you are recognized for an opening statement. And Dr. Augustine, you are going to speak for the Commission.

TESTIMONY OF NORMAN AUGUSTINE

Mr. AUGUSTINE. Yes, please. We will share our remarks. I'll begin.

Mr. Chairman and members of the committee, we welcome the opportunity to share with you our findings in our review of conflict of interest policies at the NIH.

We are very well aware of the support that this committee has given to NIH over the years, and also the expectations you have for the NIH and I might add that we, as private citizens are sharing those expectations.

Dr. Alberts and I today appear on behalf of the entire members of our panel, a list of which is attached in the submittal. And we do appreciate your including our formal statement for the record. Dr. Alberts and I will briefly summarize it in a more informal fashion this morning with the committee's permission.

Our panel, as you know, was established at the request of Dr. Zerhouni. We were asked to complete our work in 90 days because of the urgency that the NIH assigned to this particular issue.

As has been mentioned, we were asked to focus on policy issues, not on specific cases. And the reason for that was that there are least three other investigations underway by official government agencies into specific matters.

During our efforts we had over 30 witnesses appear before us from a variety of perspectives. We established a website at NIH which we received responses from over 300 employees of NIH with respect to a series of questions we had asked of them. We spoke one-on-one generally, often by telephone with the director of all 27 institutes and centers of NIH and we put the notice in the Federal Register that we would welcome input from the public.

NIH, as has been pointed out several times this morning, is indeed a great national asset, a treasure. Its impact on health, not only in America but throughout the world, has clearly been profound. The more we learned about NIH the more apparent it became to us that NIH's principal asset, far above anything else, were the scientists and the clinicians that worked for the institutes and the centers.

The easiest thing in the world for us to have done would have been simply to have put an outright ban on all consulting, to insist that everybody's related personal activities, emphasize related, be placed on the web. But we were also mindful of the fact that there were at least two ways that we could damage NIH even though our efforts would be well meaning.

The first of those would be that if we were to recommend policies with regard to conflicts of interest that were too liberal, too easy and the NIH were to continue to suffer from publicity of apparent conflict of interest violations, that this could be very damaging to the support for the NIH by the public, damaging to its science and damaging to those who put their faith in the NIH. On the other

hand, we also realized that if we placed recommended rules that were so restrictive and some analytical to common accepted practices in the scientific community, we truly believed that it would be very hard to hire the world class scientists, many of whom have decades of education, to serve the NIH's role.

Similarly, we encountered the fact that NIH researches, as all other citizens, have certain rights to privacy in their private life. By the same token, those of us who depend upon NIH researchers, the public, have every right to be aware of what activities there are in their private lives that might impact their impartiality of carrying out their responsibilities as public servants.

Further, we were well aware that it's inappropriate for a private organization to benefit from government sponsored work in a discriminatory fashion. At the same time, we realized that it's almost through the activities of commercial firms that the basic research conducted at NIH is able to impact the health of America's citizenry.

Considering these factors, we arrived at three principal findings, which I will just generalize and Dr. Zerhouni has really touched on them very thoroughly.

The first is that we recommend that the NIH conflict of interest policies be substantially tightened, they be made more restrictive particularly for the senior leadership at NIH.

Second, we believe that more disclosure by more people both public and private is very much needed.

And third, we believe that in cases where there are not conflicts of interest, that steps should be taken to give scientists the latitude to participate in the accepted cultural approaches practiced by the scientific community at large.

Well, that is a brief introduction. Let me ask Dr. Alberts to use our remaining 5 minutes to summarize some of the specific instructions.

Mr. GREENWOOD. Dr. Alberts, you are recognized.

TESTIMONY OF BRUCE ALBERTS

Mr. ALBERTS. Thank you, Mr. Chairman.

There are 18 recommendations in our report, and you have them and I have no time to really go over them in detail here. Let me just point out a few essential recommendations that I want to pay special attention to in view of the comments already made.

Recommendation one at the top deals with the senior leadership issue and would prohibit any paid consulting for a set of senior employees and those having responsibility for program decisions. And Dr. Zerhouni has already spoken eloquently about accepting those recommendations, and I don't think I need to say anything more about them, except that this is a change in policy from a 1995 policy that was implemented at the NIH.

The issue of whether we should abandon any kind of contact with industry by the majority of the 5,000 scientists who work at the NIH who are just pure researchers and have nothing to do with any resource decisions or allocations or recommendations is one that you've addressed here and one that we took very seriously. We came down the side, as Mr. Augustine said, of allowing those interactions where they are appropriate after an appropriate screening

and specifically said these people should be able to consult for either industry or academia where there is no conflict and wherever it makes sense after the decision is made centrally at the NIH. Why?

Well, let me say, I have 30 years in the universities at a research scientist before I came to Washington 10 years ago. I was at the UCSF, which is the place where all this biotech stuff started. And at the beginning, I was very much against any academic involvement with industry. And personally, I had never had any. But I have talked to many, many scientists including the young scientists at NIH who are coming there to do public service and have no actually plans or actually activities yet with industry. But the fact is that this is very much a two way street. People who do this often tell me that they gain more from knowing about what industry is doing and enlarging their thinking by seeing what these people are doing in new kinds of ways. They are often ahead of academia. I'm talking about colleagues at UCSF now. That in fact these kinds of interactions changed the ambitions and often the effectiveness of the research that people are doing both in universities and by analogy at the NIH. And so that's the basic reason why I personally came down on the side of allowing it where appropriate.

However, we are very concerned about what we call conflict of commitment. We talk about this as a shower test. What are you thinking about when you're in the shower? Are you thinking about your NIH job or are you thinking about something else? And so we wanted to make sure that it's the NIH job that you're thinking about, and we therefore have recommendation three which puts real limitations on both how much compensation you could receive and how many hours you can spend and, I think very importantly, whether you could take equities. Equities, we feel, creates a different kind of sense of involvement than money received. You would become, in a sense, an owner and you tend to get a lot of attention, may get a lot of attention from an employer that we don't want. We don't want them to be primarily concerned with their outside activities.

Now these recommendations, obviously, represent restrictions from current policy. We also have recommendation five, which is designed to promote more interactions between NIH scientists and their colleagues elsewhere; we move in the direction of more leniency. This involves a change recommended in OGE regulations allowing them to behave like other scientists and receive small honoris where they go to speak about their work and be able to speak about their work in a public forum and provided it's been published already in the literature freely.

We found these restrictions had come from—the regulations are very confusing. In fact, I was very surprised by them. And I think it hampers the ability of scientists to, again, interact with the scientific community, do the best they can to disseminate what they're doing and also get information back from their colleagues. Because science is very much a highly cooperative interactive activity.

Then we go on to recommendation ten which deals with ensuring a complete internal disclosure of financial interests and other potential conflicts of interests. This has to do with form 450. I learned

all these facts. I am hoping I can erase all this information that I have learned.

Form 450. We want more form 450 filers. That may be limited. If not, we want NIH to get it some other way so they know every possible conflict of interest and can regulate it more efficiently.

The other issue which of course we're very concerned, for Dr. Zerhouni and for the panel, is transparency. Transparency we would mean public availability of information. Disclosure we use NIH's accessibility to the information.

And we supported the idea that this Title 240, it is sort of bizarre, regulation that prevents NIH from getting information from people publicly who they want to have information for should be changed somehow, either by OGE regulation or by law if necessary. And the NIH, as Dr. Zerhouni said, has now requested some 500 people be put under that regulation and we'll see what happens. We would certainly support that.

We also would produce transparency in a different way by requiring an employee in recommendation 13 to publicly disclose all relevant outside relationship and financial holdings in their work products; that is their publications, speeches and invention disclosures. So it is another form of public disclosure.

Finally, we looked at the comparative salary scales of academia and NIH for scientists. And we found that at the lower levels, the scientists are well compensated. They are fairly compensated. The problem comes at the higher levels of the leadership where, for whatever reason, the marketplace is at much higher salary levels for many of the people you would like to have as senior leaders than NIH can actually pay. And so because leadership is so crucial, it is crucial to have the right leaders in the organization, we have recommendation 18 that the NIH Director working with Congress should ensure that the agency has authority under Title 42 or some other hiring mechanism to recruit senior scientific staff in a highly competitive market and asking the HHS to also to review and if appropriate, raise the current annual salary cap of \$200,000 for the most senior Title 42 employees at NIH. We are concerned that the present ceiling is limiting the agency's ability to retain and recruit the very best leadership. And, again, I cannot emphasize the leadership issue.

Let me just go through this transparency issue, because personally I would be very much in favor of having all the information that you want posted on our public website. In fact, our panel was leaning strongly in that direction when we encountered the Privacy laws. That was at our last meeting. And, in fact, we have learned that this would, or what we believe is that some government wide legislation would be needed to change the Privacy law in order to do what the panel was heading for in our recommendations. And so we concluded in the end that the strong governmental policy protecting personal information against disclosure would be a formidable challenge to overcome and thought there was no use in recommendations that are meaningless and instead we have constructed several recommendations to the end of making more effective both the internal disclosure, as I said, and public disclosure through the public disclosure at speaking and work products stage that I mentioned, and finally by requested an agency wide public

report that annually summarizes the amount and the nature of the outside activity of NIH employees, which is recommendation four which I didn't have a chance to mention.

Thank you very much.

[The prepared statement of Norman Augustine and Bruce Alberts follows:]

PREPARED STATEMENT OF DR. BRUCE ALBERTS AND MR. NORMAN AUGUSTINE, REPRESENTING THE NATIONAL INSTITUTES OF HEALTH BLUE RIBBON PANEL ON CONFLICT OF INTEREST POLICIES

Mr. Chairman and Members of the Committee, thank you for this opportunity to share with you the findings of our Panel which evaluated Conflict of Interest Policies affecting the National Institutes of Health (NIH). We are, of course, well aware of the support given by this committee to the NIH over the years and of the high expectations you, and indeed the American people, hold for NIH.

We appear today on behalf of the members of the Panel, a complete list of whom is attached to this testimony. Our Panel was established at the request of Dr. Elias Zerhouni, Director of NIH, and was requested to complete its work within 90 days because of the urgency of the matter at hand. Administratively, we were formed as a Working Group of the Advisory Committee to the Director of the National Institutes of Health. We should note that our assignment was forward-looking; that is, we were concerned with policy rather than with specific cases that occurred in the past. As you are aware, there are a number of on-going investigations of prior matters being conducted by entities within the government. Other than providing our basic charter, which was to review existing conflict of interest policies and to propose new policies where appropriate, no constraints were placed by NIH on the content of our work.

In carrying out the Panel's responsibilities we met a total of five days and held one telephone conference. We heard testimony from over 30 individuals, including members of the public, and established an internal web site which received over 300 responses from NIH employees. In addition, we interviewed the Directors of all 27 NIH Centers and Institutes. Notices of meetings were placed in the Federal Register.

The National Institutes of Health represents a national and global treasure. Its principal asset is the truly remarkable scientists and practitioners who choose to serve as its employees. In many ways the future health of our nation depends on a robust and productive NIH. But if care is not taken, the ability of NIH to continue to serve the public's health could be severely damaged in either of two ways by issues affecting conflict of interests. On the one hand, if the science NIH conducts or its funding decisions are, or even appear to be, biased or corrupted, the public, the broader scientific community, and the government's funding officials could lose faith in the institution's credibility. On the other hand, if a unique set of rules were to be enacted that is so inconsistent with the established practices of the scientific community, it could drive talented individuals away from NIH as an employer and at the same time discourage the dissemination of knowledge.

Developing sound policies for managing and preventing conflicts of interest requires the balancing of several sometimes competing values and considerations. First, government employees, like all citizens, are entitled to a life of their own with reasonable privacy—but at the same time, the public has a right to complete assurance that outside activities will not inappropriately influence an employee's judgment or commitment to public service. Second, although sound arguments can be made for the enactment of consistent and uniform conflict of interest rules across the federal government, each agency, including NIH, has unique circumstances and needs. Third, it is clear that a government employee should not receive personal financial gain for outside activities by exploiting knowledge gained through his or her government position, yet much of the accumulated knowledge and value of a scientist might well have resulted from efforts made and accomplishments achieved outside of government service. The Panel has sought diligently to balance these sometimes conflicting considerations as it developed its recommendations.

In its deliberations the Panel found an extremely complex set of rules governing conflicts of interest at NIH and, in fact, across the federal government. In the context of NIH, with its unique mission to conduct and support biomedical and health-related research on its own campus, across the country, and internationally, these rules are widely misunderstood by some of the very people to whom they are intended to apply. This has created uncertainty about allowable behavior and has en-

gendered fear that inadvertent transgressions could occur—significantly damaging morale.

The Panel found that most of NIH's policies and procedures for managing conflicts of interest are reasonable and appropriate and it believes that the agency has been responsive to direction provided to it in this area by the Department of Health and Human Services (HHS), the Office of Government Ethics (OGE), and Congress. However, significant improvements can be made, including imposing greater restrictions on some types of activities, relaxing some restrictions that are inappropriate and counterproductive, enhancing disclosure and transparency, and improving the overall management of these issues at NIH through better training, education, and resource management.

We believe the existing conflict of interest policies affecting NIH do not sufficiently discriminate among groups of employees who have widely differing responsibilities and therefore widely differing susceptibility to conflicts of interest. In particular, we conclude that the policies affecting senior officials of NIH should, as a matter of policy, be tightened—that is, made more restrictive. It is our view that greater internal and, in some circumstances, public, disclosure can be beneficial in assuring the continued quality of the NIH's work and the confidence the public can place in that work. In particular, some senior NIH staff members, absent case-by-case approval authority, are, under present interpretation of the relevant laws, not expected to file public disclosure forms.

On the other hand, we found that many well-intentioned constraints that have been placed on researchers at NIH who perform purely scientific work have been counterproductive. As but one example, NIH scientists are generally prohibited from indicating their affiliation with NIH when giving lectures, even when those lectures are accompanied by appropriate disclaimers.

At present, only a relatively small number of NIH employees are engaged in consulting arrangements with industry. In contrast, a substantial number of NIH employees are involved in outside activities with professional societies and with academic and research institutions—primarily in the forms of teaching, speaking, or writing (including editing). In addition, NIH scientists who are recognized for outstanding scientific achievements, leadership, or public service are sometimes the recipients of awards, which may be accompanied by a cash prize. The Panel believes these are important—even essential—activities for NIH scientists, since they are part of the tradition of science and provide evidence of the value and significance of the NIH research community to the larger scientific community. For example, speaking at academic institutions or other similar public fora is a critical part of being a productive and contributing scientist. It provides an important avenue for the exchange of scientific ideas, and both the speakers and the audiences benefit.

What did the Panel not accomplish that we sought initially to do? During our initial meetings, and in the first full draft of the report that was used to frame our Panel discussions at our April 5-6 meeting, we seriously considered proposing that selective information from the Form 520 be posted on a publicly accessible portion of the NIH website. (Form 520 must be submitted to obtain permission for any outside activity). More specifically, we discussed the possibility of requiring, as part of the permission process, the public posting of both the nature of each paid outside activity, as well as the exact amount of the compensation received each year. The Panel was thinking that such complete transparency could serve as a “disinfectant” to remove suspicions that might otherwise persist concerning the internal NIH disclosure and permission system.

In the course of these deliberations, we encountered the federal Privacy Act and other relevant federal statutes and regulations. We asked the lawyer on our Panel, Dorothy Robinson, to consider these matters further and to discuss them with NIH legal counsel. She reported that the federal Privacy Act presents a serious barrier to virtually any agency-mandated public disclosure of the sort we were considering, other than the public disclosure mandated for those senior level employees designated as Form 278 filers—including those so designated through equivalency rulings by the Office of Government Ethics. (See also Letter from Marilyn L. Glynn, Acting Director of OGE, to Bruce Alberts and Norman Augustine, April 19, 2004, attached).

The Panel considered the possibility that the Privacy Act might be amended to allow for this type of disclosure, but concluded that the strong governmental policy protecting personal information against disclosure would be a formidable challenge to overcome. Instead, as you will hear, the Panel constructed recommendations aimed at augmenting and making more effective internal disclosure within NIH. We want NIH to have all of the information and abilities it needs to make thorough and effective conflict of interest reviews. We have also recommended enhanced public disclosures in connection with all speaking and publications by NIH personnel,

as well as an agency-wide public report that annually summarizes the amount and nature of the outside activity by NIH employees.

Our recommendations are as follows:

Recommendation 1: NIH senior management and NIH extramural employees who are responsible for program funding decisions and recommendations, and professional staff managing grants and contracts and application review should not engage in consulting activities with pharmaceutical or biotechnology companies or in paid consulting for academia. The Panel considers speaking for compensation at an industry site as equivalent to consulting for industry. In addition, the Panel does not include in this prohibition time spent in clinical practice by health care practitioners, if approved as an outside activity free of conflicts.

Recommendation 2: The Panel reaffirms current federal law that intramural scientists conducting research with human subjects—for example, investigators and research team members involved in patient selection, the informed consent process, and clinical management of a trial—should not be allowed to have any financial interest in or relationship with any company whose interests could be affected by their research or clinical trial, except with an appropriate waiver or authorization.

Recommendation 3: In addition to existing requirements for engaging in outside activities, the following additional requirements should be in place for employees directly involved in the administration or conduct of NIH research programs and who are not subject to the restrictions posed in Recommendations 1 and 2:

- a. The total amount earned annually from compensated consulting with industry or academia should not exceed an amount equal to 50 percent of the employee's annual salary, and no one source should account for an amount in excess of 25 percent of annual salary.
- b. Employees eligible to engage in compensated outside professional activities should not:
 - i. receive compensation in the form of stock options or other forms of equities for their services
 - ii. spend more than 400 hours per year on these activities (writing excepted).
- c. An exclusion to the above limits should exist for NIH employees who are health care practitioners. For these employees, there should be a more flexible time limitation and the capitation for compensated outside medical care and patient services should be 100 percent of base pay, with the one-source limitation removed.

Recommendation 4: To improve NIH's ability to manage and track approved outside activities:

- a. all requests for outside activities (Form 520) should be updated on an annual basis (with such updates indicating only those changes that have occurred)
- b. supervisors should be held accountable for the evaluation and approval of outside activity requests, and this supervisory function should be a component of a supervisor's performance evaluation
- c. NIH should publish an annual institute-wide statistical report on the number and types of outside activities approved for its employees.

Recommendation 5: NIH should seek a change to OGE regulations so as to allow NIH scientists to receive compensation for teaching, speaking, or writing about their research, only if the information is to be shared in a public forum and it has appeared in the published literature.

Recommendation 6: NIH intramural scientists should continue to be allowed to engage in compensated speaking, teaching, and writing for professional societies and for academic and research institutions as an outside activity as long as all ethics review and approval requirements are met.

Recommendation 7: NIH should seek a change to OGE regulations to permit employees to be identified by their title or position (and institutional affiliation) when engaged in teaching, speaking, or writing as an approved outside activity. Disclaimers should be provided that the activity is not being conducted in the employee's official capacity as an NIH employee and that the views expressed do not necessarily represent the views of NIH.

Recommendation 8: There should be no restrictions on royalties received on works written, edited, or published or on income received from patents licensed by any NIH employee who conducted the work as an approved outside activity.

Recommendation 9: The current OGE rules regarding receipt of bona fide cash awards for meritorious public service or achievement and NIH's interpretations of the rules are reasonable and should apply to all employees. There should be no limit on the amount of money received from a bona fide award. These awards are considered gifts under current law and are not considered outside activities because the employee accepts the award in his or her official capacity.

Recommendation 10: To increase NIH's ability to manage conflicts of interest, it should either move immediately to increase the number of employees required to annually file a confidential disclosure form 450 or find some other means to achieve comparable levels of internal disclosure.

Recommendation 11: NIH should ask OGE to make a regulatory change or seek statutory modifications to provide NIH with greater discretion in determining whether certain Title 42 employees should file public financial disclosure form 278. This would promote the public interest by increasing transparency and thereby enhance trust in government. In the meantime, NIH should seek additional equivalency rulings from OGE to increase the number of public filers to include all the senior employees as specified in Recommendation 1.

Recommendation 12: NIH supervisors should be provided with enhanced training on the criteria to be used for their annual review of financial disclosures so as to become more effective in managing and avoiding employee conflicts of interest.

Recommendation 13: To preserve public confidence in NIH, the agency should put in place a policy that requires employees to disclose all relevant outside relationships and financial holdings in their work products, such as publications, speeches, and invention disclosures. In addition, where relevant, such disclosures should be made to potential research subjects as part of the informed consent process.

Recommendation 14: NIH employees should be required to submit recusals in writing to immediate supervisors when a potential conflict of interest emerges. The supervisor should then be required to inform those who should be aware of the employee's need to be recused from the official duties for which there is a conflict. As is currently the case, when an employee must be recused from official duties, those duties can be reassigned only to someone at an organizational level above the employee. As such, recused employees or their supervisors will need to inform both superiors and affected subordinates of the recusal.

Recommendation 15: The NIH Ethics Office should prepare a user-friendly document and website that displays ethics rules in simple language and emphasizes examples of outside activities and financial interests that are permissible as well as those that are not. Employees seeking approval of outside activities should, as part of their submission of form 520 and its supplements, indicate in writing that they have reviewed these summary materials and have discussed any questions they have with their relevant ethics official and/or supervisor.

Recommendation 16: The NIH Ethics Advisory Committee should issue a report of its findings, in the form of anonymous case studies and generalizable principles, on a regular basis to provide the NIH community with a clear common body of knowledge by which to understand and interpret ethics rules.

Recommendation 17: NIH management should assure that sufficient resources are provided for the administrative and management functions of its ethics activities to guarantee that the expanded program proposed in this report can be implemented.

Recommendation 18: While the Panel has not addressed the application of Title 42 to the hiring and compensation of senior scientific staff, it is clear that some such hiring and compensation authority needs to be applicable to this group of employees if NIH is to remain competitive in the market for talent. In addition, the NIH Director should ask HHS to review and, if appropriate, raise the current annual salary capitation of \$200,000 for the most senior Title 42 employees at NIH. The Panel is concerned that the present ceiling is limiting the agency's ability to recruit and retain the nation's best scientists as the leaders of NIH.

Mr. Chairman, since our report is not unduly long and contains substantiation for these recommendation, we would like, with the committee's permission, to have it considered for inclusion in the record as an attachment to this statement.

Among the more significant changes these recommendations, if implemented, would impose are:

- Senior NIH officials would not be permitted to engage in paid consulting with biotechnology or pharmaceutical companies or academic institutions.
- In instances where paid consulting is permitted (i.e., no conflicts of interest exist), such activity would be subject to a 400 hour annual limitation and a compensation cap of 50 percent of the individual's annual base salary, with no more than 25 percent being derived from any one source.
- The number of individuals filing disclosures, both public and private, would be increased, and all work products would bear a disclosure statement indicating related financial interests or activities of the researcher(s).
- Compensation for outside work in the form of equity would be (prospectively) prohibited.
- Scientists, where no conflicts exist, would be encouraged, not discouraged, in participating in outside activities which are innate to the workings of the scientific community at large. Thus, scientists would be permitted to receive outside com-

pensation for speaking or writing about their work without having to wait one year after that work has been completed and published.

- The salary ceiling for employees hired under Title 42 authority would be increased to an extent which would assure that the NIH is competitive in the marketplace for world-class scientists and managers of science.

In arriving at its findings and recommendations, the panel noted that for virtually every policy it could conceive it could also identify extraordinary circumstances under which the application of that policy would be counterproductive to the accomplishment of the NIH mission. For this reason, it is important that, within the constraint of applicable laws, the NIH Director be granted the authority to make carefully considered exceptions when deemed appropriate.

In conclusion, the Panel believes that the recommendations presented in our report can correct many of the concerns that have in the past been expressed about conflict of interest practices at NIH. We urge that the recommendations be adopted as quickly as possible. This is needed to assure the continued, deserved public confidence in the extraordinary work of NIH, to enhance the continued quality of the scientific staff at NIH, and to rectify what the Panel perceives to be a growing morale problem among an excellent NIH staff.

Thank you, and we would be pleased to answer your questions.

NIH BLUE RIBBON PANEL ON CONFLICT OF INTEREST POLICIES

A WORKING GROUP OF THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

ROSTER

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Mr. GREENWOOD. We thank you, both Dr. Augustine, Dr. Alberts.

And the Chair would recognize for questioning the chairman of the full committee, the gentleman from Texas Mr. Barton.

Chairman BARTON. Thank you, Mr. Chairman. I appreciate the courtesy. I have got a hearing downstairs, too, on a telecommunications issue. So I appreciate be able to go out of turn.

Dr. Zerhouni, I am told that in the last 5 years there have been about 1500 agreements covering over 500 of NIH employees that cover some sort of outside consulting or compensation agreement with someone who has business with the NIH. Does that number seem approximately correct to you?

Mr. ZERHOUNI. I agree with your 1500 and 500 employee over 5 years. All outside activities that we were able to record. I am not sure that all of them had relationships with people that had business with the agency.

Chairman BARTON. Okay.

Mr. ZERHOUNI. I am not sure of that.

Chairman BARTON. Some sort of an agreement, maybe not a business relationship?

Mr. ZERHOUNI. Right. It may be all kinds of agreements, and we have reported that in detail to the committee.

Chairman BARTON. Okay. With some sort of a drug company or a biotech company?

Mr. ZERHOUNI. Some of them would have relationship with drug companies, but not necessarily that the drug company had business with NIH.

Chairman BARTON. Okay.

Mr. ZERHOUNI. If the company has official business with that scientist, our current rules prohibit outside activities in that context.

Chairman BARTON. Okay.

Mr. ZERHOUNI. Okay.

Chairman BARTON. Well, just as an example, this is a director who is no longer with the agency. I will not list the gentleman's name. But while he was a director of NIH, just as an example, this particular individual, director of the institute, he served on the board of directors of a private company, a biotech company and held one-half of the stock equity in that company. So I would think that was some sort of relationship. Now that gentleman is no longer with us. No longer with the NIH I should say. He is still alive and healthy.

On December 8 the committee staff sent a request to NIH that asked for details on all these agreements covering 5 years. And a funny thing happened. Apparently a lot of those agreements that were in effect were terminated on the date of the letter. We don't know the exact number, but it could be as many as half of the agreements just coincidentally all of a sudden were terminated. Does that strike you as a little bit odd?

Mr. ZERHOUNI. Well, first of all, I think the relationship that you pointed out first with the Director, I think should be off limits. I said that the very first time. I consider stock ownership, fiduciary duties in an outside entity when you have a responsibility, that should be off limits. And I think the rules address that.

The second about the numbers. At the time of the December 8 subcommittee request we recorded about 228 agreements at that time—no, 228 scientists involved in about 300 agreements. Now do not hold me to the numbers. Then I requested, I said if you want to continue you have to put a hold on all your agreements and come to the newly formed—the one that I formed in November—the NIH Ethics Advisory Committee. In that process, two of the directors that had been reported in the L.A. Times out of the 27 directors we have, the two that were involved, terminated their agreements. And as we requested, the review—the uncertainty I think and perhaps what you are, I think, alluding to that perhaps some scientists were not so happy or were not so comfortable with this being reviewed by an independent panel. It says two things.

One, the system failed and two, the new system is sending a message that if you want something at NIH, you are going to come to an independent panel that is not related to your institute or your ethic's advisor, it is in the Director's office and you had better be sure about what you are doing before you come forward.

So you can look at it two ways, Mr. Chairman.

Chairman BARTON. Is it also true that when you talked earlier in your oral testimony that there is some things that you do not

have the authority to require that, that there is some Privacy rules that apparently apply to the entire government that overrule your ability to get information, but when you request legal opinion from the Office of General Counsel at HHS—I do not want to put words in your mouth. But did the Office of General Counsel encourage you to find a way to encourage your agency to cooperate with this committee or did the Office of General Counsel at HHH encourage you to find a way to not cooperate? Put that in your own words.

Mr. ZERHOUNI. Right.

Let me just says this, that my instructions to my staff and my interactions with the Office of General Counsel, reflected a desire to find every possible way to cooperate. And if there is, and you mentioned the cooperation——

Chairman BARTON. I want to make sure.

Mr. ZERHOUNI. Right.

Chairman BARTON. You said the Office of General Counsel told you to find every way to cooperate?

Mr. ZERHOUNI. No, I said that.

Chairman BARTON. Oh, you said that.

Mr. ZERHOUNI. I said that. I said please——

Chairman BARTON. I did not ask what you said. I want to know what their attitude was when you asked them for——

Mr. ZERHOUNI. The first event was that NIH could not change its rule without new regulations. That was the advice we received. That is why we created this NIH advisory committee.

After the December 7 media reports, we did a full analyses of exactly what happened in 1995. The Office of Government Ethics at the time had set some rules.

When we were asked to provide the information you needed, Chairman Greenwood called me because we did not have the compensation amounts. So I immediately said, well, frankly we need to have them. I do not have——

Chairman BARTON. But apparently those are not required under current regulation——

Mr. ZERHOUNI. They are not required under government——

Chairman BARTON. [continuing] and so we have no clue what some of these people are being compensated for.

Mr. ZERHOUNI. But, Mr. Chairman, I would like to point out this is not an NIH specific issue. This is Government Ethics 1993. And I think you will have the acting director of OGE and you will ask. I can assure you, this was not an option of NIH. In 1998 we requested that that disclosure be made so that we could have more disclosure.

Chairman BARTON. Well, let me ask, has it to your personal knowledge at anytime has NIH been able and actually request and receive compensation figures from individuals who have outside arrangements that result in financial enumeration or stock enumeration? Have you ever asked for and been able to receive that? Not you, but I mean NIH?

Mr. ZERHOUNI. To my knowledge between 1995 and now, I do not think so. I do not know before 1995, Mr. Chairman. I will check and let you know.

Chairman BARTON. Could you find that out?

Mr. ZERHOUNI. I will find that out for you.

Chairman BARTON. Okay. Well, my time is getting close to expiring.

If you were to make a recommendation to the Office of General Counsel at HHS to testify before this subcommittee voluntarily, what would you recommend?

Mr. ZERHOUNI. That they should.

Chairman BARTON. Are you aware that we asked them and that particular individual said no.

Mr. ZERHOUNI. No, I am not. I am not aware of that.

Chairman BARTON. Do you think that shows an attitude of cooperating or noncooperating with this committee?

Mr. ZERHOUNI. I cannot comment, Mr. Chairman, on what they decide. I was not aware of that.

Chairman BARTON. Because it is no, does that indicate cooperation? You came.

Mr. ZERHOUNI. And I will come again.

Chairman BARTON. Yes. I would say you are cooperating.

Mr. ZERHOUNI. I will cooperate to the greatest extent I can, and I think we should all do that.

Chairman BARTON. All right.

I could go, Mr. Chairman, but I am going to excuse myself to go downstairs. But I want this panel to understand this is the first hearing and NIH, to some extent, is the first agency. But this will not be the last hearing and this will not be the last agency. We are going to have accountability.

This committee is going to reestablish the oversight responsibility that former Chairman John Dingell was noted for, and we are going to do it on a bipartisan basis. And I would encourage you to encourage the people in your agency that if we ask for information, they can do it voluntarily or involuntarily, but they will do it. We are going to get to the bottom of this.

And with that, I would yield back to the distinguished subcommittee chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for 10 minutes for purposes of inquiry, the gentleman from Colorado.

Ms. DEGETTE. Thank you, Mr. Chairman.

Dr. Zerhouni and the other panelists, I have been thinking about something for a few days, which is of course the Blue Ribbon panel recommendations. And the whole idea, the premise you all seem to be coming from now is that we really should not eliminate this outside income and payment, so instead what we should try to do is have transparency. And I frankly, I will be honest like the Chairman, have some questions about that fundamental premise.

Dr. Zerhouni, you said that a blanket prohibition might not be the most satisfying thing to do because scientists need to interact with others and outside groups in order to do their work. Would that be a fair summary of your statement, Doctor?

Mr. ZERHOUNI. I said a blanket prohibition would be the easiest.

Ms. DEGETTE. Right.

Mr. ZERHOUNI. And most superficially satisfying. But I think if you look into it more, remember NIH has two functions. One is to do the research in its own laboratories and then granting.

Ms. DEGETTE. But the bottom line is you feel that these scientists need to interact—

Mr. ZERHOUNI. Right.

Ms. DEGETTE. [continuing] with outside groups and industry to do their research, right?

Mr. ZERHOUNI. To enhance their ability to understand research and translate that research into real tangible benefits.

Ms. DEGETTE. Okay. Right. Why do they have to be paid large amounts of money to have that interaction.

Mr. ZERHOUNI. Okay.

Ms. DEGETTE. I mean, the money is not central to the interaction, right?

Mr. ALBERTS. We look into this. If you want to consult with industry, we were talking about that very seriously on the panel, you have to sign a confidentiality agreement with industry that you will not disclose their private information. If you are government employment doing it as an official duty, you are not allowed to sign any such agreement.

So one of the things we explored could this contact with industry occur purely as unpaid official duty activity.

Ms. DEGETTE. Right.

Mr. ALBERTS. What we concluded was it wouldn't happen.

Ms. DEGETTE. Why? Why.

Mr. ALBERTS. Because industry would refuse it.

Ms. DEGETTE. You mean industry just wants to force these people to take money for cooperating like this?

Mr. ALBERTS. Well, you can only do—

Ms. DEGETTE. You have the top research scientist in the country at NIH cooperating with private companies. And I would assume there is also a mutual confidentiality agreement that they will not disclose governmental proprietary information as well.

Mr. ALBERTS. Of course. That's true, yes. That is right. We were told that industry will not—

Ms. DEGETTE. Who told you that, Doctor?

Mr. ALBERTS. Various witnesses. I cannot remember their names.

Ms. DEGETTE. Would you supplement responses?

Mr. ALBERTS. Legal people.

Basically that if you are going to be on a scientific advisory board, for example, for a biotech company they will not have you do that as your official duty activity unpaid because you cannot—it is illegal for you to sign any confidentiality agreement that you will not reveal trade secrets that you learn in this relationship. So—

Ms. DEGETTE. Okay. Doctor, could you supplement your answers with the names of the individuals who told you that it was illegal to—

Mr. ALBERTS. We will submit that afterwards, yes. I cannot remember.

Ms. DEGETTE. Thank you.

Dr. Zerhouni, did you want to clarify that?

Mr. ZERHOUNI. Basically when industry works with a government employee under official duty activity, essentially anything that is done within that work product, the employee cannot receive any compensation. The product of that interaction is owned in part

by the government. So what industry wants is to have a scientist on his or own time, because you know, the rules are such that if you are doing this on your own time, the current government ethics rules say that this is your own work product. And that is why I think industry prefers to work with scientists on their own private—

Ms. DEGETTE. I completely understand that.

Mr. ZERHOUNI. Right.

Ms. DEGETTE. That does not go to the issue of why they have to be paid large amounts of money to do that, sir.

Mr. ZERHOUNI. The large amounts of money, I think we can give you the data since we have it. We have the current data—

Ms. DEGETTE. I have some data right here that I am going to talk about in a minute.

Mr. ZERHOUNI. Okay.

Ms. DEGETTE. And I have some slides. But before we put those up, I would like to ask Dr. Augustine something. Because you something about it is hard to hire top tier scientists at the NIH without this compensation. Is that really what we are talking about. I mean, is that the unspoken message in this room that really the money we are paying these scientists, as the Chairman said, some of them—many of them are paid more than the Vice President of the United States. One of them made \$290,000 on the government payroll last year. Is what we are really saying is we do not think we can hire these scientists unless we allow them to get private contracts for substantially more money? Is that really what we are saying, sir?

Mr. AUGUSTINE. Well, you start out exactly where we were. With regard to compensation, the higher level scientists are clearly underpaid compared with their marketplace.

Ms. DEGETTE. Right. But you know something? I am clearly underpaid compared to lawyers of my level of experience in the private market. I mean, people go into these jobs for public interest, not for the salary, I would assume. Is that not an assumption you thought of, too?

Mr. AUGUSTINE. I was going to finish. I would respectfully submit that these people are within their marketplace, the academic community, they are significantly underpaid. We also found that that probably is not the principal driver in this issue. The principal driver we found was their desire to be treated as other members of the academic community who are permitted to do consulting, who are permitted to interact with industry and have this two way exchange.

The difficulty, if I could take a moment, as I understand it is that if they do this as an official duty—let me back up. If they do consulting with a firm, the firm obviously wants a confidentiality statement. You are not allowed to sign that if you are on official duty. Furthermore, if you are on official duty, you are not allowed to give preference to a single company. It would be unfair.

Ms. DEGETTE. Right. I understand those are the rules. And I am sorry to be rushing. I only have 10 minutes to question.

And I understand all of those concerns. But one thing we have found, and I know we are going to have more investigations, is that some of the payments that are being made by these private compa-

nies when the researchers are on their own time, aside from their NIH research, are disproportionate to the amount that people, say, at the University of Colorado Health Sciences Center are being paid, because they are the NIH and they do control big grants. In other words, you know, the payments they are getting may not be in not direct correlation to the actual work you are doing. Do you share that concern, Doctor?

Mr. AUGUSTINE. We do.

Ms. DEGETTE. I would think so.

Mr. AUGUSTINE. The reason we put on the limit on as to the amount they could receive was exactly that consideration. But it should also be noted that these people that are allowed to consult under our recommendation are not involved in making grants. They have nothing to do with grant making.

Ms. DEGETTE. Well, I understand that. But that may not be what some of the private companies are thinking.

Here is why I am concerned. If we can show slide No. 1, we have some slides here to talk about the extent—now these are individuals. And I think these are in your notebooks, too. Are they in the notebooks? No, they are not in the notebooks. We will hand you a copy of it.

These are agreements that have been authorized under NIH procedures. I think some of these may be unauthorized under the new procedures Dr. Zerhouni is talking about and the Blue Ribbon panel, however those rules have not yet been enacted. So these financial agreements could happen right now.

The first one is Michael Brownstein who is the Chief of NIMH Genetic Lab. He has received almost \$2 million from four biotech firms. In each case, he is either a member of the board or the scientific advisory board or both.

Here is my question: How can the public be assured that nothing he knows from his work at NIH, nothing he learns about the projects of competitors of these firms from his work at NIH or any subject involving his work at NIH will not be brought up at these meetings? Anybody have any idea? How do we know because he is making all this money from four biotech firms that there is not going to be any kind of crossover? Doctor—

Mr. AUGUSTINE. Well, you raised the concern we had, namely that we place a limit on what they can take and we ruled out stock.

Ms. DEGETTE. But, Doctor, you have recommended a limit. That limit has not been enacted.

Mr. AUGUSTINE. Well, we recommended it about a week ago.

Ms. DEGETTE. Right. Okay. Yes, last week.

Mr. AUGUSTINE. Hopefully, it will be.

Ms. DEGETTE. With this hearing coming up this week.

Well, let me ask you a question Dr. Zerhouni. What do you think Michael Brownstein is thinking about in the shower? Seriously, that is what you all said the standard is.

Mr. ZERHOUNI. Well, I think that, and again I said that publicly before the Blue Ribbon panel, I say it again. I think people have stock, stock ownership, board positions in private entities, I do not think that should happen for senior officials. Even, I mean for anybody. I mean we are prohibiting that for everybody.

Ms. DEGETTE. Is that part of the rules you are enacting?

Mr. ZERHOUNI. Yes.

Ms. DEGETTE. And when do you intend to enact those rules?

Mr. ZERHOUNI. ASAP. As soon as I can.

Ms. DEGETTE. Okay. Let us take a look at slide No. 2. This is about consulting arrangements between NIH employees and drug and biotech firms. This is Dr. Germain, who is the Deputy Chief of Lymphoma Bio Section of the NIAID. Now, he is receiving \$430,000 roughly, a little more, plus stock of an unspecified value from seven different companies. Even if there is no actual conflict, and it sure looks like there might be to me because apparently all he stated on his ethics forms is he is a consultant to these firms, how do we know that he has time to do his work and manage his section?

Mr. ALBERTS. Okay. That is the—

Mr. ZERHOUNI. First of all, I think that Dr. Germain was the object of the media reports, so we looked very carefully at that.

Fundamentally what we have looked at is this conflict of commitment, how much time do you really spend on these things within your own time as a scientist. It turns out that if you look carefully at Dr. Germain these are long—I mean this total for example that you are reporting is for over 10 years. So that what you really need to look at is not just the ethics consideration, and this is why we think we need independent peer review for every one of these agreements and this is what the new system is doing.

Ms. DEGETTE. Okay. Just one last question. And first of all it is over 4 years, not 10 years at least in this slide. But second, and this is my question, the Blue Ribbon panel recommendation is \$100,000 compensation and no more than 400 hours per year. That adds up to an 8-hour day every week of the year. I want to ask all of you, do you think that is reasonable for our research scientist at a place like NIH who are well compensated compared to other people who are in the public service, do you think one work day, or I guess Saturday, every week would be a reasonable amount of time for these people to be spending on outside activities?

Mr. ALBERTS. That is basically the academic standard. Most universities allow that kind of effort.

Ms. DEGETTE. So your answer is yes?

Mr. ALBERTS. That is the limit. And I was at Princeton for 10 years, we were allowed this. But not on Princeton time, but we were allowed to spend as much as 1 day a week on outside activities.

Ms. DEGETTE. But Dr. Augustine, when you were over at Lockheed Martin—you were at Lockheed Martin, right?

Mr. AUGUSTINE. I retired.

Ms. DEGETTE. Did they let the people their researchers take 1 day a week for outside activities?

Mr. AUGUSTINE. We would not.

Ms. DEGETTE. Thank you.

Mr. GREENWOOD. I just want to follow up on that. I just want to understand something before I get into my inquiries here.

One day a week for outside activities, does that leave 4 days a week for the NIH?

Mr. AUGUSTINE. Extra days.

Mr. ZERHOUNI. Extra days. On their own time.

Mr. GREENWOOD. That seems that they have 5 days a week that they are giving to us, of course.

Mr. ZERHOUNI. Yes.

Mr. GREENWOOD. And how do they account for that?

Mr. ALBERTS. It depends. In universities they have to account in different ways depending on the university.

Mr. GREENWOOD. Did you recommend that there be an accounting process so that when I take that day, I—

Mr. ZERHOUNI. Right. And that is what I refer to in my fourth opening statement about the need for monitoring and oversight. In other words, the system as it stands today, Mr. Chairman, I could not tell you that I know for sure Dr. X is spending so many hours doing whatever they do. But I know for a fact that you can manage that if you have a data base that's managed centrally where you have the requisite review not of what the scientist says, but of the original documents that say you should work 1 day a week at this place or that place so you can accumulate them in one place.

Universities have done that. I came from a university that implemented such a system. And I think you can do it if you really centralize it.

Mr. GREENWOOD. I have questions. I mean, there are a lot of questions that that raises. When I talk about the swivel chair, I am talking about somebody sitting at a desk and saying okay, Doctor, you have a call from XYZ company. He takes the call or he cannot take the call and he calls later on an NIH phone and spends 2 hours. Is that a system to account for all of that?

Mr. ZERHOUNI. Mr. Chairman, I would sleep so much better if I just gave you what you want, what you are expressing, which is total separation firewall between the Federal agency and the private sector.

Mr. GREENWOOD. I think there needs to be.

Mr. ZERHOUNI. You know, and that would be much easier to do, much easier to—but having been myself a scientist at managing a university—Lockheed Martin is not a university. And I think we need to really look at that carefully and make a decision. But, frankly, I would be where you are if I had my full drothers, make my life easier.

Mr. GREENWOOD. All right. Let me pose another question to you. Today's Los Angeles Times reports that internal documents show that the Blue Ribbon panel was concerned about how little is known about the extent of financial ties between drug companies and NIH personnel. According to minutes of a closed door meeting early in April of that Blue Ribbon panel, the panel was "was surprised to learn that many people do not disclose at all. The panel thinks there needs to be an internal review that picks up significant financial interests."

The question is, I guess I should address this to Drs. Alberts and Augustine, do these minutes reflect the fact that many NIH employees are not disclosing their outside consulting even to their institutes to get approval?

Mr. AUGUSTINE. Yes, and I will begin if you look.

We were concerned. There are two basic mechanisms for disclosure at NIH that you are aware of that really apply to the govern-

ment as a whole. One has private disclosure within the agency, the other is more public disclosure.

With regard to the former, which is the form 450, only people who are specifically prescribed to submit that form have to submit it. There is not a blanket group that has to submit. And so we were concerned that there are a large number of people that do not submit at all, and they comply with the rules as they are written today.

With regard to the latter form, the 278, the public disclosure form you have already heard this problem with the artifact of the interpretation of the legislation denies the NIH leadership the ability to compel people to file. And that we recommended be changed or at least the interim steps be taken of the type that Dr. Zerhouni has already taken to cause more people to have to file public disclosures.

The bottom line is that they are basically complying with the rules as they are written, but they need much more latitude to have more people disclose both publicly and privately.

Mr. GREENWOOD. And we are disclosing: (a) the fact that they have a private consulting arrangement or; (b) the income derived therefrom?

Mr. ALBERTS. I think this needs some clarification. There is yet another form, 520. So the outside activities require review process in the form of filing the form 520 for any new outside activity, and every employee as far as I know has gone through that process. So outside activities are covered.

What we were talking about in our panel was well suppose a researcher inherited \$10 million worth of Merck stock and held it and was doing something that might effect his or her activities, bias them by that holding. Well, there was no way unless that person was filing a form 450 for the NIH to know about that holding. And so what this recommendation that I talked about, recommendation ten, focused exactly on this issue. We think the NIH must know the financial holdings that might be relevant as well as the outside activities.

They do know about the outside activities because of form 520. 450 deals with the financial interests, and we are not sure that OGE will actually allow enough 450 filers. So we recommend if they do not, then find some other way to get the information.

Mr. GREENWOOD. Well, OGE ultimately is going to follow the laws and the committee is going to help the rest.

Mr. ALBERTS. Yes, of course. We encourage that.

Mr. GREENWOOD. But let me understand one other issue here. There are two ways to gather information of this kind. One is to say if you are engaged in this activity or if you own these stocks, then you need to submit a form.

Mr. ALBERTS. Yes.

Mr. GREENWOOD. The other one is to say everybody needs to submit a firm. And you either affirmatively declare these things—

Mr. ALBERTS. Yes.

Mr. GREENWOOD. [continuing] or you declare that you have no such entanglements.

Mr. ALBERTS. The latter would be our recommendation.

Mr. GREENWOOD. And the latter is your recommendation?

Mr. ALBERTS. Yes.

Mr. GREENWOOD. Okay. All right.

What is the factual basis for your statement that there are “approximately 120 of NIH’s employees currently involved in consulting agreements?” How reliable is that statement?

Mr. ALBERTS. It was mentioned, we had an extensive interaction with NIH staff to get information. And as you can see from the report, we started from zero knowing about any of these things except for a few people. Steven Potts who is the former Director of OGE understood these things, but most of us for the first time ever encountered all this complex set of forms and regulations.

And so in preparing our report, we relied on request for information back and forth to NIH staff to give us the information. That was one of the specific requests we made, and that was the number we got back from—

Mr. GREENWOOD. So that was 120 employees affirmatively said, yes, I am doing that?

Mr. ALBERTS. That was for the NIH data base. We did not contact the employees directly, we asked the NIH what they knew.

Mr. GREENWOOD. And when you say 120 employees have these arrangements, that is a minute in time?

Mr. ALBERTS. That is a minute in time.

Mr. GREENWOOD. Right. So it could be that the next day, 40 more start consulting agreements. What is your sense of over the course of a year how many employees at NIH are involved in these consulting arrangements.

Mr. AUGUSTINE. Mr. Chairman, we were told that there were 118 employees in March of 2004; that’s the moment in time, involving 196 different activities. We were told that that number is probably suppressed because of the attention that has been given to the issue at this time. It could be higher or lower.

We do not have a projection for the future, but it was higher in the past.

Mr. GREENWOOD. Well, did you consider asking for information as to the state of affairs 6 months previously or a year previously so that you would nullify this suppressing effect?

Mr. AUGUSTINE. I do not have the specific data with me. I would be glad to provide it for the record, if possible.

Mr. GREENWOOD. After reviewing the spreadsheet of consulting agreements data and the accompanying documentation, the committee staff found at least 90 instances where a consulting agreement appears on an employee’s financial disclosure form, yet did not appear on the spreadsheet which was supposed to contain a comprehensive list of all agreements. Does the Blue Ribbon panel have any reason to believe that not all consulting agreements have been and are being disclosed to the agency? How can you be certain that all employees are making full disclosure?

Mr. AUGUSTINE. I believe that the answer to that is that you have to depend upon the employees to comply with the rules. And I think one failing probably has been that the rules have not been adequately explained and understood by the employees. In addition, it is probably appropriate to conduct spot checks to be sure that the compliance is there.

Mr. GREENWOOD. In my first question I referred to today's L.A. Times story and there was a quote that was taken from minutes according to the L.A. Times. And that was the quote that I read that says that the panel was "was surprised to learn that many people do not disclose at all" etcetera.

The NIH provided the committee the minutes of the panel's closed sessions and the staff did not find any such quotes in the minutes. Are there draft meeting minutes that the NIH has not provided to the committee?

Mr. ZERHOUNI. I can check into that.

Mr. GREENWOOD. Either we did not get that or the L.A. Times made it up.

Mr. ZERHOUNI. I do not know, but I can shed some light to that. After the article I asked Dr. Kington our Deputy where did that come from. And emails were the source of that, not minutes to my knowledge.

Mr. GREENWOOD. So when the L.A. Times says that these were from minutes of a closed door meeting in April, you are saying that that is not the case. That they were from—

Mr. ZERHOUNI. Mr. Chairman, give me some time to look into that. Because this happened this morning. I really cannot—but I will follow up with you and tell you what our best guess is where that information is from.

Mr. GREENWOOD. In the same L.A. Times article today it is reported that the Deputy Director Raynard Kington wrote in an email that he feared the panel members did not understand "that there is not a bright line" between those involved with intramural research and those involved with outside extramural research. Kington also wrote "I think, and I think many outside people would agree, that our IM, intramural scientists, should not consult with universities and other institutions that are funded by us," Kington added.

Dr. Zerhouni, do you agree with Dr. Kington?

Mr. ZERHOUNI. I asked Dr. Kington to see if he had the email, and again I have the email here. I would be happy to give it to you.

If you look at the discussion that went back and forth, you will see that the context of the quote and the context of the email are a little different. That Dr. Gottesman was talking about teaching writing and academic activities. Dr. Kington was talking about having influence over granting mechanism. And you can see through the email the conversation.

I think it is healthy to have good debate about these issues, but I think that is the source, and I would be happy to give you the copy of the email I have, Mr. Chairman.

Mr. GREENWOOD. Yes, we will ask you to submit that email for the record.

My time has expired. And the gentleman from Maine, Mr. Allen is recognized is for 10 minutes.

Mr. ALLEN. I thank you. Thank you all for being here.

And, Mr. Chairman, I thank you very much for holding this particular hearing.

I did not hear all that you said at the beginning, so I want to make sure I am understanding where you are recommending we go. I take Dr. Zerhouni's point about an academic institution and

the need for in academic institutions, most of the academics I know are doing something else on the side as well. But clearly this is an area of great concern because of the reputation of NIH, because of the function as an independent body doing research and yet in the private sector today it is pretty clear that the pharmaceutical and biotech industries are large, and certainly at least the pharmaceutical industry is very profitable and has these networks of relationships are being formed. And I think as Members of Congress we really have to be concerned about the issues that you are all dealing with today.

But it sounds to me, correct me if I am wrong, there are different ways to go at this problem of whether or not there is a conflict of interest. And it sounds to me from what I picked up that one way is to have a review of the content of the agreement so we know what the agreement itself is.

A second way would be to put some sort of cap on the amount of money that can be earned by any NIH employee.

A third way is the amount of time that the employee could spend, and we have already discussed that.

And a fourth way, which I do not think has been mentioned yet, is to really look at the nature of the outside entity, whatever corporate entity it is, whatever subsidiary relationships that it may have.

So let me ask you about a few of those. The time spent, Dr. Zerhouni, I think you said the 400 hours a year is what is traditional in the academic world. Do you have any idea whether for NIH employees who are doing consulting today that 400 hours is what they do, I mean 400 hours a year is sort of typical of what many employees are doing so far or is it more or less? And, you know, are we really reining them in or not when it come to the hours they actually would do one form of consulting or another?

Mr. ZERHOUNI. I do not have this information right in front of me, but my experience with that is that 90 percent probably spend 20-30 hours, 1 or 2 interactions. And then a small percentage may be at the 400 hours or more.

So typically the percentage of individuals who have discoveries or real advances in science that would be of greater interest is very small in a university as well as a Federal agency.

Mr. ALLEN. So a 400 hour a year restriction for NIH employees would be the kind of restriction that would only effect a few people today is what you are saying?

Mr. ZERHOUNI. My sense would be that based on my experience people who have the opportunity to provide 400 hours are those who would typically have made a breakthrough discovery, know something that no one else knows, something like that. Well, you know that in a research institution it is not going to be 100 percent of the people, but more like 10 percent or 15 percent of the people. But that is my guess, and I can certainly look it up for you.

Mr. ALLEN. When it comes to the review of the content of the agreement, I am a little bit curious about is that going to be done by independent panel or the NIH Ethics Advisory Committee, is that going to be involved in doing a sort of peer review of agreements?

Mr. ZERHOUNI. That is the idea. It should be done independently by individuals who are not in the reporting relationship to the person who is requesting this and are directly reporting to the director of the agency, so that you do not have a conflict there.

Mr. ALLEN. Do you expect the committee to meet on a regular basis? And if so, will it make its judgments as a committee and not as individuals? I mean, how—

Mr. ZERHOUNI. The committee will meet on a regular basis. It is managed by the Deputy Director of NIH, Dr. Kington, and will make its recommendation on a regular basis as well as keeping a case history of every single case that comes to their attention so that we can over time identify patterns if we need to.

Mr. ALLEN. Okay. I would like if we have time to put up some slides. Slide A dealing with Pfizer. You have that?

This is one slide that basically looks at some of the more prominent drug and biotech companies that are currently paying NIH employees. I wanted first to note that really only Abbott Labs and Schering Plough cooperated with Mr. Waxman and Mr. Brown. But we got information on the other firms.

This one dealt with Pfizer.

Just looking at this, you cannot see that, but Mr. Brewer the chief the molecular disease branch, Dr. Brewer, is receiving \$19,000 a year in 2001, \$16,500 in 2002, \$20,000 in 2003 and \$18,000 a year fee for the future.

I mean, my understanding, correct me if I am wrong, is that the recommendation in the report is that people would be—I mean employees would be limited to earning no more than 50 percent of their current income per year outside. Is that a restriction that is going to have a material bearing on many of the people who are currently NIH employees or is it a restriction that will effect only a tiny fraction of the current consultants?

Anyway who would like to.

Mr. AUGUSTINE. Mr. Allen, if I might respond. I think there is a fifth criterion on your list of four. I think the four were very good.

The fifth one we felt has to do with responsibility of the individual at NIH. And so we would differ between a person in a leadership role, a person who is performing human subject work, a person who is overseeing an allocation of grants to the outside, and finally what I would call the bench scientist working entirely in the laboratory.

And so I think the restrictions, the more important restriction rather than the dollar amount is that we would simply preclude those first few groups from having any outside consulting and it would only be the latter group that we would permit under our recommendation to have consulting. And only then when it did not pose a conflict of interest with ongoing work.

Mr. ALLEN. I see. So the higher up the chain you go, the less you can do by way of outside consulting?

Mr. AUGUSTINE. And at the upper levels the answer is one.

Mr. ALLEN. None.

Mr. ALBERTS. There is also the 25 percent from any one source restriction that we are recommending.

Mr. ALLEN. Okay. Okay. But your position is that you think the 50 percent of income for those to whom it applies is a restriction that should deal with part of this particular problem, anyway?

Mr. AUGUSTINE. I think we would characterize it much as Dr. Zerhouni did. I think it will not effect the average person. But the person who is trying to do something extreme, I think we have stopped them.

Mr. ALLEN. Okay. Thank you.

Let me just check one more slide here. Slide B for Wyeth, do you have that? Just calling your attention to a couple of the people.

I mean, there you have—no, these are not broken out quite the same way. But Melissa Kitner Triolo, almost \$120,000 over 3 years. And Germain, the past is spread out, but the future \$25,000 a year.

I mean, those are numbers that you are comfortable with for people in their positions? Excuse me 1 second.

I do not know where they are in the chain.

Mr. ALBERTS. I do not either, so I cannot answer that question.

Mr. ALLEN. Dr. Zerhouni, do you know where they are in the chain?

Mr. ZERHOUNI. Yes. I mean, Dr. Germain is a laboratory chief. He's a chief of the biotech. So he is an intramural scientist.

Mr. ALLEN. Yes.

Mr. ZERHOUNI. Am I comfortable with them making \$25,000 a year or half of their salary? The answer is yes, as long as it is completely reviewed, completely disclosed and that we understand the content of the relationship.

Dr. Germain is a world class immunologist who invented, discovered many of the fundamentals of immune system response. He is basically in the Nobel Prize equivalent category. Many people want to talk to him about his knowledge of immunology.

It is going to be the case that if you look at this, many of them are 2500 or 10 or 15; there is a relationship between the amount of activity and the importance of the research of that person, typically.

Mr. ALLEN. Okay.

Mr. ZERHOUNI. So that is where we need to cap. That is where we have to have clear rules of only so much.

Mr. ALLEN. Thank you very much.

I yield back.

Mr. GREENWOOD. The Chair would announce that we face a series of four votes now. Dr. Zerhouni, I know that you need to be back at NIH to meet with the President. What time do you need to leave here, sir?

Mr. ZERHOUNI. Right now.

Mr. GREENWOOD. About now?

Mr. ZERHOUNI. About now, Mr. Chairman.

Mr. GREENWOOD. Pardon me?

Mr. ZERHOUNI. About now, Mr. Chairman.

Mr. GREENWOOD. About now. Okay.

In that case, what we will do is we will recess for these votes. We will return in about a half an hour. Drs. Alberts and Augustine, I assume you can remain with us?

Mr. AUGUSTINE. Yes.

Mr. GREENWOOD. You will have time to grab some lunch. We will be back here as soon as the series of votes are over, which should be 30 minutes or so.

And then, Dr. Zerhouni, we are probably going to ask you to come back at another time and drill you all over again.

Mr. ZERHOUNI. Absolutely. I am sorry about the event today.

Mr. GREENWOOD. So the committee will stand in recess until the series of votes is completed.

[Brief recess.]

Mr. GREENWOOD. Mr. Bilirakis for 10 minutes.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

Let me ask you gentlemen since the Director is not here, you heard him make his statement where he talked about reviewing and he had certain steps to try to address this problem, this situation and whatnot. I guess my question has to go with does he have the authority to do what is needed to be done, whatever he may decide? Does he have the authority?

Mr. AUGUSTINE. Mr. Bilirakis, I think our answer to that would be that he does not have the total authority he needs. Part of it relates to his ability to compel additional people to file form 450, the private disclosure form. In addition, the interpretation of Title 42 is such that it makes it very difficult for him to compel people to file form 278, the public disclosure form. In each case there probably is a way around it, but in each case that way is cumbersome. And in the case of the form 278, he can file exceptions by positions, but it is a major undertaking. And every time you reorganize NIH, you would have to refile.

Mr. BILIRAKIS. And apparently his lawyers advised him that he did not have the authority necessary, as I understand it.

Mr. AUGUSTINE. Our sense has been very much that Dr. Zerhouni has tried mightily to comply with the rules as he understands them and the constraints that are placed on him, including the Privacy Act.

Mr. BILIRAKIS. Well, he has told us the same thing about the allocation of research dollars to what disease and that sort of thing that he does not—I mean my impression is at least that he does not have the authority to do anything about that. So here he is a director and he is being held responsible for these particular acts that we are talking about and, you know, some of the other areas, apparently the allocation of the dollars and whatnot.

But let me ask you then, should he have that authority?

Mr. AUGUSTINE. The two specific authorities that I mentioned we believe he should have. And we tried to stand back and understand the context of the problem. And the issue, I think, begins with some years ago when there were dissimilarities throughout the government in conflict of interest rules. And there was a feeling that that was unfair to the employees and there should be more standardization. And as a result of that standardization, we do not reflect properly the uniqueness of the NIH. And I think the rules that are there or the intention was probably good, but they just do not apply very well to NIH's situation.

Mr. BILIRAKIS. So, yes. And the staff just reminded me, certainly your people have spent an awful lot of time on your study and your

recommendations and whatnot. So are we saying then that he does not have the authority to put all those into effect?

Mr. AUGUSTINE. I think that some of the recommendations he would have to get relief from OGE and from HHS. Many of them he could put into place, and some he could put in temporary circumventions, if you will.

Mr. ALBERTS. Could I also refer you to the letter that we submitted with our testimony that was addressed to Norman and I from Marilyn Glynn, who is the Acting Director of the Office of Government Ethics that deals directly with the transparency question and it would imply that he doesn't have some authority he needs.

Mr. BILIRAKIS. Well, all right. You heard the Chairman say earlier that we want to certainly make every effort to reauthorize NIH. We have not done that in a long time. It hasn't, at least from a financial standpoint, adversely affected the working of NIH. Maybe in other areas it has, but the point of the matter is that it has continued to function and function relatively well. But we would like to think that we will reauthorize this year. It is a tough year. It is a tough year to reauthorize or legislate or anything. But hopefully we can work that out.

So, I guess it is an opportunity I think to do a lot of things in reauthorization, and that Dr. Zerhouni previously in the hearing testified that he needed some congressional authority to be able to put his road map into effect. Somehow we are talking about in the other areas of authority here. So that being the case, we need your help. And you may have covered it in your recommendations, I do not know, but I do not think your recommendations have really gone into well the director has the authority for this, does not have authority for that.

So we plead with you on behalf of the committee, I am sure the chairman would agree, that inputs from you in that regard would be very, very helpful. And, again, this year is fleeting with elections and that sort of thing, so sooner rather than later, obviously, in that regard. So there is an opportunity too, for you all to basically say hey, Congress this is what is needed.

I said this, sort of tried to say it I guess in my opening statement, we do not want to do anything here to hurt the research effort. This entire hearing and some of these problems and whatnot, or potential problems, the perception as we have already indicated is awfully important. And so, you know, keep that in mind, too.

I had a hearing yesterday that looked like it was kind of a clear cut hearing, and boy we found out that we conceivably could be doing an awful lot of harm without realizing it as a result of digging into things and listening to some of the testimony. So I think the same thing is true to here.

And I hesitate to do this, but I guess I am—I am trying to figure out in my mind in the NIH, in this booklet—well, there are spreadsheets but they are not numbered, and that is the problem. They are not numbered. But toward the end we have the list of ongoing consulting arrangements for IC employees. I guess it would probably be page 4 if it were numbered.

Mr. AUGUSTINE. I do not believe we have a copy.

Mr. BILIRAKIS. All right. Let me just go over this with you and see if you can respond without having it before you.

There is a William Paul. It is funny, but I have a good friend back home by that name, William Paul. And his brother is a staff member of mine. But it is not why I picked on this.

But he is the laboratory chief. That is his position title, outside organization Suntory Pharmaceuticals Research Lab LLC, and then also Novartis Pharmaceutical AG Science Board. The former or biotech is Formac Pharmaceutical. The nature of activity, member. What does that mean, member? He is a member of those companies?

Mr. ALBERTS. It means he is a member of the scientific advisory board of a corporation.

Mr. BILIRAKIS. A corporation?

Mr. ALBERTS. Yes. Yes. Novartis is a big pharmaceutical company and they obviously have a special board to advise them on science. And he—I do not know often they meet, but several times a year, at least.

Mr. BILIRAKIS. Right. And that is against his being a consultant, right? Because a consultant also is on there but not in this particular case.

Mr. ALBERTS. Yes. Norman could probably explain it better than I can.

Mr. AUGUSTINE. Well, I think if he was paid to serve on an advisory board, we would group that basically as being a consultant, in our view.

Mr. BILIRAKIS. Yes. Okay. Well, and really I want to make it public, no reflection on Mr. Paul. I mean a person, I hate to say innocent until proven guilty but this is not a criminal thing. But my point in the manner is that he has conducted himself in the way he should have ethically conducted himself unless proven to the contrary.

Mr. AUGUSTINE. Yes.

Mr. BILIRAKIS. And so I don't insinuate anything.

What I am trying to understand here. He is a member or consultant with these two companies. His fee in one case from 5/1/00 to present was \$280,000. His fee in the other case with Novartis 2/1/01 to present fee is \$100,000. And his travel here. And then it says future fee, in the first case \$350,000, travel \$8,000. And future fee in the Novartis case \$120,000 over 5 years, travel expenses \$40,000.

And, again, I am not saying there is anything wrong here. We Members of Congress are accused all the time by people that are well, you know, I have to live on \$15,000 a year and you guys are making X amount of government money and you are overpaid. And we hear that all the time. And we are accused of getting campaign contributions, political action committee money or whatever the case may be. And in 22 years there I can think of one case when I had a Member of Congress said to me that he had looked when someone was making an appointment, he looked at the rooster to see if that person or that association—it would not have been an individual—would have contributed. So I understand. We are not here throwing stones.

But can you tell me if you can, not whether this money is more than it should be, but what role could this person play? I mean he is a member, a consultant to these organizations. Pharmaceutical, he is also the laboratory chief. What could go wrong in terms of conflict, in terms of things that we are all concerned about?

Mr. ALBERTS. I can answer that. First of all, I do know William Paul. He is a distinguished immunologist and a member of the National Academy of Science.

Mr. BILIRAKIS. I am sure he is and I hope everybody will take it the right way.

Mr. ALBERTS. He is a senior member of the National Academy of Sciences and internationally known leader in the field of immunology.

According to the rules that allow him to do this, he cannot use any specific knowledge from his research at NIH in advising the corporation or whoever he is advising about science. He can only use his general knowledge of immunology. That is an important point. He is not allowed to take any of his official duty information and get compensated for it. And that, obviously, was cleared by the NIH review——

Mr. BILIRAKIS. Yes, but how could——

Mr. ALBERTS. So now what is he doing?

Mr. BILIRAKIS. Yes, what is he doing? Who knows what kind of knowledge is——

Mr. ALBERTS. Okay. so these companies are obviously trying to produce drugs that will either prevent auto-immune diseases or deal with bacterial and virus infections. And if you are doing that, this is actually my field of cell biology, it is very important to know and deeply understand how the immune system works. So I am quite sure he is there because he has a deep understanding, a broad understanding of all of the very complex molecular interactions that make the immune system work, and he brings that to the corporation in ways that they cannot otherwise get. Because their employees, presumably, are not as distinguished and do not know all the things that he knows. So that would be the general nature of what he would be doing there.

He would hear from them what they are trying to develop and say well here is what I know from my field of immunology that would enable you to do it better or here is why it will not work. And so they go through different projects one at a time with the scientific advisory board and get scientific advice on what the best direction for them to go.

Mr. BILIRAKIS. All right. But if he were not the person that you say he is and that I would assume he is, and wanted to misuse his position with the NIH on behalf of these companies who are compensating him pretty darn royalty, I would say, could he do so and basically who would find out about it, etcetera?

Mr. ALBERTS. I suppose anybody could be dishonest. I do not think there is any way of monitoring that from the NIH side exactly what he says inside that room. You would have to rely on his integrity.

You should ask the same question to Dr. Zerhouni when he is here.

Mr. BILIRAKIS. Yes, I would have to. Of course, he is not here.

Well, how much authority—could Dr. Zerhouni say, hey, no, you cannot do this?

Mr. ALBERTS. Well, the NIH has all the authority to prevent any outside activity and it has the responsibility of preventing any outside activity that poses a possible conflict of interest. And that is why before anybody could do any of these outside activities, they must file a form 520. And every time they have any new activity, they must file that form. And we are recommending that even if nothing has changed, they must file it at least annually. That is the new recommendation.

Mr. BILIRAKIS. Yes.

Mr. ALBERTS. So they have the full authority to prevent him from doing that. They have to say yes before he could do that.

Mr. BILIRAKIS. I guess my time is up, trying to interpret that clock up there. But would it be better that should we not be paying these people maybe more and not basically allowing things like this to take place? Because of the perception out there as far as Members of Congress are concerned, we have had to cut out honorariums and just so many of these things, gift laws, gift ban laws and things of that nature. There have been some changes to the campaign finance whatnot because of the concerns of perception and image.

Mr. ALBERTS. Well, there is a perception problem. We are very worried about that. I do not actually know William Paul's responsibility at the NIH. If he has any responsibility for making funding decisions, then the answer is no according to us. If he has no such responsibilities, is purely a scientist, then we are recommending that he should be allowed to continue with the limitations. I mean, we have limitations. And I mean, he may be exceeding the limitations on income and hours; I do not know anything about that. But this would be generally allowed if it had no conflict in other standards; no stock options, no equities, not more than 25 percent of his income from one source, you know all those things.

Mr. BILIRAKIS. In a number of these it does say stock. That means they have got stock options.

Mr. AUGUSTINE. Yes. About one-fourth hold some kind of equity.

Mr. BILIRAKIS. Well, on that I say wow very loudly.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman, and he recognizes the gentlelady from Colorado for 10 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

You had better watch out whenever Mr. Bilirakis says "wow" very loudly.

I want to go back to this example of Dr. Paul, not to pick on him because it is really just an example of what I think are some of the ethical issues folks are facing.

He sits on the scientific advisory board of Novartis and other organizations. And I think what you testified, Dr. Alberts, is that he as part of his NIH duties, he can share his generalized scientific knowledge but not specific proprietary knowledge that he might have as a result of his activities at NIH, correct?

Mr. ALBERTS. Right.

Ms. DEGETTE. You need to say words.

Mr. ALBERTS. Pardon?

Ms. DEGETTE. You need to speak for the record. Say yes or no.

Mr. ALBERTS. That is, if you are sharing knowledge as part of your job that you have developed in your laboratory——

Ms. DEGETTE. Right. Yes or—I mean is that an accurate summary of your statement that I did?

Mr. ALBERTS. That is right. That is accurate.

Ms. DEGETTE. Okay. The concern I have is this: I do not have such a concern about someone like Dr. Paul being dishonest. My concern is, first of all, he is an expert in his field. How is he going to know as he is sitting there giving this information whether or not it is proprietary information of the NIH or not? I mean, if it is in his field of information and he is asked to reply on something, is that not a very, very fuzzy line?

Mr. ALBERTS. Well, I would be in exactly the same position. I am not in exactly that field. But I could imagine myself in the same position.

Ms. DEGETTE. Right.

Mr. ALBERTS. And I could clearly distinguish what I had done in my own laboratory from general knowledge——

Ms. DEGETTE. But what about knowledge that you had received from things you had done in your laboratory that then entered into your knowledge?

Mr. ALBERTS. It is very hard to explain. But I could separate that personally.

Ms. DEGETTE. Okay. But let me ask you a further question from that then. Let us say that Dr. Paul or someone else is sitting on one of these advisory boards, and let us say that Novartis or some other organization comes to them with an issue, a study they are going to do, and Dr. Paul has specialized knowledge of his work at NIH that would effect what Novartis was planning to do with that study, and maybe in a way that is detrimental to patients. Who is Dr. Paul's fiduciary and ethical responsibility to at that point? Is it to Novartis to give them the information he knows that might affect a patient study or is it to NIH?

Mr. ALBERTS. It is to NIH. And this is why we——

Ms. DEGETTE. Well, the what happens if Novartis goes forward with a study that might be detrimental——

Mr. ALBERTS. Oh, I am sorry, I missed you. Detrimental, I see. I am sorry. You are saying prevent something bad from happening.

Ms. DEGETTE. Right. Well, let us say that they're doing some kind of a human——

Mr. ALBERTS. Well, if I was in that position and I was being very careful, I would say I think you need to talk somebody, I would recommend somebody else to talk to who knew the same thing.

Ms. DEGETTE. But what if he is the one that knows it because he is the one that did the study at NIH? That is the problem with——

Mr. ALBERTS. He would give somebody who actually knows it. Nobody in science who——

Ms. DEGETTE. You can see why we are concerned about some of these ethical concepts.

Mr. ALBERTS. Right.

Ms. DEGETTE. I mean if you look at the L.A. Times series that we saw, why you have so many blurring of lines, correct?

Mr. ALBERTS. Yes. But I am just saying that if I was in that position, I could like make my way out of that without preventing—

Ms. DEGETTE. Do you have a 100 percent view that everyone else can figure that—

Mr. ALBERTS. Of course not.

Ms. DEGETTE. Of course not. Okay.

Now, I want to talk about some more parts of the panel recommendations. I am not meaning to pick on you all. I think we are just really concerned this be clarified.

In recommendation four of the Blue Ribbon panel the report states: "A research clearly should not consult with a company that has applied for or received a research contract from the employee's own laboratory or branch." My question is should a researcher consult with a company that is a subsidiary of the company has applied for or received a research contract from the employee's own laboratory or branch?

Mr. AUGUSTINE. I would view the subsidiary as being the parent company itself in that regard.

Ms. DEGETTE. Okay. Should a researcher consult with a company that is partnered with a company that has applied for or received a research contract from the employee's own laboratory or branch?

Mr. AUGUSTINE. If it is partnered on the specific issue at hand, the answer would be no. If it was a partner in the other area, the answer might be yes.

Ms. DEGETTE. Why the distinction between a subsidiary and a different company that is partnered with it?

Mr. AUGUSTINE. Well, a subsidiary would be owned by the company, whereas a partnership would be for a specific purpose. And you might have partnerships for different purposes and one purpose may have nothing to do with what this employee does.

Ms. DEGETTE. Okay. That makes sense.

Should a researcher consult with a company that has a direct financial interest in a company that has applied for or received a research contract from the employee's own laboratory or branch?

Mr. AUGUSTINE. If I understand that question correctly, I think the answer would be no unless it was a de minimis issue.

Ms. DEGETTE. Well, how would you know that?

Mr. ALBERTS. I am not clear about the question.

Ms. DEGETTE. But the question is let us say company A has a direct financial interest in company B but they are not a subsidiary, but they have got a big investment. And the employee has a contract with company B. Can they also have one with company A?

Mr. AUGUSTINE. My answer would still be no the way you described it.

Ms. DEGETTE. Okay. Now do ethics officers generally conduct background checks to identify subsidiary partner and/or shared interest companies?

Mr. AUGUSTINE. I do not know the answer to that.

Mr. ALBERTS. I do not know the answer either. But we heard that NIH wanted to make a extensive data base that would provide that information.

Ms. DEGETTE. Right. Because here is the problem—

Mr. ALBERTS. We heard people say that.

Ms. DEGETTE. You do not know that, and it is hard to know. It would be hard for an ethics officer to find that out. But here is why it is important. You know from all of the publicity Dr. Katz, who were talking about, was consulting with AG Schering when his institute had dealings with Burlac which is a U.S. subsidiary of Schering, right?

Mr. AUGUSTINE. Well, without addressing the specific case, which we did not do, clearly it is up to the individual who is doing the consulting to know who owns your company and who has interest in it.

Ms. DEGETTE. Right. And in this case, Dr. Katz disclaimed knowledge that his institute was a subsidiary. So you can see how this would be a problem. And I guess my view would be what are we going to do about that?

Mr. ALBERTS. I think that is a good question for Dr. Zerhouni.

Dr. Katz would not be allowed to do any consulting in the new regulations that Dr. Zerhouni is supporting, because he is too high a level. But——

Ms. DEGETTE. Well, okay.

Mr. ALBERTS. But we were——

Ms. DEGETTE. But let us take it somebody else. I mean, under your proposed regulations someone is going to have to figure out all of these relationships out.

Mr. AUGUSTINE. Well, it is really up to the individual who wants to do the consulting to know——

Ms. DEGETTE. But how are they going to know? Because, see, Dr. Augustine, you see what I am saying. Is like I am asking you, okay, can someone have these relationships and it is yes/no, yes/no. But that is not in the recommendation. And who is going to educate these researchers about what they have to do?

Mr. AUGUSTINE. Yes. I would draw the parallel to the SEC rules where you are expected to know who you are investing in. And there are enforcement procedures to run tests to make sure that you are being honest.

Ms. DEGETTE. But these rules are not similar to the SEC rules in the sense we are talking about institutional researchers. I do not think you can draw those parallel at all, because a lot of the relationships they have people probably would not be able to have in the financial services industry without full disclosure.

Mr. AUGUSTINE. I think the employer would go to the prospective firm that wanted to hire them as a consultant and say give me a list of the firms that you own or have financial interest in.

Ms. DEGETTE. Okay. Maybe you could make that in your recommendations or maybe Dr. Zerhouni can put it in his rulemaking.

Mr. ALBERTS. Yes. We did not get to that detail. We said the NIH should take care of this problem.

Ms. DEGETTE. Well, it is a thorny problem and believe me, I will bring it up with him.

Let me just ask about one more of your recommendations. Recommendation two suggests that the NIH intramural scientists should not be allowed to have any financial interests in or relationship with any company whose interest could be effected by their research or clinical trial “except in special circumstances.”

What types of special circumstances does this exception refer to?

Mr. AUGUSTINE. Well, you picked a terrific example of the sort thing you struggled with. It seemed that for every policy we could prescribe, we ourselves could think of exceptions.

Ms. DEGETTE. Right.

Mr. AUGUSTINE. This is a great example. The example of the case where a medical researcher has developed a new technique that only that researcher has practiced or new instrument that only that researcher has learned to use, and to deny them participation in the trial would increase the risk of the trial. And so in our view there would be an exception in a case like that, but the exception would stipulate that there were special steps to be taken where others would monitor the work of this individual and further the patient would be informed.

Ms. DEGETTE. Right. But the issue really is not the participation, it is the payment for the participation, right?

Mr. ALBERTS. There is no payment here. These are people doing official duty work.

Mr. AUGUSTINE. Yes.

Ms. DEGETTE. Well this is called financial interest. Your recommendation two is financial.

Mr. ALBERTS. I mean there is no payment. They are doing clinical trials at the NIH.

Ms. DEGETTE. Right.

Mr. ALBERTS. They must not have any outside financial interest that could effect them. And so if this is the inventor of the technique, they may have the patent for the technique.

Ms. DEGETTE. Right.

Mr. ALBERTS. There is no way you can get around that.

And we strongly support—

Ms. DEGETTE. But who is going to decide—my question was—

Mr. ALBERTS. The director of the NIH has to decide.

Ms. DEGETTE. Dr. Zerhouni is going to decide—

Mr. ALBERTS. Well, eventually he has to.

Ms. DEGETTE. Well, what do you mean “eventually”?

Mr. ALBERTS. Well, it goes to this special panel that he set up, NIH Ethics Advisory Committee. There is a new committee, a central committee which he spoke about. If they had any trouble, they would obviously bounce it to him.

Ms. DEGETTE. What do you mean if they had any trouble?

Mr. ALBERTS. The ultimate decisionmaking has to be him. If they thought it was ambiguous. You would have to ask them how they would actually do it, but let me just make the one point.

The American Association of Medical Colleges put out a major report, I think about a year ago, which was a surprise to all—recommendations on exactly this issue, human subject research, which was a very thorough well done report.

Ms. DEGETTE. Yes, I am aware of it. I work a lot in human subject research.

Mr. ALBERTS. William Danforth was the Chair, I believe.

At any rate, the panel in our report strongly supports that report and its recommendations, and for the NIH as well. And they have a specific set of procedures to be gone through in exactly this case, this kind of case with an oversight panel. And we would support

exactly those recommendations. And we could submit those recommendations to the record, if you like?

Ms. DEGETTE. I would love it.

Mr. ALBERTS. Okay.

Ms. DEGETTE. And, Mr. Chairman, let me just say, I am more confused now than when we started the day and I am really glad we are having a whole series of hearings on this. Because I think it is critically important to the research of this country, and I have a lot more questions.

Thank you.

Mr. GREENWOOD. The Chair thanks the gentlelady. And without objections, the slides presented by the gentlelady will be entered as part of the record.

[The information referred to follows:]

SLIDE A

Pfizer Inc.

- Pfizer Inc develops, manufactures, and markets leading prescription medicines for humans and animals and many consumer brands. The company has three business segments: health care, animal health and consumer health care.
- 1) Adrian Bax – NIDDK: Senior Investigator – 11/1/2003 - 11/1/2004
- \$2,000 Fee
 - 2) H. Bryan Brewer: NHLBI: Chief, Molecular Disease Branch – 6/29/2002 - 6/28/2006
- 2001: \$19,000 Fee; \$2,600 Travel
- 2002: \$16,500 Fee; \$3,400 Travel
- 2003: \$20,000 Fee; \$2,400 Travel
- Future: \$18,000/year Fee; \$4,000/year Travel
- “Member: Consulting with Renumeration”
 - 3) Wayne Drevets – NIMH: Chief, Neuroimaging in Mood & Anxiety Disorders – 3/28/04 - 3/29/04
- \$350 Fee plus in-kind expenses (airfare, hotel, meals)
- Participate in Ziprasidone advisory board meeting (one day)
 - 4) Hussein Manji – NIMH: Chief, Lab. of Molecular Pathophysiology – 3/23/2004 - 3/24/2004
- \$2,000 Fee
- “Participate in one-day meeting on the pathophysiology of bipolar disease.”
 - 5) Judith Rapoport – NIMH: Chief, Child Psychiatry Branch – 10/6/2003 - 12/31/2006
- No consulting assignments to date; Fee is rated at \$450/hr., not to exceed \$3,000.
- “Consultant: Advise on planning studies for childhood onset conditions; advising on selections of diagnostic and behavioral rating instruments; reviewing preliminary data.”
 - 6) Susan Bates – NCI: Lead Clinical Investigator – 3/1/2004 - 2/28/2005
- \$2,000 honorarium; \$1,429 Expenses
- “Review a technology related to drug resistance in cancer and to give lecture.”

SLIDE B

Wyeth Pharmaceuticals

- Wyeth has a long history in pharmaceuticals and biotechnology, with products in the areas of women's health care, neuroscience, musculoskeletal disorders, cardiovascular therapy, vaccines and infectious disease, hemophilia, immunology, and oncology. Wyeth is also a leader in the development of nutritional.

- 1) Melissa Kitner-Triolo – NIA: Research Psychologist – 11/30/2001 - 12/31/2004
 - \$119,322.74 Fee; \$3,297.74 Travel Expenses
 - "Consultant"
- 2) Ronald Germain – NIAID: Deputy Chief, Lymphoma Bio Section – 1/15/1995 - 11/11/2011
 - Past: \$112,500 Fee; \$4,160 Travel
 - Future: \$25,000/year (contract renewed yearly)
 - "Consultant"
- 3) Adriaan Bax – NIDDK: Senior Investigator – 10/01/1995 – Cont.
 - 1995 - 2003: \$3,000 Fee Each Year; \$400 Travel Each Year
 - Total Paid Between 1995 – 2003: \$27,000 Fee; \$3,600 Travel
- 4) Benjamin Wilfond – NHGRI: Staff Clinician – 2002 - 2004 (Awaiting Approval)
 - 2002: \$5,000 Fee
 - 2003: \$2,500 Fee
 - "Provides advice regarding clinical research consent forms."

SLIDE C

AstraZeneca

- AstraZeneca concentrates on specific areas of medical need - cancer, cardiovascular, central nervous system, gastrointestinal, infection, pain control, and respiratory and inflammation.
- 1) H. Bryan Brewer – NHLBI: Chief, Molecular Disease Branch – 3/14/2002 - 11/11/2011
 - 2001: \$6,000 Fee; \$1,000 Travel
 - 2002: \$10,000 Fee; \$3,000 Travel
 - 2003: \$15,000 Fee; \$2,975 Travel
 - Future: \$8,000/year Fee; \$3,000/year Travel
 - “Member: Service on Advisory Board Committee with remuneration.”
 - 2) Neal Young – NHLBI: Chief, Hematology Branch – 9/25/2003 – 11/11/2011
 - \$1,000 Fee/year (final fee not negotiated yet; activity 2-3 hours annually)
 - “Consulting with remuneration.”
 - 3) Thomas N. Chase – NINDS: Chief, Experimental Therapeutics Branch – 5/1/1996 -1/31/2005
 - \$28,000/5 years
 - Stocks: 1999-2003: \$4,000/year in consulting fees
 - “Consulting Services”
 - 4) James L. Gulley – NCI: Staff Clinician – 9/23/2002 - 9/30/2010
 - \$1,500/per year; \$3,000 to date
 - “Case discussions, education regarding cancer related topics to health practitioners/support groups.”

SLIDE D

Procter & Gamble

- Pharmaceutical company.
- 1) Pal Pacher – NIAAA: Research Fellow – 1/2/2003 – indefinite
 - 2003: \$7,144
 - 2004: Less than \$10,000
 - “Pharmaceuticals work and Loop model development, data acquisition and analysis consultation and training.”
- 2) Vincent J. Hearing, Jr. – NCI: Research Biologist – 1/1/2003 - 9/30/2004
 - \$2,000 Fee; \$600 Expenses
 - “Lecture and critique research program.”
- 3) Stuart H. Yuspa – NCI: Senior Investigator – 2/1/2002 – ongoing
 - 2002: \$2,830
 - \$2,000/day, not to exceed \$8,000/year
 - “Consulting regarding hair growth control.”

SLIDE E

Abbott Laboratories

- Abbott Laboratories focus on advancing medical science and the practice of health care with expertise in the therapeutic areas of diabetes, pain management, respiratory infections, HIV/AIDS, men and women's health, pediatrics, and animal health.
- 1) Deborah Ader – NIAMS: Program Director, Behavioral and Prevention Research – 9/15/2003 - 12/15/2005
 - \$13,000 Fee; \$3,000 Travel
 - “Serve as a consultant to develop a protocol of cyclical mastalgia/fibrocystic breast disease.”
 - 2) Dennis Charney – NIMH: Chief, Mood and Anxiety Disorders Research Program – 1/2004 – ongoing
 - No fees or expenses received to date.
 - Fee is paid at a rate of \$350/hour or \$3,500 per day with a maximum not to exceed 70 hours or \$25,000.
 - Estimated time and expense: 20 hours/per
 - “Chairman of data monitoring committee for study of the mood stabilizer Depakote as used in a multicenter clinical trial of children and adolescents with bipolar disorder.”
 - 3) Henry F. McFarland – NINDS: Clinical Director and Chief, Neuroimmunology Branch – 12/10/2002 - 11/19/2005
 - \$250/hour, not to exceed \$20,000 – nothing received to date.
 - “Consulting services.”

SLIDE F

Genecor Intl.

- Genecor International, Inc. is a diversified biotechnology company. Genecor focuses on two markets: bioproducts and health care. For the bioproducts market, Genecor discovers, develops and sells biocatalysts and other biochemicals for the industrial, consumer and agri-processing markets. For the health care market, Genecor has drug development programs in protein therapeutics and immunotherapeutics targeting viral infectious diseases and cancer.
- 1) Ronald Germain – NIAID: Deputy Chief, Lymphoma Bio Section – 4/15/2002 - 11/11/2011
 - Past: \$22,500 Fee; \$6,600 Travel
 - Future: \$7,500/year
 - “Consultant”
 - 2) Jonathan Yewdell – NIAID: Section Chief – 4/19/2002 - 11/11/2011
 - Past: \$15,000 Fee; \$3,000 Travel
 - Future: \$5,000/year Fee; \$1,000/year Travel
 - “Consultant”
 - 3) Jay A. Berzofsky – NCI: Medical Officer – 7/21/2003 - 8/11/2006
 - \$3,000/Day -- \$15,000 to date
 - “Consult on protocols for clinical testing of Hepatitis B vaccine.”

SLIDE G

Ortho Biotech

- Ortho Biotech Products, L.P. is a biopharmaceutical company that provides products and services designed to help individuals with serious chronic illnesses. Ortho Biotech markets a prescription medication for correcting anemia associated with cancer chemotherapy for patients with most types of cancer; AZT-treated, HIV-infected patients; chronic kidney disease patients not on dialysis; and elective, non-cardiac, nonvascular, surgery patients.
- 1) Luigi Ferrucci – NIA: Chief, Longitudinal Studies Section – 12/6/2002
 - 12/31/2004
 - \$17,250 Honorarium; \$2,418 Travel Expenses
 - “Consultant – Research on Anemia”
 - 2) Jack Guralnik – NIA: Medical Officer – 5/15/2003 - 5/14/2006
 - \$2,500 Honorarium
 - “Consultant – Advice re general issues concerning the epidemiology, methods and approaches to research on elderly.”

CORRELOGIC VS. BIOSPECT (AKA PREDICANT BIOSCIENCES) #1

	Correlogic	Biospect/Predicant Biosciences
Mission Statement	Correlogic's mission is to advance the early identification of various cancers and other diseases, and to accelerate the new drug discovery process by applying its proprietary software to the development of proteomic and other biomarkers.	Biospect Inc. is developing technology for the early identification of biomarker patterns. The Biospect system will serve as the foundation for the discovery and detection of patterns of proteins, protein fragments, and peptides that reflect and differentiate various states of health and disease.
Current Work	Ongoing development of patent-pending pattern recognition and pattern discovery software with a wide variety of applications for bio-marker discovery, disease detection, and new drug discovery processes.	Working on pattern recognition based technology to improve the diagnosis and clinical management of patient health and enable new approaches to drug development.

CORRELOGIC VS. BIOSPECT (AKA PREDICANT BIOSCIENCES) #2

	Correlogic	Biospect/Predicant Biosciences
NIH Connections to Company	<p>NONE</p>	<p>1) <u>Richard Klausner</u> (former Director of NCI)</p> <p>- Biospect Board of Directors</p> <p>- Executive Director of Biospect's Global health Program</p> <p>2) <u>Carol Dahl</u> (former Assistant to the Director of the NCI; also formerly Program Director at NCHGR)</p> <p>- Vice-President, Biospect's Strategic Partnerships</p> <p>3) <u>Svetlana Strum</u> (former NCI technology transfer specialist who worked on Correlogic-NCI CRADA)</p> <p>4) <u>Judith Swain</u> (formerly on NIH Director's Standing Committee on Clinical Research; Advisory Council of the Director of the NIH; Member of NIH's National Advisory Research Resources Council)</p> <p>- Biospect Board of Directors</p> <p>5) <u>Lance Liotta</u> (Chief, Laboratory of Pathology; Chief of section of Tumor Invasion and Metastases in the Center for Cancer Research, NCI)</p> <p>- Consultant for Biospect</p> <p>6) <u>Emanuel "Chip" Petricoin</u> (Senior Investigator, Office of Cell Tissue and Gene Therapies, Center for Biologics Evaluation and Research)</p> <p>- Consultant for Biospect</p>

SLIDE 1

Michael Brownstein

NIMH – Chief, Lab of Genetics

- N-Gene Research Laboratories (Biotech) – Member of Board of Directors and Scientific Advisory Board – 9/1/1998 - ongoing
 - Between 1999-2000: \$3,000; Travel: \$400
 - Stock: \$30,000
- Serenix (Biotech) – Scientific Advisory Board Member – 5/1/1997 - ongoing
 - Stock: Owns 7% of company valued at \$100,000
- Neurocrine Biosciences, Inc. (Biotech) – Member of Board of Directors and Scientific Advisory Board Member – 1/1/1992 - ongoing
 - Fee: \$1,500 a day plus expenses – earned \$9,000 in 2003; \$3,000 per year between 1999-2002 + \$3,000 for in-kind tickets, rooms, meals
 - Stock: Approx. 30,000 shares; trading at \$57.64/share -- \$1,729,200 total value
- Thyreos Corporation (Biotech) – Originally Member of Board; Company now dormant and exists only to hold intellectual property – 1/1/1996 - ongoing
 - Invested his own money in company and received equity in return; Owns about 50% of company, valued at approximately \$100,000

**TOTAL MONEY RECEIVED: \$27,400 +
STOCK VALUED AT \$1,959,200**

SLIDE 2

Ronald Germain

NIAID – Deputy Chief, Lymphoma Bio Section

- Wyeth/Genetics Institute (Biotech) – Consultant – 1/15/1995 - 11/11/2011
 - Fee: \$112,500; Travel: \$4,160
 - Future: \$25,000/year (contract renewed yearly)
- Fish and Neave – Consultant – 3/10/2000 - 11/11/2011
 - Fee: \$57,125
 - Future: \$19,000 - \$36,000
- Perseus LLC – Consultant – 10/30/2000 - 11/11/2011
 - Fee: \$8,000
- Hybridon, Inc. (Biotech) – Consultant – 3/21/2001 - 11/11/2011
 - Fee: \$70,000; Travel: \$500
 - Future: \$24,000/year
- Cell Genesys, Inc. (Biotech) – Consultant – 6/1/2001 - 11/11/2011
 - Fee: \$131,250 + Stock Options; Travel: \$14,900
 - Future: \$25,000 per year + 2,500 Stock Options
- Genecor Intl (Biotech) – Consultant – 4/15/2002 - 11/11/2011
 - Fee: \$22,500; Travel: \$6,600
 - Future: \$7,500/year
- Schroder Ventures Life Sciences – Consultant – 5/9/2003 - 11/11/2011
 - Fee: \$3,000

TOTAL MONEY RECEIVED: \$430,535 + STOCK OPTIONS

SLIDE 3

William Paul

NIAID – Laboratory Chief

- Suntory Pharmaceuticals Res. Lab., LLC (Pharmaceutical) – Member –
5/1/2000 - 11/11/2011
 - Fee: \$280,000; Travel: \$6,400
 - Future: \$350,000; Travel: \$8,000
- Novartis Pharma AG Science Board (Pharmaceutical) – Member – 2/1/2001 -
11/11/2011
 - Fee: \$100,000; Travel: \$40,000
 - Future: \$120,000/5 years; Travel/Expenses: \$40,000

TOTAL MONEY RECEIVED: \$426,400

SLIDE 4

Elizabeth Nabel

NHLBI – Scientific Director for Clinical Research;
Chief, Vascular Biology Section

- Boston Scientific Corp. – Practitioner: Consulting with remuneration –
9/7/1999 - 11/11/2011
 - 1999: \$23,333 Fee; \$750 Travel expected
 - 2000: \$70,000 Fee
 - 2001: \$70,000 Fee
 - 2002: \$60,000 Fee; \$845 Travel expected
 - 2003: \$50,000 Fee; \$800 Travel expected
 - 2004: Estimated \$50,000 Fee; \$1,000 Travel expected
 - Future: \$50-60,000/year Fee; \$1-4,000/year Travel

TOTAL MONEY RECEIVED: \$326,728 + STOCK

SLIDE 5

Gary Nabel

NIAID – Director, VRC

- Boston Scientific (Biotech) – Consultant – 8/29/1999 - 11/11/2011
 - Fee: \$275,700; Travel: \$4,000
 - Future: \$50 - 60,000/year; Estimated Travel: \$6,000/year
- Celltech R&D Ltd. (Pharmaceutical) – Member/Consultant – 11/15/2003 - 11/15/2010
 - Fee: \$8,000; Travel: \$11,000
 - Future: \$20,000; Estimated Travel: \$30,000
- Trivium Capital Management (Biotech) – Member – 11/3/2003 – 11/3/2005
 - Fee: \$15,000
 - Future: \$20,000; Estimated Travel: \$2,000

TOTAL MONEY RECEIVED: \$313,700

SLIDE 6

Irwin J. Kopin

NINDS – Special Volunteer (Scientist Emeritus)

- National Parkinson Foundation – Member, Medical Advisory Board –
1/1/1999 - 1/1/2005
 - Fee: \$300/year for 5 years (total: \$1,500)
- Nippon Zoki Pharmaceutical Co., Ltd. (Pharmaceutical) – Consulting
services – 1/1/2000 - 12/31/2004
 - \$290,000 over 5 years
- Self Employed – Consulting Services – 6/1/2003 - 6/1/2005
 - \$19,000

TOTAL MONEY RECEIVED: \$310,500

SLIDE 7

Karl Sirotkin

NLM – Staff Scientist

- Avalon Pharmaceuticals (*Pharmaceutical*) – Consultant – 6/2000 – ongoing
 - 2000: \$24,750 Fee + 6,000 stock options vested
 - 2001: \$76,140.75 Fee + 4,000 shares left to purchase per vesting schedule
 - 2002: \$79,040.50 Fee
 - 2003: \$70,661.40 Fee

TOTAL MONEY RECEIVED: \$250,592.65 + STOCK

SLIDE 8

H. Bryan Brewer

NHLBI – Chief, Molecular Disease Branch

- Eli Lilly & Company (Pharmaceutical) – Consulting with remuneration – 3/11/2004 - 3/12/2004
 - Fee: \$2,000; Travel: \$500
- Novartis Pharmaceuticals Corporation (Pharmaceutical) – Consulting with remuneration – 11/18/2003 - 11/30/2007
 - 2003: \$2,000 Fee; \$3,000 Travel
 - Future: \$6,000/year Fee; \$2,500/year Travel
- Pfizer (Pharmaceutical) – Member: Consulting with remuneration – 6/29/2002 - 6/28/2006
 - 2001: \$19,000 Fee; \$2,600 Travel
 - 2002: \$16,500 Fee; \$3,400 Travel
 - 2003: \$20,000 Fee; \$2,400 Travel
 - Future: \$18,000/year Fee; \$4,000/year Travel
- AstraZeneca (Pharmaceutical) – Member: Service on Advisory Board/Committee with remuneration – 3/14/2002 - 11/11/2011
 - 2001: \$6,000 Fee, \$1,000 Travel
 - 2002: \$10,000 Fee, \$3,000 Travel
 - 2003: \$15,000 Fee, \$2,975 Travel
 - Future: \$8,000/year Fee; \$3,000/year Travel
- Lipid Sciences (Pharmaceutical) – Consultant: Service on Advisory Board/Committee with remuneration – 4/4/2001 - 11/11/2011
 - 2002: \$5,000 Fee + Stock; \$1,800 Travel
 - 2003: \$78,000 Fee + Stock; \$4,765 Travel
 - Future: \$50,000/year Fee, \$7,500/year Travel

TOTAL MONEY RECEIVED: \$198,940 + STOCK

SLIDE 9

Eric Green

NHGRI – Scientific Director

- Monsanto Company (*Biotech*) – Consultant: Serves as an advisor in the area of plant genetics and genomics – 2000 - ongoing
 - 2000: \$18,500 honoraria; \$7,596.96 expenses
 - 2001: \$36,000 honoraria; \$1,396.25 expenses
 - 2002: \$24,000 honoraria
 - 2003: \$23,000 honoraria; \$1,334.57 expenses
 - 2004: \$5,000 honoraria; \$631 expenses

TOTAL MONEY RECEIVED: \$117,458.78

SLIDE 10

Kenneth Korach

NIEHS – Chief, Lab. Reproductive & Dev. Tox.

- Schering AG (Biotech) – Consultant: Consults on biochemical and pharmacological actions of estrogens – 1/1/2004 - 12/31/2004
 - Fee: \$52,580; Travel: \$25,600

76

TOTAL MONEY RECEIVED: \$78,180

SLIDE 11
Norman Salem
NIAA – Chief, LMB

- Discovery International (*Pharmaceutical*) – Panel Member: Answers questions on DHA supplements for infant nutrition – 12/5/2003 - indefinite
 - Fee: \$12,000
 - Future: \$4,000/year
- Hoffman LaRoche (*Pharmaceutical*) – Editorial Board Member: PUFA newsletter scientific reviewer – 12/1/1997 - indefinite
 - Fee: \$3,000 yearly since 1997
- Martek Corp. (*Biotech*) – Consultant: Consults on issues regarding essential fatty acids in nutrition including study design – 4/9/2001 -indefinite
 - Fee: \$3,000 yearly since 2001
- Bayer Corp. (*Pharmaceutical*) – Consultant: Consults on potential vitamin supplements; also serves as member of “Bayer Consumer Care Nutrition Advisory Board” – 3/27/2003 - indefinite
 - Fee: \$16,000
 - Future: \$2,000/year

TOTAL MONEY RECEIVED: \$58,000

SLIDE 12

Richard Rothman

NIDA – Chief, Clinical Psychopharmacology Section

- Sedgwick, Defert, Moran & Arnold (Bristol Myers) (Pharmaceutical) – Medical Consultative Services – 1/9/2003 - 11/1/2005
 - Fee: 2003 - \$16,167
 - Future: Estimate for 2004: \$2,500
- McKenna Long & Aldridge LLP (EonLabs) (Pharmaceutical) – Medical Consultative Services – 4/4/2003 - 11/1/2005
 - Estimated Fee: \$2,500
- Orrick, Herrington, and Sutcliffe, LLP (Hoffman LaRoche) (Pharmaceutical) – Medical Consultative Services – 4/4/2003 - 4/1/2005
 - Fee: \$2,500
- Orrick, Herrington, and Sutcliffe, LLP (Abbott) (Pharmaceutical) – Medical Consultative Services – 4/4/2003 - 4/1/2005
 - Estimated Fee for 2003: \$27,075

ESTIMATED TOTAL MONEY RECEIVED: \$48,242

SLIDE 13

Minoru Ko

NIA – Chief, Developmental Genomics & Aging Section

- Daiichi Pharmaceutical Co. (Pharmaceutical) –
Consultant: Advice on genomics and developmental
biology for drug target discovery program – 4/7/2003 -
4/6/2005
– Fee: \$11,200
- Neo-Morgan Lab, Inc. (Biotech) – Consultant: Biological
Research – 1/1/2004 - 12/31/2004
– Fee: \$1,000

TOTAL MONEY RECEIVED: \$12,200

SLIDE 14

Mahendra Rao

NIA – Section Chief, Stem Cells

- Toucan Capital (Theradigm/Cancer Co.) (Biotech) – Consultant: Advice on cell replacement therapy – 9/1/2003 - indefinite
 - Fee: \$10,000 + Stock Options
- Cue Therapeutics (Biotech) – Consultant: Advice on company's stem cell research – 8/1/2002 - indefinite
 - Fee: Stock Options
 - Travel Expenses: \$2,400
- Amedica, Inc. (Biotech) – Consultant: Advice regarding ceramics as a bone substitute – 7/1/2001 - indefinite
 - Fee: Stock Options
 - Travel Expenses: \$50

TOTAL MONEY RECEIVED: \$12,450 + STOCK

SLIDE 15

Stanley Rapoport

NIA – Section Chief, Brain Physiology & Metabolism

- Faegre & Benson (*Pharmaceutical*) – Expert witness in litigation involving thimerosal for Aventis Pasteur, Inc. – 11/12/2000 - indefinite
 - Fee: \$17,885
- Best Practice (*Pharmaceutical*) – Consultant: Advice regarding how to evaluate efficacy of drugs for human brain disorders – 3/1/2003 - indefinite
 - Fee: \$3,750; Travel: \$250

TOTAL MONEY RECEIVED: \$21,885

SLIDE 16

Darrell Abernathy

NIA – Chief, Laboratory of Clinical Investigation

- Gray Cary (*Pharmaceutical*) – Expert witness in litigation in patent dispute involving client Cobalt Pharmaceuticals – 12/10/2003 - 11/30/2006
 - Fee: \$9,375; Travel: \$625
- Centocor (*Pharmaceutical*) – Consultant – 4/15/2003 - 4/14/2006
 - Fee: \$7,500; Travel: \$2,500
- Penwest Pharmaceuticals Co. (*Pharmaceutical*) – Scientific Advisory Board Member – 5/1/2003 - 4/30/2008
 - Fee: \$5,000; Travel: \$2,000
- Kirkland and Ellis (*Pharmaceutical*) – Expert witness for client Boston Scientific and Scimed Life Systems – 6/1/2003 - 5/31/2006
 - Fee: \$10,000; Travel: \$2,000

TOTAL MONEY RECEIVED: \$39,000

SLIDE A1

COMPANIES WHO DECLINED TO PROVIDE INFO IN RESPONSE TO WAXMAN-BROWN LETTER

1. Allergan, Inc.
2. Bristol-Myers Squibb Company
3. Eli Lilly and Company
4. Pfizer Inc.
5. Wyeth Pharmaceuticals
6. Merck & Co. Inc.
7. Johnson & Johnson
8. Amgen

Mr. GREENWOOD. And the Chair recognizes himself for purposes of inquiry.

It seems to me, gentlemen, that I have identified two reasons why we need to be permitting NIH employees to have extra income, whether that income is pursuant to Title 42, whether that extra income is derived from consulting, whether it is from speaking fees and so forth. And one of them is retain and recruit good people, and the other is to advance the science because you do not necessarily want the NIH science to be insular, and there is a two way education streaks that occurs between the scientists and private sectorsphere, which is good for both. Good for America. Good for the patients that benefit from the cures that come from all of that shared knowledge.

So let us look at recruitment and retention. The question is, does the NIH or the Blue Ribbon panel have any actual evidence that NIH scientists have left because of consulting fees being cut? Was such data requested by the panel? Was such data requested by the NIH? What I am trying to get it is sort of an undischarged assumption that if you do not provide these extra enumeration, that somehow we will lose quality people. How do we discharge that assumption? What is the evidence of that?

Mr. AUGUSTINE. Well, we did not gather statistical data. I am not sure what is available. One reason we did not, is there are so many other factors that bear on people leaving and not leaving.

We did in our conversations that I mentioned that we had with each of the center and institute directors ask if they have encountered situations where they had trouble recruiting a senior scientist or retaining a senior scientist due to salary issues and also due to conflict of interest issues. And with regard to the former, there were a number that had indicated they had had such circumstances. So our evidence is anecdotal, but fairly convincing.

Mr. GREENWOOD. Well, it would be fairly human nature to say hey boss if you do not pay me more I am out of here. But that may be the truth.

Mr. ALBERTS. Let me just say a word about, we talked to some young scientists in closed session. We were worried they would not speak completely frankly in open session. We also talked to some in open session, so we tried both ways.

And the young scientists who came were basically focused on doing public service and they were—I could tell that these were really outstanding people you want at the NIH.

And one of the things—none of them were doing any outside consulting. But we asked them specifically whether they thought it was important that they sometime in the future have this opportunity, and they said that it was important to them. They did not want to be treated as second class citizens compared to all their colleagues. And so from that I would take it that it would have an affect on their long range career plans if they thought they could never engage in the kind of activities that other colleagues—

Mr. GREENWOOD. Because of the money or because of the opportunity, experience?

Mr. ALBERTS. I do not think it is really the money, actually.

Mr. GREENWOOD. Well, that is an interesting point. Because I am sure that there are—I would guess that there are lots of employees

at the NIH who are receiving excess compensation because of Title 42 who in fact would not leave if it were not for that.

Mr. ALBERTS. I do not know. I do not know.

Mr. GREENWOOD. Right. But how is that determination made. In other words, if I am at NIH and I see all my friends are on Title 42 and they are making an extra \$50,000 a year more than I am, I want that. So I, how did you get that? Well, I filled out this Title 42 form and then it got signed off by my director. In your study of this, is there any actual criteria used to determine who is deserving of the extra cash and whether it is necessary to give that to them to be retained?

Mr. ALBERTS. We were looking forward at policies. We did not have the opportunity. I must emphasize, 66 days, we all have full time jobs. It was a killer already. And we did not have time to look into—

Mr. GREENWOOD. You did not look into that. I mean, it is an important point because that goes to Mr. Bilirakis' question of resources that the taxpayers put into NIH, is it going to cure diseases or is it going to pay salaries that are in excess of what is necessary in order to keep those folks there.

Obviously, 42 does not allow the most menial tasks, because the assumption is you can get the menial tasks done without paying the extra salary, but I have not encountered any actual criteria that anyone uses to decide whether someone should or should not qualify.

Do you know what the turnover rates for scientists is at NIH?

Mr. ALBERTS. I'm sorry, what rates?

Mr. GREENWOOD. The question is what are the turnover rates for NIH scientists? Do we know anything about that? Do we know what they were 10 years ago? Do we know what they are now?

Mr. ALBERTS. I do not know.

Mr. GREENWOOD. Do we know whether if Title 42 has in fact made a difference? I mean, has anybody ever looked to see whether the turnover rate is lower after Title 42 was put in place to provide these extra salaries?

Mr. ALBERTS. There is one thing I can say. I do not know the turnover rates, but as a scientist I could say something about the quality of the work being done at the NIH. And the quality of the scientists that are there since I came to Washington, there has been a major change. I came to Washington in 1993. It corresponds with Title 42. I cannot say it was the cause. But I was once offered a job at the NIH a long time ago and I did not want to go there. So I know what it was like then and I know what it is like now. And I think the quality of the science has vastly improved.

Mr. GREENWOOD. Why did you not want to go?

Mr. ALBERTS. Pardon?

Mr. GREENWOOD. Why did you not want to go?

Mr. ALBERTS. I was at the University of California, San Francisco, and I preferred to stay there.

Mr. GREENWOOD. It was not a financial decision?

Mr. ALBERTS. No. No.

Mr. GREENWOOD. On page 4 of your report it says "employees in a position to influence the financial interests of an outside entity such as current or possible future recipient of an NIH grant or con-

tract should neither receive financial benefits from the organization nor have a significant financial interest in it." And Ms. DeGette was inquiring about this kind of thing.

Does the term "financial benefits" as used in this statement include financial benefits associated with an award?

Mr. AUGUSTINE. That is a good question. If the organization—let me back up a little bit.

That is a very detailed question in a specific case here. But applying our general rule if the award were to be made by an organization that was seeking a contract with that employee's work group, we would view that as being inappropriate. And I think—

Mr. GREENWOOD. But let us be specific about that. Does that mean they have to have a current pending application in for that budget year, or could it be that their potential contenders down the road? I mean, suppose I decided that my university wants to start getting into the NIH game and we have not been in it much, or we opened up a new center for a particular kind of disease and we say who is the center director there, let us pay him \$25,000 to come on out. And then maybe a year or 2 hence, we will make application.

Mr. AUGUSTINE. I think the current rules on that say that if there is a likelihood of a future application, you cannot take a position with that firm or you cannot consult for it.

Second, if unforeseen they do turn in an application for a grant, you then have to disqualify yourself with regarding the terms of the award of that grant.

Mr. ALBERTS. My understanding, I guess Dr. Zerhouni should be here to answer that. You cannot form a new award and give it to an NIH employee. It has to be an award that has been around for a while and have a drawn track record.

Mr. GREENWOOD. All awards start somewhere.

Mr. ALBERTS. Yes, yes. But my position if I was director, I would not allow a new award to be given to an NIH employee.

Mr. GREENWOOD. Although that has happened?

Mr. ALBERTS. I do not know anything about it.

Mr. GREENWOOD. Yes. We have got plenty of evidence to that affect.

Also on page 4 your report states "In addition, NIH scientists who are recognized for outstanding scientific achievements, leadership or public service are sometimes the recipients of awards which may be accompanied by a cash prize. The panel believes these are important, even essential activities for NIH scientists, because they are part of the tradition of science and provide evidence of the value and significance of the NIH research community to the larger scientific community."

If awards are an important part of the tradition of sciences, raises the visibility of NIH and NIH scientists, why hasn't the NIH posted a listing of the scientists who have received awards, the names of the awards and the citation of the award what the scientists is being honored for? Why did the Blue Ribbon panel not recommend that NIH post such award listings?

Mr. AUGUSTINE. It is a terrific idea, and I wish we had thought of it.

Mr. GREENWOOD. Okay.

Mr. ALBERTS. I did not know they did not do it.

But, you know, I mean in general at my university, University of California San Francisco they advertise every award as much as they can. So I would assume that the NIH does that as well, but we did not receive any information about that.

Mr. GREENWOOD. You now, if Boeing decided to give awards to the defense Pentagon employees, and that became the tradition, I mean I am sure that health care is not the only place where scientists are really smart and want to do good things. I mean, DuPont could give awards to EPA employees. What is the difference?

Mr. AUGUSTINE. I think there are distinctions. I have struggled with your questions in the past.

One distinction is that the NIH has as part of its mission to spread the knowledge that develops outside, whereas Boeing—

Mr. GREENWOOD. But you do not have to get paid for that.

Mr. AUGUSTINE. I am sorry?

Mr. GREENWOOD. But you do not have to get paid for that.

Mr. AUGUSTINE. But that is a separate issue can come back to.

Mr. GREENWOOD. Yes. But I am talking about awards.

Mr. AUGUSTINE. Okay. I again think there are two distinctions. One is that Boeing has no desire to build a particular—to spread its information; NIH does. Second, Boeing pays a competitive salary and the NIH at the senior levels does not.

Mr. GREENWOOD. I guess what I am trying to get at is if I am an employee of the Environmental Protection Agency, just like somebody at NIH wants to save the world from some dread disease, somebody over at EPA wants to save the world from some dread toxin. Same thing in terms of both altruistic, okay. And yet we seem to have one whole set of rules and traditions that the people who are saving the world through medicine, that they are so special that you have to treat them differently and give them prizes and awards and consulting fees. But some smock who is over at the EPA who is just trying to save the world from pollution, maybe he is trying to save the world from catastrophic global climate change, shut up do your job and take your Federal salary.

Mr. AUGUSTINE. The question we addressed was why not just rule that you cannot accept awards given by companies, firms. And we are told that there are a number of awards that are very prestigious, long established that scientists in this field would like to have. There are not in the aerospace field, and I do not know about the EPA.

Mr. ALBERTS. General Motors Cancer Fund is one such prize.

Mr. GREENWOOD. In recommendation one the Blue Ribbon panel proposes that in addition to NIH senior management, NIH extramural employees who are responsible for program funding decisions and recommendations should not engage in outside consulting. Is the rationale for this recommendation that these extramural program administrators are high level officials who are responsible for making funding decisions on grants, contracts and cooperative agreements?

Mr. AUGUSTINE. Really it was the latter. It was not necessarily that they were high level, it was just that anybody who has responsibility for grants or contracts we felt should not be prevented to consult.

Mr. ALBERTS. We specifically took some case studies and discussed them. The initial review of grants is done by a panel of outside people, maybe 12 people from outside. It's called a study section. And it has an NIH extramural employee who is staffing that evaluation, initial evaluation of event. And we said specifically, the panel agreed, that it should extend to that level. That is not a very high level, but it is a very important level because it is where the first judgments are made about scientific quality, even though the staff member is just managing a group of outside scientists. The thought there was a possibility of perceived conflict. And so we took some case studies. We were not able to go through every position, but it does reach pretty low in that part of the NIH.

Mr. GREENWOOD. Okay. In recommendation 11 you state that the NIH should seek additional equivalency rulings from OGE to increase the number of public filers to include the senior employees specified in recommendation one.

On January 12, 2004 the HHS associate general counsel for ethics requested the Office of Government of Ethics to determine if the following positions be required to file public disclosure reports: Institute, center directors, IC deputy director, IC scientific directors and IC clinical directors. The Office of Government Ethics granted this request the following month.

Does the Blue Ribbon panel consider NIH extramural employees covered by HHS request and OGE determination?

Mr. AUGUSTINE. Did we consider them?

Mr. GREENWOOD. The question does the Blue Ribbon panel consider NIH extramural employees to be covered by the HHS request and OGE determinations.

Mr. ALBERTS. The senior employees.

Mr. GREENWOOD. Pardon me?

Mr. ALBERTS. Certainly the senior employees.

I understand from Dr. Zerhouni's testimony they just asked for 500 more positions, and I assume that's mostly what those are. I do not know what they are. But Dr. Zerhouni can answer.

Mr. GREENWOOD. Since NIH extramural program administrators have high level responsibilities, why aren't they covered in the January 2004 HHS request to OGE to cover senior Title 42 officials under public disclosure requirements?

Mr. AUGUSTINE. My understanding is that that was a first step, but that he has got additional ones he is going to ask for exceptions on.

Mr. GREENWOOD. Okay. All right.

I have got four more questions that I am trying to get in here. What did the Blue Ribbon panel mean in recommendation 18 that "the NIH director working with Congress should ensure that the agency has authority under Title 42?"

Mr. AUGUSTINE. It was our view that some mechanism was needed to pay senior scientists beyond what's allowed exclusive of Title 42. We are also aware of the issue that has gone back and forth between the committee and the HHS as to the applicability of Title 42 at all.

We did not enter into that. Most of us are not lawyers. We do not know which side has the merit. The one thing we know is that there needs to some mechanism, whether it is Title 42 or some

other mechanism, to be sure that these people can be paid adequately.

Mr. GREENWOOD. Title 42 authority used by the NIH to compensate NIH institute directors and other senior officials at annual salaries of up to \$225,000 is section 209(f). This section provides that under certain circumstances special consultants may be employed "to assist and advise in the operations of the Public Health Service" without regard to Civil Service laws. Do you believe that the statutory provision was intended to authorize the compensation of NIH officials already occupying continuing full time positions in order to evade the pay caps under the Federal Civil Service pay scale?

Mr. AUGUSTINE. I think neither of us are lawyers and would not be qualified to opine.

Mr. GREENWOOD. Without being lawyers, the question is having looked at this issue, we are seeing what appears to be a gap between the intent of the law, which is to bring in special people to assist and advise in the operations of the Public Health Service, and that is a very different model than somebody who has been working there for years, going to continue to work there for years and that is their job as opposed to somebody we have to bring in a special consultant and that person is going to need more money to give us his or her time.

Mr. AUGUSTINE. I could certainly understand that point of view could be defended. I could understand the point. But we really did not examine it at any depth.

Mr. GREENWOOD. Okay.

Last question. Does the Blue Ribbon panel have concerns that NIH did not work with the Congress previously on clarifying Title 42 authority?

Mr. AUGUSTINE. In 1985 you mean or currently?

Mr. GREENWOOD. Heretofore. Recent.

Mr. AUGUSTINE. The hiring authority of Title 42 or the pay of Title 42?

Mr. GREENWOOD. Both, I think.

Mr. AUGUSTINE. I guess with regard to hiring authority, we really did not involve ourselves with that.

With regard to compensation, our view was that the Director of NIH would work with whoever it takes to try to seek relief for the more senior employees.

Mr. GREENWOOD. Okay. Thank you. You have been very generous with your time, not only today but for the 10 weeks that you spent doing this work. And the committee and the country owes you a debt of gratitude. Thank you for your time.

Mr. ALBERTS. Thank you.

[Whereupon, the subcommittee at 2:08 p.m. was adjourned.]

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April 19, 2004

Bruce Alberts
Norman R. Augustine
Co-Chairmen
Blue Ribbon Panel on Conflict
of Interest Policies
National Institutes of Health
Bethesda, MD 20892

Dear Co-Chairmen Alberts and Augustine:

I very much enjoyed meeting with the NIH Blue Ribbon Panel on Conflict of Interest on April 5, 2004. The Panel members asked very good questions, and I was happy to provide whatever assistance I could. In the same spirit, I also wanted to give you the benefit of my Office's views on a subject that did not come during my meeting with the Panel: public financial disclosure.

The Office of Government Ethics (OGE) is mindful of concerns raised by Members of Congress and others about the level of public financial disclosure among higher level officials at NIH. As you know, OGE recently approved a request from the Department of Health and Human Services (HHS) for "equal classification" determinations to require a number of NIH officials to file public financial disclosure statements. Letter of Marilyn N. Glynn, Acting Director, OGE, to Edgar M. Swindell, Associate General Counsel for Ethics, HHS, dated February 6, 2004. Moreover, we stand ready to evaluate any further requests for equal classification determinations with respect to any additional positions requested by the Department.

At the same time, however, OGE believes that the issue of public disclosure is separate from the issue of what constitutes an ethically permissible outside activity. First, as I discuss more fully below, OGE does not have the authority to approve any proposed agency supplemental regulation, pursuant to 5 C.F.R. § 2635.105, that would require public financial disclosure as a condition of the permissibility of certain outside activities. Second, as I also explain below, OGE would have policy concerns about a regulatory or legislative proposal that ties the permissibility of certain outside activities to the public disclosure of those activities.

209040

Co Chairman Bruce Alberts
Co-Chairman Norman R. Augustine
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It is important to remember that public financial disclosure for employees of the executive branch is governed by title I of the Ethics in Government Act of 1978 (EIGA). 5 U.S.C. app. §§ 101-111. The legislative history of the EIGA indicates that Congress viewed public reporting for executive branch employees as an extraordinary and almost unprecedented measure. E.g., S. Rep. 170, 1st Sess. 28 (1977) (existing Executive order on ethics required no executive branch officials to file public reports); H.R. Rep. 642, Part I, 95th Cong., 1st Sess. 19 (1977) (only two agency-specific statutes required public disclosure). In view of constitutional and other issues concerning the privacy of employees, Congress sought "to strike a careful balance between the rights of individual officials and employees to their privacy and the right of the American people to know that their public officials are free from conflicts of interest." H.R. Rep. No. 800, 95th Cong., 1st Sess. 18 (1977).

For these reasons, OGE has long held that the public reporting provisions of the EIGA constitute the exclusive authority under OGE's jurisdiction to require public financial disclosure. OGE has eschewed any effort to extend public disclosure beyond the limits carefully prescribed by Congress in title I of that Act. Moreover, the EIGA itself states that "the provisions of this title [title I] requiring the reporting of information shall supersede any general requirement under any other provision of law or regulation with respect to the reporting of information required for purposes of preventing conflicts of interest or apparent conflicts of interest." 5 U.S.C. app. § 107(b).¹

Therefore, OGE does not view its authority to approve agency supplemental standards of conduct regulations as extending to any additional requirements for public financial disclosure beyond those set out in title I of the EIGA. This would include any proposed supplemental provision conditioning the permissibility of an outside activity upon the public disclosure of the activity or any income earned therefrom (beyond whatever public disclosure may be required for the employee already under title I of EIGA).²

¹Section 107(b) excepts only the reporting requirements of the Foreign Gifts and Decorations Act, 5 U.S.C. § 7342.

²OGE regulations do permit agencies to impose supplemental financial disclosure requirements, with OGE approval, but any such requirements pertain only to confidential, not public, disclosure. See 5 C.F.R. § 2635.103(a)(2).

Co-Chairman Bruce Alberto
 Co-Chairman Norman R. Augustine
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Beyond the question of OGE's authority under existing law, my Office would have policy concerns about any proposal, regulatory or legislative, that ties the permissibility of certain outside activities to public disclosure of those activities. In our view, expanded public disclosure is neither a sufficient nor a necessary remedy for many ethical concerns about the outside activities of executive branch employees.

For one thing, such a standard might carry an implicit message: otherwise problematic outside activities are permissible as long as they are publicly disclosed. From OGE's perspective, outside activities that otherwise raise serious questions under the Standards of Ethical Conduct for Executive Branch Employees, including the standard prohibiting the use of public office for private gain, 5 C.F.R. § 2635.702, are not necessarily cleansed from any taint by public disclosure. We recognize that some non-governmental organizations, including certain academic institutions and professional journals, have adopted the philosophy that public disclosure is sufficient to resolve ethical concerns.³ However, this philosophy has not been adopted generally for the executive branch of the Federal Government. Indeed, Congress has expressly provided otherwise: "Nothing in this Act [EIGA] requiring the reporting of information shall be deemed to authorize the receipt of income, gifts, or reimbursements; the holding of assets, liabilities, or positions; or the participation in transactions that are prohibited by law, Executive order, rule, or regulation." 5 U.S.C. § 107(c). Given the importance of maintaining the integrity of the Federal workforce, disclosure is a complement, not an alternative, to compliance with substantive rules of ethical conduct.

Expanded public disclosure also is not necessary to address the most serious ethical concerns about outside activities. Pursuant to section 107(a) of the EIGA, OGE has established a confidential financial disclosure system for certain employees whose positions are not covered by the public reporting

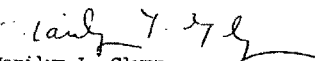
³Although mere disclosure seems to be the rule for many organizations, there appears to have been some movement, at least in the area of biomedical research, toward substantive prohibitions on certain financial interests. See, e.g., Lo, et al., "Conflict-of-Interest Policies for Investigators in Clinical Trials," New England Journal of Medicine, vol. 343, no. 22 (November 30, 2000); Cho, et al., "Policies on Faculty Conflicts of Interest at U.S. Universities," Journal of the American Medical Association, vol. 284, no. 17 (November 1, 2000).

Co-Chairman Bruce Alberts
 Co-Chairman Norman R. Augustine
 Page 4

requirements but whose duties nevertheless pose a risk of conflict of interest. As we provide in our basic statement of the "policies of confidential financial disclosure reporting," the purpose of these confidential reports is to "assist an agency in administering its ethics program and counseling its employees." 5 C.F.R. § 2634.901(a). Furthermore, agency approval requirements for outside activities, pursuant to 5 C.F.R. § 2635.803, assist agency ethics officials in helping employees to avoid outside activities that are inconsistent with Federal ethics requirements. If the confidential reporting system and any outside activity approval system work as intended, agency ethics officials will identify the vast majority of potentially problematic outside activities. To the extent that ethical problems may have arisen with certain outside activities at NIH, one could conclude that the most direct remedy would be to bolster the NIH systems for reviewing confidential reports and outside activity requests. Expanded public disclosure would not appear necessary for this purpose.

I hope this has been helpful to the Panel in understanding the role and views of OGE. If you have any further questions, please do not hesitate to contact me, at 202-482-9292.

Sincerely,


 Marilyn L. Glynn
 Acting Director

cc: Edgar M. Swindell
 Designated Agency
 Ethics Official
 Department of Health
 and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

NOV 20 2003

TO: IC Directors
OD Senior Staff

FROM: Director, NIH

SUBJECT: Awards, Travel, and Official Duty and Outside Activity Approvals–ACTION

Congress has completed the doubling of the NIH budget, which is an expression of the priority given to biomedical research by the American people. It is also emblematic of the trust and confidence the Nation's lawmakers have in NIH and its employees. This trust is a precious commodity that must be maintained through outstanding performance and strict adherence to ethical principles. Should the public lose faith in the ability of NIH to support excellent research and practice high standards of ethical behavior, the biomedical research enterprise in the United States will lose its momentum.

Recently Congress and the media have been scrutinizing the implementation of ethics rules at the NIH. They are reviewing a wide range of activities that are allowed under Federal regulations, including lecture awards, outside activities, consultant arrangements, and financial holdings. Care must be taken to ensure that we continue to adhere to strict ethical practices and that we avoid the perception of conflicts of interest, even in situations where remuneration or awards are considered permissible.

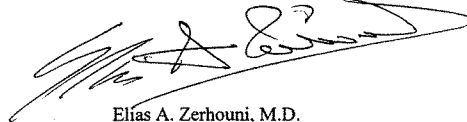
As you know, NIH employees cannot accept compensation from outside entities for the performance of activities that are part of our official responsibilities. Even in cases where we are permitted to accept compensation for teaching, speaking, and writing on subjects within our field of expertise, or to accept awards recognizing our achievements, I urge you to exercise cautious judgment in accepting such honors. Although the applicable rules permit us to accept these

rewards, they also encourage us to exercise sound judgment, noting "it is never inappropriate and frequently prudent for an employee to decline a gift." Each of us must ultimately assess whether the risk of adverse perception counsels against accepting the financial benefits associated with various honors. Please consider the greater good of the NIH when deciding whether to accept financial benefits offered in recognition of your work or public service. As the Director of NIH, I will not accept any financial or travel benefit offered as part of any award from an entity that does business with the NIH.

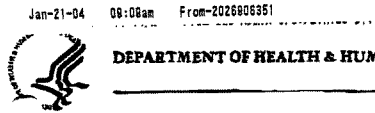
Although I am confident that our system of managing conflicts of interest at NIH has been successful in preventing breaches of Federal ethics rules, I believe we can improve our performance by subjecting ethics deliberations to a more transparent process of peer review. Therefore, I will establish a committee to provide advice to the NIH Deputy Ethics Counselors on specific activities such as the acceptance of lecture awards and consulting arrangements. This committee will provide NIH Deputy Ethics Counselors with valuable deliberative information to ensure final ethics decisions are consistent with Federal rules and avoid the perception of conflicts. The committee will also help NIH officials determine the appropriateness of engaging in activities that are not part of their official duties.

Finally, in order to coordinate better the efforts of the ethics program staff and the Office of Management (OM), effective immediately, copies of approved official duty clearances (required by our manual issuance for all IC Directors and staff) must be attached to travel paperwork when it is submitted to OM for approval. Please remind your employees that timely prior approval is required for official duty and most outside activities prior to the start of such activities.

Thank you for your cooperation.

A handwritten signature in black ink, appearing to read 'E. Zerhouni', is written over a horizontal line.

Elias A. Zerhouni, M.D.



DEPARTMENT OF HEALTH & HUMAN SERVICES

T-462 P. 602/003 F-286

Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

January 12, 2004

Ms. Marilyn L. Glynn
Acting Director
Office of Government Ethics
1201 New York Avenue, N.W.; Suite 500
Washington, DC 20005-3917

Dear Ms. Glynn:

I am writing to request your determination pursuant to § 101(f) of the Ethics in Government Act of 1978, as amended (Title I, 5 U.S.C. App., Pub. L. No. 95-521) (hereafter "the Act"), that certain employees of the National Institutes of Health (NIH), by virtue of their level of authority, should be required to file Public Financial Disclosure Reports (SF 278s). Specifically, I request that you determine that Institute/Center (IC) Directors, IC Deputy Directors, IC Scientific Directors, and IC Clinical Directors are of "equal classification" to the filing positions that are specifically designated in the statute by category or salary level.

Although these determinations are appropriately evaluated on a "case-by-case," rather than a "class or category" basis, the four identified titles are replicated in each of the institutes and centers with substantially identical functions; only the subject matter of each component's medical research would be different. The National Institutes of Health will endeavor to provide any additional information that you require to make this determination. Inasmuch as these functional responsibilities were staffed under special authorities within Title 42 of the Public Health Service Act, I am informed that they do not have "position descriptions" as would normally be expected within the civil service. Accordingly, in support of this request, and in order to fully demonstrate that these roles carry particularly high levels of responsibility, similar to that of Senior Executive Service (SES) positions, please consider the following information provided by NIH:

The NIH is presently comprised of 27 Institutes and Centers (ICs). In fiscal year 2003, the NIH budget was \$27.9 billion. The senior leadership of each of the ICs manages their respective budget allocations, collectively identifies major areas of biomedical research within the expertise of their IC staff, establishes the research objectives and plans for their ICs, approves the individual intramural research programs within the labs of the IC and the extramural research supported by NIH funding, and serve as liaisons to the media, special interest groups, high ranking scientific and executive officials throughout the Department of Health and Human Services and other federal agencies, and to Congress. They are, at various times, involved in international relations related to healthcare issues, and policy development discussions at the highest levels of the Executive Branch.

IC Directors are appointed by the Director, NIH, report directly to the Director, and are charged with fulfilling the statutory mandates established under the Public Health Act, Title 42 of the U.S. Code. IC Directors provide overall leadership and vision to the national programs of the

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Page 2 - Marilyn L. Glynn

NIH. They are responsible for integrating key national and agency goals, priorities, and values into the intramural and extramural programs of their ICs. Along with the NIH Deputy Directors, they serve as key policy advisors to the Director, NIH, on issues such as research priorities, strategic planning, and management. IC Directors regularly speak on behalf of their organizations before special interest groups, the media, and national and international scientific experts. In the interest of ensuring that scientific discoveries are translated as broadly as possible into the tools, diagnostics and pharmaceuticals of the future, they are tasked with fostering and maintaining working relationships with other NIH ICs through inter-IC initiatives, and with developing and enhancing alliances with an ever-widening range of stakeholders.

The Deputy Directors of each of the ICs are responsible for the overall management of their respective large and diverse extramural research programs. They develop new approaches to funding research on innovative high priority studies, often involving the most vulnerable populations. Working with the Directors of their ICs, they are integral to the creation of strategic plans for their ICs.

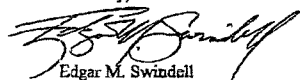
IC Scientific Directors manage and coordinate the intramural programs of each of the ICs. They set research goals and priorities, oversee the scientific and technical peer review of all intramural laboratories within their respective ICs, and advise the NIH in relation to agency-wide policies.

IC Clinical Directors provide scientific leadership and management for the intramural clinical research performed within the ICs and the NIH Clinical Center. They provide the infrastructure needed to promote high quality studies of the safety and efficacy of new and novel approaches to the vast array of human illnesses through protocol review, clinical informatics, and data and safety management. They are responsible for creating and maintaining research environments in which clinical findings influence the direction of lab studies, and coordinate inter-IC research programs.

Based upon the high level of responsibility associated with each of these functional titles, I request that you determine that their roles are of equal classification to those specifically designated in § 101 of the Ethics in Government Act and, therefore, that employees holding these appointments are required to file public financial disclosure reports.

Should you need any additional information or wish to discuss this request, please contact me, at (202) 690-7258, or Gretchen Weaver of my staff, at (301) 594-8166.

Sincerely,


Edgar M. Swindell
Associate General Counsel for Ethics
Designated Agency Ethics Official

cc: Raynard S. Kington, M.D., Ph.D., M.B.A.
Deputy Director, NIH; Deputy Ethics Counselor, NIH/OD



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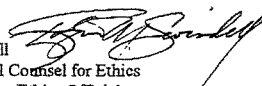
T-481 P.002/003 F-370

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

January 27, 2004

MEMORANDUMTO: Deputy Ethics Counselors
Ethics ContactsFROM: Edgar M. Swindell 
Associate General Counsel for Ethics
Designated Agency Ethics OfficialSUBJECT: Internal Agency Procedures or Processes for Reviewing
HHS 520 Outside Activity Request Forms

Following consultation with the Office of Government Ethics (OGE), and pursuant to my authority as the Designated Agency Ethics Official (DAEO) under the Ethics in Government Act of 1978 and 5 C.F.R. Part 2638, I am directing that Deputy Ethics Counselors, supervisors and others who review and approve outside activity requests must inquire of the applicant the *amount* and *type* (e.g., cash, stock, or stock options) of income, compensation, fees, remuneration, expenses, or reimbursement that is to be received in connection with the proposed activity. When evaluating any previously approved, ongoing outside activity for continued compliance with existing law, the reviewer must also inquire retrospectively as to the cumulative amount of any income or other monetary receipts (including the type or method of payment) that was received from the outside source in connection with the approved activity. Employees will be required to provide this information if they desire to have their request considered or continued, and a failure to do so will result in denial of the request.

The information that is collected from this review process shall be annotated in "Item Number 17" on the reverse of the HHS Form 520. In this manner, the data is maintained within the existing government-wide system of ethics records, OGE/GOVT 1 (for public filers and others) and OGE/GOVT 2 (for confidential filers), and is available for the routine uses therein described.

As you know, the purpose of the prior approval process is to ensure that the proposed activity does not violate any statute or regulation, including the OGE Standards, 5 C.F.R. Part 2635, and the HHS supplemental ethics regulation, 5 C.F.R. Part 5501. To that end, eliciting the dollar amount is relevant for determining whether the compensation is so excessive or disproportionate to the time expended as to suggest, for example, that public office is being used for private gain, 5 C.F.R. § 2635.801(c); that the bribery or illegal gratuities statute is implicated, 18 U.S.C. § 201; or that a salary supplementation for performing official duties has been proffered, 18 U.S.C. § 209. Moreover, non-career Senior Executive Service employees who pursue outside activities are subject to an annual compensation limitation, currently \$23,550, under 5 C.F.R. § 2636.304.

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Page 2 - Deputy Ethics Counselors

This change is effective immediately, and all internal agency procedure or process statements, policies, or manuals used within the respective operating and staff divisions for handling HHS 520s shall be amended to comply with this directive. Copies of these amendments shall be filed with the DAEO on or before February 17, 2004.

Thank you for your cooperation in implementing this requirement. If you have any questions, please call the Ethics Division at (202) 690-7258.

cc: Deputy General Counsels
Associate General Counsels
Chief Counsels, Regions I-X

LA Times Article

SUNDAY
Los Angeles Times

On The Internet: WWW.LATIMES.COM

DECEMBER 7, 2003

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pages A1, A14 - A17

Stealth Merger: Drug Companies and Government Medical Research

Some of the National Institutes of Health's top scientists are also collecting paychecks and stock options from biomedical firms. Increasingly, such deals are kept secret.

By DAVID WILLMAN
Times Staff Writer

BETHESDA, Md. — "Subject No. 4" died at 1:44 a.m. on June 14, 1999, in the immense federal research clinic of the National Institutes of Health.

The cause of death was clear: a complication from an experimental treatment for kidney inflammation using a drug made by a German company, Schering AG.

Among the first to be notified was Dr. Stephen I. Katz, the senior NIH official whose institute conducted the study.

Unknown to the participants, Katz also was a paid consultant to Schering AG.

Katz and his institute staff could have responded to the death by stopping the study immediately. They also could have moved swiftly to warn doctors outside the NIH who were prescribing the drug for similar disorders. Either step might have threatened the market potential for Schering AG's drug. They did neither.



'SUBJECT NO. 4':
 Jamie Ann Jackson

Questioned later, Katz said that his consulting arrangement with Schering AG did not influence his institute's decisions. His work with the company was approved by NIH leaders.

Such dual roles — federal research leader and drug company consultant — are increasingly common at the NIH, an agency once known for independent scientific inquiry on behalf of a single client: the public.

Two decades ago, the NIH was so distinct from industry that Margaret Heckler, secretary of Health and Human Services in the Reagan administration, could describe it as "an island of objective and pristine research, untainted by the influences of commercialization."

Today, with its senior scientists collecting paychecks and stock options from biomedical companies, the NIH is no longer an island.

Interviews and corporate and federal records obtained by the Los Angeles Times document hundreds of consulting payments to ranking NIH officials, including:

- Katz, director of the NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases, who collected between \$476,369 and \$616,365 in company fees in the last decade, according to his yearly income-disclosure reports. Some of his fees were reported in ranges without citing exact figures. Schering AG paid Katz at least \$170,000. Another company paid him more than \$140,000 in consulting fees. It won \$1.7 million in grants from his institute before going bankrupt last year.

- Dr. John I. Gallin, director of the NIH's Clinical Center, the nation's largest site of medical experiments on humans, who has received between \$145,000 and \$322,000 in fees and stock proceeds for his consulting from 1997 through last year. In one case, Gallin co-wrote an article highlighting a company's gene-transfer technology, while hiring on as a consultant to a subsidiary of that company.

[See Scientists, Page A14]

'If I am a scientist working in an NIH lab and I get a lot of money in consulting fees, then I'm going to want to make sure that the company does very well.'

—DR. ARNOLD S. RELMAN, former editor of the *New England Journal of Medicine*

Public Experts on Private Payrolls

(Scientists, from Page A1)

■ Dr. Richard C. Eastman, the NIH's top diabetes researcher in 1997, who wrote to the Food and Drug Administration that year defending a product without disclosing in his letter that he was a paid consultant to the manufacturer. Eastman's letter said the risk of liver failure from the drug was "very minimal." Six months later, a patient, Audrey LaRue Jones, who was taking the drug in an NIH study that Eastman oversaw, suffered sudden liver failure and died. Liver experts found that the drug probably caused the liver failure.

■ Dr. Ronald N. Germain, deputy director of a major laboratory at the National Institute of Allergy and Infectious Diseases, who has collected more than \$1.4 million in company consulting fees in the last 11 years, plus stock options. One of the companies collaborated with his laboratory on research. The founder of another of the companies worked with Germain on a separate NIH-sponsored project.

■ Jeffrey Schlom, director of the National Cancer Institute's Laboratory of Tumor Immunology and Biology, who has taken \$331,500 in company fees over 10 years. Schlom helped lead NIH-funded studies exploring wider use for a cancer drug — at the same time that his highest-paying client was seeking to make the drug through genetic engineering.

■ Jeffrey M. Trent, who became scientific director of the National Human Genome Research Institute in 1993 and, over the next three years, reported between \$50,608 and \$165,000 in industry consulting fees. Trent, who accepted nearly half of that income from a company active in genetic research, was not required to file public financial-disclosure statements as of 1997. He left the government last year.

Hidden From View

Increasingly, outside payments to NIH scientists are being hidden from public view. Relying in part on a 1998 legal opinion, NIH officials now allow more than 94% of the agency's top-paid employees to keep their consulting income confidential.

As a result, the NIH is one of the most secretive agencies in the federal government when it comes to financial disclosures. A survey by *The Times* of 34 other federal agencies found that all had higher percentages of eligible employees filing reports on outside income. In several agencies, every top-paid official submitted public reports.

The trend toward secrecy among NIH scientists goes beyond their failure to report outside income. Many of them also routinely sign confidentiality agreements with their corporate employers, putting their outside work under tight wraps.

Gallin, Germain, Katz, Schlom and Trent each said that their consulting deals were authorized beforehand by NIH officials and had no adverse effect on their government work. Eastman declined to comment for this article.

Dr. Arnold S. Relman, the former editor of the *New England Journal of Medicine*, said that private consulting by government scientists posed "legitimate cause for concern."

"If I am a scientist working in an NIH lab and I get a lot of money in consulting fees, then I'm going to want to make sure that the company does very well," Relman said.

Relman and others in the field of medical ethics said company payments raised important questions about public health decisions made throughout the NIH:

■ Will judgment calls on the safety of individual patients be affected by commercial interests?

■ Can study participants trust that experimental treatments are chosen on merit and not because of officials' personal financial interests?

■ Will scientists shade their interpretations of study results to favor their clients?

■ Will officials favor their clients over other companies that seek NIH grants or collaborations?

Conflict-of-interest questions also arise in the potentially lucrative awarding of patents.

Thomas J. Kindt, the director of in-house research at the National Institute of Allergy and Infectious Diseases, accepted \$63,000 in consulting fees from a New York biotechnology company, Innovir Laboratories, and wound up an inventor on one of its patents.

Asked why the government received no consideration, Kindt said that he had contributed to the "basic idea" while using vacation time.

"No work was done on it as a government employee," said Kindt, whose annual salary at the NIH is \$191,200. His consulting with Innovir was approved by NIH officials, Kindt said.

Others worry that the private arrangements can undermine the public interest.

"The fact that paid consulting is happening I find very disturbing," said Dr. Curt D. Furberg, former head of clinical trials at the National Heart, Lung and Blood Institute. "It should not be done."

Private consulting fees tempt government scientists to pursue less-deserving research and to "put a spin on their interpretation" of study results, he said.

"Science should be for the sake of gaining knowledge and looking for the truth," Furberg said. "There should be no other factors involved that can introduce bias on decision-making."

Dr. Ruth L. Kirschstein, who as the deputy director or the acting director of the NIH since 1993 has approved many of the top officials' consulting arrangements, said she did not believe they had compromised the public interest. "I think NIH scientists, NIH directors and all the staff are highly ethical people with enormous integrity," she said. "And I think we do our business in the most remarkable way."

In response to *The Times*' findings, Kirschstein said, she would "think about" whether administrators should learn more about a company's ties to the NIH before approving the consulting arrangements.

"Systems can always be tightened up," Kirschstein said on Oct. 29. "And perhaps, based on this, we will do so."

On Nov. 20, NIH Director Elias A. Zerhouni told agency leaders that he would form a committee to help "determine the appropriateness" of employees' consulting and other outside arrangements.

"I believe we can improve our performance by subjecting ethics deliberations to a more transparent process," Zerhouni said in a memo.

In a brief telephone interview last week, Zerhouni said he wanted the NIH "to manage not just the reality, but the perception of conflict of interest."

"If there is something that could be viewed as improper, I think we need to be able to advise our scientists not to get into these relationships," he said. "My sense is our scientists are people of goodwill."

Temptations Abound

The NIH traces its beginnings to the Laboratory of Hygiene, founded in 1887 within a Navy hospital on Staten

"I think NIH scientists, NIH directors and all the staff are highly ethical people with enormous integrity. And I think we do our business in the most remarkable way."

— DR. RUTH L. KIRSCHSTEIN, deputy director of the National Institutes of Health

Island in New York. It became the federal government's first research institution for confronting such epidemic diseases as cholera, diphtheria, tuberculosis and smallpox.

The laboratory's success convinced Congress of its value in seeking cures for diseases.

In 1936, the renamed National Institute of Health moved to its present, 300-acre headquarters in Bethesda, about nine miles north of the White House.

The agency's responsibilities — and prominence — have grown steadily.

In 1948, four institutes were created to support work on cardiac disease, infectious diseases, dental disorders and experimental biology. "Institute" in the agency's name became "institutes."

President Nixon turned to the NIH in 1971 to lead a war on cancer. The agency has led the government's fight against AIDS. Two years ago, President Bush enlisted the NIH to help counter biological terrorism.

Republican and Democratic administrations have boosted spending for the 27 research centers and institutes that compose today's NIH. Since 1990, the annual budget has nearly quadrupled, to \$27.9 billion this fiscal year.

Senior NIH scientists are among the highest-paid employees in the federal government.

With billions of dollars in product sales potentially at stake for industry, and untold fortunes riding on biomedical stock prices, commercial temptations abound.

Researchers poised to make a breakthrough in their NIH labs can, the same day, land paid consulting positions with companies eager to exploit their insights and cachet. Many companies cite their connections to NIH scientists on Web sites and in news releases, despite an agency rule against the practice. Selection of a company's products for an NIH study can provide a bankable endorsement — attracting investors and boosting stock value. If the study yields positive results, the benefits can be even greater.

Conflicts of interest among university medical researchers have received wide attention in recent years. U.S. Rep. W.J. "Billy" Tauzin (R-La.) also raised questions recently about cash awards that several nonprofit institutions made to a previous director of the National Cancer Institute.

The consulting deals between drug companies and full-time, career employees at the NIH, however, have gone all but unnoticed.

The wide embrace of private consulting within the NIH can be traced in part to calls from Congress for quicker "translation" of basic federal research into improved treatments for patients. And for decades industry has pressed for more access to the government's scientific discoveries.

As the number of government-held patents soared, companies sought legislation encouraging commercialization of federally funded inventions. The proponents said the changes also would make U.S. firms more competitive with foreign companies whose research and development programs were subsidized by their governments.

Laws enacted in the 1980s for the first time authorized formal research collaborations between companies and scientific arms of the government, including the NIH. Starting in late 1986, in-house researchers at the NIH were permitted to arrange cooperative research agreements with companies. The agreements were intended to benefit both sides while advancing scientific discovery.

Other changes in law permitted the government agencies, and the researchers, to share in future patent royalties for inventions.

The new laws said nothing about government employees being hired by the companies.

Yet by the end of the 1980s, more companies were putting NIH researchers on their payrolls, albeit within limits imposed by the NIH.

Agency leaders in the 1990s began weakening those restrictions.

In November 1995, then-NIH Director Harold E. Varmus wrote to all institute and center directors, rescinding "immediately" a policy that had barred them from accepting consulting fees and payments of stock from companies.

The changes, he wrote, would bring the NIH ethics rules more in line with new, less stringent, executive branch standards. Loosening of restrictions on employees' outside pursuits was occurring throughout the government. And with biomedical companies ready to hire, few were better positioned to benefit than employees at the NIH.

Varmus' memo — which until now has not been made public — scuttled other restraints affecting all employees, including a \$25,000 annual limit on outside income, a prohibition on accepting company stock as payment and a limit of 500 hours a year on outside activities.

His memo also offered a narrowed definition of conflict of interest.

Employees had been barred from consulting for any company that collaborated with their NIH lab or branch. But Varmus said the ban would be applied only if the researcher was personally involved in the company's collaboration with the agency.

Furberg, the former NIH official, said Varmus' actions invited, at minimum, appearances of conflict of interest.

"I'm amazed at what he did," said Furberg, a professor at Wake Forest University. "And to do it in secrecy I find very objectionable. This is a critical change in the NIH policy."

In 1999, Varmus wrote a letter to the institute directors that cautioned them to "avoid even the appearance of a conflict of interest." But in an attachment to the letter, he told them that employees "may briefly discuss or mention current work" to outsiders, in effect giving agency scientists permission to reveal their unpublished, confidential research.

Varmus, now president and chief executive of the Memorial Sloan-Kettering Cancer Center in New York, declined to be interviewed for this article. His spokeswoman, R. Anne Thomas, said that Varmus, who in 1989 shared a Nobel Prize for research into the genetic basis of cancer, believed that NIH employees should take personal responsibility for avoiding conflicts of interest, regardless of what agency rules allow.

Kirschstein, after taking over as Varmus' interim successor at the NIH three years ago, said in a May 2000 speech to medical researchers that conflicts of interest posed "a major concern."

"While the federal government was once the dominant force for supporting clinical research, today we share the arena with biotechnology companies, pharmaceutical firms and many others — all interested in the possibility of financial gain from their research."

"Profit raises issues of public trust," she said. "When scientific inquiry generates findings that can make a profit for the researcher and the institution,

'I have always received official permission to perform . . . consultations and have performed [them] outside of my normal NIH work schedule and according to strict government guidelines and rules.'

— DR. STEPHEN I. KATZ, director of the NIH's arthritis institute

their images become clouded."

Yet officials have lifted controls on consulting even as industry's stake in NIH research has deepened. When Zerhouni, the current NIH director, appeared before the House Subcommittee on Environment, Technology and Standards last year, he cited 274 ongoing research and development agreements between the federal agency and industry.

At the same time, NIH leaders have moved to what they describe as "managing" conflicts of interest. Employees are allowed to consult if they receive prior clearance from an administrator at their institute or, in the case of most institute directors, from NIH headquarters.

An Honor System

Potential conflicts are typically addressed by allowing employees to sign "recusals." Under these agreements, NIH employees pledge not to participate in decisions affecting an outside client. Agency officials, Kirschstein said, rely on an honor system to enforce recusals and other conflict-of-interest rules.

The Times found instances in which the recusals did not work as intended.

In the mid-to-late 1990s, Eastman, the diabetes researcher, participated in a series of decisions affecting the drug company employing him as a consultant, despite having signed a recusal. Separately, Katz, the director of the arthritis institute, signed a recusal involving his client, Schering AG, which nevertheless supplied the NIH with the drug involved in the kidney patient's death in 1999.

Katz said that he did not know at the time that Schering AG was the maker of the drug his institute was testing.

Compliance with the recusals can, itself, undercut the interests of the NIH and taxpayers, who support the agency. When heads of institutes and laboratories recuse themselves, they sometimes constrain their ability to carry out their government duties.

Kirschstein, who for the last eight years has personally reviewed requests from the institute directors to consult

(See *Scientists*, Page A16)

Changes in Ethics Rules Came From the Top

[Scientists, from Page A15] privately for pay, said she tended to approve the deals, unless she saw "real conflict."

"I've disapproved some — and I've approved many," she said.

In her view, recusals have worked "extremely well" in avoiding conflicts of interest.

Other present and former officials say it is difficult, if not impossible, for researchers to keep separate their confidential government information when they consult for companies.

"You can't police the thing," Philip S. Chen Jr., a senior advisor in the NIH director's office who has served as an agency scientist or administrator since the 1980s, said in an interview last year. "The rules are there — whether they follow the rules is another thing."

A former NIH director voiced surprise at the agency's loosened approach to conflicts of interest.

"There has been a lot of relaxation," said Dr. Bernadine P. Healy, who served as director from 1991 to 1993. Before, Healy said in an interview, "there were very strict ethics rules for NIH scientists. You couldn't have virtually any connection with a company if your institute was in any way doing research involving their products."

At least one vestige of the old days remains.

During last year's holiday season, workers were advised to refuse gifts from outsiders worth more than \$20.

"Just a reminder," ethics coordinator John C. Condray wrote, introducing a five-page memo, "that sometimes gifts and events can create the appearance of a lack of impartiality."

Where secrecy reigns

The Ethics in Government Act has generally required highly paid federal workers to file annual financial disclosure reports that are open to public review. Many National Institutes of Health employees make or exceed the threshold salary of \$102,168. Most of them have been exempted by changes made to their payroll status.

Out of a total of 18,000 NIH employees:

Those making more than \$102,168: 2,259

Those subject to public disclosure of outside income: 127



Sources: NIH records and interviews

Los Angeles Times

Fewer Public Filings

While making it easier for scientists to cut consulting deals, the NIH has made it harder for the public to find out about them.

The Ethics in Government Act requires yearly financial-disclosure reports from senior federal employees. This year, employees paid \$102,168 or more generally must disclose outside income by filing a "278" form, which is available for public review. Other employees may file a "450" form — which does not specify the amount of money received from an outside party and is kept confidential.

At the NIH, 2,259 employees make more than \$102,168, according to data provided by the NIH. Those records show that 127 of the employees — about 6% — are filing disclosure forms available to the public.

From 1997 through 2002, the number of NIH employees filing public reports of their outside income dropped by about 64%, according to the agency records. Most of those employees have

switched to filing the confidential 456 form.

At the National Institute of Allergy and Infectious Diseases — which researches treatments for AIDS and other life-threatening maladies — only three officials file public reports revealing their outside income, according to NIH records.

Officials at the NIH said that an advisory legal opinion from the U.S. Office of Government Ethics gave them the discretion to bypass public disclosure.

Issued in 1998, the opinion said that the threshold for public disclosure was to be set, not by a federal employee's actual salary, but by the low end of his or her pay grade. If the minimum salary in an employee's grade is beneath the \$102,168 threshold, he or she is exempt from filing a public report.

The NIH has shifted many of its high-salaried employees into pay plans with minimums that dip below the threshold.

For instance, two prominent NIH laboratory leaders, Schlom and Germain, make \$180,400 and \$179,900, respectively. Within roughly the last year, NIH changed each of their pay plans, and they now are exempt from public disclosure.

They file confidential forms, which instruct employees to not specify the dollar amounts they receive from outside parties.

Asked why the NIH has assigned highly paid staff to plans that eliminate public disclosure of employees' outside income, an NIH spokesman, John Burklow, provided a written response:

"The primary benefit of the alternate pay plans is to attract and retain the best scientists in a highly competitive environment."

Said Donald Ralbovsky, another NIH spokesman: "What it really boils down [to] is that fewer people are filing 278s because of changes in pay plans."

The shift imparts an implicit message to employees, said George J. Galasso, a former NIH researcher and administrator who retired in 1996.

"If you've got something to hide, you file a 456. If you don't, you file a 278."

Make-or-Break Grants

As director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, Katz is one of the few at the NIH who still must file public financial-disclosure reports.

Katz, 62, is paid \$200,000 a year — more than members of Congress, justices on the Supreme Court and the vice president.

His institute leads the government's research into the causes, treatment and prevention of disorders of the joints, bones and overall musculoskeletal system.

With a yearly institute budget of \$485.4 million, Katz's decisions are watched closely by industry. The director's office decides how much of the budget will be spent on grants and contracts coveted by companies.

And Katz has been available for outside consultation: From 1993 through 2002, Katz took between \$476,369 and \$616,365 in fees from seven biotech and pharmaceutical companies, according to his annual disclosure statements. He consulted while chief of the dermatology branch at the National Cancer Institute and continued after becoming arthritis institute director in 1995.

Katz said that his private consulting broke no rules and that he relied in part on Varmus' 1995 memo while entering arrangements with companies.

"The consultations provided my global knowledge as a dermatologist and research scientist," Katz said in written responses to questions from The Times. "I have always received official permission to perform these consultations and have performed these consultations outside of my normal NIH work schedule and according to strict government guidelines and rules."

One of his clients was Advanced Tissue Sciences Inc.

The struggling biotech company in San Diego hired Katz as a consultant



IN DEMAND: From 1993 through 2002, Dr. Stephen I. Katz, director of the NIH's arthritis institute, took between \$476,369 and \$616,365 in fees from seven biotech and pharmaceutical companies, according to his annual disclosure statements.

JOANNE CAROLE FOR THE TIMES

'Science should be for the sake of gaining knowledge and looking for the truth.
There should be no other factors involved that can introduce bias on decision-making.'

—DR. CURT D. FORBERG, former head of clinical trials at the National Heart, Lung and Blood Institute

in 1997, a year after he had announced a new NIH research initiative for bone and connective-tissue repair.

Advanced Tissue installed Katz on its scientific advisory board and paid him fees between \$142,500 and \$212,500 from 1997 through 2002, according to his income-disclosure reports.

During that time, Katz's institute pledged \$1.7 million in small-business research grants to the company. The company announced nearly every grant in a news release; Advanced Tissue's president termed the grants "an endorsement by the government."

In his written response, Katz said that he had signed a recusal "withdrawing myself from any interactions between Advanced Tissue Sciences and the government to remove any real or potential conflict of interest." The grants were awarded following evaluations by NIH reviewers outside of Katz's institute.

Responsibility for administering the grants to Advanced Tissue was delegated to one of his subordinates, Katz said.

The NIH policy manual says officials may not take fees from companies seeking or receiving agency grants "if the employee is working on or involved in these matters" or "supervising others who work on these matters."

Katz said his subordinate "handled all decisions regarding these grants without informing me."

However, Advanced Tissue kept him apprised as NIH grants were obtained, a company executive said.

"He was informed," said Anthony J. Ratcliffe, the firm's vice president for research until its collapse a year ago. "We would have made a written report to the SAB (scientific advisory board) members twice a year. There would have been a report to the SAB meetings on all grants, all grant activities."

Ratcliffe said the company dealt with Katz's potential conflict of interest by paying him in fees alone, and not stock options. Both men said Katz did not advise the company on the NIH grants.

His consultations, Katz said, were limited to his scientific expertise and "never involved, directly or indirectly, the preparation or discussion of material which could relate to any financial dealings between [Advanced Tissue] and the NIH."

A federal partner

Some of the ways the National Institutes of Health helps biomedical companies:

Studies: Research conducted by NIH scientists, frequently using drugs or technology from industry.

Contracts: NIH outsourcing of research and development for agency studies.

Consultants: NIH scientists consult for companies in exchange for personal payments in fees or stocks.

Sources: NIH Web site and records



Grants: NIH funding of private-sector research.

Cooperative research and development agreements: Collaborations between the NIH and the private sector that share costs and benefits.

Los Angeles Times

Kirschstein, the senior NIH official who each year approved Katz's consulting with Advanced Tissue, said she did not learn the company held grants with the arthritis institute until The Times inquired.

"I didn't even know there were grants," Kirschstein said.

As it turned out, the grants would be among the few positive financial developments for Advanced Tissue.

By December 2001, its cumulative net operating losses were approximately \$292.7 million. Barely a year later, the company entered bankruptcy and shut its doors, having collected about \$1.5 million of the \$1.7 million in small-business research grants.

Life-and-Death Decisions

While Katz was consulting for Advanced Tissue, he also was on the payroll of Schering AG, which made Fludara, a drug that his research staff was using as an experimental treatment for autoimmune diseases.

From the time he began consulting for Schering AG in 1996 through 2002, Katz collected between \$170,000 and \$240,000 in fees from the company, his disclosure reports show.

In his responses to questions, Katz said that he "first became aware" that Fludara was a Schering AG product when The Times made inquiries.

Fludara had been approved by the Food and Drug Administration in 1991 to treat leukemia, but the company wanted to expand its use to other diseases, a goal the NIH studies could advance.

Two people died in the studies conducted by Katz's institute.

In one study using Fludara to treat muscular disorders, a patient suffered what agency researchers reported in July 1998 as a "sudden death ... not thought to be drug related."

The second fatality, indisputably, resulted from the treatment. It involved "Subject No. 4," who had enrolled in a separate study, designed to treat kidney inflammation related to lupus, a disease of the immune system.

Schering AG provided Katz's institute with a supply of Fludara and with analyses of patients' blood samples through its U.S. affiliate, Berlex Laboratories, records and interviews show. The company also contributed a total of \$60,000 to the institute to support the research, eliciting a July 1, 1998, thank-you letter from Katz.

Participants entering the study were warned of some risks. The NIH advised them that Fludara might cause damage to their blood cells and that, as a result, "blood transfusions may be required."

2000. The NIH's human protection office had just opened an internal review of the lupus-related study, questioning the researchers' failure to protect against graft-versus-host disease, as well as their failure to report the death to agency investigators in a timely fashion.

"Dr. Katz and his scientific director came to me . . . to tell me about a study in which a drug was used and there was a death," Kirschstein said. "They did not tell me the name of the drug, and did not tell me much about the study, but told me that they and the [department] were looking into it."

In a follow-up letter two years later, the internal review absolved the institute of responsibility for Jackson's death. Her husband has filed a wrongful-death lawsuit against the government in U.S. District Court. The lawsuit does not refer to Katz.

Jackson's mother, Carmella Tarte, said time had not eased her grief.

"We all went to the hospital, but we never even got to talk to her," Tarte said in an interview. "It's been four years and, well, Thanksgiving was just another day, you know? She has children she didn't see graduate."

Contributors

Times researcher Janet Lundblad in Los Angeles assisted in this report. Researchers Robert Patrick and Christopher Chandler in Washington also contributed.

About This Report

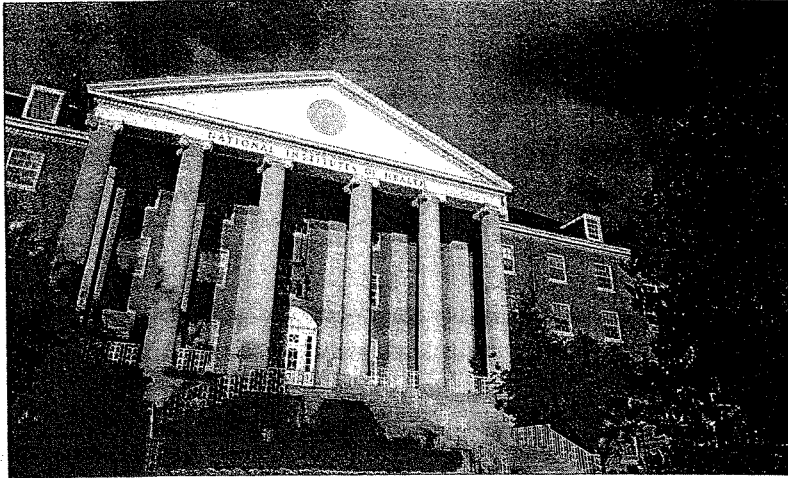
In late 1998, the Los Angeles Times began examining payments from drug companies to employees of the National Institutes of Health and the agency's research collaborations with industry. This report is based on records from the federal government and from companies, as well as scores of interviews.

In early 1999, the newspaper first sought income-disclosure reports for all eligible employees of the 27 research institutes and centers of the NIH. The newspaper, as of this month, had filed 36 requests with the NIH for documents under the Freedom of Information Act.

According to NIH staff, the agency has provided documents totaling 13,784 pages, including annual financial-disclosure reports, memos and internal e-mails.

A significant number of NIH employees had by this year stopped filing yearly income reports that are open to public inspection. To assess the relative extent of public financial disclosure at the NIH, The Times in July queried dozens of other federal agencies under the Freedom of Information Act.

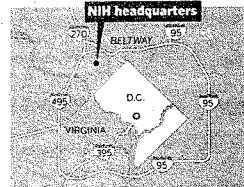
Other documentation, describing products and hundreds of research collaborations between the NIH and industry, was retrieved from company and NIH Web sites, from filings with the Securities and Exchange Commission, and from lawsuits filed in federal and state courts. Other related documents were obtained from the Food and Drug Administration under the Freedom of Information Act.



A PRESCRIPTION FOR CONFLICTS: The wide embrace of private consulting within the National Institutes of Health can be traced in part to calls from Congress for quicker "translation" of federal research into improved treatments for patients. Industry also has pressed for more access to the government's scientific discoveries.

National Institutes of Health

Headquarters: About 300 acres in Bethesda, Md.



Mission: "NIH is the steward of medical and behavioral research for the nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability."

— from NIH mission statement

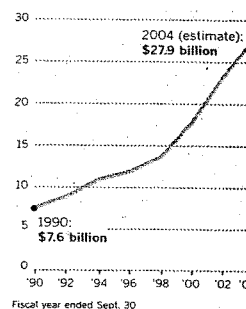
Founded: In 1887 as the Laboratory of Hygiene.

Organization: 27 institutes and centers committed to an array of scientific specialties; a research hospital with a laboratory complex.

Affiliation: Part of the U.S. Department of Health and Human Services.

Staff: About 18,000 employees; some 45,000 fellows, research grant recipients and trainees.

Budget (in billions)




Source: NIH Web site

REBECCA PERRY Los Angeles Times

Opening the door

The following 1995 internal memo from then-National Institutes of Health Director Harold E. Varmus eliminated or eased several rules intended to prevent conflicts of interest among agency scientists.

	DEPARTMENT OF HEALTH & HUMAN SERVICES	Public Health Service
NOV 03 1995	National Institutes of Health Bethesda, Maryland 20892	
TO: ICD Directors OD Staff		
FROM: Director, NIH		
SUBJECT: Changes in NIH Policies on Outside Activities		
As discussed at the ICD Directors meeting on September 21, the recently completed an audit		
1. Activities Performed by High-Level Officials		
High level officials may now perform the same types of outside activities as all other NIH employees. High level officials include the NIH Director, Deputy Directors and Associate Directors, and ICD Directors and Deputy Directors, except Presidential appointees.		
Page 2 - ICD Directors		
2. Prohibited Source Criteria for Intramural Employees		
Intramural employees may now engage in activities for any outside organization except those with whom they have direct official business dealings as government employees. They are no longer precluded from engaging in activities with outside organizations that had or currently have research agreements or contracts with the employees' laboratory or branch.		
4. Stock as Compensation		
Employees may accept stock as payment for approved outside activities. The former policy prohibited the acceptance of stock as full or partial payment for outside activities.		
5. Compensation Limits		
There is no longer a dollar limit on the amount of income that can be received from activities performed for one or more outside organizations.		

CASE STUDY | RICHARD C. EASTMAN

A Federal Researcher Who Defended a Client's Lethal Drug

BETHESDA, Md. — When Dr. Richard C. Eastman talked about the controversial diabetes drug Rezulin, doctors listened. After all, he was the top diabetes researcher at the National Institutes of Health.

Eastman's views were heard clearly in the fall of 1997, when the Food and Drug Administration received reports of liver injury among patients taking the pill.

At the time, Eastman was supervising a \$150-million NIH study exploring whether Rezulin or another drug could prevent diabetes in adults who had slightly elevated blood-sugar levels.

In light of the reports of liver injury, an FDA medical officer questioned the prudence of the NIH's nationwide study. Eastman, one of four members of the study's executive committee, said all was well.

"At this point in time, we consider the risk of [Rezulin] to be very minimal," Eastman told the FDA in a Nov. 6, 1997, letter obtained by the Los Angeles Times. "[W]e continue to think that the drug is safe," he wrote. "The risk to benefit ratio in the trial continues to be one that we think is very acceptable."

Eastman signed the letter to the FDA using his government title, director of the NIH's diabetes division. The letter did not disclose that he was also a paid consultant to Warner-Lambert Co., the maker of Rezulin.

The FDA allowed the use of Rezulin to continue in the study. Warner-Lambert went on to collect \$2.1 billion in sales revenue from Rezulin before it was pulled from the U.S. market in 2000 after being cited as a suspect in 556 deaths, including 68 that involved liver failure.

Some aspects of Eastman's dual role were reported earlier by The Times. Hundreds of pages of newly obtained internal company and federal documents show that Eastman took previously unreported actions regarding the drug.

Reached by telephone last month, Eastman, 57, declined to be interviewed for this article.



Dr. Richard C. Eastman

He was hired by Warner-Lambert in October 1995, less than three weeks after he met with a company executive on behalf of the NIH to discuss the drug's safety, records show. As part of his consulting arrangement, Eastman spoke to diabetes "thought leaders" assembled by the company. He also signed a contract prohibiting him from disclosing "confidential and proprietary information" without the company's prior, written consent.

Eastman's consulting was approved in November 1995 by two senior officials, including the then-director of the NIH diabetes institute.

In March 1996, Eastman signed a federal recusal, pledging to disqualify himself "to judge or otherwise act [as a federal official] on any matter or matters pertaining to" Rezulin's status in the NIH study.

However, the NIH has no procedure for verifying that officials comply with the terms of their own recusals. And Eastman continued to participate in decisions of the study's four-person executive committee regarding Rezulin, according to records and interviews.

When the inspector general of the Department of Health and Human Services inquired years later, Eastman said he had not thought he was violating his recusal, records show.

Eastman and his boss also told the inspector general that they had never seen a 1996 memo from an NIH attorney warning Eastman: "recuse yourself from all official matters" involving Warner-Lambert. Both Eastman and his boss, then the deputy director of the diabetes institute, stated that an office aide had filed away the attorney's warning before they had a chance to read it.

From 1995 through 1997, while collecting upwards of \$43,000 in consulting fees and related compensation from Warner-Lambert and its affiliates, Eastman repeatedly defended Rezulin in his government capacity.

On Nov. 28, 1997, Eastman wrote to the 22 physicians around the U.S. who were carrying out the NIH's diabetes prevention study, telling them that the British distributor of Rezulin was about to pull the drug.

"This is apparently a marketing decision, rather than a regulatory one," Eastman wrote. The withdrawal was voluntary, but it was made in consultation with officials at Britain's Medicines Control Agency, who concluded that Rezulin was unsafe.

An internal Warner-Lambert document circulated about that time termed Eastman and his NIH colleagues "the strongest advocates for the safety of this drug."

On May 17, 1998, a participant in the major NIH study that Eastman supervised suffered sudden liver failure and died.

The victim was Audrey LaRue Jones, a 55-year-old high school teacher from East St. Louis, Ill. The death loomed as an indictment of Rezulin because Jones fell into liver failure despite having her liver functions monitored monthly, consistent with the product labeling. Some 580 other patients remained on the drug in the NIH study.

For nearly three weeks, Eastman and his colleagues on the executive committee held off on informing the patients or the other doctors conducting the study about Jones' death, the new documents show.

On June 2, 1998, Eastman and a handful of other NIH officials met in Bethesda with the study's six-member data monitoring board to decide whether to banish Rezulin from the experiment.

Experts retained by the NIH to evaluate the case had found that Rezulin probably caused the woman's liver failure. The death certificate attributed the "underlying cause" to the liver failure.

Newly obtained handwritten minutes of the NIH meeting show that Eastman called the case "unusual" and asked, "Do we want to write off [Rezulin] because of a very bizarre death?"

The board recommended unani-

mously that Rezulin be removed; the director of the NIH's diabetes institute upheld the recommendation.

On June 4, 1998, 18 days after Jones died, the chairman of the NIH's executive committee informed doctors conducting the study about her death.

"It is possible that you may be contacted by the press," the official wrote. "Please be polite, but refer all questions to Dr. Richard Eastman."

In May 2000, the inspector general's office found that Eastman's arrangements "were reviewed and approved in accordance with the internal NIH regulations."

The investigation report concluded that unspecified "administrative errors . . . contributed to the appearance of a conflict of interest associated with Dr. Eastman's outside activities with Warner-Lambert Company."

In June 2000, after nearly a decade on the job, Eastman, whose federal salary was \$144,000, left the NIH to join a medical device company based in Redwood City, Calif.

Eastman was not alone in taking Warner-Lambert's money.

At least 12 of the 22 academic researchers selected by the NIH to help conduct the nationwide study received company fees or research grants, according to records and interviews.

The chairman of the study's data monitoring board, responsible for protecting patients from unnecessary risks, also took fees from a Warner-Lambert affiliate.

— DAVID WILLMAN



DAVID KENNEDY For The Times

PATIENT: Audrey LaRue Jones died after sudden liver failure in 1998 while in an NIH study that Dr. Richard C. Eastman supervised. Outside experts found that the drug Rezulin probably caused her liver failure. Eastman had defended the drug while receiving consulting fees from its maker.

CASE STUDY | JOHN I. GALLIN

A Clinic Chief's Desire to 'Learn About Industry'

BETHESDA, Md. — Dr. John I. Gallin is director of the NIH Clinical Center — the nation's largest site of medical research on humans.

Thousands of patients go there each year seeking experimental treatments that, if successful, can pioneer new standards of care for all Americans. Drug companies, eager to get new products to market, vie to have their medicines and technologies tested in the NIH research.

This places Gallin and the 600 physicians he oversees in a delicate position. He is an intermediary between the hopes of patients and the ambitions of industry.

Yet Gallin, whose government salary is \$225,200, has reported investments in eight biotechnology and pharmaceutical companies. And he received between \$145,000 and \$322,000 in consulting-related stock proceeds and fees from 1997 through last year, according to his government filings.

The potential for conflicts of interest is raised by Gallin's government positions. He is the Clinical Center director and a leader of the NIH Laboratory of Host Defenses, where he has helped manage gene therapy experiments.

Gallin has filed recusals, pledging not to participate in government decisions affecting the companies in which he has disclosed a financial interest. His outside dealings have, been approved by other NIH leaders.

"I thought the experience of working with a biomedical company would give me an opportunity to learn about industry as well as broaden my exposure to current research," Gallin said. "It is necessary that all entities work together to improve the health of the nation."

But taking industry's money, while at the same time avoiding the companies in his NIH role, has proven a challenge, as his dealings with a company specializing in gene therapy, Cell Genesys Inc., show.

In June 1997, Gallin and his lab were completing work on a gene therapy study in collaboration with industry partners. That same month, Cell Genesys acquired one of those partners — a company that had contributed crucial gene-transfer technology.

In July 1997, Cell Genesys made a "demand," according to Gallin. The company wanted the published results of the gene therapy study to identify Cell Genesys as the contributor of the technology — even though it had not performed the work.

Gallin's top lab deputy granted the company's request; Gallin did not object. When they submitted the article to a journal that month for publication, the authors cited Cell Genesys as the contributor of the gene technology. On Sept. 3, 1997, Gallin became a paid consultant to a Cell Genesys subsidiary, Abgenix Inc.

The article appeared in the Proceedings of the National Academy of Sciences in October 1997. Describing the results as "encouraging news," the NIH issued a news release that credited Gallin and his lab for leading the research. At the company's request, Gallin said, the release also cited Cell Genesys for providing the technology.

Gallin made between \$132,700 and \$319,776 from Abgenix consulting fees and stock-option proceeds from 1997 through 2002, according to his yearly income reports. (He reported payments in ranges, not exact amounts.)

Cell Genesys owned Abgenix when Gallin was hired and held a majority stake in the subsidiary until July 1998, records show. As of last month, Cell Genesys maintained a minority position.

Gallin also became a shareholder in Cell Genesys in 1999, but for two years he did not disclose the holding on his annual financial reports. "It was an error," Gallin said. He sold shares in Cell Genesys last year for \$15,000 to \$50,000, according to his income report.

In written responses to questions from the Los Angeles Times, Gallin said that when he was hired to consult in 1997, "I was assured by Abgenix staff that Abgenix was an independent company." He added, "I did not consult for Cell Genesys."

In March 2000, Gallin acknowledged the relationship between the two companies. He filed a recusal, saying that "since Abgenix is partially owned by Cell Genesys, I have been advised that an activity with these outside organizations may present an actual or the appearance of a conflict of interest."

Regarding Cell Genesys' requests that it be cited publicly as the contributor of the gene-transfer technology used by his NIH lab, Gallin said that he

deferred to his deputy, who was the first-named author on the article.

"I had no involvement other than the first author informed me that this was to be done," Gallin said.

He said agency leaders approved his consulting and stock ownership.

"I was very careful to solicit advice from NIH leadership as to whether or not my accepting the position of serving on the Abgenix scientific advisory board was a conflict that should be avoided," said Gallin, 60, who arrived at NIH in 1971 after graduating from Cornell University Medical School.

Gallin said nearly all of his other investments in biomedical companies were initiated by a financial advisor "in my wife's name, without her or my consultation."

Gallin added, "The stock purchases were not with companies I had any relationship with in my position at NIH. I listed them in my annual [NIH disclosure reports]. If I thought there was a possibility of a conflict I filed a recusal." He said nearly all of the holdings were sold by the end of last year.

Dr. Ruth L. Kirschstein, the NIH deputy director, at first told The Times that she had never allowed an official to own a drug company stock if it required filing a recusal. But Kirschstein later corrected herself, acknowledging that she personally approved recusals that allowed Gallin to own stock in several companies.

For Gallin, avoiding matters involving Abgenix could grow more complicated because of its many new research partners, including industry giants Pfizer, Amgen and AstraZeneca.

— DAVID WILLMAN



Dr. John I. Gallin

CASE STUDY | RONALD N. GERMAIN

A Federal Lab Leader Who Made \$1.4 Million on the Side

BETHESDA, Md. — Dr. Ronald N. Germain has been a paid advisor to a dozen drug-development companies, a law firm that specializes in patent litigation and an investment fund that buys and sells biotechnology stocks.

By his own accounting, he has collected more than \$1.4 million in fees over the last 11 years and gathered company stock options valued at \$865,000.

Germain's full-time job is deputy director of the National Institutes of Health's Laboratory of Immunology, which explores how the immune system protects against infections, cancer and other maladies.

His annual government salary is \$179,900 — but his consulting income surpassed it in one recent year and nearly matched it another year.

He has taken fees from a company collaborating formally on research with his laboratory. Another company's founder collaborated with Germain in his NIH capacity. Four more of his clients had grants or research agreements with the institute that houses his lab. He made plans last spring to begin consulting with a new client, a venture capital firm that invests in nascent biotechnology companies.

In written responses to questions from the Los Angeles Times, Germain, 55, said he had always followed NIH rules and had consulted with the approval of agency officials. He said he had not made government decisions affecting companies that paid him.

"I have a well-regarded reputation both inside and outside of NIH for adhering strictly to the rule preventing me from revealing or using specific knowledge of my NIH research during consulting activities and for keeping all outside activities from having any bearing on the conduct of my activities as a [government] employee," Germain said.

By consulting for the companies, he said, "my general insight into immunology and related biomedical sciences can be used to help develop new drugs and treatments for Americans." He said he provided the law firm with "expert opinion on immunological matters." His advice to the investment

fund, Germain said, concerned whether or not he believed that a particular technology or approach has a strong scientific base.

His consulting work also provides his family with "greater financial security," he said. "This is of special importance to me because as a former Hodgkin's lymphoma patient, it was difficult until recently to obtain adequate life insurance coverage while being at increased risk for an early death."

Germain, a graduate of Harvard Medical School, has been deputy director of his laboratory, housed in the National Institute of Allergy and Infectious Diseases, since 1987.

He was warned about conflicts of interest two years ago by an NIH lawyer, Karen Santoro.

But the lawyer's concern focused only on Germain's investments in mutual funds composed of biotech and health-care companies, some of which held contracts with his NIH lab. "Each underlying company may pose a potential conflict," Santoro told Germain in a May 11, 2001 e-mail.

Two companies on the mutual fund list were consulting clients for Germain. Yet Santoro's e-mail said nothing about the fees and stock options they and other companies were paying him.

Germain, in an e-mail to Santoro three days later, agreed to exchange his securities for "holdings that are not concentrated in the health and biotech areas."

Germain told The Times, "Ms. Santoro was fully aware of all my consulting arrangements and compensation."

Many firms for which Germain has consulted have sought to develop products in the same frontiers he or others at the NIH explore, including:

- Genetics Institute, a Massachusetts-based branch of an industry titan, Wyeth.

In 2001, Genetics Institute and Germain's lab entered a formal collaboration called a cooperative research and development agreement, or CRADA, to study the effect that genes have on the immune system. That same year, Genetics Institute paid Germain \$37,500 in fees. Germain accepted \$25,000 last year.

From 1992 through 2002, the company paid him a total of \$322,749, according to Germain's annual income-disclosure reports.

Officials at the NIH have continued

to approve Germain's consulting with Genetics Institute despite a provision in the agency's policy manual forbidding employees from taking fees paid by a company that is collaborating with their labs. While the policy remains on the books, a 1995 memo from the NIH director said it would be enforced only if the researcher was directly involved in the collaboration.

Germain said that he was not informed in advance that Genetics Institute and his NIH lab had taken steps to formally collaborate. When he did learn this, Germain said, he approached his institute's ethics office.

"The decision was that my consulting arrangement, having predated the [collaborative agreement], did not need to be terminated," Germain said.

- Mojave Therapeutics Inc., a biotech company developing treatments for cancer and viral diseases.

From 1998 through 2002, the New York firm paid Germain \$93,929, plus stock and stock options worth up to \$15,000. Germain has been a member of Mojave's scientific advisory board.

Mojave calls itself a leader in developing "heat-shock" proteins as potential therapeutic agents.

While consulting for Mojave, Germain, in his capacity as an NIH scientist, co-wrote a June 2000 journal article describing the role of heat-shock proteins. His co-authors included two scientists affiliated with Mojave, which posted the study on the company Web site.

Germain said he did not consider the study a collaboration with Mojave researchers and did not know the article appeared on the Web site.

The 2000 article, he said, reflected work done in his NIH lab in "an academic collaboration" with researchers at the Memorial Sloan-Kettering Cancer Center. Germain said the project "did not involve Mojave."

However, one of his co-authors, James E. Rothman, was a founder of Mojave and served, with Germain, on its scientific advisory board. Rothman also is an executive at Sloan-Kettering. The other co-author accepted a position at Mojave during the study.

Asked about these circumstances, Germain said that he had known about his collaborators' ties to Mojave, but he considered the work to be only with Sloan-Kettering.

Germain said he had told Rothman "that I would continue the research with Sloan-Kettering only if it were



Dr. Ronald N. Germain

kept separate from the activities of the company," adding:

"I was not a party to the company's posting of this published paper on their Web site and was in fact unaware of this.... Given that Dr. Rothman is an author on the paper, I had no right to demand that the company not display the work on its Web site after it was published."

Rothman declined through an aide to be interviewed.

Germain said that while the research was being done, "I informed my immediate supervisor at NIH of the situation." He noted that his lab's work with heat-shock proteins predated the collaboration.

■ Alexion Pharmaceuticals Inc., a Connecticut company developing antibody-based drugs for cardiovascular and autoimmune disorders and cancer.

Alexion collaborated with Germain's lab from 1993 to 1997 under a CRADA.

In 1994, Alexion announced the NIH had signed an agreement giving the company "worldwide exclusive rights to U.S. and foreign patent filings" for discoveries that might result from the collaboration. When the company reported financial results in 1996, it said the NIH collaboration and funding had helped to reduce losses.

Germain became a paid consultant to Alexion in 1996, about a year after his lab finished collaborating with the company. Over the next five years, he accepted \$51,000 in fees, plus vested stock options worth up to \$100,000.

Germain joined Alexion's scientific advisory board, he said, at the behest of an executive who used to work at the NIH with him.

"He was interested in my acting as a consultant for a long time, both preceding and during the period of the CRADA," Germain said. "I agreed to take the position only after the CRADA ended."

Alexion's head of research, Stephen P. Squinto, said the company relied on Germain and the other scientific board members to review its programs "and potentially introduce us to some newer things, newer technologies or drug targets."

■ Cell Genesys Inc., a developer of therapeutic cancer vaccines and gene therapies for AIDS and other life-threatening illnesses.

The company has had a long affiliation with Germain and the National

Institute of Allergy and Infectious Disease, which houses his lab.

In financial reports, the company has cited its reliance on a "collaborative relationship" with the institute and its affiliation with Germain, who sits on its scientific advisory board.

The South San Francisco company from 1992 through 2002 paid Germain \$352,000 and provided stock options that he has listed as worth up to \$250,000. During this period, Cell Genesys collaborated on research with the institute, although not directly with Germain's lab.

Germain said he has "reviewed and provided advice" regarding Cell Genesys' overall research programs.

■ MedImmune Corp., a Maryland biotech company that makes treatments for viral diseases and other maladies. MedImmune over the last 11 years has paid Germain \$163,350 in fees — plus up to \$500,000 in vested stock options.

MedImmune's top-selling product, an antibody for preventing a respiratory infection in infants, was developed jointly throughout the 1990s with the allergy and infectious disease institute. Germain's lab was not involved.

■ Hybricon Inc., a Massachusetts pharmaceutical company that develops medicines and diagnostics based on synthetic DNA.

In October 2001, Hybricon's chairman, Dr. James B. Wyngaarden, a former NIH director, announced the hiring of Germain, saying his "expertise and experience in the area of immunology will be extremely helpful."

Hybricon paid Germain \$30,000 last year.

In October 2002, Hybricon said it and the NIH had clashed over three agency-held patents, triggered by Hybricon's application for its own patent. The matter, related to synthetic DNA, is pending before the U.S. Patent and Trademark Office.

Both Germain and the chief executive of Hybricon, Stephen E. Seiler, said that Germain's consulting had not involved the patents.

"The only point of contact between us and the NIH is we share Ron's time," Seiler said.

As of last month, Germain no longer must publicly disclose his outside income. He instead will file reports that are kept confidential. Germain said he did not request the change, which was made by the NIH.

— DAVID WILLMAN

CASE STUDY | JEFFREY M. TRENT

A Government Accolade From a Paid Consultant

BETHESDA, Md. — Until late last year, Jeffrey M. Trent was the scientific director of the National Human Genome Research Institute.

He led efforts to find applications for discoveries from the Human Genome Project, the historic mapping of the genetic code that his federal institute completed on the government's behalf.

At the same time, Trent was a paid consultant to RHeoGene Inc., which billed itself as a cutting-edge player in gene therapy technology. For nearly two years, RHeoGene posted on its Web site this accolade from Trent, while identifying him by his government title:

"[W]e need to focus on how nature regulates itself, which begins with genes. RHeoGene has technology to address key questions in these areas."

Trent's endorsement, which the company included in a news release issued May 30, 2001, clashed with conflict-of-interest rules of the National Institutes of Health, home of the genome institute.

Agency employees seeking approval for consulting deals sign a form saying, "The Outside Employer will not refer to the consultant or to an affiliation with NIH in anything distributed for publicity or product promotion."

The rule is intended to prevent the implication that the NIH is vouching for a company or its products. Agency officials said they relied on employees to police themselves in such circumstances.

In recent interviews and in written responses to questions from the Los Angeles Times, Trent, 51, said that he had tried to conduct himself properly.

"I do not recall making the quote attributed to me in the RHeoGene press release and was unaware that it was on the company's Web site until you brought it to my attention," he said.

The company's chief executive said any quoted statements from Trent were handled by prior management.

Trent had been hired by the NIH in late 1993, from the faculty of the University of Michigan. In his new role, he began overseeing all of the genome institute's basic laboratory research. And he

was made chief of his own lab, specializing in cancer genetics. His federal salary as of last year was \$194,300.

Trent was a paid consultant to several drug-development companies while employed at the NIH. From 1994 through 1996, Trent accepted between \$50,608 and \$163,000 in industry consulting fees, according to his yearly public disclosure reports.

One of his clients during that period was Amoco Technology Co., which paid him between \$30,000 and \$101,000. (Trent reported his fees in broad ranges.) He said that Amoco, a "hold-over" client from before his arrival at the NIH, had focused on detecting genetic abnormalities and gene technology.

After 1996, the NIH shifted Trent to confidential reports of outside income. Corporate documents show he continued to serve on the scientific advisory boards of biomedical companies. One of them was Ilex Oncology Inc. of Texas. Another was RHeoGene; the Pennsylvania company paid Trent \$10,000 from spring 2001 to last year, he said.

His consulting deals, he said, were approved by NIH officials.

Most of his private consulting while at the NIH, Trent said, was "based on my general scientific expertise, as somebody that's knowledgeable in the area of cancer genomics and cancer genetics."

Trent declined to discuss what he did for each company. But he said that he viewed all of his paid consulting as part of the NIH's obligation to "translate" basic research for the benefit of patients.

"If we can help [the companies] more effectively do what they do, then I think that furthers science, helps people," Trent said. "That's the right thing to do."

Asked how an NIH scientist avoids using unpublished, confidential government information while advising paying clients, Trent said that he did not present companies with details of his ongoing NIH research.

"I'm not saying that in your mind isn't information that has broadened your understanding as a scientist," he said. "And some of that came from your work in the government."

Since leaving the NIH in October 2002, Trent has been president and scientific director of the Translational Genomics Research Institute, a nonprofit center in Phoenix.

— DAVID WILLMAN



Jeffrey M. Trent

CASE STUDY | JEFFREY SCHLOM

A Cancer Expert Who Aided Studies Using a Drug Wanted by a Client

BETHESDA, Md. — While managing one of the National Cancer Institute's major laboratories, Jeffrey Schlom has built a busy outside career as a consultant.

Within a decade, he has accepted fees totaling \$331,500 from 20 biomedical companies, his yearly income-disclosure reports show.

The company that paid him the most — \$127,000 — was Cytoclonal Pharmaceuticals Inc. of Dallas. While Cytoclonal

worked on a more efficient way to produce the popular cancer drug Taxol, Schlom helped lead two NIH-funded studies in which Taxol played a crucial part.

Schlom was a co-author of two medical journal articles that reported positive results from that research, conducted at the University of Alabama and published in August 2001 and September 2002.

Taxol was used to enhance the effectiveness of a second cancer drug, developed by Schlom at the NIH.

Schlom's twin roles — as Cytoclonal consultant and NIH leader — posed a potential conflict of interest because the study results could help create more demand for Taxol.

Schlom, in written comments to the Los Angeles Times, said all of his consulting work was done properly, in compliance with NIH rules.

He said he had advised companies "based on my general knowledge and expertise in immunology."

Schlom joined Cytoclonal's scientific advisory board in 1992.

"At our request, the scientific advisors review and evaluate our research programs and advise us with respect to technical matters in fields in which we are involved," Cytoclonal said in various public financial reports, starting in July 1996.

The company repeatedly touted its development of Taxol in news releases.

The company sought to produce Taxol through genetic engineering and fermentation, instead of deriving the drug's active ingredient from the bark of the rare Pacific yew tree.

In June 1998, Cytoclonal entered a licensing and research agreement with Bristol-Myers Squibb Co., the pharmaceutical giant that markets Taxol. Cytoclonal announced that its deal with Bristol-Myers was potentially worth "up to \$50 million."

As recently as August 2001, the company, renamed as eXegenics, said that its development of Taxol was one of two projects "with the greatest potential for rapid commercial success."

The company has recently laid off most of its employees and abandoned all research, including the Taxol project.

"We're not seeking to develop it," said David E. Riggs, the company's new chief financial officer.

Schlom, 61, whose government salary is \$180,400, has led the National Cancer Institute's Laboratory of Tumor Immunology and Biology since 1982. He supervises nine research groups seeking new ways to treat and prevent cancer.

According to its Web site, the laboratory investigates potential cancer-fighting vaccines. It examines substances, called antigens, that stimulate the body's production of antibodies. And lab researchers design and develop certain "monoclonal" antibodies that show promise in recognizing and targeting cancer cells.

During his decade of consulting for Cytoclonal, Schlom said he "was never involved in any conversations or provided any advice concerning Taxol."

Schlom said he saw no conflict of interest in his role with the NIH-funded studies that reported positive results using Taxol. His involvement related only to the studies' use of a monoclonal antibody developed at his lab, not Taxol, Schlom said.

Yet the studies used both drugs together to treat patients with ovarian cancer.

The antibody developed by

Schlom, with a radioactive element attached to it, was given to patients who two days earlier took Taxol.

The researchers had hoped Taxol would make the cancer cells more vulnerable to being damaged or killed by the radiation. The positive results were consistent with other studies that suggested Taxol's value as a sensitizer to radiation.

"I provided expertise only involving the use of the antibody," Schlom said. "Therefore, there was no need for a recusal." Under recusals, NIH employees pledge not to participate in decisions affecting outside clients.

In addition to Cytoclonal, several other companies that have paid fees to Schlom have conducted cancer research.

■ Jenner Biotherapies Inc. of San Ramon, Calif., a developer of vaccines for colorectal and prostate cancer, paid Schlom \$71,000 from 1993 through 1998.

■ AltaRex Corp. of Canada, a developer of antibody treatments for ovarian and other cancers, paid Schlom \$17,800 from 1999 through 2001.

■ Titan Pharmaceuticals Inc., based in South San Francisco, has tried to develop two monoclonal antibody agents for treating colorectal cancer. Both are being tested in an NIH-funded study. Titan paid Schlom \$27,000 from 1996 through 1999.

■ Biomira Inc., a Canadian company, is developing an experimental vaccine for lymphoma under a cooperative agreement with another lab at the National Cancer Institute. In May of 2001, Schlom collected a \$9,000 consulting fee from Biomira. A spokesman for the company said in November that Schlom was no longer under contract.

Schlom said that he had not, in his NIH capacity, discussed or "promoted any of the studies done by the organizations for which I have been a consultant."

Until last fall, Schlom's ongoing payments from industry were disclosed in annual financial reports open to public review. He now files confidential reports.

— DAVID WILLMAN



Jeffrey Schlom

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Home Edition

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LENGTH: 1468 words

HEADLINE: THE NATION;

Curbs on Outside Deals at NIH Urged;

A draft report by a blue ribbon committee calls for limits and public disclosure on consulting work, but stops short of suggesting a ban.

BYLINE: David Willman, Times Staff Writer

DATELINE: WASHINGTON

BODY:

The National Institutes of Health should publicly disclose all drug company payments to its scientists, and should bar employees from accepting stock or stock options from industry, according to a draft report from a panel examining conflict of interest at the agency.

The report stops short of calling for a ban on company consulting deals with NIH scientists, but it recommends that the agency block top officials from participating in such arrangements. A copy of the report was obtained by the Los Angeles Times.

The federal panel, called the NIH Blue Ribbon Committee on Conflict of Interest Policies, recommends that paid consulting not exceed 500 hours a year and that "special scrutiny be applied" if outside compensation exceeds half of an employee's yearly salary at NIH.

The committee compiled the recommendations in recent weeks as it prepared to present its final report to NIH Director Elias A. Zerhouni in early May.

If implemented by Zerhouni, the recommendations would reverse many actions taken by the agency in 1995 that loosened conflict-of-interest standards, including allowing NIH scientists to spend unlimited time consulting for outside employers, with no ceiling on the resulting income.

Zerhouni appointed the 10-member committee after The Times reported in December that NIH employees had accepted hundreds of payments of company fees and stock options, totaling millions of dollars.

Los Angeles Times April 9, 2004 Friday

Directors of two of the NIH's research institutes -- whose government salaries are \$200,000 and \$225,200 -- received company fees or stock options worth hundreds of thousands of dollars. More than 94% of the top-paid NIH employees were not filing public income-disclosure reports.

At a congressional hearing Jan. 22, Sen. Arlen Specter (R-Pa.), who chairs the subcommittee that approved NIH's \$27.9-billion budget, warned Zerhouni to make major changes.

In the House, Rep. James C. Greenwood (R-Pa.), chairman of the Oversight and Investigations subcommittee, said NIH policies had led to, not a revolving door, but a "swivel chair" in which agency employees were paid simultaneously by the public and by industry.

Related inquiries have been opened by the inspector general of the Department of Health and Human Services and by the General Accounting Office, the investigative arm of Congress.

Meanwhile, the work of the blue ribbon committee is being watched closely by officials at NIH, by congressional leaders and by industry.

The blue ribbon committee's co-chairmen, Bruce Alberts, president of the National Academy of Sciences, and Norman D. Augustine, retired chairman of Lockheed Martin Corp., said this week that they would not discuss the committee's conclusions until a final report was submitted to Zerhouni.

Zerhouni was traveling Thursday and not available for comment, an NIH spokesman said. The spokesman said members of the committee were continuing to discuss the recommendations they would make.

Near the outset of their work, Alberts and Augustine met privately with Specter and the senior Democrat on the Appropriations subcommittee, Sen. Tom Harkin (D-Iowa). According to an aide to Harkin, the senator emphasized his desire for drastically increased public disclosure of outside payments received by NIH employees.

Harkin also voiced strong opposition to the payments of company stock or stock options to NIH employees and warned that, if he regained chairmanship of the subcommittee, he would demand changes.

"He's interested, he has a lot of concern and he wants to see the report before he comes to any final conclusions," said Harkin's aide.

Much of the committee's work has been closed to the public.

From March 1 through Tuesday, the committee had met during parts of four days in public and at least that many times in private. Although its members have spoken by phone or in person with all 27 directors of NIH research institutes or centers, only two have appeared in public sessions. The committee members have not discussed in a public session whether it is appropriate for the directors to accept consulting payments from a drug company.

Three of the NIH directors who have met privately with the committee told The Times this week in e-mails that they regarded the payments as inappropriate.

"I do not believe that institute or center directors at NIH should accept compensation from pharmaceutical or biotechnology companies in the future," said Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases. "Receiving compensation from one or more of these for-profit organizations creates a precarious situation for a director that in my mind is best avoided."

Dr. Stephen E. Straus, director of the National Institute of Complementary and Alternative Medicine, said: "Institute or center directors should not consult for money with drug or biotech companies to avoid any real or perceived conflicts of interest in the decisions they are entrusted to make."

Dr. Francis Collins, director of the National Human Genome Research Institute, said: "The credibility and integrity of the NIH are critically important. Therefore I believe that, in the future, institute and center directors should forgo arrangements involving financial compensation from pharmaceutical or biotechnology companies."

Los Angeles Times April 9, 2004 Friday

Zerhouni, a radiologist who was appointed NIH director two years ago by President Bush, has said that he will make necessary policy changes. In addition to forming the committee, Zerhouni in recent weeks forced up to 93 top-level NIH decision makers to begin filing yearly income-disclosure reports that would be open to public inspection.

Zerhouni also announced that, as of late January, none of the directors of the NIH's research institutes or centers were still accepting compensation from drug companies.

Nonetheless, Zerhouni has said that he prefers case-by-case decisions over outright prohibitions against company consulting fees for most NIH scientists.

"You can have a policy that says, 'All right, all prohibited,' " Zerhouni told reporters last month. "But how does that help the public in terms of translating the discoveries in our laboratories into real things?"

Yet NIH has a separate and tightly controlled way to translate its discoveries into marketable remedies: cooperative research and development agreements. Staff scientists throughout NIH have entered into at least 1,300 such agreements with biomedical companies since Congress passed legislation in the 1980s authorizing the pacts, according to agency officials. Controls surrounding the pacts discourage conflicts of interest by barring NIH employees who are involved with the agreements, and for a year or more afterward, from accepting any payment from a participating company.

"[The agreements] are designed to encourage government scientists to work with private sector scientists in order to speed the translation of research findings to the marketplace," Barbara M. McGarey, an NIH lawyer, told the committee last month. "The result is that government research doesn't sit around and never get developed into products, she added.

When McGarey described the cooperative agreements last month to the committee, she elicited surprised reactions.

"This is a very vigorous program," said Alberts, the committee's co-chairman. "I didn't realize this was so big."

Yet in its draft recommendations, the committee says paid consulting deals, apart from the formal agreements, are "essential to accomplishing the goal of technology transfer."

In a statement filed with the committee on April 1, the Biotechnology Industry Organization said that paid consultations with NIH employees "are of significant benefit to biotechnology companies in focusing their research and development activities."

Dr. Drummond Rennie, a professor of medicine at UC San Francisco and a critic of corporate influence in medical research, said the NIH committee had a crucial opportunity to help restore integrity. Any compensation paid by industry to NIH scientists, he said, undermines the agency's research agenda and results.

"Research is going down the toilet if nobody can believe it, or if it has been distorted," said Rennie, who also is a deputy editor for the Journal of the American Medical Assn. "The obvious answer is a very simple one: You pay these folk enough to make them competitive. And then you say, 'That's it. You take nothing else.' "

Based on figures presented to the blue ribbon committee by NIH staff, salaries for most of the agency's scientists are on a par with researchers in academia. The NIH is less competitive at the highest ranges of pay, above roughly \$150,000, because the government generally caps salaries at \$200,000 a year, according to the staff presentations.

Times staff writer Jon Marino in Washington and researcher Janet Lundblad in Los Angeles contributed to this report.

GRAPHIC: GRAPHIC: National Institutes of Health CREDIT: REBECCA PERRY Los Angeles Times PHOTO: Awaiting Report: NIH Director Elias A. Zerhouni has vowed to make necessary policy changes at the agency. PHOTOGRAPHER: Associated Press

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May 7, 2004 Friday
Home Edition

SECTION: MAIN NEWS; National Desk; Part A; Pg. 1

LENGTH: 1410 words

HEADLINE: The Nation;
Panel Wants Top Health Officials Off Drug Payrolls

BYLINE: David Willman, Times Staff Writer

DATELINE: BETHESDA, Md.

BODY:

Senior officials at the National Institutes of Health should be barred from accepting income of any kind from drug companies, a panel examining conflict of interest at the agency recommended in its final report Thursday.

The long-anticipated report of the Blue Ribbon Panel on Conflict of Interest Policies places the greatest pressure to date on NIH Director Elias A. Zerhouni to toughen agency policies. The report urged Zerhouni to adopt the recommendations "as quickly as possible."

Zerhouni appointed the 10-member panel in response to articles in the Los Angeles Times in December revealing that NIH employees had accepted hundreds of payments from drug companies totaling millions of dollars, and that more than 94% of the top-paid NIH employees were not filing public income-disclosure reports.

The panel also recommended that nearly all of the 5,000 or more career scientists at the NIH be prohibited from accepting stock or stock options as compensation.

"This is needed to assure the continued, deserved public confidence in the extraordinary work of NIH," the report concluded.

However, the panel said that most career NIH scientists should be allowed to accept company consulting fees and should not be required to publicly disclose such payments -- a position that is likely to draw questions next week at a congressional hearing into NIH's relations with industry.

Zerhouni did not say whether he would embrace the recommendations. The NIH director told reporters Thursday that he wanted to meet "one more time" with the panel.

Zerhouni is already under pressure to enact changes.

Los Angeles Times May 7, 2004 Friday

The inspector general at the Department of Health and Human Services is investigating the conduct of several NIH employees, according to people familiar with the inquiry.

Both the inspector general and the General Accounting Office, the investigative arm of Congress, are examining NIH ethics policies. And the House Oversight and Investigations Subcommittee has scheduled for Wednesday the first of what are expected to be at least two hearings this spring into drug company payments to NIH employees.

Just before the blue-ribbon report was released, the subcommittee's chairman said the NIH had not complied with requests to identify all of the agency scientists who have accepted payments from industry in recent years, and the circumstances surrounding those arrangements.

Rep. James C. Greenwood (R-Pa.) said that he complained to Zerhouni by phone Tuesday.

"I told him I thought we'd been slow-rolled and stonewalled," Greenwood said in an interview. "As far as I'm concerned, widespread reluctance to divulge this information is the message in and of itself."

A senior Democrat on the subcommittee, Rep. Henry A. Waxman of Los Angeles, said that, contrary to the blue-ribbon panel's recommendations, the NIH should require far-reaching public disclosure of any payments from drug companies. The blue-ribbon report, he said, "doesn't appear to go far enough."

"We know that there are financial relationships at all levels, not just at the top, and the taxpayers deserve to know the extent of those relationships," Waxman said.

When Zerhouni appears before the House subcommittee Wednesday, he is to be joined by the two men he appointed to co-chair the blue-ribbon panel: Bruce Alberts, president of the National Academy of Sciences; and Norman R. Augustine, retired chairman of Lockheed Martin Corp.

Both Alberts and Augustine lauded and thanked the NIH staff for its assistance in the panel's work. Their goal, the chairmen said, was to "do no harm," while making recommendations to strengthen the agency's handling of conflicts of interest.

In explaining why they proposed a complete ban on employees accepting company stocks or stock options, Augustine and Alberts said such compensation could prompt people to become unduly concerned with a company's financial success.

Of the NIH scientists now employed as paid consultants to industry, roughly 25% of them have been paid in such securities, Augustine said. The panel reported that 120 NIH scientists as of this month have active consulting deals. Zerhouni noted that as of late January, the total stood at 228 scientists. He acknowledged that some employees could be waiting for the agency's policies to be resolved before resuming outside employment.

Under the panel's recommendations, outside pay would not exceed 50% of the employee's government salary, and the employees would devote no more than 400 hours a year to such outside arrangements.

The scores of NIH officials who would be barred by the new recommendations from receiving compensation from companies would be the directors of the agency's 27 research institutes and centers, plus all deputy directors, officials who direct research on humans, scientific directors and officials responsible for dispensing NIH grants.

"Because of the public and national leadership roles played by senior NIH officials, financial relationships with industry may have the appearance of giving preference to certain private interests over the public's interests or of giving preference to one private interest over another," the report said.

The panel recommended that senior employees at the NIH begin filing annual income-disclosure reports that were open to public inspection. Zerhouni early this year ordered at least 93 additional officials to begin filing the public disclosure reports.

Los Angeles Times May 7, 2004 Friday

But the panel declined to endorse such disclosure for many other NIH employees. Instead, the panel called for increased "internal disclosure" by NIH employees of outside income. Such disclosures would be exempt from the Freedom of Information Act, keeping payments to employees from drug companies locked from public view.

As an alternative to banning paid deals with industry or requiring far wider public disclosure, the panel saluted Zerhouni's recent formation of an ethics advisory committee, composed of senior agency officials, which evaluates employees' requests to engage in paid deals with drug companies and other entities.

Augustine and Alberts said that they feared that an agencywide ban could impede hiring or retaining the best scientific talent; that they wanted the NIH's policies to be consistent with those of major universities that allow faculty to moonlight; and that consulting for industry could help translate scientific discoveries into beneficial health treatments or products.

Representatives of the NIH distributed advance copies of the blue-ribbon report Wednesday to members of Congress. One, Sen. Edward M. Kennedy (D-Mass.), said the panel's "thoughtful recommendations will help NIH make certain that its integrity is untarnished by financial conflicts of interest."

Kennedy termed the report an "urgent call for positive change," saying, "Congress has a responsibility to give Dr. Zerhouni and NIH the strong support they need to implement these essential reforms."

Others greeted the report less enthusiastically.

If Zerhouni continues to embrace drug-company consulting payments for NIH employees while resisting full public disclosure, the public will be ill-served, said Michael S. Josephson, a lawyer in Los Angeles who specializes in ethics and conflict-of-interest policy.

"We need to try to prohibit those kinds of relationships which under the best of circumstances can create an appearance of impropriety," Josephson said, adding, "Disclosure provisions are cumbersome, but they're required of all kinds of government officials, because experience has taught us that the 'trust us' rationale is not reliable.... Transparency is the most effective antidote."

Much of the specific conduct detailed by The Times would be prohibited under the changes recommended by the blue-ribbon panel.

For instance, two senior-level officials, Dr. Stephen I. Katz, director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and Dr. John I. Gallin, director of the NIH Clinical Center, accepted hundreds of thousands of dollars in industry consulting payments.

On Thursday, Zerhouni noted that both Katz and Gallin, whose federal salaries were \$200,000 and \$225,200, respectively, ended their involvement with the companies after publication of the articles in The Times. Both officials have said that their outside deals were approved by others at the NIH.

The blue-ribbon panel's report said that the group "did not investigate specific allegations or review individual cases under investigation elsewhere." The report did not elaborate.

GRAPHIC: PHOTO: UNDER PRESSURE: Dr. Elias A. Zerhouni of the NIH. PHOTOGRAPHER: Associated Press

LOAD-DATE: May 7, 2004



<http://www.latimes.com/news/nationworld/nation/la-na-nih12may12,1.3001166.story>

NIH Conflict Findings Left Out

Ethics panel's final report did not detail all permissive practices, agency documents show.

By David Willman
Times Staff Writer

May 12, 2004

WASHINGTON — A blue-ribbon panel that examined conflict of interest at the National Institutes of Health found permissive practices that were not detailed in its final report last week, internal agency documents show.

The documents also show that top aides to NIH Director Elias A. Zerhouni were allowed to review and comment privately on the panel's draft findings.

Congressional investigators have expressed interest in the circumstances surrounding compilation of the report, issued Thursday. The next day, the chairman of the House Oversight and Investigations subcommittee, Rep. James C. Greenwood (R-Pa), wrote to Zerhouni, seeking "all records relating to the minutes and records of closed sessions of the Blue Ribbon Panel, as well as all drafts of the report."

Greenwood, whose letter was co-signed by the chairman of the House Energy and Commerce Committee, Rep. Joe Barton (R-Texas), said the information from the NIH would aid in "understanding the basis for the panel's observations and findings." Greenwood's subcommittee plans to question Zerhouni and other NIH officials about conflict-of-interest matters at hearings today and next week.

The NIH is the nation's premier agency for medical research, spending \$27.9 billion this year. Zerhouni appointed the panel after articles in the Los Angeles Times in December documented hundreds of payments by drug companies to NIH scientists, totaling millions of dollars, and reported that more than 94% of the agency's top-paid employees were not required to publicly disclose outside income.

The panel recommended that top agency officials — totaling scores of management positions — be banned from accepting payments of any kind from drug companies. The panel also said that all NIH employees should be prohibited from accepting company stock or stock options as compensation.

On the other hand, the panel said that a majority of NIH scientists should be allowed to accept fees or other income from industry, and that those payments in many instances need not be publicly disclosed.

The internal documents show that the panel was concerned about how little is known about the extent of financial ties between drug companies and NIH personnel. According to minutes of a closed-door meeting in early April, the panel "was surprised to learn that many people do not disclose at all. The panel thinks there needs to be an internal review that picks up significant financial interests."

One panelist, Dorothy K. Robinson, who also is general counsel at Yale University, said that, generally,

NIH's "rules on conflict of interest are really too narrowly defined." The rules, she said, employ "very tight words or phrases of art and do not capture appearances that are quite problematic." An NIH document reciting Robinson's comments was obtained by The Times.

Another panelist, Stephen D. Potts, a former director of the U.S. Office of Government Ethics, encouraged his colleagues to recommend wider public financial disclosure. In an e-mail on March 18 he said, "I learned at OGE that sunshine is the best disinfectant and saves taxpayer dollars because less will have to be spent to identify violators. The press and the public do a remarkably good job."

Potts added that The Times articles "did expose abuses and, if the conduct described cannot be sanctioned under existing rules, the rules should be amended to proscribe the conduct."

Zerhouni has called repeatedly over the last five months for greater "transparency" in the NIH's handling of conflict of interest. He appointed the panel to recommend any policy changes it deemed necessary. But the panel's proceedings were carried out mostly behind closed doors.

The panel met privately at NIH offices in Bethesda, Md., on seven occasions, from March 1 through April 28. It convened meetings during parts of four days that were open to the public.

Directors of some NIH research centers or institutes voiced concern about whether information they provided to the panel could be subjected to public release, according to the internal documents. Moreover, Zerhouni's top subordinates were given opportunities to privately review and comment upon the committee's draft recommendations, the internal documents show. The drafts were circulated by scientific policy advisors within Zerhouni's office, whom he had assigned to assist the panel.

A spokesman for Zerhouni, John Burklow, said that the director's staff "only provided information as requested" to the panel. "They asked us to review the report for accuracy," Burklow said.

One of Zerhouni's top aides, Dr. Michael M. Gottesman, told the panel that the NIH's scientific mission could be undermined if all agency scientists were banned from paid consulting for drug companies. "I addressed the general issue of what might be lost to the NIH and the public if all NIH scientists were not allowed to consult with private industry and academia," Gottesman said in an interview.

The internal documents show that Gottesman, the NIH deputy director in charge of the agency's in-house, or "intramural" research, clashed with a high-level colleague, Dr. Raynard S. Kington, a physician-administrator who also holds the title of deputy director and whom Zerhouni assigned in January to take charge of a range of NIH ethics policies.

On April 22, Kington wrote in an e-mail to Gottesman and four other officials that he feared the panel members did not understand that in some institutes and centers at the NIH "there is not a bright line" between those involved with intramural research and those involved with outside, "extramural" research.

For instance, the in-house scientists at the NIH help decide whether they and the agency participate in cooperative research projects with various drug companies. Because of their government roles, the scientists also are well positioned to advise, for pay, universities or other outside research entities interested in NIH grants.

"I think (and I think many outside people would agree) that our IM [intramural] scientists should not consult with universities and other institutions that are funded by us," Kington said.

Gottesman responded by e-mail, telling Kington and the other officials — each of whom assisted the panel in preparing the report — "I must respectfully disagree."

Los Angeles Times: NIH Conflict Findings Left Out

Page 3 of 3

In its final report, the panel disregarded Kington's advice, saying that if the in-house scientists are not directly involved in dispensing NIH research grants, they should be allowed to consult with universities receiving those awards.

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**Report of the
National Institutes of Health
Blue Ribbon Panel on Conflict of Interest Policies**

**A Working Group of the Advisory Committee to the Director
National Institutes of Health**

DRAFT: May 5, 2004

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EXECUTIVE SUMMARY

Recently, concerns have been raised in the media and Congress that some employees at the National Institutes of Health (NIH) have engaged in paid consulting arrangements with, or held shares in, biotechnology companies or other entities that could influence their work as government employees, thereby creating real or perceived conflicts of interest. These concerns have brought new attention to NIH policies regarding approval of such consulting arrangements, the nature of these arrangements (e.g., consulting versus speaking, teaching, or writing), the viability of the NIH system for monitoring outside activities, and the substantial number of high-level NIH employees who are not currently required—by existing laws and regulations—to file public financial disclosure statements.

This report responds to NIH's own inquiry into its conflict of interest policies. Are they sufficient to uphold agency standards and maintain public trust in NIH and its activities? As part of the NIH examination of the consulting activities of NIH investigators, the NIH Director established the Blue Ribbon Panel on Conflict of Interest Policies as a working group of the Advisory Committee to the Director, NIH. This Panel was charged to:

- 1) Review the existing laws, regulations, policies, and procedures under which NIH currently operates regarding:
 - Real and apparent financial conflict of interest of NIH staff where compensation or financial benefit from outside sources is received, including consulting arrangements and outside awards; and
 - Requirements and policies for the reporting of financial interests by NIH staff, including which interests are subject to public disclosure, and what portion of NIH staff file public disclosures;
- 2) Make recommendations for improving existing laws, regulations, policies, and procedures as appropriate;
- 3) Complete the review and development of recommendations within 90 days;¹ and
- 4) Provide recommendations to the Advisory Committee to the Director, NIH, for deliberation and final recommendations to the Director, NIH.

In keeping with this charge, and in making its recommendations, the Panel did not investigate specific allegations or review individual cases under investigation at NIH. Its primary goal was to assess the current status of conflict of interest policies and procedures and make recommendations for improvement, looking to the future.

In its deliberations the Panel found an extremely complex set of rules governing conflicts of interest at NIH. These rules are widely misunderstood by some of the very people to whom they are intended to apply, thereby creating uncertainty as to allowable behavior and adversely affecting morale.

The Panel adhered to one guiding principle in developing its recommendations: NIH employees must avoid conflicts of interest incompatible with the proper exercise of their authority and the

¹ To accommodate NIH and congressional schedules the Panel completed its work in 66 days.

proper performance of their duties. Employees in a position to influence the financial interests of an outside entity such as a current or possible future recipient of an NIH grant or contract should neither receive financial benefits from that organization nor have significant financial interests in it.

The Panel found that relatively few NIH employees engage in consulting agreements with biotechnology or pharmaceutical companies—an activity that currently involves approximately 120 of NIH's 17,526 employees. Yet the high level of reasonable concern expressed by Congress and the media about the potential for conflicts of interest when consulting with industry—itsself a small fraction of the outside activities engaged in by NIH scientists—has had a decidedly negative impact on the morale of a large number of NIH intramural scientists.

In contrast to industry related activities, a substantial number of NIH employees are involved in outside activities with professional societies and with academic and research institutions—primarily in the forms of teaching, speaking, or writing (including editing). In addition, NIH scientists who are recognized for outstanding scientific achievements, leadership, or public service are sometimes the recipients of awards, which may be accompanied by a cash prize. The Panel believes these are important—even essential—activities for NIH scientists, because they are part of the tradition of science and provide evidence of the value and significance of the NIH research community to the larger scientific community.

In its interviews with NIH scientists, the Panel observed that the heightened scrutiny about all ethics issues has further increased the confusion about the existing policies, with a widespread sense that rules are being changed midstream or suddenly overly interpreted out of caution. This has caused heightened concern that NIH scientists will be unable to fully participate in the community of science in the future and has contributed to fears about the impact that possible new policies could have on the recruitment and retention of scientists at NIH. Worse yet, there seems to be widespread fear among NIH employees that they could commit an inadvertent transgression resulting from the difficulties involved in interpreting the sometimes arcane and complex rules.

The Panel believes that the recommendations presented in this report are important for correcting these concerns, and it urges that they be adopted as quickly as possible. This is needed to assure the continued, deserved public confidence in the work of NIH. It should be noted that the Panel did not limit its review to what is possible within existing laws or regulations, but rather focused on those actions that it believes will best serve the NIH mission in the future.

RECOMMENDATIONS

Recommendation 1: NIH senior management and NIH extramural employees who are responsible for program funding decisions and recommendations, and professional staff managing grants and contracts and application review, should not engage in consulting activities with pharmaceutical or biotechnology companies or in paid consulting for academia. The Panel considers speaking for compensation at an industry site as equivalent to consulting for industry. The Panel does not include in this prohibition

time spent in clinical practice by health care practitioners, if approved as an outside activity free of conflicts.

Recommendation 2: The Panel reaffirms current federal law, which states that intramural scientists conducting research with human subjects—for example, investigators and research team members involved in patient selection, the informed consent process, and clinical management of a trial—should not be allowed to have any financial interest in or relationship with any company whose interests could be affected by their research or clinical trial, except in special circumstances, and with an appropriate waiver or authorization.

Recommendation 3: In addition to existing requirements for engaging in outside activities, and the restrictions posed in Recommendations in 1 and 2, the following requirements should be in place for all employees who are involved in the administration or conduct of NIH research programs:

- a. The total amount earned annually from compensated consulting with industry or academia should not exceed an amount equal to 50 percent of the employee's annual salary, and no one source should account for an amount exceeding 25 percent of annual salary.
- b. Employees eligible to engage in compensated outside professional activities should not:
 - i. receive compensation in the form of stock options or other forms of equities for their services
 - ii. spend more than 400 hours per year on these activities (writing excepted).
- c. An exclusion to the above limits should exist for NIH employees who are health care practitioners. For these employees, there should be a more flexible time limitation and the capitation for compensated outside medical care and patient services should be 100 percent of base pay, with the one-source limitation removed.

Recommendation 4: To improve NIH's ability to manage and track approved outside activities:

- a. all requests for outside activities (Form 520) should be updated on an annual basis (with such updates indicating only those changes that have occurred);
- b. supervisors should be held accountable for the evaluation and approval of outside activity requests, and this supervisory function should be a component of a supervisor's performance evaluation; and
- c. NIH should publish an annual agency-wide statistical report on the number and types of outside activities approved for its employees.

Recommendation 5: NIH should seek a change to OGE regulations to allow NIH scientists to receive compensation for teaching, speaking, or writing about their research providing that the information is to be shared in a public forum *and* that it has appeared in the published literature.

Recommendation 6: NIH intramural scientists should continue to be allowed to engage in compensated speaking, teaching, and writing for professional societies and for academic and research institutions as an outside activity providing that all ethics review and approval requirements are met.

Recommendation 7: NIH should seek a change to OGE regulations to permit employees to be identified by their title or position (and institutional affiliation) when engaged in teaching, speaking, or writing as an approved outside activity. Disclaimers should be provided that the activity is not being conducted in the employee's official capacity as an NIH employee and that the views expressed do not necessarily represent the views of NIH.

Recommendation 8: There should be no restrictions on royalties received on works written, edited, or published or on income received from patents licensed by any NIH employee who conducted the work as an approved outside activity.

Recommendation 9: The current OGE rules regarding receipt of bona fide cash awards for meritorious public service or achievement and NIH's interpretations of the rules are reasonable and should apply to all employees. There should be no limit on the amount of money received from a bona fide award. These awards are considered gifts under current law and are not considered outside activities because the employee accepts the award in his or her official capacity.

Recommendation 10: To increase NIH's ability to manage conflicts of interest, it should move immediately to either increase the number of employees required to annually file a confidential disclosure form (Form 450) or find some other means to achieve comparable levels of internal disclosure.

Recommendation 11: NIH should ask OGE to make a regulatory change or seek statutory modifications to provide NIH with greater discretion in determining whether certain Title 42 employees should file a public financial disclosure form (Form 278). This would promote the public interest by increasing transparency and would thereby enhance trust in government. In the meantime, NIH should seek additional equivalency rulings from OGE to increase the number of public filers to include the senior employees specified in Recommendation 1.

Recommendation 12: NIH supervisors should be provided with enhanced training on the criteria to be used for their annual review of financial disclosures so that they can become more effective in managing and avoiding employee conflicts of interest.

Recommendation 13: To preserve public confidence in NIH, the agency should put in place a policy that requires employees to disclose all relevant outside relationships and financial holdings in their work products, such as publications, speeches, and invention disclosures. In addition, where relevant, such disclosures should be made to potential research subjects as part of the informed consent process.

Recommendation 14: NIH employees should be required to submit recusals in writing to immediate supervisors when a potential conflict of interest emerges. The supervisor should then be required to inform those who should be aware of the employee's need to be recused from the official duties for which there is a conflict. As is currently the case, when an employee must be recused from official duties, those duties can be reassigned only to someone at an organizational level above the employee. As such, recused employees or their supervisors will need to inform both superiors and affected subordinates of the recusal.

Recommendation 15: The NIH Ethics Office should prepare a user-friendly document and website that displays the ethics rules in simple language and emphasizes examples of outside activities and financial interests that are permissible, as well as those that are not. Employees seeking approval of outside activities should, as part of their submission of Form 520 and its supplements, indicate in writing that they have reviewed these summary materials and have discussed any questions they have with their relevant ethics official and/or supervisor.

Recommendation 16: The NIH Ethics Advisory Committee should issue a report of its findings, in the form of anonymous case studies and generalizable principles, on a regular basis to provide the NIH community with a clear common body of knowledge by which to understand and interpret ethics rules.

Recommendation 17: NIH management should assure that sufficient resources are provided for the administrative and management functions of its ethics activities to guarantee that the expanded program proposed in this report can be implemented.

Recommendation 18: The NIH Director, working with Congress, should ensure that the agency has authority under Title 42, or some other hiring mechanism, to recruit senior scientific staff in the current highly competitive market. In addition, the NIH Director should ask HHS to review and, if appropriate, raise the current annual salary capitation of \$200,000 for the most senior Title 42 employees at NIH. The Panel is concerned that the present ceiling is limiting the agency's ability to recruit and retain the nation's best scientists as the leaders of NIH.

The Panel believes that the recommendations presented in this report are important for addressing these concerns, and it urges that they be adopted as quickly as possible. This is needed to assure the continued, deserved public confidence in the extraordinary work of NIH, and the quality of its scientific staff. It also critical for rectifying what the Panel perceives as a growing morale problem among the agency's excellent staff.

Section I. Introduction

Since the middle of the twentieth century, the American people have invested generously as a nation in biomedical research, believing that such an investment constitutes a public good by improving human health and welfare, directly or indirectly yielding economic dividends, and increasing overall understanding of the human condition. The impact of U.S.-funded medical research has proved to be among one of this country's greatest achievements, saving countless lives and significantly improving the quality of life of people around the world. Each year gains are made in the prevention, diagnosis, and treatment of many diseases, including cardiovascular disease, infectious diseases, stroke, cancer, and depression.

For example, research conducted or sponsored by the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS), has led to a major reduction in mortality related to coronary heart disease and stroke, helping to reduce deaths from coronary heart disease from an expected number of more than 1,300,000 in 2000 to 514,000. Progress has been equally remarkable for hepatitis B and C infections, new cases of which are on the decline, in part because of improved vaccines and the reduced risk of infection from blood transfusion—both outcomes of NIH-funded research. These are but two of hundreds of examples that could be cited to show the benefit of the nation's investment in NIH.

NIH has been the principal steward of this nation's public investment in health research. Through its 17,526 full-time equivalent employees in 27 institutes, centers, and the Office of the Director, NIH conducts and funds biomedical and behavioral research, research training, and related programs for the promotion of health and the dissemination of health information. Its mission is "science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability." More specifically, the NIH mission is to:

- 1) foster fundamental creative discoveries and innovative research strategies and their applications as a basis for advancing significantly the nation's capacity to protect and improve health;
- 2) develop, maintain, and renew scientific human and physical resources that will assure our capability to prevent disease;
- 3) expand the knowledge base in medical and associated sciences in order to enhance the nation's economic well-being and ensure a continued high return on the public investment in research; and
- 4) exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

At the same time that NIH pursues fundamental knowledge related to the prevention, diagnosis, and treatment of a wide variety of common and rare disorders, steady change in the landscape of disease and public health concerns requires that it continuously adopt new approaches and accelerate the pace of its discoveries. For example, NIH has been asked by the public to respond to new challenges posed by an aging population that is experiencing more chronic disease; an

epidemic of obesity, especially among children; AIDS and other emerging infections such as SARS; health disparities; and biodefense.

In addition, the science and technology critical to conducting research is constantly evolving. Powerful and unifying concepts of biology are emerging from the fields of molecular biology, genomics, and proteomics, with the potential to lead to rapid progress. As one example, in the past, cancer research was considered vastly different than heart or brain research. Today, with recent discoveries in molecular and cell biology, we know that biological systems obey common laws and follow similar pathways in both health and disease.

Another critical NIH mandate is to sustain and improve the national clinical research enterprise to ensure that it optimally translates basic discoveries made in the laboratory into clinical application. As a result, the agency supports multidisciplinary clinical research training career paths, innovations in clinical trial design, translational research, and shared clinical resources such as tissue banks and research networks. A phenomenon that extends across the entire scientific enterprise is its need to build, sometimes slowly, on previous work and on a continuum of knowledge and information from disparate fields—an important concept to remember when trying to draw bright lines between one scientific activity and another.

Efforts to fully pursue this wide array of fundamental and clinical lines of inquiry are beyond the reach of any one laboratory, group of investigators, or institution. This has changed the dynamics of today's research teams and will change those of the future as well, for increasingly the translation of fundamental knowledge into practical solutions to health needs requires integrated teams of specialists from numerous disciplines in the public, academic, and commercial sectors. NIH is continually searching for new organizational models for conducting research, including those that encourage risk-taking and novel partnerships, as well as those between the public and private sectors.

The Nature of NIH Research Activities

NIH scientists conduct basic and clinical research at facilities in Bethesda, Maryland, and elsewhere as part of the agency's *intramural research program*. The excellence and success of the intramural research program rests almost entirely on the ability of NIH leadership to attract and retain the best scientists and clinicians. The research that NIH funds at the nation's universities, medical centers, research institutes, and other nonprofit and for-profit organizations through grants, cooperative agreements, and contracts is referred to as the *extramural research program*. The extramural program is administered by NIH employees working on the Bethesda campus and in outlying areas. The intramural and extramural programs are distinct, administratively and through hiring authorities and funding mechanisms. The extramural program currently constitutes approximately 83 percent of total NIH activity, as measured by resource allocations; the intramural program roughly constitutes 10 percent. (These programs are discussed in greater detail in section II of this report.) The remaining 7 percent is allocated for research management and support and other administrative functions.

Both the intramural and extramural programs interact with academia and with pharmaceutical and biotechnology companies in many ways, including funding agreements, formal research agreements, and intellectual property licenses authorized by statutes intended to encourage the commercialization of technologies beneficial to the public health.

Three laws primarily govern this commercialization activity, including the Stevenson-Wydler Technology Innovation Act (P.L. 96-480) in 1980, the Bayh-Dole Act, and the Federal Technology Transfer Act of 1986, as amended. Under these laws, research agencies are encouraged to give licenses to commercial entities for the development of technologies from government-owned patents, and collect royalties for the government (and its employee inventors) as a result of these licenses. Grantees and contractors are also encouraged to retain title to government-funded inventions. Finally, federal agencies are authorized to enter into Cooperative Research and Development Agreements (CRADAs) with non-federal partners to conduct research. Together these three laws have resulted in substantial increases in the transfer of government-funded technologies from government and university laboratories to the private sector in the United States.

In addition to NIH's leading role, industry funding of its own research plays a substantial and growing role in the conduct of medical- and health-related research, with the industrially funded component now far surpassing the annual NIH investment.

These trends, combined with steady encouragement by the public and policymakers to accelerate the translation of basic research into clinical practice, have progressively blurred the once clear lines between academic, government, and commercial research. Moreover, the complexities of science increasingly require that this be a cumulative, interconnected, and competitive enterprise, because now, perhaps more than ever, scientists and their institutions must balance the essential principles of collaboration and collegiality with requirements of competition and secrecy.

Conflict of Interest Practices

In addition to collaborating with academia and industry as part of its mission, NIH employees are also permitted, under strict laws and regulations, to engage in "outside activities," that is, compensated or noncompensated activities that do not constitute their *official duties* or in any way use their public office or public resources for private gain (see Box A). The difficulty of ascertaining the meaning of official duties cannot be overemphasized when assessing whether real or perceived conflicts of interest arise, because this concept is particularly difficult to delineate in dealing with employees who primarily carry out scientific research.

Outside activities might include providing consultative or professional services, including service as an expert witness or consultant; engaging in teaching, speaking, writing, or editing; or providing services to a nonfederal entity as an officer, director, or board member—or as a member of a group, such as a planning commission, an advisory council, an editorial board, or a scientific or technical advisory board or panel. The receipt of bona fide cash awards for meritorious public service or achievement is *not* considered an outside activity. Rather these awards are considered gifts under current law and the employee accepts the award in his or her

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official capacity. However, because some particularly prestigious awards can be sizable, they are worth considering when assessing ethics policies. In all cases, employees must receive prior approval before engaging in any of these types of outside activities (see section IV for an extensive discussion of these issues).

Box 1: Outside Activities

An employee may not receive compensation for outside activities that relate to his or her official duties. The basis for this rule is the federal annual salary schedule, which prohibits federal employees from receiving salary or any contribution to or supplementation of salary as compensation for any other service from a source other than the federal government. An exception to regulation of outside activities is considered for certain employees. If an employee's primary duty was in the primary interest of his or her position, the employee is not prohibited from receiving private gain or that deals with any matter to which the employee is presently assigned or has been assigned during the previous one-year period, or if it deals with any ongoing or announced policy, program, or operation of NIH.

In addition, federal regulations establish uniform procedures and requirements for certain federal officials to disclose financial interests that could affect their conduct of official duties (e.g., the ownership of certain stocks and other investments). The Ethics in Government Act of 1978 was enacted to preserve and promote public confidence in the integrity of federal officials through, for example, requiring certain officials to disclose their financial interests. This act also established the government's regulatory agency for ethics, the Office of Government Ethics (OGE), to provide overall direction of executive branch policies related to preventing conflicts of interest, including the development of rules and regulations establishing procedures for the filing, review, and, if applicable, the public availability of financial statements, and criteria to guide agencies in determining which employees should submit these reports. NIH requires its employees to meet OGE regulations for financial disclosure and implements these regulations through the processes and procedures required by these regulations, as interpreted by HHS.

These two sets of laws and regulations—those regarding outside activities and those specifying financial disclosure—are intended to prevent conflicts of interest and ensure that public trust and duties are not compromised by inappropriate interests and that citizens can have confidence in the integrity of the federal government.

In the narrower world of biomedical research, conflicts of interest are a set of conditions in which professional judgment concerning a primary interest (e.g., patient welfare or the validity of research) tends to be unduly influenced by a secondary interest (e.g., financial gain from third parties). In the still narrower context of research with human subjects, if professional judgment is swayed by financial or other interests, subjects can be harmed by, for example, implementing study designs that pose unacceptable risks, enrolling subjects inappropriately, or continuing studies that should be modified or stopped. Thus, in some cases conflicts can increase the chances that tangible or even mortal harm could occur.

In the broader world of public service, avoiding conflicts of interest is based on following a set of principles: (1) employees should not engage in financial transactions that conflict with the conscientious performance of duty; (2) employees should not use public office for private gain;

(3) employees should act impartially and not give preferential treatment to any private organization or individual; and (4) employees should not engage in outside employment or activities, including seeking or negotiating for employment, that conflict with official government duties and responsibilities.² As employees of the federal government, NIH employees are subject to federal statutes and regulations that implement these principles of ethical conduct.

Another term, conflict of commitment, is used to describe conflicts in which outside activities, even if not directly in violation of ethics rules, nonetheless distract the employee from one or more of his or her employer's primary interests. For example, an NIH scientist who owns and operates a restaurant nights and weekends might be too tired or distracted to function adequately while at his or her government job.

Although financial interests are typically the main concern when discussing conflicts of interest, they are not the only interests that can cause conflicts. Other interests and activities are inherent to the scientific profession and less tangible than financial compensation and therefore may be more difficult to identify. These include the desire for professional recognition, the need to compete successfully for research resources and promotions, and the desire to disseminate and communicate research findings. Scientists rely on the ability to share information, meet with other scientists regularly, and publish their work. A free exchange of ideas to the extent possible is needed to advance the goal of science, which is to gain new knowledge by building continually on existing knowledge. Over the past 25 years, however, the research environment has increasingly created opportunities for investigators and institutions to profit financially from research, thus intensifying the focus on the potential financial conflicts of interest that are the main focus of this report.

Conflict of Interest Concerns

Tensions are bound to arise between the appropriate drive of individual government scientists to expand their own lines of inquiry through interactions with the private sector and the real or apparent conflicts that might surface between these activities and their public service responsibilities. In addition, issues of disclosure reflect a tension between the need for transparency regarding issues of public importance and the rights of government employees, as citizens, to some measure of privacy. Difficulties also arise from the generally laudable effort to apply one set of rules across the federal government, yet recognize the unique mission and role of NIH as a research organization.

In 2004, NIH's total budget of over \$28 billion is by far the largest public investment in biomedical and behavioral science made by a single nation. In recent years (1999-2003), NIH's budget has doubled, reflecting the generally positive attitude of the public and its representatives toward biomedical science. However, despite nearly universal agreement that NIH is a national treasure, with a level of public support envied the world over, the perception of conflicts of

² These principles of ethical conduct are set forth in Executive Order 12674 (April 12, 1989).

interest among NIH scientists could endanger NIH's mission and reputation and result in diminished public trust. It also could have disastrous consequences for the broader scientific community and NIH itself, as integrity in research is crucial for maintaining scientific excellence and sustaining the public's trust and participation in, and commitment to, scientific research. This requires accountability and transparency in setting priorities, making funding decisions, and conducting the research itself, as well as ensuring that actions are not subject to suspicion or question.

Recently, however, concerns have been raised that some senior NIH scientists have been receiving consulting payments from, or have held shares in, biotechnology companies or other entities that were benefiting from decisions that those scientists could have influenced at least in principle. Concerns also have been expressed regarding the extent of outside consulting engaged in by NIH employees and the potential for conflicts with their official duties. These concerns have brought new attention to the NIH policies that result in approval of such consulting arrangements, the nature of these arrangements (e.g., consulting versus teaching, speaking, or writing), the viability of NIH policies and procedures for monitoring outside activities, and the substantial number of high-level NIH research employees who are not currently required—by existing laws and regulations—to file public financial disclosure statements. They have also led to a series of responses by Congress, federal investigative offices, and NIH itself.

Charge to the NIH Blue Ribbon Panel on Conflict of Interest Policies

This report responds to NIH's own inquiry into its conflict of interest policies and whether they are sufficient to maintain public trust in the agency and its activities. As part of the NIH examination of the consulting activities of NIH investigators, the NIH Director established the Blue Ribbon Panel on Conflict of Interest Policies as a working group of the Advisory Committee to the Director (ACD), NIH. This Panel consists of members of the ACD and outside experts, who are charged to:

- 1) Review the existing laws, regulations, policies, and procedures under which NIH currently operates regarding:
 - Real and apparent financial conflict of interest of NIH staff where compensation or financial benefit from outside sources is received, including consulting arrangements and outside awards.
 - Requirements and policies for the reporting of financial interests by NIH staff, including which interests are subject to public disclosure and what portion of NIH staff file public disclosures.
- 2) Make recommendations for improving existing laws, regulations, policies, and procedures as appropriate.
- 3) Complete the review and development of recommendations within 90 days.³

³ To accommodate NIH and legislative schedules the Panel completed its work in 66 days.

- 4) Provide recommendations to the ACD, NIH, for deliberation and final recommendations to the Director, NIH.

In keeping with this charge, the Panel did not investigate specific allegations or review individual cases under investigation elsewhere. Its primary goal was to assess the current status of conflict of interest policies and procedures and make recommendations for improvement, looking to the future. The Panel met three times in person and once by telephone between March 1, 2004, and April 28, 2004, and heard testimony from over 30 individuals (see appendix C). On the Panel's behalf, a website was established to collect NIH staff views on outside activities, with over 300 responses received (see appendix D). In addition, individual Panel members interviewed, either in person or by telephone, all 27 NIH institute and center directors. At each open meeting of the Panel, time was set aside for public comment, and notices of all meetings were posted in the *Federal Register*.

At the same time the Panel was conducting its work, NIH was also responding to other investigations, including the following:

- HHS Office of Inspector General (OIG): The OIG review is focusing on outside activities and, in addition to writing a descriptive report, it will examine compliance with requirements to provide information on outside activity request forms. OIG held an entrance conference with NIH on March 26, 2004. The final design for the OIG review calls for completing data collection by May 14 and data analysis by June 14. The exit conference will not be held until mid-July 2004 at the earliest.
- OGE program/compliance review: OGE is examining compliance and effectiveness of certain elements of the NIH ethics program (e.g., financial disclosure, outside activities, acceptance of sponsored travel) in selected units of NIH (three institutes or centers and the NIH Ethics Office). OGE has completed its site review, and NIH is awaiting a preliminary report.
- U.S. General Accounting Office (GAO): this review probably will not begin until mid-summer of 2004. GAO's focus will be NIH's implementation of changes in policies and procedures recommended by Advisory Committee to the Director, OGE, and OIG.

Prior to creating the Blue Ribbon Panel, NIH has taken steps to bring greater transparency to employees' reports of financial interests and provide more stringent review of requests for approval of outside activities. On November 20, 2003, the NIH Director announced the establishment of a standing internal committee to strengthen NIH's review of requests for approval of certain outside activities and management of approved outside activities. This review body, the NIH Ethics Advisory Committee (NEAC), is internal to NIH and advisory to the NIH Deputy Ethics Counselor and charged with the review of outside activities for NIH employees in certain positions (e.g., senior NIH officials) and other NIH employees who want to participate in certain types of outside activity (e.g., involving a biotechnology or pharmaceutical company or more than \$10,000 annually in compensation). As of May 1, 2004, NEAC had met 15 times and reviewed 211 cases.

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In other events, on February 6, 2004, OGE notified NIH of its approval of the agency's request that 93 high-level positions be considered of "equal classification" to positions subject to the requirement for filing public financial reports. Thus, before and during the Panel's deliberations, events were transpiring to strengthen NIH's system for oversight and management of conflicts of interest.

This report has been organized to directly respond to the Director's charge to the Panel. Following this introduction, section II provides background information on the structure and culture of NIH as a backdrop to the sections that follow. Section III addresses the requirements and policies for reporting by NIH staff of financial interests, including which interests should be subject to public disclosure and who should be required to publicly disclose such information. Section IV addresses the issue of outside activities, focusing on the adequacy of existing laws, regulations, policies, and procedures. Section V provides a summary of the Panel's views and recommendations on these complex issues.

Section II. Background

Understanding some of the key organizational and administrative elements of the National Institutes of Health (NIH) is essential in developing an appreciation of its unique status as a federal agency as well as the difficulties it faces in achieving a uniformly executed ethics policy. These elements include the division of NIH's 27 institutes and centers into intramural and extramural programs, its various hiring authorities and the implications for salary and disclosure of personal financial information, and NIH's mandate to transfer knowledge and technology to the private sector. Each of these elements provides a particular context for implementing conflict of interest ethics rules, which are described in greater detail in subsequent sections of this report.

Overview of the Structure of NIH

NIH is a large, complex, decentralized organization, with headquarters in Bethesda, Maryland. Originally a small set of federal research laboratories supporting the public health mission of the Public Health Service (PHS), NIH has evolved into a group of 27 major institutes and centers and the Office of the Director, each conducting research and related activities on an aspect of human health and disease—mostly through grants to scientists in universities and other nonfederal research institutions.

In the current fiscal year (2004) NIH has a budget of over \$28 billion. Approximately 10 percent of it is dedicated to the intramural research program. Of that amount, roughly \$900 million is spent on clinical research. Other than a percentage dedicated to purely administrative functions, the remainder of the budget (approximately 83 percent) is expended on the extramural research program.

In 2004, the NIH extramural program expects to fund 37,229 research project grants; a number of other research grants, cooperative agreements, and contracts; and 17,566 full-time training positions. These funds are awarded to an extramural research community of an estimated 212,000 research personnel affiliated with approximately 2,800 organizations, including universities, medical schools, hospitals, and other research facilities, both commercial and not-for-profit, in all 50 states as well as the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and international venues. Of the 17,526 full-time equivalent NIH employees, approximately 3,400 provide support for the extramural program. These individuals are responsible for administering the grants and contracts programs—from the development of programs, to peer review, to disbursement of funds, to monitoring of and accounting for ongoing grants and contracts. In general, extramural program employees, many of whom are scientists, do not conduct research as part of their official duties.

In contrast, the intramural research program consists of more than 2,000 research projects conducted by approximately 5,000 government scientists and technical support staff in laboratories and a 250-bed research hospital on the NIH campus. All but six of the 27 institutes and centers have an intramural program. The intramural research program complements and

supplements the extramural program by providing an environment in which long-term, cutting-edge research can be conducted in response to public health needs.

To understand how conflicts might arise from the activities or financial holdings of NIH employees, it is important to appreciate the various roles and functions that might be assigned to an employee as part of his or her official duties. These responsibilities differ markedly depending on whether the employee is in the extramural or intramural program and by role, including leadership rank within the institute or center.

The Extramural Research Program

NIH provides three major types of awards to the extramural community: grants, cooperative agreements, and contracts. *Grants* for health-related research and research training projects or activities make up the largest category of funding. Research project grants are awarded to institutions on behalf of a principal investigator in order to facilitate the pursuit of research on a scientific objective by the investigator's laboratory. The funds to support this research are awarded through a highly competitive peer review process (review by scientists working in the field who are not NIH employees) on the basis of research plans submitted by each investigator. For such grants, NIH itself anticipates no substantial program involvement. In addition, intramural scientists have no influence on decisions made by extramural program staff. These peer reviewers received a modest honorarium. Most disclose all potential conflicts of interest and recuse themselves from decisions that involve a conflict.

Most applications for grant support are unsolicited and originate with the individual investigators, who develop proposed plans for research or research training within an area of interest to NIH. Occasionally, to hasten the development of a program or to stimulate submission of applications in an area of high priority or special concern, an institute will issue a Program Announcement to describe new, continuing, or expanded program interests, or issue a Request for Applications (RFA), inviting grant applications in a well-defined scientific area to accomplish a scientific task.

Cooperative Agreements are similar to grants in that they are awarded to assist and support research and related activities in the extramural community. However, they differ from grants in that the awarding NIH institute or center has a substantial involvement in carrying out the project's activities. The rights, responsibilities, and authorities of the prospective awardee and the NIH institute are developed in advance. To begin the process, the awarding institute typically issues a specific RFA that describes the expected program, functions, and activities, as well as the nature of the shared responsibilities.

As mandated by law, and with few exceptions, the review of grant and cooperative agreement applications involves two sequential levels of review for each application. In this system, the scientific assessment of proposed projects is kept separate from priority-setting decisions about the scientific areas to be supported and the level of resources to be allocated. The first level of review, the evaluation of scientific and technical merit, is conducted by one of many chartered scientific review groups, referred to as SRGs, managed by the NIH Center for Scientific Review, or by the institutes. The group or panel, established according to scientific disciplines or medical

specialties, may consist of as many as 16 to 20 members who are primarily nonfederal scientists with the appropriate range of expertise in the disciplines and areas of research being reviewed.

The second level of review is performed by National Advisory Boards, or Councils, of the NIH institutes and centers. These panels of 12 to 18 members consist of a mixture of scientists and laypersons chosen for their interest in matters related to health and disease. Council members review the applications against a broad background of considerations, including relevance, program goals, and available funds of the institute; they also consider the appropriateness of the scientific review conducted previously by the SRG.

Contracts for research and development (R&D) are awarded to academic institutions and other nonprofit and commercial organizations in order to procure specific activities for scientific inquiries in particular areas of research and development that are needed by NIH. Contract performance is monitored closely by NIH staff to ensure compliance with the specified statement of work.

Contract projects are subject to a multifaceted review process prior to the award. Usually, institute program staff develop the concept for a project, which must be cleared by an outside advisory panel. The concept for a planned project is then translated by NIH program staff into a Request for Proposals (RFP), which clearly specifies the work that must be done by the contractor. Thus, the review process for solicited R&D contracts differs from that for grants in that all offerors are responding to a government-defined, precise statement of work contained in the RFPs.

The proposals responding to the contract solicitation are evaluated against the evaluation criteria specified in the RFP by technical evaluation groups composed typically of nonfederal scientists, who receive a modest honorarium and must disclose all potential conflicts of interest and recuse themselves from decisions that involve a conflict of interest. The recommendations of peer reviewers and the results of separate NIH staff reviews provide the basis for discussions with offerors that are found to be in the competitive range. At the conclusion of these discussions, the viable offerors are asked to submit their best and final offer. The award is then made based on the final offer judged to be most advantageous to the government. An institute may occasionally make an award in response to an unsolicited proposal for a contract if it meets specific NIH program needs and can be adequately justified as a noncompetitive award.

The institute program staff plays an important role in the funding of high-quality extramural research projects. Their responsibilities within an institute are variously allocated according to grant award mechanisms, medical disciplines, or disease areas. These may be determined by the legislation that authorized the institute, by the language of budget authorizations, by specific delegations of authority from the institute directors or the NIH Director, or, within broad limits, by the actions of the appropriate Councils. Thus, the extramural program staff of the institutes is charged with planning and implementing scientific programs and consulting with the Councils about future program developments. They are responsible for keeping up with scientific developments in relevant areas, and they may convene task forces, workshops, or conferences to assess scientific progress in a field or identify new initiatives for an institute. The tasks involved in implementing these program responsibilities range from providing advice to interested

investigators to organizing extensive collaborative projects requiring a multidisciplinary approach by investigators in one or several research institutions.

In summary, the decisions regarding extramural resource allocations are guided, organized, and overseen by a large team composed of some 3,400 NIH employees. However, because of the magnitude, diversity, and complexity of the NIH mission, the agency draws on a large national pool of non-government scientists actively engaged in research for advice on the selection of the most promising research projects for support. Through a process of peer review, these scientists rate applications for grants and proposals for contracts, and they attend review meetings at NIH to discuss and make final recommendations. These recommendations are in turn considered and acted on by National Advisory Boards, or Councils, that are again composed of individuals who are not NIH employees.

This elaborate system of dual review and oversight makes it exceedingly difficult for any one individual to affect or alter the outcome of a funding decision. However, because NIH employees in the extramural program are involved in the allocation of funds to external entities, they are currently held to the same requirements regarding outside activities as intramural employees (even though intramural employees are not involved in funding decisions)(discussed further in section IV). In addition, OGE regulations permit NIH to prohibit or restrict the acquisition or holding of a financial interest or class of financial interests by agency employees and the spouses and minor children of those employees, based on the agency's determination that the acquisition or holding of such financial interests would cause a reasonable person to question the impartiality and objectivity with which agency programs are administered.

The Intramural Research Program

The intramural program consists of basic and clinical research conducted by NIH employees at the Clinical Center in Bethesda or in laboratory facilities on campus or elsewhere. Research programs focus on specific health problems of special concern to a particular institute or sector, including basic research that may not target a specific disease, but that relates to the overall mission of the institute or center. As with extramural research, taking advantage of scientific opportunities requires continuous adjustments to the intramural research programs.

Each institute or center intramural research program is led by a scientific director, who reports to the relevant institute or center director, and along with the institute or center director is responsible for organizing and administering both laboratory and clinical research. The evaluation of NIH intramural research programs, projects, and investigators is performed by Boards of Scientific Counselors, composed of nonfederal scientists with outstanding achievement and expertise in the areas of research pertinent to each of the NIH categorical disease institutes or centers. They assess the research in progress, the proposed research, and the productivity and performance of staff scientists. The boards serve a dual function; they not only provide expert scientific advice to the institute director and scientific director regarding particular projects and employees, they also assess the overall quality of intramural efforts. The intramural programs of the institutes are also reviewed by the National Advisory Councils and sometimes by additional panels of outside experts convened to address specific issues.

The structure and performance of the entire intramural research program (as well as the individual programs of the institutes and centers) has been evaluated many times over the past 25 years by numerous advisory groups, in response to administrative and legislative mandates. Most recently, Dr. Elias Zerhouni, Director of NIH, convened a Blue Ribbon Panel on the Future of Intramural Clinical Research, which focused exclusively on the clinical research programs across NIH. The intramural research program has been highly scrutinized by outside experts for a number of reasons, including its relevance to the extramural program; problems with recruitment and retention of senior scientists; expansions and contractions of its postdoctoral training programs; its sometimes cumbersome administrative requirements and organizational structure; inadequately funded congressional and administrative mandates; and its once deteriorating facility infrastructure, in particular that of the Clinical Center. In response to each of these reviews, NIH leadership has made adjustments to improve the quality and oversight of the program.

Since 1990, the intramural research program's proportion of the total budget decreased steadily from 11 percent of the total budget to about 9.5 percent, although in dollar amounts it has grown with the doubling of the overall NIH budget. Despite these changes, the program retains a distinctive status in the national research enterprise. Its scientists enjoy relatively long-term and stable funding of research programs, which allows them to engage in particularly innovative inquiry, including research with high potential payoff but considerable risk of failure. This stability stands in stark contrast to that found in the extramural scientific community, where investigators spend significant time writing grant applications that might never be funded. In addition, intramural scientists conducting clinical research have access to the NIH Clinical Center, the only hospital in the United States dedicated solely to research. In general, these scientists are not required to teach or serve on the many committees required of their academic colleagues.

Finally, the NIH campus has been an exceptional training ground, especially for clinical investigators. About 3,700 intramural fellows are on campus at any given time working in laboratories and preparing for their research careers. A significant fraction of the senior leadership of the extramural biomedical research community today received its training at NIH in the 1960s and 1970s.

For all of these reasons, the intramural program is an ideal setting to conduct research and has had a long history of attracting excellent scientists. Nonetheless, there are some drawbacks to being an NIH intramural scientist. In general, salaries and laboratory space do not compare favorably with what can be found in the nonfederal sectors, particularly in the case of more senior investigators. In addition, conflict of interest constraints make it more difficult to work with industry, which restricts the flow of technology and information both out of and into NIH.

The rapid growth in the NIH extramural program since the 1970s has enabled biomedical research across the country to expand greatly in size and scope, providing superb opportunities for research and training at academic facilities elsewhere. Thus, it has become increasingly more challenging for NIH to recruit and retain the best scientists, despite progress made in recent years in removing some of the administrative impediments to research and in enhancing the attractiveness of employment through changes in the pay scale and retirement options for senior investigators and the improvement of facilities.

NIH Hiring Authorities⁴

NIH uses a variety of personnel appointment authorities that are applied across the intramural and extramural programs. These are worth briefly mentioning because they have had important implications for salaries and for requirements regarding the disclosure of financial information.

Title 5 USC provides the basic government system for hiring, consisting of the General Schedule (GS) which has 15 grade levels with 10 seniority steps within each level (salary range \$17,152 - \$124,783). More than 13,000 NIH employees are employed under Title 5 authority. Title 5 includes a provision authorizing the payment of up to \$30,000 Physician's Comparability Allowance (PCA) to facilitate recruitment and retention of physicians. At NIH, non-clinical physicians are authorized PCA payments. NIH has separate legal authority under Title 42 USC that authorizes the use of Title 38 USC (Veterans Administration authority) to pay "Physicians Special Pay" (PSP) to physicians and dentists and other special pays to nurses and allied health professionals. HHS policy limits the combination of Title 5 and Title 38 PSP pay for physicians and dentists to \$200,000 total compensation, although the legal limits are higher, and nurses and allied health professionals to Executive Level I.⁵ The special pay authorities were requested to make NIH positions more competitive with those in academe. As of January 2004, there were 97 NIH physicians receiving PSP under Title 38, and their median total compensation was \$178,268.

A second major appointment authority under Title 5 is the Senior Executive Service (SES). This is a government-wide authority, with a pay band of \$131,342⁶ to \$142,500. SES positions typically are managerial or supervisory, having oversight for large organizations, budget authority, and procurement authority. As of January 2004, there were 89 NIH employees in SES positions, and the median pay was \$142,357.

Title 42 USC refers to the Public Health Service (PHS) Act, which contains a number of special hiring authorities under which PHS agencies (e.g., NIH, CDC, FDA) may appoint scientists and "administratively determine" their pay (AD pay plan). Title 42 USC 209(f) and (g) authorities have been established in law for many years (at least since the 1960s). The authority in Title 42 USC 209(g) has been used for many years at NIH to appoint doctoral-level scientists to conduct biomedical research. In 1999, PHS agencies began using the authority in Title 42 USC 209(f) to employ scientists engaged in biomedical research, science policy, administration, and research evaluation. In 2001, NIH established the NIH Title 42 Pay Model to assure appropriate use of the section 209(f) and (g) authorities and provide a flexible and consistent framework for setting pay. Pay under the Model ranges from \$38,000 to \$200,000 (HHS policy limit on pay; there is no legal limit). Compensation committees, both at the institute or center level and at the NIH level, implement the Pay Model under Title 42. The median salary is \$96,589.

The Title 42 CRS (Clinical Research Support) Alternative Personnel System is not a separate authority, but rather refers to the approved usage of Title 42 USC 209(f) authority by the Clinical Center, for a pilot project, which began in 2001. The pilot program was implemented to improve

⁴ All data on numbers of employees, average salaries, and salary ranges is based on what was in NIH pay system databases on January 24, 2004. This means that the salary data do not reflect a recent cost of living adjustment.

⁵ The 2003 rate for Executive Level I was \$171,900, for 2004 it is \$175,700.

⁶ Subsequent to January 24, 2004, legislation *lowered* the bottom of the SES salary range.

recruitment and retention, predominantly in the nursing and allied health personnel fields for patient care. Thus, while Title 42 USC 209(f) is used elsewhere at NIH for doctoral-level scientists, Title 42 CRS is narrower and restricted to the Clinical Center. It has a market rate driven pay model. As of January 2004, there were 484 nursing and allied health employees in this system with a median salary of \$64,473.

Hiring authority also exists under 42 USC sections 282(d)(1), 285a-2(b)(5), and 5b-3(b), which provide for the hiring of special experts. In addition, the Senior Biomedical Research Service is a separate authority under 42 USC, section 237, enacted in law in 1990, as an alternative personnel system for the employment of doctoral level scientists directly engaged in biomedical research or clinical research evaluation. Five hundred positions are authorized across the Public Health Service. NIH's allocation is 337 positions. By law, SBRS pay band runs from Grade 15, Step 1, to Executive Level I, total compensation. As of January 2004, 127 NIH employees held SBRS positions, and the median salary was \$156,042.

An additional hiring authority is the Commissioned Corps of the Public Health Service. It employs a military pay system that had a range of pay for officers in January 2004 of \$43,560 to \$167,316 per year.

In addition to base salary, federal employees can receive recruitment bonuses and retention allowance of up to 25 percent of base pay to attract and retain outstanding personnel. In addition, managers may reward outstanding performers with cash awards up to \$10,000.

Overall, the revamping of the pay bands has made NIH more competitive at the lower and middle career levels, but salaries lag far behind those in the academic and private sectors at the highest levels of management. The differences become especially large for senior-level M.D.s with clinical responsibilities

Significance of Hiring Authorities on Financial Disclosure Requirements

Certain NIH employees are required to disclose their financial interests to NIH staff involved in the ethics program. An employee's responsibility to disclose his or her financial interests depends on position, pay, and/or responsibilities. In some cases, the employee's hiring appointment, described above, also determines whether and how the employee reports his or her financial interests. (See section III for a chart comparing hiring mechanisms and financial disclosure filing requirements.) Similarly, the office(s) or person(s) at NIH (or sometimes at HHS) who is responsible for collecting, reviewing, and certifying such information depends on the filing employee's position, pay, and/or responsibilities. The many hiring authorities used by NIH, combined with different regulatory and statutory requirements regarding financial disclosure, create a patchwork of policies and procedures that could easily lead to misunderstandings.

Commercialization of Government-Owned and Government-Funded Technologies

NIH has a mandate to facilitate the commercialization of its discoveries and inventions, a mandate that has blurred the lines between the public and private sectors and that has fostered an environment in which public-private interactions are encouraged. Although commercialization has merit because of the potential for increased translation of knowledge into clinical application, it is an issue that complicates discussions concerning potential conflicts of interest.

In 1980, in response to concerns about U.S. competitiveness in the global economy, Congress enacted two laws that encourage government-owned and government-funded research laboratories to pursue commercialization of the results of their research. These laws are known as the Stevenson-Wydler Technology Innovation Act (P.L. 96-480) and the Patent and Trademark Amendments of 1980 (P.L. 96-517), the latter also known as the Bayh-Dole Act. Their stated goal is to promote economic development, enhance U.S. competitiveness, and benefit the public by encouraging the commercialization of technologies that would otherwise not be developed into products because of a lack of incentives in the commercial arena.

The Stevenson-Wydler Technology Act established the basic federal technology transfer policies. This legislation enables NIH and other federal agencies to execute license agreements with commercial entities that promote the development of technologies discovered by government scientists. The act also provides a financial return to the public in the form of royalty payments and related fees. In 1986, the directives of this act were augmented by its amendment, the Federal Technology Transfer Act of 1986 (FTTA), which authorizes federal agencies to enter into cooperative research and development agreements with nonfederal partners to conduct research. The FTTA also authorized federal agencies to pay a portion of royalty income to inventors who had assigned their rights to the government, currently a maximum of \$150,000 per inventor per year from all royalty sources. These payments are not considered to be outside income; they are part of the employee's federal compensation.

The Bayh-Dole Act was designed to address barriers to commercial development affecting nongovernment entities, with the aim of moving federally funded inventions toward commercialization. A key provision of the act is that it provides grantees and contractors, both for-profit and not-for-profit, the authority to retain title to government-funded inventions, and it charges them with the responsibility to use the patent system to promote the utilization, commercialization, and public availability of inventions.

If the grantee or contractor institution declines title or elects not to pursue practical application of the technology, the federal agency can elect title to the invention. By law, the funding agency retains a residual interest in all grant- and contract-supported inventions, including a royalty-free, paid-up license to use the technology for government purposes. However, this right does not extend to a licensee's final commercial product, nor does it extend to proprietary information or trade secrets that belong to another party and may be incorporated in the final product. Recipients of extramural NIH research funds, NIH intramural researchers, other federal agencies, and industry have now had 20 years of experience in technology transfer under Bayh-Dole. To accomplish the transfer of technology, both NIH and NIH-funded extramural institutions typically seek patent protection for inventions arising out of their research and license the rights

to private entities to promote commercialization. In this way, private entities interested in practicing an invention in which they have no ownership may obtain rights to use and commercialize it by entering into a licensing agreement with the patent owner.

A license is a contract with binding commitments on each party, usually involving compensation (i.e., royalties, milestone payments). A license does not grant title, or ownership, to the invention. A license can be exclusive, when only one party is permitted to use or commercialize the technology; co-exclusive, when a limited number of parties have rights to use or commercialize the technology; or nonexclusive, when many parties are allowed to use or commercialize such rights.

Conclusion

Collectively, the organizational configuration, authorities, and mandates of NIH create an environment of competing tensions and interests. First, the unique mission of NIH as a research organization that both funds and conducts research creates two worlds within one agency. The official duties of employees in the extramural program are vastly different from those of employees in the intramural program. Second, the intramural program must compete with the academic and industrial sectors to recruit and retain scientists, who provide the intellectual capital for the agency. This has led to a progressively more competitive pay system that has done much to attract employees at the lower- and mid-career levels but not at the upper levels of management. Third, the various hiring authorities used by NIH have different requirements regarding disclosure of personal financial information by certain employees, creating a complex web of rules and procedures that are not always obvious. Finally, a 25-year-old mandate from Congress to accelerate the transfer of discoveries and inventions to the private sector has created an environment in which the lines once easily drawn between public and private activities are less clear and are at times not congruent with the conflict of interest rules that otherwise limit such interactions.

Against this background, section III will focus on the Panel's findings regarding the appropriate requirements for financial disclosure by NIH employees.

Section III. Disclosure of Financial Information and Outside Activities

The Ethics in Government Act of 1978 was issued to preserve and promote public confidence in the integrity of government through, for example, requiring certain employees to disclose their personal financial interests. This act also created:

- (1) rules and regulations establishing procedures for the filing, review, and, if applicable, the public availability of financial statements; and
- (2) criteria to guide agencies in determining which employees should submit these reports.

The act also required the Office of Government Ethics (OGE) to issue regulations establishing uniform procedures and requirements for the two types of financial disclosure reporting required of certain employees: public and nonpublic (confidential).⁷ These regulations require high-level officials to report certain financial interests *publicly*, (that is, available to the public through the Freedom of Information Act [FOIA]). In addition, to guarantee the efficient and honest operation of the government, less senior employees, whose government duties involve the exercise of significant discretion in certain sensitive areas, must *confidentially* report their financial interests and outside business activities to their employing agencies. The National Institutes of Health (NIH) holds its employees to these OGE regulations for financial disclosure.

OGE regulations also permit an agency, through supplemental regulations, to prohibit or restrict the acquisition or holding of a financial interest or class of financial interests by agency employees, and the spouses and minor children of those employees, based on the agency's determination that the acquisition or holding of such financial interests would cause a reasonable person to question the impartiality and objectivity with which agency programs are administered. For example, HHS issued regulations that further restrict certain financial interests of financial disclosure report filers in the Food and Drug Administration (FDA).⁸ This is because FDA "is a unique consumer protection and regulatory agency within the [HHS]," and the HHS' standards of conduct needed "further supplementation to reflect this role."⁹ However, these supplemental HHS regulations do not augment the OGE regulations for non-FDA employees who file financial disclosure reports. As such, the supplemental HHS regulations that further restrict financial interests of certain FDA filers do not apply to NIH employees.

Recent media attention has raised several issues about financial disclosure by NIH employees. These include concerns regarding the outside activities that have been allowed for a few highly paid employees and the fact that a large number of highly paid employees are required to file confidentially rather than publicly. Members of Congress have questioned NIH's reliance on an OGE legal opinion that informed the agency that Title 42 employees, including those in senior and/or high-paid positions, could not be classified as public filers. The need to increase the

⁷ Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture, at 5 CFR Part 2634.

⁸ See 5 CFR 5501.106(c)(3).

⁹ See 37 *Federal Register* 24347, 24348.

number of NIH employees who file public financial disclosure reports has been a consistent theme of critics. NIH does not have unilateral authority to compel employees to make public disclosure, but it does have the discretion to request that the need for disclosure be determined by OGE through a process of “equal classification determinations,” which recently resulted in the reclassification of 93 NIH employees.

The Panel focused on whether and how financial disclosures by NIH employees should be expanded or otherwise modified to promote public confidence in the integrity of NIH officials. These issues were reviewed in the context of NIH’s implementation of OGE regulations governing confidential and public financial disclosure, as well as the reasoning behind the regulations and interpretations.

To assess the appropriate requirements for maintaining public trust in NIH, it is important to understand the current policies and procedures—specifically, which employees are required to disclose financial interests, and when, how, and to whom? Also relevant is the distinction between the reporting processes themselves and the degree to which such information is publicly accessible, for example readily available (through a website) or accessible only through a FOIA request. For the purpose of clarity in this report, the Panel will refer to the confidential filing of financial information by NIH employees to NIH as “disclosure” and to the public availability of such information as “transparency.”

Financial Disclosure Reporting Requirements

An employee’s responsibility to disclose his or her financial interests generally depends on position, pay, and/or responsibilities. In some cases, the employee’s hiring appointment (e.g., Senior Executive Service [SES]) also determines filing status. Similarly, the office or person responsible for collecting, reviewing, and certifying such information is determined by the filer’s position, pay, and/or responsibilities. For example, financial disclosure reports of deputy ethics counselors are reviewed by the Office of General Counsel, Ethics Division, while the financial disclosure reports of other, nonsenior NIH staff are reviewed by ethics officials in the employee’s institute or center, or in the Office of the Director.

In general, financial disclosure requires the employee to provide information about assets and income, liabilities, outside positions, financial agreements or arrangements, and gifts and travel reimbursements. However, the breadth and depth of information requested in these reports varies with the type of form the employee is required to complete. For example, public reporting Form 278 was developed to collect more specific financial information than the confidential disclosure Form 450. Form 278 requires certain officers and high-level employees in the executive branch to provide information on the actual monetary value of assets and financial transactions. This information is not reported in the confidential financial disclosure Form 450.

Confidential Financial Disclosure¹⁰

Some NIH employees must file the standard government-wide OGE form 450 (see appendix E)¹¹, disclosing significant financial information internally to NIH supervisors and ethics officials. These filings are not subject to FOIA requests.

Who Files

Unless subject to public financial disclosure, the following NIH employees are required to file confidential financial disclosure reports:

- In each institute and center: deputy ethics counselors, associate directors, assistant directors, division directors, National Institute of Child Health and Human Development Center directors, executive officers, and deputy executive officers.
- Special Government Employees who are not subject to public disclosure.
- All other employees designated by NIH who perform one or more of the following duties or activities and who have not been excluded from the filing requirements:
 - contracting or procurement;
 - administration, monitoring of grants, licenses, cooperative research and development agreements, or CRADAs, or other federally conferred benefits, regulating or auditing nonfederal entities;
 - other activities that will have a substantial economic effect on the interests of a nonfederal entity; or
 - other activities that have the potential to create real or apparent conflicts of interest.

In reference to the latter category of “all other employees designated by NIH,” OGE permits the agency to require employees in certain positions to file confidential financial disclosure reports. Although hypothetical examples of employees who are required to file confidential financial disclosure reports are provided in the regulation (e.g., a contracting officer who performs certain duties and works with substantial independence), a 1994 memorandum from the Director, OGE,

¹⁰ Confidential financial disclosure reporting requirements are set forth in regulations at 5 CFR 2634, Subpart I. Federal statute requires that these reports and the information that they contain be kept confidential, even in de-identified form. Accordingly, confidential financial disclosure reports are exempt from being released to the public, under exemptions 3 (A) and (B), 4, and 6 of the Freedom of Information Act (FOIA), 5 USC 552(b)(3) (A) and (B), (b)(4), and (b)(6). Agency personnel shall not publicly release the reports or the information that these reports contain, except pursuant to an order issued by a federal court, or as otherwise provided under applicable provisions of the Privacy Act (5 USC 552a), and in the OGE/GOVT-2 government-wide executive branch Privacy Act system of records, as well as any applicable agency records system. FOIA exemption 3 covers information “specifically exempted from disclosure by statute”; exemption 4 protects “trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential”; exemption 6 permits the government to withhold all information about individuals in “personnel and medical files and similar files” when the disclosure of such information “would constitute a clearly unwarranted invasion of personal privacy.”

¹¹ See also ethics.od.nih.gov/forms/forms450.htm for the form. For most NIH employees, the process for preparing, reviewing, and certifying confidential financial disclosure forms involves the employee and the institute or center deputy ethics counselor (or the person with delegated authority).

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to the Designated Agency Ethics Officials found, “The most consistent concern which agencies expressed about the system was the process of designating positions in which employees are required to file an [OGE] 450.”¹² There appears to be insufficient uniformity in these determinations.

The responsibility for designating confidential filers generally occurs at the level of the deputy ethics counselor within the institute or center, in many cases with input from an administrative or executive officer or the appropriate office director (e.g., scientific director or deputy director). However, although the institutes and centers use general regulatory criteria to determine which employees must file, each can apply the criteria differently. For example, some institutes and centers require all project officers to file a confidential financial report, while others require only those project officers above a certain pay level (e.g., GS-12 or 13) to file. These determination decisions are presumably due to guidance provided by the 1994 memorandum, which specifies that “designations should be limited to those pay grades where the duties and responsibilities clearly make filing necessary and relevant.”¹³ In 2003, there were 5,533 filers of confidential reports. This number is expected to increase to 5,845 in 2004. The instructions and forms for this report are 6 pages long.

The Process for Confidential Financial Reporting

Most NIH employees who are required to report financial interests use the confidential financial disclosure report (OGE form 450). As an alternative to the OGE 450, an employee may use a different form if he or she has no new financial interests. This form, the OGE 450-A, the Certificate of No New Interests, contains no requests for substantive financial information. As such, the deputy ethics counselor or reviewing official performs only a procedural review of that form to ensure it is properly completed by the employee and tracked by the deputy ethics counselor or reviewing official. However, reviewers may refer to previous OGE 450 forms to ensure the employee does not have any unresolved issues.

What Information Is Disclosed

The confidential reporting system seeks from employees only information that is relevant to the administration and application of criminal conflict of interest laws, administrative standards of

¹² September 14, 1994, available at www.usoge.gov/pages/daeograms/dgr_files/1994/do94031.txt.

¹³ In the 1994 memorandum, OGE continues to add examples of positions or employees who should not be required to file: “In reevaluating which positions require confidential disclosure, consider the following guidance: For those positions involving responsibilities enumerated in 5 CFR 2634.904(a)(1), the regulation compels designation only if the employee will be required to participate personally and substantially through decision or the exercise of significant judgment. For assistance with the terms “personal and substantial,” see the definitions at 5 CFR 2635.402(b)(4) and 2637.201(d). Additionally, the exclusion criteria in § 2634.905 should be considered in conjunction with the designation process, to eliminate designation of positions where, for example, there is a substantial degree of supervision or only a remote possibility of a conflict of interest. Thus, not all employees who must sign a procurement integrity certification under the Office of Federal Procurement Policy Act must also be required to file a confidential financial disclosure report. Agencies may use an appropriate demarcation, such as a position’s monetary level of procurement authority, a de facto pay grade floor, or degree of supervision over the position. For positions being designated under the more general criteria in 5 CFR 2634.904(a)(2), designations should be limited to those pay grades where the duties and responsibilities clearly make filing necessary and relevant.

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conduct, and agency-specific statutory and program-related restrictions. The basic content of the reports required by the regulations reflects certain information that is generally relevant to all agencies. However, depending on an agency's authorized activities and any special or unique circumstances, additional information may be necessary. In these situations, and subject to the prior written approval of the Director of the OGE, agencies may formulate supplemental reporting requirements.

Public Financial Disclosure

In contrast to confidential filing requirements, as described above, employees who file *public* financial disclosure reports (SF 278 form [see appendix F])¹⁴ currently make the disclosure internally, knowing of the possibility of public access. Before certain financial disclosure reports can be made available to the public, however, two things have to happen. First, the employee must fulfill his or her responsibility to complete the disclosure form and provide it to the appropriate certifying official within the agency (a process that occurs internal to the agency, generally). Second, a member of the public must request access to the information through an application process specified in the Freedom of Information Act (FOIA).¹⁵ To this end, the right of the public to access certain financial disclosure reports is distinguishable from the employee's responsibility for making the required disclosure.

Who Files

Public filers are defined by regulation to include the following positions:

- Members of the SES and the Senior Scientific Service (SSS).
- Employees whose positions are classified above GS-15, generally described as "senior level" (SL) or "scientific and technical" (ST).
- Commissioned Corps at O-7 pay levels.
- Non-GS employees whose annual rate of basic pay¹⁶ is equal to or greater than 120 percent of GS-15, Step 1,¹⁷ not inclusive of locality adjustments, with the exception of Title 42, Career GS/GM-15 level employees and Commissioned Corps Officers at the O-6 level and below.
- Experts, consultants, or advisory committee members appointed as Special Government Employees (SGEs), who are reasonably expected to serve more than 60 calendar days in any calendar year, and whose annualized salary is equal to or greater than 120 percent of pay for a GS-15, Step 1.

¹⁴ See ethics.od.nih.gov/forms/forms278.htm for the SF 278.

¹⁵ Specified at 5 CFR 2634.603.

¹⁶ Per a February 11, 1998, OGE legal opinion, "rate of basic pay" in 5 USC app., § 101(f)(3) means the lowest step or entry level pay authorized for a particular pay grade or range. See www.usoge.gov/pages/advisory_opinions/advop_files/1998/98x2.txt.

¹⁷ As of January 2004, 120 percent of GS-15, Step 1 is \$104,927 (based on the base GS-15, Step 1 salary of \$87,439, at www.opm.gov/oca/04tables/pdf/gs.pdf). This base amount excludes locality adjustments and "additional" pay (such as bonuses, awards, and allowances), but includes annual or periodic pay adjustments (such as cost-of-living raises). The base amount is used in calculating the 120 percent of GS-15, Step 1.

- As of February 6, 2004, through an “equal classification” determination¹⁸ from OGE (as requested by NIH), institute and center directors,¹⁹ deputy directors, scientific directors, and clinical directors are also required to file public financial disclosure reports.

Unless holding one of the positions listed above, career GS/GM-15 level employees, Commissioned Officers at the O-6 level and below, and employees under the Title 42 appointment mechanism are exempt from the public financial disclosure requirement, even though their salaries may exceed 120 percent of the GS-15, Step 1 pay level. For example, the Title 42 mechanism can be used to support *specific* public disclosure by individuals in positions (e.g., doctoral-level scientists and certain allied health personnel for patient care) at pay ranges from \$38,000 to \$200,000. However, the appointments made under Title 42 are not *required* to file public financial disclosure reports because the regulations require employees to file only if they are in a pay *category* which has a “basic rate of pay” that is equal to or greater than 120 percent of the minimum rate of basic pay for GS-15, Step 1, or \$104,927. The Title 42 appointment mechanism has no basic rate of pay (i.e., Title 42s have no minimum pay), and because of this, such employees do not meet the public financial disclosure filing criteria.

Although members of the SES do file public financial disclosure reports, shifting higher-paid Title 42 employees to the SES does not provide a general solution for several reasons:

- Many Title 42 employees do not meet the SES qualifications. The SES is for senior managerial, supervisory, and program policy personnel; while Title 42 is for doctoral-level scientists and physicians, nurses, and allied health personnel engaged in biomedical research, clinical care, and/or scientific management/leadership activities.
- The ceiling placed on the number of SES positions at NIH cannot accommodate the expansion that would be entailed in such a shift.
- The top SES pay level is well below the top pay provided under Title 42, and mechanisms to supplement salary (e.g., bonuses and allowances for recruitment and retention) cannot be guaranteed because they are not part of base pay.

In February 1998, OGE wrote the following in response to queries about exclusions from the public financial disclosure:

...some [division] employees who receive relatively high amounts of pay would not be required to file. We agree that this may occur, but that is also the case with a number of other pay systems. It would be up to Congress to amend the financial disclosure statute, if they intended a different result. As an alternative, [division] employees may be required

¹⁸ Under the authority under 5 CFR 2634.202(c), the OGE (not NIH) may require any other officer or employee in any other position determined to file a public financial disclosure report if that individual occupies a position that is equivalent to a position that is already specifically designated in the statute by category or salary level. This determination is called “equal classification.”

¹⁹ The “equal classification” determination for institute and center directors was previously requested by NIH on June 6, 1994, in a memorandum to OGE; however, OGE ruled that such determination at that time could not be provided “without additional details concerning these positions.” NIH at the time did not seek to provide additional information. Note, however, that prior to the 2004 OGE “equal classification” determination, institute and center directors voluntarily filed the public financial disclosure report.

by [the Department] to file confidential financial disclosure reports, under subpart I of 5 CFR part 2634, if the criteria therein for defining confidential filers are met. While less intrusive of filers' privacy, the confidential system serves the same goal as the public system, which is primarily to prevent conflicts of interest.²⁰

The Process for Public Financial Disclosure Reporting

Public financial disclosure reporting requirements are described in the regulations,²¹ and the information is filed on the SF 278 form. For most NIH employees, the process for preparing, reviewing, and certifying public financial disclosure forms involves the employee and the institute's or center's deputy ethics counselor.

What Information Is Disclosed?

The public financial disclosure reporting system seeks the following information from employees: a brief description of any interest in property held by the filer or his or her immediate family; origin and total investment and noninvestment income; purchases, sales, and exchanges above a certain amount; certain gifts and reimbursements; liabilities and categorization of amount; agreements and arrangement for future employment; and outside positions, including income above a certain amount. The instructions and forms for this report are 18 pages long.

Table 1 at the end of this section compares the requirements for qualification as a public versus a confidential filer.

Discussion

Current requirements for reporting income from outside activities, or from investments that might have relevance to one's official duties, do not always capture the information needed to manage conflicts of interest. The only employees who must currently *publicly* disclose all outside activities as well as financial interests are those required to file an OGE Form 278 annually.

The most obvious problem that needs to be corrected is the accident of legislative and regulatory history that exempts even highly paid Title 42 employees from this disclosure. NIH has been eliminating this problem by securing equivalency determination from OGE with respect to its most senior employees, so that these employees are now required to file Form 278. This is an effective first step to ensuring that potential conflicts of interest at the highest level of NIH are properly managed. In addition, the complexity of Form 278 weakens its intent and it is therefore the Panel's opinion that OGE should seek simplification of reporting, a change requiring legislation and that would be applied government-wide.

²⁰ Letter to a Designated Agency Ethics Official from Stephen P. Potts, dated February 11, 1998. Available at http://www.usoge.gov/pages/advisory_opinions/advop_files/1998/98x2.html

²¹ 5 CFR Part 2634, Subpart F.

As specified by OGE, the filing of an annual confidential disclosure of financial interests (OGE Form 450) is limited to “those pay grades where the duties and responsibilities clearly make filing necessary and relevant.” At present, more than 5,000 of the more than 17,000 NIH employees are required to disclose in this manner. Individuals who file this relatively brief confidential form need to disclose outside activities with industry and academia, and if the income from these activities exceeds \$200. However, there is no way of knowing the exact amounts of compensation involved. Form 450 is a government-wide form established by OGE, and therefore not easily changed. Further, if an individual is not required to file either a public or confidential financial disclosure form, and does not have an outside activity approved through the HHS Form 520—as can be the case—NIH might have no way of knowing whether a potential conflict of interest exists.

Conclusion

It is critical to maintain public confidence that NIH’s ethics standards and practices ensure that all potential conflicts of interest are managed or eliminated. There are three key considerations in determining whether and what type of disclosure should be required: 1) does NIH know enough to prevent and manage conflicts of interest? 2) do those who would be directly affected by such interests (e.g., subjects of research) have the information necessary to make informed choices? and 3) does the public have access to sufficient information to maintain public confidence in the integrity of NIH? In answering these questions the Panel attempted to balance the needs of NIH, as well as those of research subjects and the public, with the rights of NIH employees as U.S. citizens to an appropriate and reasonable degree of privacy.

Recommendations are made in Section V of this report to improve financial reporting policies and practices.

Table 1: Financial Filing Requirements by Appointment Mechanism

		Title 42 ¹		SES, Senior Level (SL), Senior Technical (ST)	Special Government Employees	Commissioned Corps	Title 5 ² (including employees that receive Title 38 ³ Physician Special Pay)
		NIH Deputy Directors, Institute and Center (IC) Directors, IC	All Others				
Public Financial Disclosure	Presidential Appointee, Presidential Appointee-Senate Confirmed	Yes.	No.	Yes.	Yes, if expected to serve >60 days in one year and pay is equal to or over \$104,927.	Yes, if O-7.	No, unless designated by OGE as requiring public financial disclosure (See **)
Confidential Financial Disclosure	No.	No.	Yes, if position or responsibilities meet requirements. (See *)	No.	Yes, if not subject to public disclosure.	Yes, if below O-7 and if position or responsibilities meet requirements (See *)	Yes, if position or responsibilities meet requirements (See *)

* Required for associate director, assistant director, division director, NICHD center directors, executive officers, deputy executive officers and all other employees designated by the deputy ethics counselor who meet one or more of the following criteria and who have not been excluded from the filing requirements: contracting or procurement, administration, monitoring of grants, licenses, CRADAs, or other federally conferred benefits; regulating or auditing nonfederal entities; other activities that will have a substantial economic effect on the interests of a nonfederal entity, or other activities that have the potential to create a real or apparent conflict of interest.

** Under the authority under 5 CFR 2634.202(c), the OGE (not NIH) may require any other officer or employee in any other position determined to file a public financial disclosure report if that individual occupies a position that is equivalent to a position that is already specifically designated in the statute by category or salary level. This determination is called "equal classification."

1 Unique to PHS agencies. Used to hire scientists in both the intramural and extramural programs who are engaged in biomedical research, science management, science administration, science policy, and research administration. Includes those employees in the Senior Biomedical Research Service (SBRS) and Administratively Determined (AD) pay plan.

2 This mechanism is used to fill most positions within the federal government at GS-1 through GS-15 and positions in the wage grade trades and labor occupations. Pay is based on the qualifications of the appointee and is limited by Office of Personnel Management pay regulations.

3 Authorizes the NIH Director to pay physicians and dentists appointed in the civil service (Title 5) additional pay subject to the provisions of Chapter 74 Title 38 USC, a Department of

* Required for associate director, assistant director, division director, NICHD center directors, executive officers, deputy executive officers and all other employees designated by the deputy ethics counselor who meet one or more of the following criteria and who have not been excluded from the filing requirements: contracting or procurement administration, monitoring of grants, licenses, CRADAs, or other federally conferred benefits; regulating or auditing nonfederal entities; other activities that will have a substantial economic effect on the interests of a nonfederal entity; or other activities that have the potential to create a real or apparent conflict of interest.

*** Under the authority under 5 CFR 263.4, 207(c), the OGE (not NIH) may require any other officer or employee in any other position determined to file a public financial disclosure report if that individual occupies a position that is equivalent to a position that is already specifically designated in the statute by category or salary level. This determination is called "general classification."

“equal classification”

1) Unique to PHS agencies. Used to hire scientists in both the intramural and extramural programs who are engaged in biomedical research, science management, science administration, research policy, and research administration. Includes those employees in the Senior Biomedical Research Service (SBRS) and Administratively Determined (AD) pay plan.

science policy, and research administration, includes those employees in the Department of Energy (DOE) and the Department of Defense (DOD). This mechanism is used to fill most positions within the federal government at GS-1 through GS-15 and positions in the wage grade trades and labor occupations. Pay is based on the General Schedule (GS) pay scale.

This mechanism is used to fill most positions within the Federal Government at GS-1 through GS-15 and positions in the major grant-making agencies. The mechanism is limited by Office of Personnel Management pay regulations, qualifications of the appointee and is limited by Office of Personnel Management pay regulations.

2. Authorizes the NIH Director to pay physicians and dentists appointed in the civil service (Title 5) additional pay subject to the provisions of Chapter 74 Title 38 USC, a Department of

Veterans Affairs authority:

Section IV. Outside Activities

National Institutes of Health (NIH) employees, like other government employees, can legally choose to engage in outside activities (paid or unpaid) under certain conditions, with the primary stipulation that the activity must not pose a conflict of interest for the individual as a government employee. Thus, the activity can in no way interfere with the ability of the employee to conduct his or her official duties, provide the individual or institution engaging the federal employee with an advantage regarding policy and resource decisions, or allow the employee to use public resources for personal gain.

Many outside activities have no relationship at all to the employee's official duties, such as, for example, playing the violin in an orchestra, while others are so closely related that it is exceedingly difficult to draw the line between a scientist performing official duties and a scientist using his or her personal, intellectual, and creative capital in outside activities. This is especially challenging when the proposed activity draws on the expertise and knowledge of the employee, of which only a portion could be rightly attributed to his or her career as an NIH scientist.

Scientists typically complete extensive postgraduate programs, often with multiple postdoctoral fellowships at different institutions. In many cases, scientists are recruited to NIH after several years, possibly decades, of conducting research and teaching at an academic institution or working for industry. Thus, the value of the scientist becomes his or her accumulated knowledge, which is manifest in that individual's accomplishments, discoveries, writings, and considered opinions. Deciding at what point knowledge and expertise become elements of a federal employee's "official duties," particularly in complex fields, is a major challenge facing those determining the policies that govern conflicts of interest at NIH.

Despite the potential for conflicts of interest to arise when a government scientist engages in outside activities, a number of arguments can be made in favor of a policy that allows some NIH employees to engage in outside activities—albeit within strict guidelines, subject to thorough oversight, and with a high level of transparency. First, absent good reasons otherwise, Americans, including federal employees, are free to work beyond their primary employment and to be paid for that work. Second, for NIH to compete with the other likely employers, it must not unduly restrict opportunities for interesting and remunerative outside activities. In order to achieve excellence and pursue its mission most effectively, NIH must be able to compete for the very best scientists. Finally, Congress and every recent administration has embraced technology transfer as one of the missions of NIH. Allowing individual outside activities, including those that involve consulting with industry, is an important aspect of technology transfer, both to and from NIH. This interaction facilitates the transfer of research advances at NIH to those entities that are most likely to bring the benefits of these results to the public, namely commercial firms.

It is unrealistic to assume that an optimal level of interactions with scientists in academia and industry for achieving the mission of NIH can be reached if all NIH scientists are prohibited from accepting compensation for such activities, which are traditional in much of the scientific community and often require a level of effort well beyond one's official duties. Moreover, the

interactions with industry sometimes will require confidentiality agreements concerning the commercial information provided by industry that are forbidden in any official duty activity. These outside activities complement, but do not duplicate more formal relationships between NIH scientists and industry, such as cooperative research and development agreements (CRADAs).

The proportion of NIH employees engaged in compensated outside activities with industry is relatively small. Of the 17,526 full-time equivalent employees at NIH as of March 2004, 118 employees were involved in 196 consulting arrangements with pharmaceutical or biotechnology companies. Of the 196 activities, all but 5 involve compensation: 173 involve cash payments, and 49 involve owning stock in the company (these compensation elements are not mutually exclusive).

No argument in favor of allowing outside compensated activities for NIH employees precludes strict limits or prohibitions on certain employees (for example, those in position of authority or with control over allocation of resources). There clearly is a need to consider the official duties of the employee with respect to each type of compensated activity being proposed (e.g., consulting, speaking, writing, teaching, receiving awards) and to the specific circumstances surrounding such activity. Thus, determining whether an outside activity poses a real or perceived conflict of interest should be decided on a case-by-case basis, as is currently done at NIH. Nevertheless, the system of making such determinations must be guided by clear principles, provide reasonable consistency, and have transparent procedures.

This section describes the Panel's findings concerning the current policies and procedures used by NIH to oversee compensated outside activities, discusses the implications of these policies in the context of different classes of outside activities and of NIH personnel, and makes recommendations for improvement.

Current Policies and Procedures Governing Outside Professional Activities

Consistent with the government's Principles of Ethical Conduct, regulations are in place at NIH to mitigate against actual or apparent conflicts of interests, which can result from financial interests and outside professional activities, whether compensated or non-compensated. A conflict of interest arises under two circumstances. The first can occur when an employee is involved in a particular matter as part of his or her official duties with an outside organization with which he or she also has a financial interest, or one that is imputed²² to him or her. The second occurs when an employee is involved with a specific party in a matter and has a covered relationship²³ with the outside organization. In either case, the conflict can be real²⁴ or

²² Imputed interests include financial interests of the employee's (1) spouse; (2) minor child; (3) general partner; (4) an organization in which the employee serves as an officer, director, trustee, general partner, or employee; or (5) a person or organization with which the employee is negotiating or has an arrangement for prospective employment.

²³ An employee has a covered relationship with (1) a person, other than a prospective employer described in 5 CFR 2635.603(c), with whom the employee has or seeks a business, contractual or other financial relationship that involves other than a routine consumer transaction; (2) a person who is a member of the employee's household, or who is a relative with whom the employee has a close personal relationship; (3) a person for whom the employee's spouse, parent or dependent child is, to the employee's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee; (4) any person for whom the employee

apparent,²⁵ and in limited circumstances, it may be waived²⁶ or the employee's participation may be authorized²⁷ in order to allow him or her to be involved in the matter.

Conflicts, or the appearance of them, may arise either as a result of an employee's outside activities or because of his or her personal financial interests. Although many outside activities and financial interests do not constitute a conflict of interest, or the appearance of one, federal agencies such as NIH review many of the activities and interests of its employees to ensure adherence to the Principles of Ethical Conduct, as well as to other relevant federal statutes and regulations. NIH holds its employees to the federal ethics regulations as well as to HHS supplemental regulations, as described below.

NIH and all other federal agencies and employees must comply with generally applicable statutes and Office of Government Ethics (OGE) regulations²⁸ that state that an employee shall not engage in any outside activity that:

- Is prohibited by statute or by an agency supplemental regulation;
- Would, because of a financial conflict of interest or an appearance of such a conflict, require the employee's disqualification from matters so central or critical to the performance of his or her official duties that the employee's ability to perform those duties would be materially impaired.
- Would involve compensated or uncompensated service as an expert witness, other than on behalf of the United States, in any proceeding before a federal court or agency in which the United States is a party or has a direct and substantial interest, unless, as provided in the OGE regulations, the employee's participation is authorized by the agency in which he or she serves; or
- Would involve compensation from any source other than the Federal Government for teaching, speaking, or writing that relates to the employee's official duties.

HHS has issued a supplemental regulation²⁹ that prohibits for all HHS employees:

- Compensated outside work preparing or assisting in the preparation of any grant application, contract proposal, report, or other document intended for submission to HHS; and

has, within the last year, served as officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee; or (5) an organization, other than a political party described in 26 USC 527(e), in which the employee is an active participant.

²⁴ A real conflict exists when an employee participates personally and substantially in particular matters that have a direct and predictable effect on a financial interest of the employee, or one of the five "others" listed above. In this case, participation in the official matter is in violation of the criminal statute 18 USC 208.

²⁵ An appearance of a conflict exists when an employee is involved in a particular matter involving specific outside parties (including individual or corporate entities), and the employee knows that the matter will have a direct and predictable effect on the financial interests of a member of his or her household or knows that a person with whom he or she has a covered relationship is, or represents, a party to the matter.

²⁶ Waiver issued pursuant to 18 USC 208(b)(1) by the person responsible for the employee's appointment to his or her position is used to resolve a real conflict of interest.

²⁷ Authorization given pursuant to 5 CFR 2635.502(d) by agency designee is used to resolve an apparent conflict of interest.

²⁸ Title 5 CFR Part 2635, entitled *Standards of Ethical Conduct for Employees of the Executive Branch*.

²⁹ 5 CFR Part 5501.

- Compensated outside work in an activity funded by an HHS grant, contract, cooperative agreement, cooperative research and development agreement (CRADA), or other funding mechanism authorized by statute.

OGE regulations state that, when required by an agency supplemental regulation, an employee will obtain prior approval before engaging in outside employment or other outside activities. The standard for approval of an outside activity request is that it “shall be granted unless it is determined that the outside employment or other outside activity is expected to involve conduct prohibited by statute or federal regulation, including 5 CFR Part 2635 and [the HHS supplemental regulation].”

If it wishes to impose additional restrictions, an agency must issue a regulation that supplements the OGE regulation. However, an agency may explain how federal statutes and the OGE regulations apply to employees of that agency, as NIH has done in its Policy Manual, in which the rules applicable to the outside activities of NIH employees are as follows:

Activities Must Not Be Related to Official Duties. An employee may not receive compensation for outside activities that relate to his or her official duties.³⁰ An outside activity is considered related if the employee was invited primarily because of his or her official position (this would be a prohibited use of public position for private gain), or if it deals with any matter to which the employee is presently assigned or has been assigned during the previous one-year period, or if it deals with any ongoing or announced policy, program, or operation of NIH. Exception: An employee may teach a course, with or without compensation, on topics related to his or her official duties when that course involves at least two presentations and is offered as part of a regularly scheduled curriculum at an accredited institution of higher education.

Prohibited Activities. An employee may not accept compensation for service of any kind that is funded by an HHS contract, grant, cooperative agreement, or other funding mechanism. Compensation is also prohibited for assisting in the preparation of or preparing a grant application or other document intended for submission to HHS.³¹

Restrictions on Outside Medical or Similar Professional Practice. In order to obtain approval for outside professional practice involving patient care, an employee must agree and assure that (1) the employee will not have outside patient contact, including telephone calls during official working hours, and patient support, including emergency services, must be provided by someone other than the employee during those hours; (2) NIH patients may not be referred to the private practice of an NIH employee, or from such practice to NIH, and the patients must be informed in advance of this policy; (3) the employee will never knowingly establish a physician-patient relationship in outside practice with any current or recently discharged NIH patient; (4) no employee with final responsibility for the admission of patients to the Clinical Center may

³⁰ The basis for this rule is the federal criminal statute, 18 USC 208, which prohibits a federal employee from participating personally and substantially, as part of his official duties, in any matter that would have a direct and predictable effect upon the financial interest of the employee, the employee's spouse, minor child, general partner, an organization in which the employee serves as an officer, director, trustee, general partner, or employee, or an organization with which the employee is negotiating or has an arrangement for prospective employment.

³¹ This prohibition is imposed by 5 CFR 5501.106(c), the HHS regulation that supplements the OGE ethics regulation.

receive a fee for service as consultant to another physician where the patient's condition would appear to make him or her eligible for Clinical Center admission in an area currently supervised by that employee; and (5) an employee will not accept primary responsibility for the care of an outside patient except in circumstances where it will clearly not impose on, or interfere with, his or her responsibilities as a federal employee.

Participation in the Business Affairs of Outside Organizations. Under some circumstances, an employee may participate in the internal and external business operation of an outside organization as an outside activity, including involvement in the human resources, financial, and fund-raising activities of the organization. Such involvement usually occurs when an employee serves as an officer or member of the board of directors of an outside organization. Such service requires that the employee be disqualified (recused) from any involvement with the organization in the course of carrying out his or her duties for NIH.

Unlimited Use of Personal Time. An employee must conduct all outside activities on personal time. If outside work is to be performed during normal NIH working hours, the employee must be on approved annual leave, leave without pay, credit hours, or compensatory time and not be present at his or her duty station. There is no limit on the amount of personal time an employee may spend on outside activities as long as it does not affect his or her ability to carry out official duties.

No Use of Government Resources. An employee may not use government resources (e.g., equipment, services, stationery, or other supplies or staff) in the performance of outside activities. Only information that is in the public domain may be used, and that information must not derive from work the employee has done within the last year. An employee may provide information on work performed prior to the last year which has been publicly disclosed, provided the information is not the subject of ongoing research, programs, or policies. The employee may also provide information that is based on his or her general scientific or professional knowledge and expertise and not derived specifically from employment at NIH.

With certain exceptions, both the employee and an outside organization are prohibited from referencing the title and place of work of an employee in connection with any outside activity or employment, including speaking or writing.

Any Form of Compensation Is Acceptable. An employee may receive compensation for his or her outside work in the form of money, stocks, or any other financial instruments that have monetary value.

Advance Written Approval Required. Under the HHS supplemental regulation, the following outside activities require advance approval whether or not they are compensated: (1) consultative or professional services, including service as an expert witness; (2) teaching, speaking, writing, or editing that relates to an employee's official duties, or that would be undertaken as a result of an invitation extended by a person who is a prohibited source³² within the meaning of the OGE

³² The OGE regulation defines a covered relationship as any person who: (1) is seeking official action by the employee's agency; (2) does business or seeks to do business with the employee's agency; (3) conducts activities regulated by the employee's agency; (4) has interests that may be substantially affected by performance or

regulation; and (3) services to a nonfederal entity as an officer, director, or board member, or as a member of a group, such as an editorial board, or scientific or technical advisory board or panel, that requires the provision of advice, counsel, or consultation—unless the service is provided without compensation to a political, religious, social, fraternal, or recreational organization and the position held does not require the provision of professional services.

The NIH policy on outside activities and on avoiding conflicts of interest states that an “apparent conflict of interest” arises when an employee is involved in a particular matter involving specific outside parties (including individuals and corporations) and the circumstances are such that a reasonable person with knowledge of the relevant facts would question the impartiality of the employee in the matter.

The NIH policy is interpreting the OGE regulation³³ that refers to a loss of impartiality as a situation in which an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his or her household, or knows that a person with whom the employee has a covered relationship is or represents a party to such matter and that the circumstances would cause a reasonable person with knowledge of the relevant facts to question the employee’s impartiality.

In a general sense, an appearance of a conflict of interest is something less than a real or actual conflict or what is sometimes referred to as a direct conflict. Prior to 1995 (see below) NIH restricted an employee from engaging in an outside activity with a company that has business dealings not directly involving the employee but falling within the laboratory or branch in which the employee works. That restriction was addressing an *appearance* of a conflict of interest. The appearance of a conflict would be reduced if the company had business dealings only with the institute or center in which the employee works or only with NIH, HHS, or the federal government rather than his or her laboratory or branch. In thinking about these degrees of appearance or the line between a real and an apparent conflict, it is helpful to consider the degree to which an employee with an outside consulting agreement can influence or appear to influence official interactions with his or her outside employer. The degree of real or apparent influence would thus be greater for a high-level employee than it would be for a lower-level employee. The degree of the appearance also may depend on the scope and potential impact of the interaction of the employee’s agency or agency component with the company or industry with which the employee has an outside activity.

Other Terminology and Concepts

Preferential Treatment. Conflicts can be created if an outside party is given preferential treatment by an NIH employee conducting official duties, for example, the employee provides a lecture at only one industrial firm and refuses invitations to conduct similar activities at other firms.

nonperformance of the employee’s official duties; or (5) is an organization a majority of whose members are described in clauses (1) through (4) of this sentence.

³³ 5 CFR § 2635. 501.

Conflict of Commitment. This term refers to the potential adverse effect on an employee's ability to carry out the duties of his or her primary job when engaging in an outside activity. A conflict of commitment might arise because of time constraints or because of competing loyalties or responsibilities. The current restrictions on the outside activities of NIH employees do not use this term, but they do state that an employee's outside activities cannot interfere with the performance of his or her official duties.

Prior to 1995 (see below), the NIH limit on the total number of hours that could be devoted to outside activities (all of which had to be conducted on "personal" time) was a way of ensuring that there was no interference based on the amount of time devoted to the outside activities. Similarly, the previous NIH limitations on the amount of compensation from a single outside source and on compensation in the form of stock or stock options could be seen as addressing a potential conflict of commitment. The greater an employee's involvement with a single company, either through time or compensation, the more that company could be seen as competing with the employee's commitment and loyalty to NIH, his or her primary employer.

Institutional Conflict of Interest. This term is not used in federal ethics statutes or regulations or in past or present NIH policies. However, it is a concept that has been of interest to HHS and NIH in the context of institutions that conduct research involving human subjects. In a 2001 report to Congress, the General Accounting Office (GAO)³⁴ concluded that a research institution's equity ownership or other financial interest in a company sponsoring research at the institution may affect the institution's review, approval, or monitoring of research conducted by the institution or the allocation of equipment, facilities, and staff for research. Although GAO's recommendation regarding institutional conflicts of interest was not limited to a particular type of research, the agency noted that recent interest in the issue had been prompted by reports that financial conflicts of interest may have been associated with harm to research subjects. The GAO report called on HHS to develop specific guidance or regulations addressing institutional conflicts of interest.

On March 31, 2003,³⁵ HHS requested public comment on draft guidelines entitled *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection*. The draft guidelines recommend that institutions engaged in federally conducted or supported human subjects research should consider the following actions regarding institutional financial conflicts of interest:

- Establish criteria to determine what constitutes an institutional conflict of interest, including identifying leadership positions for which the individual's financial interests are such that they may need to be treated as institutional financial interests.³⁶

³⁴ U.S. GAO, *Biomedical Research: HHS Direction Needed to Address Financial Conflicts of Interest* (GAO-02-89) (November 2001), 7.

³⁵ 68 *Federal Register* 15456.

³⁶ The October 2002 report of the Association of American Medical Colleges Task Force on Financial Conflicts of Interest in Clinical Research, entitled *Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research*, concludes that an institutional official's position may convey an authority that is so pervasive or a responsibility for administration of research programs that is so direct that a conflict between that individual's financial interests and the institution's human subjects research should also be considered an institutional conflict of interest. The report does not address

- Establish a conflict of interest committee (COIC), to address both individual and institutional financial interests, or establish a separate COIC to address institutional financial interests.
- Establish procedures for the disclosure of institutional financial relationships to COICs.
- Use independent organizations to hold or administer the institution's financial interest.

The draft guidance applies to "federally conducted or supported" human subjects research and thus would apply to elements of the NIH intramural research program. NIH's intramural research program has drafted a policy that is directed toward the disclosure and management of financial conflicts of interest. The draft policy would apply to individuals who substantially participate in the development, conduct, or analysis of clinical research protocols or in the oversight of human subjects research at NIH.

As a federal agency, NIH cannot have any equity or ownership interest in a company, but it can and does have financial interests in companies through receipt of royalties from the licensing of NIH inventions, from the receipt of monetary and other support from companies under CRADAs, through gifts, or through formal or informal collaborative research arrangements. The definition of a financial conflict of interest in the draft intramural research program policy includes obtaining royalties or being an inventor of products being evaluated in human subjects research or of products that could benefit from the human subjects research.

Authorization. An appearance of a loss of impartiality in performing official duties can be waived under the OGE regulation.³⁷ Where an employee's participation in a particular matter involving specific parties does not violate laws or regulations, but would raise a question in the mind of a reasonable person about the employee's impartiality, the agency designee may authorize the employee to participate in the matter, based on a determination that the interest of the government in the employee's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations. Factors that may be taken into consideration include (1) the nature of the relationship involved; (2) the effect that resolution of the matter would have on the financial interests of the person involved in the relationship; (3) the nature and importance of the employee's role in the matter, including the extent to which the employee is called upon to exercise discretion in the matter; (4) the sensitivity of the matter; (5) the difficulty of reassigning the matter to another employee; and (6) adjustments that may be made in the employee's duties that would reduce or eliminate the likelihood that a reasonable person would question the employee's impartiality.

The NIH policy states that an employee who has served as a consultant, employee, or board member of an outside organization within the last year may not participate in official matters involving that organization for one year after the termination of the relationship. The deputy ethics counselor may determine that a shorter period of disqualification would be appropriate based on an evaluation of the facts of the case and on the application of the factors listed above.

the effect of an institutional financial interest in a company on an employee's proposed outside work for that company.

³⁷ 5 CFR § 2635.502(d).

Disqualification or Recusal. An employee with an outside activity that creates a real or apparent conflict with his or her official duties can remove the conflict by disqualifying or recusing him- or herself from the performance of the duties that would create the conflict. This occurs at the time the outside activity is approved if the conflict is foreseeable. Under the HHS regulation, if the disqualification that would be necessary to permit the outside activity is so central or critical to the performance of the employee's official duties that his or her ability to perform the duties of the position would be materially impaired, the outside activity cannot be approved, or if previously approved, the outside activity must be discontinued. Even if a disqualification does not meet this standard of interference with an employee's official duties, it could be seen as creating a conflict of commitment, because NIH is agreeing to give up the services of the employee in certain areas so that he or she can pursue an interest in serving an outside employer.

For a high-level employee, a disqualification could pose both administrative and appearance issues. If an employee is the head of a division, institute, or center, it could appear that the official is responsible for all activities within that component, even though a recusal has been in place. Because high-level officials may not assign their responsibility for official duties that would conflict with outside activities to employees that they supervise, the responsibility must be assigned to a higher-level employee. For institute and center directors this would require assigning the duties at least to the Deputy Director of NIH, whose responsibilities are normally NIH wide, rather than being limited to a single institute or center.

Approval Process for Outside Activities

Responsibility for implementing the NIH ethics program is coordinated within the 27 institutes and centers and the Office of the Director, NIH. Some of those involved include staff in the central NIH Ethics Office, NIH deputy ethics counselors and ethics officers in each of the 27 institutes and centers, and staff in OGE and the HHS Office of General Counsel. The NIH Ethics Office serves as the main NIH ethics contact. Its responsibilities include providing assistance to the deputy ethics counselors and ethics officers in each institute and center and to other managers and supervisors on all aspects of the NIH Ethics Program, including activities with outside organizations. This office advises the Director, NIH, and other top management officials of new developments, trends, and practices associated with the participation of NIH employees in outside organizations. It also provides assistance on informal or formal training for officials as needed, disseminates ethics information to those who need to know, and conducts post-audit reviews.

The HHS supplemental regulation requires that advance written approval must be obtained by all employees for certain outside activities, whether or not they involve compensation. Supervisors review and approve or deny outside activity requests by performing two functions: 1) a supervisory management review to consider whether the outside activity could be performed more appropriately as an official duty activity and to consider the amount of time that will be involved in the activity; and 2) a supervisory ethics review to identify conflicts of interest and determine whether a conflict will require the employee to recuse (disqualify) him- or herself from critical official duties.

The process for review and approval of outside activities for NIH employees in certain positions (e.g., senior NIH officials) and other NIH employees who desire a certain type of outside activity (e.g., involving a biotechnology or pharmaceutical company or more than \$10,000 in compensation) recently changed, involving a new NIH Ethics Advisory Committee [NEAC]; described below). Activities outside NEAC jurisdiction are reviewed and approved by institute and center ethics staff. However, it is important to note that the requirement to submit outside activity requests has not changed for the employee, even though NIH's processes and procedures for reviewing outside activity requests have changed to bring certain types of cases under central NEAC oversight.

Where the outside activity creates a real conflict of interest, it is not likely to be approved. However, as described above, it is possible that a waiver or authorization could be granted, in limited circumstances, to allow the employee to have both the outside activity and participate in an official duty matter that involves the outside entity. NIH anticipates that waivers or authorizations rarely would be approved. A waiver or authorization may be granted in certain circumstances, for example, to a new NIH employee who wishes to complete a short-term research project with a previous employer while beginning to work on matters involving that previous employer as part of the employee's official duties. However, it is unlikely that NIH would issue a waiver or authorization for employees who are first assigned to a matter involving an outside organization and then wish to engage in an outside activity with that same organization. In this circumstance, the requested new activity creates the conflict and it would not be approved.

To request to participate in an outside activity, the NIH employee has to complete an Outside Activity Packet. Although there is no annual reporting requirement, any substantive change in the scope of the approved activity would constitute a new activity requiring submission of another Outside Activity Packet. This packet includes the following forms:

- HHS 520: This form is used within HHS to request approval of proposed outside activities (activities that are totally outside regular official duties and with outside organizations). The HHS 520 is required for all outside activities as described above.
- Unnumbered NIH Supplement to the HHS 520: This form provides additional information about the outside activity so that the deputy ethics counselor can make an informed decision regarding the appropriateness and permissibility of the activity. The Unnumbered NIH Supplement to the HHS 520 is required for all compensated outside activities.
- NIH 2657: This NIH form is used to provide additional information for certain outside activities. The NIH 2657 is required for consulting for industry, legal consulting/testimony, and professional practice for physicians, nurses, and allied health care professionals (e.g., respiratory technicians, social workers, phlebotomists).

The approval process for outside activities involves one of the following four processes:

No Approval Required

Some activities are exempt from the outside activities restrictions. These include activities that do not involve an employee's work-related professional skills and abilities. Examples of outside activities that are not work related include playing an instrument in an orchestra, appraising antiques, or teaching aerobic classes. Employees may engage in these types of activities without prior approval by a supervisor or deputy ethics counselor. Also not covered by the NIH outside activity definition are religious or community service (serving as an officer of a religious organization or as PTA president), or other activities that do not readily identify the employee with NIH (retail clerk or similar positions). However, if such outside activities involve a pharmaceutical or biotechnology company, they must undergo review by NEAC and receive approval from the NIH deputy ethics counselor.

Recommendation by Supervisor and Approval by an Institute or Center Deputy Ethics Counselor

An employee's request for approval of an outside activity can be granted by a deputy ethics counselor after recommendation by the supervisor, as long as the outside activity does not fall under NEAC jurisdiction.³⁸

Recommendation by Supervisor and Approval by a Deputy Ethics Counselor: Waiver or Authorization Required

Although 18 USC 208 prohibits a federal employee from taking part as a government official in any matter in which he or she has a financial interest, other provisions of the statute allow the use of a waiver to allow an employee with a real conflict of interest to continue performing official duties despite the actual conflicting interests. For example, an agency may determine that a disqualifying financial interest in a particular matter is not substantial enough to likely affect the integrity of the employee's services to the government. On making that determination, the agency can waive the employee's disqualification notwithstanding the financial interest and permit the employee to participate in the matter. To obtain a waiver, an employee using a waiver form must disclose the situation to the person responsible for his or her appointment (e.g., institute or center director or designee).

Separate from a waiver, an authorization can permit an employee to participate in a specific matter in the employee's official capacity with an outside organization in which the employee is engaged in a personal capacity, despite the appearance of a conflict of interest with the outside organization. An appearance of a conflict arises when an employee is involved in an official matter involving specific outside parties and circumstances are present that would cause a reasonable person with knowledge of the relevant facts to question the employee's impartiality in the official matter. The institute or center deputy ethics counselor determines whether such an authorization should be granted.

³⁸ NEAC reviews requests that involve (1) awards from nongovernmental sources that include a cash payment (including travel reimbursement) equal to or more than \$2,500; (2) any outside activity request involving a biotechnology or pharmaceutical company; (3) any outside activity request that involves anticipated compensation of more than \$10,000, or which is expressed as a future income stream; or (4) any outside activity for which payment will be entirely, or in part, in the form of stock, stock options, or any other equity position.

Recommendation by the Supervisor and a Deputy Ethics Counselor, Review and Recommendation by NEAC, Approval by the NIH Deputy Ethics Counselor: No Waiver or Authorization Required

Effective January 12, 2004, the approval processes and procedures were modified for certain activities and employees.

- For outside activity and cash award requests from institute and center directors, employees in the Office of the Director, NIH, and senior staff (NIH deputy, associate, and office directors), the review process involves NEAC and the NIH deputy ethics counselor.
- For outside activity and cash award requests from institute and center deputy directors, scientific directors, clinical directors, and extramural directors, the review process involves the institute or center director, NEAC, and the NIH deputy ethics counselor.
- For all other NIH employees, where the conditions for NEAC review apply, the process involves the employee's supervisor in the institute or center, the appropriate deputy ethics counselor, NEAC, and the NIH deputy ethics counselor, if the conditions for NEAC review apply.

After NEAC has reviewed the outside activity request and has made a recommendation to the NIH deputy ethics counselor, the NIH deputy ethics counselor either approves or disapproves the activity.

Changes in NIH Outside Activity Rules Over Time

The current NIH Policy Manual chapter governing the outside activities of NIH employees was adopted in 1998. It is based on the outside activity provisions of the 1993 OGE government-wide regulation setting forth standards of ethical conduct and the 1996 HHS regulation supplementing the OGE standards. The NIH manual explains how those provisions apply to NIH employees. More stringent restrictions can be imposed only through NIH-requested amendments to the HHS supplemental regulation, which would need to be approved by OGE.

From 1988 to 1995, NIH had more stringent limits on the outside activities of its employees than it does today. In a 1995 audit of the NIH ethics program, OGE identified several restrictions on outside activities that went beyond the restrictions in the 1993 OGE government-wide regulation. OGE pointed out that under its regulation the more stringent limits could not be applied to employees unless they were employed by an agency to which the supplemental regulation applies. Subsequently, on November 3, 1995, the Director of NIH notified institute and center directors and Office of the Director staff that NIH's outside activity policy was being changed to conform to the less restrictive government-wide standards of conduct.

The following restrictions on outside activities based on the 1993 NIH policy thereby became ineffective in 1995 because they were not issued through a supplemental regulation:

Prohibited Sources for Outside Activities. Intramural employees could engage in an outside activity only if the outside entity had no involvement with the employee's laboratory or branch. Extramural employees could engage in an outside activity only if the entity had no involvement with the employee's institute, center, or division.

Compensation Limitations. Limit of \$25,000 from any one outside source (exceptions could be approved by NIH of up to \$50,000), except compensation for books and royalty income. (From 1988 to 1993 the limit on total compensation from consulting for industry and law firms was \$25,000 per year; with no more than \$12,500 from any one company or law firm. The limits on lecturing for industry were the same, with an additional \$2,000 per activity limit.)

Service Limitations. Time for all compensated outside activities was limited to 500 hours. (From 1988 to 1993, the only service limitation was for outside clinical practice: 400 hours per year and a weekly tour of duty that did not interfere with the employee's ability to perform NIH duties.)

Stock Holdings. Employees and their spouses and minor children could not receive stock or stock options as compensation for outside work

Limits on Type of Outside Activity. Service in a management position or on boards of directors of a related activity was not permitted for any NIH employee.

Stringent Limits on High-Level Officials. High-level officials, defined as the NIH Director, NIH deputy directors, NIH associate directors, and institute and center directors and deputy directors, were limited to writing and editing, outside professional practice (patient care), and participation as members of committees or associations involved in selecting recipients of prizes, preparing professional examinations, or other similar activities.

The pre-1995 limitations on outside activities prohibiting compensation in the form of stock or stock options and on receiving more than \$25,000 from a single company addressed both conflict of commitments and the appearance of a conflict of interest.

Holding stock or stock options, particularly in a start-up company, greatly increases the potential amount of compensation and can provide the individual with an ownership interest that gives this activity a dominant role in the individual's priorities over a longer period of time.

Discussion

The Panel considered the broad classes of outside activities that could pose a potential conflict of interest, or the appearance of one, including consulting or professional practice; teaching speaking, and writing; and awards. Each of these three broad categories will be discussed separately below.

Consulting and Professional Practice

Scientific consulting currently is allowed when the “primary purpose is to render scientific or professional advice based on the scientist’s personal expertise.” This type of consulting can take a number of forms, including serving on scientific or advisory boards for biotechnology or pharmaceutical companies, serving as an expert witness in a trial, or serving as a scientific consultant to a company. Payment can be in the form of cash, stock, or stock options, according to current NIH policy.

If serving on a scientific advisory or review board for a private entity involves decisional authority, then the employee must conduct that activity outside of his or her official duties, whether compensated or not. In fact, a private entity would be unlikely to engage the employee in the activity without pay as part of his or her official government duty because doing so would expose confidential and discrete business information (the NIH employee would not be allowed to sign a confidentiality agreement under current government regulations).

Under the current system of approval, enacted in January 2004, any outside activity involving a biotechnology or pharmaceutical company must be reviewed by NEAC, in addition to all other relevant levels of review, and it must be approved by the NIH Deputy Ethics Counselor. In addition, compensation from such outside activities must be disclosed through the HHS 520 Form (see section III).

Other professional activities might include medical or allied health professional practice; for example, a physician at the Clinical Center might have a practice in which he or she sees patients on the weekend or serves as an attending physician at a community emergency room at night. The NIH employees who spoke to the Panel gave many reasons for valuing opportunities for outside activities, including the educational and professional opportunities offered by serving in an advisory capacity to an organization working in related but distinct areas of research, the ability to remain competitive with academic counterparts in the same field, the ability to apply broadened thought and expertise to their own work at NIH, and the ability to supplement income.

The difficulty, however, is determining whether the consulting activity involves matters directly related to the employee’s official duties. It is the responsibility of the employee, of his or her supervisor, and of ethics officials at NIH to determine whether such a conflict exists; if it does, the activity would be prohibited.

Teaching, Speaking, and Writing

In its 1994 report, *On Being a Scientist*, the National Academy of Sciences wrote the following:

...science is inherently a social enterprise—in sharp contrast to a popular stereotype of science as a lonely, isolated search for the truth. With few exceptions, scientific research cannot be done without drawing on the work of others or collaborating with others....The object of research is to extend human knowledge of the physical, biological, or social world beyond what is already known. But an individual’s knowledge properly enters the

domain of science only after it is presented to others in such a fashion that they can independently judge its validity. This process occurs in many different ways. Researchers talk to their colleagues and supervisors in laboratories, in hallways, and over the telephone. They trade data and speculations over computer networks. They give presentations at seminars and conferences. They write up their results and send them to scientific journals, which in turn send the papers to be scrutinized by reviewers. After a paper is published or a finding is presented, it is judged by other scientists in the context of what they already know from other sources. Throughout this continuum of discussion and deliberation the ideas of individuals are collectively judged, sorted, and selectively incorporated into the consensual but ever evolving scientific worldview. In the process, individual knowledge is gradually converted into generally accepted knowledge....The social mechanisms of science do more than validate what comes to be known as scientific knowledge. They also help generate and sustain the body of experimental techniques, social conventions, and other “methods” that scientists use in doing and reporting research....Because they reflect socially accepted standards in science, their application is a key element of responsible scientific practice.³⁹

The sharing of information is critical to the success of science. Not only do scientists publish the results of specific research projects, many also write review articles or book chapters, or serve as textbook or monograph editors for an entire area of endeavor. Science is a knowledge-based enterprise in which scientists with significant expertise are strongly encouraged, even obligated, to share that expertise with scientists-in-training and with the broader scientific community.

NIH intramural scientists routinely teach, speak, and write as part of their official duties. However, opportunities frequently arise to conduct these activities on a broader basis than is required or expected of a government employee. For example, a laboratory chief is expected to supervise the research program of his or her laboratory and to endeavor to have the research results emanating from that laboratory published. These are part of the laboratory chief’s official duties. However, asking this scientist to edit or write a textbook about his or her area of research, teach a course at a local university, or give a series of lectures would likely impinge on his or her regular work week, unless personal time was used, including evenings, weekends, or annual leave time.

Although research scientists in the NIH environment enjoy distinct advantages, they also forego participating in significant activities to work at NIH instead of at a university campus or medical school. In trying to attract and retain the best intellectual talent at NIH, particularly given the lack of comparability of government compensation to that in the private sector, it is especially important to look critically at NIH as a “campus” and to determine ways to strengthen and enliven NIH’s academic atmosphere to make it more attractive to the most talented scientists.

Three attributes characterize the academic environment: (1) multiple and diverse colleagues working in a broad interdisciplinary context; (2) a culture of scholarship that includes the opportunity for open and vigorous exchange of ideas and freedom of inquiry and discourse; and (3) a rich environment devoted to research and to educating and training the leaders of tomorrow.

³⁹ National Academy of Sciences. 1994. *On Being a Scientist*. Washington, D.C.: National Academy Press.

The breadth and diversity of the academic community can in principle be mimicked by the large number of scientists working within NIH. It would be enhanced, however, by opportunities for this community of scientists to interact with other scientists more freely. NIH, as large as it is, does not represent the universe of scholarly inquiry in the biomedical sciences. NIH scientists must be allowed to travel, to attend conferences with their colleagues, and to visit professors at other institutions. The biomedical research community is also an international network. To the degree that the ability of NIH scientists to interact with this network is stifled, we risk making it more difficult to recruit and retain the finest scientists, and we limit the ideas and the connections that inform their work. To treat NIH as an island into itself would severely detract from its ability to serve as an effective generator of new research and knowledge.

The culture of scholarship and open discourse go hand in hand. The culture of scholarship, although intangible on many levels, characterizes the finest universities in the world, where intellectual activity is valued in and of itself and scholars are encouraged to cross disciplines, to challenge one another, to ask open questions, and to express radical, unusual, and innovative ideas. This openness of scholarly discourse helps us move toward the important paradigm shifts that lead to breakthroughs in our understanding of the biology of disease and its treatment.

Although NIH does not see itself primarily as an educational institution, the ability of scientists to attract highly qualified graduate students is key to infusing new ideas into the enterprise. Also, because NIH does not have a medical school or graduate school, it is essential that NIH scientists are encouraged to teach both in NIH graduate programs and also on a consultant basis as they visit medical schools throughout the country and the world. It is certainly possible to make teaching and mentoring activities more available to NIH scientists. In addition to the salutary effect it will have on the quality of the science, it also will help the best NIH researchers have an influence on the education of many of the young scientists who will become tomorrow's leaders.

As important as this atmosphere of academic freedom is to scholarly pursuit, the fact nonetheless remains that when working as an employee of the public one must assume certain additional restraints due to the special fiduciary responsibilities imposed. Thus, an employee must request permission to conduct teaching, speaking, or writing as an outside activity. Problems arise when the teaching, speaking, or writing is related to the employee's official duties—that is, when it relates to ongoing assignments or those given within the last year—or when it relates to an ongoing program, policy, or operation of the agency. However, because science is a cumulative endeavor, this requirement can give the appearance of allowing employees to teach, speak, or write only on topics about which they know little.

There are some relatively obscure exceptions to this limitation. For example, writing or editing a scientific book as a compensated outside activity may be allowed if the publication deals only in small part with information gained through official responsibilities. The OGE regulations provide some examples of such exceptions: An NCI scientist, for example, who specializes in the molecular biology of cancer may not be compensated for a book that focuses on research that he or she performs at NIH. However, it is acceptable to edit a textbook on the treatment of all cancers that conveys "scientific knowledge gleaned from the scientific community as a whole" and that includes a chapter on the molecular biology of cancer. In addition, editing a scientific or professional journal is allowed as an official duty only if it does not involve making final

judgments about what is to be published. Yet the alternative of teaching, speaking, and writing for compensation is also restricted and is allowed “on a subject within the employee’s discipline or inherent area of expertise based on his educational background or experience even though the teaching, speaking, or writing deals generally with a subject within the agency’s areas of responsibility.”

Teaching for compensation is allowed as an outside activity if it involves multiple presentations, involves a course that is part of an established curriculum, or involves elementary or secondary schools or institutions of higher learning. If a scientist seeks permission to speak for compensation as an outside activity, he or she must do so as a private citizen, not as an employee of NIH. This leads to that individual’s name appearing on the program with no institutional affiliation (e.g., Dr. Joan Smith, Bethesda, Maryland).

In the Panel’s discussion with NIH scientists, it learned that the above set of complex and difficult to interpret regulations gives rise to many ambiguities and creates a real conflict with the scientific culture outside of the NIH. This in turn casts a shadow over the full participation of NIH scientists with the rest of the scientific community that harms both the morale and productivity of NIH scientists.

Awards

Scientists who make significant contributions to their field, serve as leaders, or excel as communicators and educators are frequently given awards by philanthropic foundations, professional societies, industry, or federal or state governments. Most scientists consider the most prestigious of these awards to be the Nobel Prizes, but many other significant awards are made annually or periodically, involving in some cases considerable cash awards. In addition to the better known and larger awards, family funds are often granted to universities to establish career achievement or leadership awards in science. The growth in the number of these awards has been attributed to many factors, including the wish to honor worthy scientists in new and emerging fields and the goal of individuals and charitable organizations to boost their scientific credentials by identifying themselves with and rewarding first-class scientists. Scientists who receive these awards are frequently required to prepare a lecture as an “acceptance speech.” The cash prizes for these awards can range from a few hundred to thousands of dollars.

Recognition is a critical incentive for motivating scientists. Awards resulting from the critical evaluation and assessment of an individual’s or group’s work or career by peers, including distinguished scientists, hold considerable value to the recipients. Awards not only raise the visibility of the scientist, but also enhance the reputation of his or her institution and research area.

In a June 2003 letter to the Director of NIH, the House Committee on Energy and Commerce announced that it was investigating whether NIH is properly implementing ethics statutes and regulations relating to “lecture awards,” which are cash awards that recognize public service and scientific leadership that are given to NIH officials by an organization in connection with the presentation of a scientific lecture sponsored by that organization. The letter stated that committee staff had identified instances of the organization making the award having applied for

or having received funds from the official's agency, doing business with or seeking to do business with the agency, or having interests that could be substantially affected by performance or nonperformance of the official's duties.

OGE has determined that bona fide awards, including the cash incident to those awards, are to be treated as gifts in recognition of meritorious public service or achievement rather than as compensation or earned income for delivering the speech that is routinely expected of an honoree at an award presentation.

The OGE government-wide ethics regulation⁴⁰ states that an employee may accept a gift that is a bona fide award for meritorious public service or is incident to such an award, subject to the following conditions:

(1) a gift of cash or investment interest in any amount and other gifts with an aggregate market value in excess of \$200 may be accepted only upon a written determination by an agency ethics official that the award is made as part of an established program of recognition under which awards are made on a regular basis, or which is funded to ensure its continuation on a regular basis, and selection of award recipients is made under written standards; and (2) an honorary degree from an institution of higher education may be accepted upon a written determination by an agency ethics official that the timing of the presentation would not cause a reasonable person to question the employee's impartiality in a matter affecting the institution; and (3) an employee who may accept an award or honorary degree under condition (1) or (2) may also accept meals and entertainment given to him or her and to members of his or her family at the presentation of the degree or award.

The OGE regulation provides the following example of a permissible award: Based on a determination by an agency ethics official regarding the requisite award program and the application of written criteria for the award, an NIH employee may accept the Nobel Prize for Medicine, including the cash award that accompanies the prize, even though the prize is conferred on the basis of laboratory work performed at NIH and requires a speech based on the employee's official duty work as a scientist.

NIH implements the OGE requirements as follows:⁴¹

- **Official Duty Activity.** Although acceptance of most awards must be approved, they need not be approved as an outside activity. The employee accepts the award as part of his official duties or in his personal capacity while on approved annual leave.
- **Prohibited Awards.** An employee may not accept an award from an organization whose interests may be substantially affected by the performance or nonperformance of the employee's official duties or from an association, the majority of whose members would be substantially affected by the performance or nonperformance of the employee's official duties.

⁴⁰ 5 CFR 2635.204(d)(1).

⁴¹ Appendix 10 of NIH *Policy Manual*, chapter 2300-735-4, Outside Work and Related Activities with Outside Organizations.

- Permissible Awards. A bona fide award for meritorious public service that is not from an organization or association described above; is not cash or an investment interest; and that has a market value of \$200 or less may be accepted. No written approval is required in that instance.
- Other Awards. An employee may accept other awards if approved as set forth below.
- Approval of a Deputy Ethics Counselor. Except for permissible awards, all awards from outside organizations must be approved in advance by a deputy ethics counselor. In order to approve an award of cash or investment interest of any value or another type of award (e.g., tangible personal property) with a market value in excess of \$200, the deputy ethics counselor must certify that the award has been made on a regular basis or, in the case of a newly created award program, is funded in such a way that continuation is ensured; and the selection of the awardee(s) is made on the basis of written standards or by an established selection committee.

In reviewing the request for approval, the deputy ethics counselor should consider:

- (1) an award may be accepted for work performed at NIH and an employee may accept any money associated with the award, upon approval; and
- (2) an award may be accepted from most sources, including those meeting the definition of prohibited sources, unless the source is an organization that has interests that may be substantially affected by the performance or nonperformance of the employee's official duties.

The first example of the application of this rule states that an intramural employee who works in a laboratory that has a CRADA and a contract with a drug company may accept an award from that drug company where the employee has no personal involvement in or responsibility for either mechanism. The second example states that an extramural NIH employee could receive an award from a university as long as the employee does not currently administer grants or contracts from that university. If an application for NIH funding is received from the university within one year of the employee's receipt of the award, the employee should be disqualified in order to avoid the appearance of a conflict of interest.

- Disqualification. If the deputy ethics counselor decides that acceptance of the award will create the appearance of a conflict of interest, the employee will be disqualified or recused from all matters involving the awarding institution. At a minimum, the disqualification will extend from the date of the decision to accept the award until the date of the award ceremony or final receipt of all monetary items associated with the award (e.g., travel expenses), whichever is later.

Conclusion

Because NIH employees have a wide variety of official duties, it is not possible to recommend one set of rules that would appropriately apply across all categories of personnel. As such, one can view the restrictions that should be placed on employees in terms of position in the organization, with the range of allowable outside activities, investments, and interests

diminishing as one's official responsibilities increase. In its deliberations the Panel found an extremely complex set of rules governing conflicts of interest at NIH, and in fact, across the federal government. In the context of NIH, with its unique mission to conduct and support research on its own campus, across the country, and internationally, these rules are widely misunderstood by the very people to whom they are intended to apply. This has created uncertainty about allowable behavior and engendered fear of inadvertent transgressions—thereby significantly damaging morale.

The Panel found that most of NIH's policies and procedures for managing conflicts of interest are fundamentally reasonable and appropriate, albeit confusing, and it believes that the agency has been responsive to direction provided to it in this area by HHS, OGE, and Congress. However, improvements can be made to impose greater restrictions on some types of activities, relax some restrictions that are inappropriate and counterproductive, and improve the overall management of these issues at NIH through better training, education, and resource management.

The Panel makes recommendations about improving policies and practices with regard to review, oversight, and disclosure of outside activities in the next section of this report.

Section V. Recommendations

Overview of Recommendations

The National Institutes of Health (NIH) is a national and global treasure. Its principal asset is its employees, including the truly remarkable scientists and practitioners who choose to serve as its employees. In many ways the future health of our nation depends on a robust and productive NIH. However, if care is not taken, unresolved concerns about conflict of interest could severely damage the ability of NIH to continue to serve the public's health. Appropriate and effective conflict of interest policies help maintain a balance by, on the one hand, ensuring that the science NIH conducts and its funding decisions are not, and do not appear to be biased or corrupted, causing the public, the broader scientific community, and the government's funding officials to lose faith in the institution's credibility, and, on the other hand, avoiding a level of restriction on activities that would drive talented individuals away from NIH as an employer and discourage the dissemination of knowledge. This could happen, for example, if a new set of rules was enacted that was highly inconsistent with the established practices of the scientific community.

Developing sound policies for managing and preventing conflicts of interest requires the balancing of several sometimes competing values and considerations. First, government employees, like all other citizens, are entitled to a life of their own with reasonable privacy. But at the same time, the public has a right to complete assurance that outside activities will not inappropriately influence an employee's judgment or commitment to public service. Second, although sound arguments can be made for the enactment of consistent and uniform conflict of interest rules across the federal government, each agency, including NIH, has unique circumstances and needs. Third, a government employee should not receive personal financial gain for outside activities by exploiting knowledge gained through his or her government position. Yet much of the accumulated knowledge and value of a scientist might well have resulted from efforts made and accomplishments achieved outside of government service. The Panel has sought diligently to balance these sometimes conflicting considerations as it developed its recommendations.

In its deliberations the Panel found an extremely complex set of rules governing conflicts of interest at NIH and, in fact, across the federal government. In the context of NIH, with its unique mission to conduct and support biomedical and health-related research on its own campus, across the country, and internationally, these rules are widely misunderstood by some of the very people to whom they are intended to apply. This has created uncertainty about allowable behavior and has engendered fear that inadvertent transgressions could occur—significantly damaging morale.

The Panel found that most of NIH's policies and procedures for managing conflicts of interest are reasonable and appropriate, and it believes that the agency has been responsive to direction provided to it in this area by the Department of Health and Human Services (HHS), the Office of Government Ethics (OGE), and Congress. However, improvements can be made to impose greater restrictions on some types of activities, relax some restrictions that are inappropriate and counterproductive, enhance disclosure and transparency, and improve the overall management of these issues at NIH through better training, education, and resource management.

Foremost among these recommended improvements is the necessity to either severely restrict or prohibit altogether compensated consulting with industry by three categories of employees: 1) senior NIH officials, 2) NIH extramural employees who are responsible for program funding decisions and managing grants and contracts and application review, and 3) scientists conducting research with human subjects.

Further, equity payments in all forms should be (prospectively) eliminated for those employees who are permitted to consult with industry. All outside consulting should, as is currently the case, be conducted on the employee's own time (e.g., vacation, annual leave, weekends). In addition, to avoid conflicts of commitment, outside professional activities should be further limited to an annual aggregate of 400 hours per year. For the same reason, the compensation for such activities should be limited to 50 percent of NIH salary (exclusive of bonuses), with no more than 25 percent of base salary being derived from any one source. Any exceptions to these limits must be reviewed by the NIH Ethics Advisory Committee (NEAC) and approved by the NIH Ethics Official.

Recusal as a means of avoiding conflicts of interest should be used sparingly. NIH should continue to disallow its employees to enter into outside consulting situations that would require them to systematically recuse themselves from official duty matters, except under exceptional circumstances and with careful NIH oversight.

All outside activities *related to NIH's mission* should be disclosed to NIH ethics officials, as is currently required, and disclosed publicly where required by statute. Similarly, all significant investments by NIH employees or their immediate families in biotechnology or pharmaceutical companies should be disclosed to NIH, as should any other significant investments that relate to, or the value of which could affect or be affected by, the employee's work, whether or not the employee is involved in outside activities. In addition, all work products related to NIH's mission that result from such activities (e.g., written material, speeches, and informed consent documents) should include a disclosure of such activities or financial interests.

Finally, employees should be *encouraged* to participate in the customary pursuits of the scientific community—even with some appropriate level of compensation—including teaching, speaking, writing, editing, and receiving awards. There should be no limit on the amount of money an employee is allowed to receive from bona fide awards for meritorious public service or achievement, from royalties generated from inventions, or from work written or edited as an outside activity (as compared to the limits proposed above for consulting). Moreover, where the activities could reasonably be considered an official duty, the reimbursement of reasonable travel expenses for NIH scientists by outside organizations should be more broadly and uniformly allowed where this facilitates *public* scientific communication and interaction. NIH employees can and should make better use of rules that allow them to accept travel and other expenses for outside activities. The Panel also recommends that federal rules be changed to allow employees engaged in such outside activities to publicly be identified as being affiliated with NIH. The current practice that denies this ability is unduly restrictive.

Framework for the Panel's Recommendations

The Panel's recommendations are presented in a manner that recognizes the hierarchy and diverse roles and responsibilities of NIH employees. Because NIH employees have a wide variety of official duties, it is not possible to recommend one set of rules that would appropriately apply across all categories of personnel. As such, one can classify the restrictions that should be placed on employees in terms of their position in the organization, with the range of allowable outside activities, investments, and interests diminishing as the level and scope of official responsibilities increase.

The most senior NIH employees include the NIH Director and his or her other senior staff (those who report directly to the NIH Director); and the institute and center directors and their senior staff (deputy, scientific director, clinical director, and other senior staff who report directly to these directors). These individuals provide leadership for the priorities, programs, policies, and procedures of their respective institutes or centers or for NIH in its entirety and have the potential to exert considerable influence over funding and policy decisions and the allocation of resources. Moreover, because of the broad reach of their authorities, it would be difficult for many of these individuals to recuse themselves from decisions or activities posing a real or perceived conflict without unduly compromising their responsibilities to their official duties.

Two other groups of employees should be subject to special restrictions to avoid conflicts of interest: NIH extramural staff responsible for program funding decisions, managing grants and contracts, and application review; and intramural scientists conducting studies with human subjects.

An additional important category of employees is those who perform intramural scientific and medical research in NIH laboratories with no special role in decisions regarding the allocation of government resources and no involvement with human subjects. Restrictions for these employees should not be as stringent as those applied to the three categories of employees described above.

Accordingly, the Panel focused its recommendations on those employees directly involved in either overseeing or executing the research programs of NIH. Although all employees support that mission, and some also might be engaged in outside activities that are subject to government ethics rules, the Panel did not examine non-research-related categories of employees.

Senior Leadership, Employees with Direct Responsibility for Extramural Grants and Contracts, and Researchers Conducting Human Subjects Research

Based on discussions with a large number of witnesses, the Panel believes that—with careful review and monitoring—it is advantageous for NIH and for the scientific enterprise to allow many NIH employees (especially intramural investigators) to engage in limited, remunerated outside activities, including those with biotechnology and pharmaceutical companies. However, the Panel recommends that other employees, specifically those in senior management positions

across the institutes and centers and designated NIH extramural staff should not be allowed to engage in consulting activities with biotechnology and pharmaceutical companies under any circumstances.

There are two primary reasons for this restriction. First, the potential for real or perceived conflicts of interest increases with rising authority, decisionmaking capacity, and proximity to the allocation of public resources. Second, because of the public and national leadership roles played by senior NIH officials, financial relationships with industry may have the appearance of giving preference to certain private interests over the public's interests or of giving preference to one private interest over another.

In addition to consulting for industry, scientists are sometimes asked to serve as consultants to academic institutions, for example, as members of a scientific advisory board or as site visitors for inspections, accreditation decisions, or funding decisions (from either public or private sources), sometimes for pay. A large majority of NIH grants and contracts are awarded to academic institutions around the country. Thus, senior NIH employees and those NIH employees in the extramural research program responsible for funding strategies and decisions should **not** be allowed to engage in such outside activities with academia for compensation. This is already prohibited by HHS supplemental regulations for all NIH employees if the program at the university is funded by an HHS mechanism. It would be exceedingly difficult for a high-level NIH official or a grants or contracts administrator to avoid real or perceived conflicts of interest if he or she were receiving compensation from a grantee institution or contractor. Except when the conflict is waived, involvement in outside activities requires individuals to recuse themselves when matters related to the sources of their outside activities come before the employee in his or her official capacity. Employees at the highest levels of an institute or a center or those directly involved in programmatic and funding decisions should do their utmost to avoid being in a position of having to recuse themselves from matters that are central to their official responsibilities. NIH would otherwise suffer from the absence of these individuals during times of critical decisionmaking.

Recommendation 1: NIH senior management and NIH extramural employees who are responsible for program funding decisions and recommendations, and professional staff managing grants and contracts and application review, should not engage in consulting activities with pharmaceutical or biotechnology companies or in paid consulting for academia. The Panel considers speaking for compensation at an industry site as equivalent to consulting for industry. The Panel does not include in this prohibition time spent in clinical practice by health care practitioners, if approved as an outside activity free of conflicts.

As a separate category of employees, clinical researchers have a special responsibility for ensuring the safety and ethical care of human subjects. Conflicts of interest have the potential to threaten the safety of research subjects, and, therefore, these employees should also be subjected to a very high level of scrutiny. NIH clinical researchers conducting clinical trials are currently not allowed to have consulting arrangements with or financial interests in companies involved in the trials they are conducting, such as drug companies providing or directly affected by the provision of the agent being tested. The Panel endorses this policy. The Panel also noted with

approval the guidelines developed by the Association of American Medical Colleges (AAMC) for research with human subjects conducted by scientists working in academia. The AAMC guidelines acknowledge that “research with human subjects is a privilege that imposes unique obligations.” The guidelines assert that financial interests in research with human subjects are “potentially problematic” and require “close scrutiny.” They urge institutions to set up policies that require “full *prior* reporting of...significant financial interests that would reasonably appear to be affected by the individual’s research....” The guidelines also promote *transparency*, described as “full and ongoing internal reporting and external disclosure of significant financial interests that would reasonably appear to affect the welfare of subjects or the conduct or communication of research.”

In simplest terms the AAMC guidelines recommend that there should be a rebuttable presumption against certain financial interests in human subjects research. The Panel concurs with this approach but also believes that there might be some circumstances in which such interests do not pose a conflict or could improve or enhance the safety of a research study. NEAC should review such exceptions and recommend to the NIH Ethics Officer an effective conflict of management plan.

Recommendation 2: The Panel reaffirms current federal law, which states that intramural scientists conducting research with human subjects—for example, investigators and research team members involved in patient selection, the informed consent process, and clinical management of a trial—should not be allowed to have any financial interest in or relationship with any company whose interests could be affected by their research or clinical trial, except in special circumstances, and with an appropriate waiver or authorization.

Compensated Outside Activities for Other Research-Related NIH Employees

Most NIH intramural scientists play no role in the allocation of NIH resources to outside entities. The Panel recommends that for these scientists a wider range of outside activities should be allowed than for the three groups or activities just described. Persuasive arguments can be made in favor of a policy that allows these NIH employees to engage in outside activities—albeit within clear guidelines, subject to thorough oversight, and with a high level of transparency.

First, absent good reasons otherwise, and in the interest of promoting the freedom of individuals, as well as academic and scientific freedom, restrictions should not be imposed beyond those that are needed to protect the interests of the primary employer, the U.S. government. Second, for NIH to compete successfully with other potential employers of NIH scientists, the agency must not prevent its employees from taking the opportunity to engage in interesting and remunerative outside activities. Third, Congress and every recent administration have embraced technology transfer as one of the basic missions of NIH. Although fundamental research is of great importance, it will in general affect the health of the American public only when it is translated through the actions of industry. Engaging in outside activities, including those with industry, is essential to accomplishing the goal of technology transfer, both to and from NIH. This type of

activity supplements and does not duplicate or overlap with the formal and public arrangements negotiated through Cooperative Research and Development Agreements (CRADAs).

In addition to consulting with industry, an NIH intramural scientist who has nothing to do with the awarding of extramural grants and contracts might be invited to perform an important service as a paid consultant to an academic institution or professional society—for example, to conduct a site visit or help prepare an academic program in his or her field for accreditation. Such activities are mutually beneficial—if not prohibited by HHS supplemental regulations because the activity is funded by HHS—as the NIH scientist can learn as much from the process as the institution gains from the scientist’s expertise. These activities are not part of the scientist’s official duties and would have to be conducted, if at all, on his or her own time.

If all NIH scientists described above were to be prohibited from accepting appropriate compensation for outside activities, it would be unrealistic to expect that their level of interaction with scientists in academia and industry would be sufficient to allow NIH to fully achieve its mission. The Panel believes that with careful oversight and monitoring, potential conflicts of interest can be effectively avoided in a way that respects the rights of individuals to pursue their personal and scientific interests while simultaneously maintaining public trust in NIH.

Restrictions on Compensation and Time

To avoid conflicts of commitment in outside activities, the Panel recommends that, for all NIH employees except those engaged in outside medical practice, both a time and an income limit be applied with respect to the outside professional activities that are permitted in any given year, similar to those specified in requirements at the agency prior to 1995. The total time spent on outside professional activities should not exceed 400 hours a year to ensure that every employee’s overriding concern is his or her NIH duties. For the same reason, total outside compensation should not exceed an amount equal to 50 percent of the employee’s annual salary (exclusive of bonuses), except in very special circumstances, and no more than an amount equal to 25 percent of annual salary should be derived from a single outside source. (Exceptions to these limits include the receipt of royalties from patents or written work attributed to approved outside activities, as well as bona fide awards, as described below, and outside medical practices, as discussed below.)

In addition, to further ensure that an employee retains a primary obligation to his or her government duties, compensation for outside activities should be limited to cash, with payment in any form of equities, including stock options, prohibited. The latter forms of payment in essence make the NIH employee an owner of the company, in addition to coupling reward with outcomes, with consequences that could cause a conflict of commitment as well as interest.

The Panel believes that there should be a special accommodation made with respect to the compensated outside activities of those NIH employees who are health care practitioners (e.g., physicians, nurses, social workers). Except where special personnel systems have been designed to more closely match salaries in the nonfederal market, this group of employees at NIH is particularly underpaid in comparison to their colleagues elsewhere. Moreover, as health care providers, this group should be encouraged to engage in a more extensive clinical practice than

that experienced at NIH. This will help them continuously hone and maintain skills derived from providing care to a wider array of patient populations than might be seen on a regular basis at the NIH Clinical Center or as part of their official duties. Providing medical care and patient services in outside settings does not pose any conflict of interest, as long as those patients are not also enrolled in NIH clinical studies with which the NIH employee is involved, a limitation imposed by existing NIH policies.

Recommendation 3: In addition to existing requirements for engaging in outside activities, and the restrictions posed in Recommendations in 1 and 2, the following requirements should be in place for all employees who are involved in the administration or conduct of NIH research programs:

- a. The total amount earned annually from compensated consulting with industry or academia should not exceed an amount equal to 50 percent of the employee's annual salary, and no one source should account for an amount exceeding 25 percent of annual salary.
- b. Employees eligible to engage in compensated outside professional activities should not:
 - i. receive compensation in the form of stock options or other forms of equities for their services
 - ii. spend more than 400 hours per year on these activities (writing excepted).
- c. An exclusion to the above limits should exist for NIH employees who are health care practitioners. For these employees, there should be a more flexible time limitation and the capitation for compensated outside medical care and patient services should be 100 percent of base pay, with the one-source limitation removed.

In general, the Panel finds the discussions in the now-superseded 1985 NIH policy on "Outside Work and Activities" to be useful for defining the types of potential conflicts that must be avoided in permitting such activities. Thus, for example, a researcher clearly should not consult with a company that has applied for or received a research contract from the employee's own laboratory or branch. But applying this principle more widely to exclude companies involved with the employee's institute, as specified in 1985, would be too expansive a restriction. It would often eliminate scientists from interactions with industry where, due to the lack of control on the part of the employee over some far off activity in a different area of work, no conflict is possible. Exactly where the line needs to be drawn will depend on individual circumstances and thus should be decided through consultation with the appropriate NIH ethics officials.

Likewise, an employee should not consult for a company whose products are leased or purchased by NIH where the employee has a role in such transaction, or for a company where the official position of the employee is likely to be used to promote a product or service. Again, determining whether an outside activity poses a real or perceived conflict of interest must be decided on a case-by-case basis, as is currently done at NIH.

Monitoring and Tracking of Outside Activities

Currently, to request to participate in an outside activity, an NIH employee has to complete an outside activity application, which includes HHS Form 520 and supplemental forms if compensation is involved, or if certain activities will be conducted, such as consulting for industry, legal consulting or testimony, and professional practice for physicians, nurses, and allied health care professionals.

Current regulations require that advance written approval must be obtained by all employees for certain outside activities, whether or not they involve compensation. In addition, the process for review and approval of outside activities for NIH employees in certain positions (e.g., senior NIH officials) and other NIH employees who desire a certain type of outside activity (e.g., involving a biotechnology or pharmaceutical company or more than \$10,000 in compensation) has recently changed, involving the newly created NEAC. These mechanisms, if properly implemented, appear to be effective means for monitoring outside activities, although the Panel believes that such approvals should be revisited on an annual basis.

Recommendation 4: To improve NIH's ability to manage and track approved outside activities:

- a. all requests for outside activities (Form 520) should be updated on an annual basis (with such updates indicating only those changes that have occurred);
- b. supervisors should be held accountable for the evaluation and approval of outside activity requests, and this supervisory function should be a component of a supervisor's performance evaluation; and
- c. NIH should publish an annual agency-wide statistical report on the number and types of outside activities approved for its employees.

Compensation for Teaching, Speaking, or Writing and Awards

As described in section III of this report, only a relatively small number of NIH employees are engaged in consulting arrangements with industry. In contrast, a substantial number of NIH employees are involved in outside activities with professional societies and with academic and research institutions—primarily in the forms of teaching, speaking, or writing (including editing). In addition, NIH scientists who are recognized for outstanding scientific achievements, leadership, or public service are sometimes the recipients of awards, which may be accompanied by a cash prize. The Panel believes these are important—even essential—activities for NIH scientists, since they are part of the tradition of science and provide evidence of the value and significance of the NIH research community to the larger scientific community. For example, speaking at academic institutions or other similar public fora is a critical part of being a productive and contributing scientist. It provides an important avenue for the exchange of scientific ideas, and both the speakers and the audiences benefit.

Some of the current restrictions placed on intramural scientists invited to speak at a public forum have been counterproductive to the dissemination and exchange of scientific knowledge, as well as to the retention and recruitment of the most outstanding individuals by NIH. Among the most

troubling requirements the Panel reviewed is that, under the current rules, employees may not be compensated for speaking or writing about their scientific work unless it has been both *completed* and published for at least a year. Here the term “completed” has been interpreted by NIH to mean that the researcher is no longer concerned with the issue. However, because of the iterative nature of scientific inquiry, most scientific work is never completed. For example, a scientist might spend an entire career (at NIH and elsewhere) pursuing one narrow area of research. Moreover, new employees may have decades of past research accomplishments in the same area prior to coming to NIH, and under current rules they could be restricted in speaking and writing as an outside activity for an extended period of time, if not indefinitely.

The need to prevent scientists, as well as other government employees, from being paid twice to conduct the same work is appropriate. Accordingly, it is reasonable to require that scientists who engage in teaching, speaking, and writing about *current, unpublished* work do so only as an *official* duty. This type of official duty communication should be encouraged and supported by NIH as promoting the free exchange of information.

However, once a research project has been concluded to the point of publication, it seems unnecessarily punitive to forbid an NIH scientist from receiving a reasonable honorarium for a lecture on that *published* work at an academic institution or elsewhere, as would any other scientist. These customary but generally modest amounts recognize the extra effort required to prepare for and attend such an activity on the employee's own time and can be monitored with appropriate oversight through the NIH ethics process. In general, the Panel believes that such compensation does not represent a conflict. Furthermore, it allows the NIH scientist to be treated in the same manner as nearly all other scientists, which is in the best interest of NIH, the public, and the scientific community at large.

In addition, it is crucial that these employees continue to be allowed to have reasonable transportation and related expenses paid for by the sponsors of seminars and colloquia delivered at universities and in other public settings where much scientific information is exchanged. Equally important, these scientists should be able to acknowledge their NIH affiliation on such occasions. In the interest of full disclosure, it is counterproductive for employees to “hide” their institutional affiliation, in accordance with current ethics rules. Any reference to one's role as an NIH employee to suggest NIH endorsement when none is intended is, of course, inappropriate, but this issue is readily resolved through disclaimers.

Regarding royalties or disbursements obtained through the outside activities of textbook writing or editing, the Panel could find no compelling reason to limit the amount of money that an employee can receive, as long as the activity received prior approval and was deemed to pose no conflict of interest, which generally should be the case.

Recommendation 5: NIH should seek a change to OGE regulations to allow NIH scientists to receive compensation for teaching, speaking, or writing about their research providing that the information is to be shared in a public forum *and* that it has appeared in the published literature.

Recommendation 6: NIH intramural scientists should continue to be allowed to engage in compensated speaking, teaching, and writing for professional societies and for academic and research institutions as an outside activity providing that all ethics review and approval requirements are met.

Recommendation 7: NIH should seek a change to OGE regulations to permit employees to be identified by their title or position (and institutional affiliation) when engaged in teaching, speaking, or writing as an approved outside activity. Disclaimers should be provided that the activity is not being conducted in the employee's official capacity as an NIH employee and that the views expressed do not necessarily represent the views of NIH.

Recommendation 8: There should be no restrictions on royalties received on works written, edited, or published or on income received from patents licensed by any NIH employee who conducted the work as an approved outside activity.

Recommendation 9: The current OGE rules regarding receipt of bona fide cash awards for meritorious public service or achievement and NIH's interpretations of the rules are reasonable and should apply to all employees. There should be no limit on the amount of money received from a bona fide award. These awards are considered gifts under current law and are not considered outside activities because the employee accepts the award in his or her official capacity.

Disclosure and Transparency

Current requirements for reporting income from outside activities, or from investments that might have relevance to one's official duties, do not always capture the information needed to manage conflicts of interest. The only employees who must currently *publicly* disclose all outside activities as well as financial interests are those required to annually file a Form 278 (see section III of this report). The most obvious problem that needs to be corrected is the accident of legislative and regulatory history that exempts even highly paid Title 42 employees from this disclosure. NIH has ameliorated this problem by securing equivalency determinations from OGE with respect to its most senior employees, so that these employees are now required to file Form 278. This is an effective first step toward ensuring that potential conflicts of interest at the highest level of NIH are properly managed. In addition, the Panel recognizes the complexity of Form 278 and encourages OGE to seek simplification of reporting, a change that will require legislation and would become government wide.

As specified by OGE, the filing of an annual confidential financial report (OGE Form 450) is limited to "those pay grades where the duties and responsibilities clearly make filing necessary and relevant." Currently, more than 5,000 of the more than 17,000 NIH employees are required to disclose in this manner. Individuals who file this relatively brief confidential form need to disclose outside activities with industry and academia if the income from these activities is greater than \$200. However, the 450 form does not capture the precise amount of compensation, and because it is a government-wide form established by OGE, it is not easily changed. Further,

if an individual is not required to file either a public or confidential financial disclosure form, as can be the case, NIH has *no* way of knowing whether a potential conflict of interest exists, unless he or she has submitted an outside activity request using HHS Form 520.

The Panel differentiates between public disclosure and internal disclosure within NIH for purposes of managing conflicts. Although public disclosure may be seen as a potential tool for managing conflicts by exposing them, it has its limitations (i.e., the desired outcome might be to eliminate or avoid the conflicted activity rather than merely expose it). Moreover, it is severely limited by government-wide statutes and regulations that govern the rules for public disclosure of private information collected and maintained by government agencies (including the Privacy Act). The Panel applauds the actions taken by NIH thus far in appealing to OGE to expand the number of officials required to file public disclosures and recommends further expansion of that approach for upper management. The Panel recognizes, however, that any expansion of the number of public filers will be limited by law, and that the heavy burden of detailed disclosure entailed by the complex form now in use makes it undesirable for general use even if permitted. Thus, the principal tool for conflict management for many employees will continue to be confidential filing within NIH, using OGE Form 450.

It is critical to maintain public confidence that NIH's ethics standards and practices ensure that all potential conflicts of interest are being managed or eliminated. There are three key considerations in determining whether and what type of disclosure should be required: 1) does NIH know enough to prevent and manage conflicts of interest? 2) do those who would be directly affected by such interests (e.g., subjects of research) have the information necessary to make informed choices? and 3) does the public have access to sufficient information to maintain public confidence in the integrity of NIH and its research? In answering these questions the Panel attempted to balance the needs of NIH, as well as those of research subjects and the public with the rights of NIH employees under law to an appropriate and reasonable degree of privacy.

Recommendation 10: To increase NIH's ability to manage conflicts of interest, it should move immediately to either increase the number of employees required to annually file a confidential disclosure form (Form 450) or find some other means to achieve comparable levels of internal disclosure.

Recommendation 11: NIH should ask OGE to make a regulatory change or seek statutory modifications to provide NIH with greater discretion in determining whether certain Title 42 employees should file a public financial disclosure form (Form 278). This would promote the public interest by increasing transparency and would thereby enhance trust in government. In the meantime, NIH should seek additional equivalency rulings from OGE to increase the number of public filers to include the senior employees specified in Recommendation 1.

Recommendation 12: NIH supervisors should be provided with enhanced training on the criteria to be used for their annual review of financial disclosures so that they can become more effective in managing and avoiding employee conflicts of interest.

Recommendation 13: To preserve public confidence in NIH, the agency should put in place a policy that requires employees to disclose all relevant outside relationships and financial holdings in their work products, such as publications, speeches, and invention disclosures. In addition, where relevant, such disclosures should be made to potential research subjects as part of the informed consent process.

Finally, NIH employees are required to recuse themselves from official duties when a conflict or potential conflict of interest arises and no waiver has been granted. For example, an employee might have a spouse who is an employee of an academic institution applying for a grant or might have financial holdings (that exceed the de minimis threshold) in a company competing to be a vendor for services provided to NIH. In some cases, an employee assigned to participate in either that grant or contract might be asked to divest those interests. In other cases, a waiver might be granted, or conversely, the employee may have to recuse him- or herself from certain matters. However, there is no current requirement that recusals be put in writing, which limits the effectiveness of this method for managing and avoiding conflicts of interest.

Recommendation 14: NIH employees should be required to submit recusals in writing to immediate supervisors when a potential conflict of interest emerges. The supervisor should then be required to inform those who should be aware of the employee's need to be recused from the official duties for which there is a conflict. As is currently the case, when an employee must be recused from official duties, those duties can be reassigned only to someone at an organizational level above the employee. As such, recused employees or their supervisors will need to inform both superiors and affected subordinates of the recusal.

Ethics Training and Administration

By any measure, the ethics rules of the federal government, enforced through law and by OGE rulings—but with additional layers of policies and procedures invoked by HHS and NIH—have created a complex set of regulations that are not readily understood. Confusion caused by vague and overly broad language in the regulations themselves has accentuated the need for many cases to be decided with appropriate attention to context and the specific facts of the situation. Add to this the complexity of 27 separate units at NIH, each interpreting the rules in a slightly different way, and what emerges is what appears to many employees to be a Conflicts of Interest Tower of Babel. This can be remedied in two ways: 1) increase uniformity and consistency in interpreting and applying the rules across NIH, and 2) provide an enhanced program of training and information dissemination for both supervisors and the employee populations in general.

Although some employees currently must complete an ethics training course, confusion about what is allowed and what is not allowed seems to be rampant. Simplified and clear information is needed to ensure that all employees understand their ethics obligations. The creation of NEAC has provided an opportunity to develop a common body of knowledge or best practices—analogue to case law—based on that committee's review of individual cases. This information should be used to instruct the NIH community on issues of particular concern, sensitivity, or confusion, using concise and thoughtful forms of communications that have been pretested using a focus group of the intended recipients and revised with its input.

Recommendation 15: The NIH Ethics Office should prepare a user-friendly document and website that displays the ethics rules in simple language and emphasizes examples of outside activities and financial interests that are permissible, as well as those that are not. Employees seeking approval of outside activities should, as part of their submission of Form 520 and its supplements, indicate in writing that they have reviewed these summary materials and have discussed any questions they have with their relevant ethics official and/or supervisor.

Recommendation 16: The NIH Ethics Advisory Committee should issue a report of its findings, in the form of anonymous case studies and generalizable principles, on a regular basis to provide the NIH community with a clear common body of knowledge by which to understand and interpret ethics rules.

Recommendation 17: NIH management should assure that sufficient resources are provided for the administrative and management functions of its ethics activities to guarantee that the expanded program proposed in this report can be implemented.

Other Observations

Strategies for Retaining the Most Senior Employees at NIH

One issue that continued to arise throughout the Panel's deliberations—related to but beyond the specific charge of the Panel—is the adequacy of government compensation for NIH employees. Although financial remuneration did not appear to be the primary or even an important consideration for many scientists engaged in outside activities, the Panel did consider whether the potential for NIH scientists to participate in compensated outside activities as a supplement to basic government pay is necessary to recruit and retain the world's best scientists. Many of these scientists have tens of years invested in higher education, and many have multiple degrees, with additional years spent in postdoctoral fellowships and completing residency requirements.

The Panel found that for lower and midlevel scientists, NIH salaries were reasonably comparable to those in academia. It heard from intramural scientists that the ability to engage in teaching, speaking, and writing as other scientists do was generally more critical than salaries in their decision to come to or stay at NIH. However, as scientists became more senior and more experienced, NIH salaries become less competitive when compared to the nongovernmental sectors: This is especially true at the highest levels of the agency and for staff clinicians, for whom compensation, in financial terms, is far from competitive.

Title 42 authority provides a special hiring mechanism through what is known as “administratively determined” pay. Title 42 addresses the authority of the agency to appoint doctoral-level scientists in biomedical research, science policy, administration, and research evaluation. Thus, it has a very specific scope and it is currently used as the authority to pay employees salaries in the range from \$38,000 to \$200,000, with the possibility of bonuses—recruitment, retention, or performance—calculated on a percentage of the employee's base pay.

The current cap of \$200,000 has been in place since 2000, contributing to severe salary compression at this level.

Because the Panel is recommending that the most senior NIH leaders be prohibited from engaging in nearly all compensated outside activities, it is especially critical that the agency consult with HHS to consider whether the current limit of \$200,000 for the nation's senior government scientists is hindering NIH's efforts to recruit and retain the preeminent scientific leaders it needs. The Panel believes that for such individuals this ceiling should be raised.

Recommendation 18: The NIH Director, working with Congress, should ensure that the agency has authority under Title 42, or some other hiring mechanism, to recruit senior scientific staff in the current highly competitive market. In addition, the NIH Director should ask HHS to review and, if appropriate, raise the current annual salary capitation of \$200,000 for the most senior Title 42 employees at NIH. The Panel is concerned that the present ceiling is limiting the agency's ability to recruit and retain the nation's best scientists as the leaders of NIH.

The Current Morale of NIH Scientists

The Panel was surprised to learn that relatively few NIH employees are in fact engaged in consulting agreements with biotechnology or pharmaceutical companies—an activity that currently involves only about 120 of NIH's 17,500 employees. Yet the high level of reasonable concern expressed by Congress and the media about the potential for conflicts of interest when consulting with industry—itself a small fraction of the outside activities engaged in by NIH scientists—has had a decidedly negative impact on the morale of a large number of NIH intramural scientists.

In its interviews with NIH scientists, the Panel observed that a heightened scrutiny with regard to ethics issues has increased the confusion about the existing policies. There is a widespread sense that rules on all outside activities are being changed midstream or suddenly overly interpreted out of caution. NIH scientists are concerned that they might be unable to fully participate in the community of science in the future, and senior management worries about the impact that possible new policies could have on the recruitment and retention of scientists at NIH. Worse yet, there seems to be widespread fear of committing an inadvertent transgression in this complex of sometimes arcane rules and interpretations. In short, many NIH scientists sense that they are unfairly being forced to live under a cloud of suspicion.

The Panel believes that the recommendations presented in this report are important for addressing these concerns, and it urges that they be adopted as quickly as possible. This is needed to assure the continued, deserved public confidence in the extraordinary work of NIH, to continue to enhance the quality of the scientific staff at NIH, and to rectify what the Panel perceives as a critical and growing morale problem among the agency's excellent staff.

Appendix A:
NIH Blue Ribbon Panel on Conflict of Interest Policies
A Working Group of the Advisory Committee to the Director, NIH

Roster

Bruce Alberts, Ph.D. (Co-Chair)
 President
 National Academy of Sciences
 Washington, DC

Norman R. Augustine (Co-Chair)
 Chairman, Executive Committee
 Lockheed Martin Corporation
 Bethesda, Maryland

Christine Cassel, M.D.
 President
 American Board of Internal Medicine
 Philadelphia, Pennsylvania

Thomas H. Murray, Ph.D.
 President
 The Hastings Center
 Garrison, New York

Phillip Pizzo, M.D.
 Dean, School of Medicine
 Stanford University
 Stanford, California

The Honorable Stephen D. Potts
 Chairman, ERC Fellows Program
 Ethics Resource Center
 Washington, D.C.

Dorothy Robinson, Esq.
 Vice President and General Counsel
 Yale University
 New Haven, Connecticut

Lawrence Sadwin
 President
 Lifestyle Security, L.L.C.
 Warren, Rhode Island

James Siedow, Ph.D.
 Vice Provost for Research
 and Professor of Biology
 Duke University
 Durham, North Carolina

Reed V. Tuckson, M.D.
 Senior Vice President
 Consumer Health & Medical Care
 Advancement
 UnitedHealth Group
 Minnetonka, Minnesota

Appendix B: Panel Biographies

BRUCE ALBERTS, PH.D. has served in the full-time position of President of the National Academy of Sciences, a private and independent non-governmental organization in Washington D.C. since July 1, 1993. In that position he also chairs the National Research Council, the operating arm of the National Academies (which also includes the National Academy of Engineering and the Institute of Medicine, two other important honorary societies). Prior to moving to Washington, Dr. Alberts was a full-time faculty member who carried out research in cell and molecular biology while teaching undergraduates, graduate students and medical students. After graduating *summa cum laude* from Harvard College in 1960, he received his Ph.D. in Biophysics from Harvard in 1965. After a year of postdoctoral research in Geneva, Switzerland, he joined the faculty at Princeton University as an Assistant Professor of Chemistry in 1966. Ten years later, he left Princeton to become a professor at the Medical School at the University of California, San Francisco (UCSF). At UCSF for 17 years, he was awarded a Lifetime Professorship by the American Cancer Society, and he served as the Chair of the Department of Biochemistry and Biophysics. Much of the scientific work that was carried out in the laboratory of Dr. Alberts focused on dissecting the detailed molecular mechanisms, involving the miniature protein machines that all cells use to make new copies of their chromosomes through a process called DNA replication. This research was funded by a series of grants from the NIH as well as by several other research agencies. The National Academies are frequently asked to study hard problems by the National Institutes of Health and many other government agencies. Recent examples include the report *Enhancing the Vitality of the National Institutes of Health: Organizational Changes to Meet New Challenges*, published in July 2003, and a report on the *Discovery of Antivirals against Smallpox* to be released in May 2004.

NORMAN R. AUGUSTINE joined the Douglas Aircraft Company in 1958 as Program Manager and Chief Engineer. Beginning in 1965, he served in the Office of the Secretary of Defense as an Assistant Director of Defense Research and Engineering. Joining the LTV Missiles and Space Company in 1970, he served as Vice President, Advanced Programs and Marketing. In 1973 he returned to government where he served as Assistant Secretary for R&D and subsequently as Under Secretary and for four months as Acting Secretary of the Army. Joining Martin Marietta Corporation in 1977 as Vice President of Technical Operations, he later served as Chairman and CEO, having previously been President and Chief Operating Officer. He served as President of Lockheed Martin Corporation upon the formation of that company in 1995, and became Chief Executive Officer and later Chairman. He currently serves as Chairman of the Executive Committee of Lockheed Martin. Mr. Augustine served as Chairman and Principal Officer of the American Red Cross for nine years and is a former Chairman of the Education Task Force of the Business Roundtable, and a member of that organization's Policy Council. He is a former Chairman of the National Academy of Engineering and a former President of the Boy Scouts of America. He has been on advisory boards to the White House, U.S. Senate, NASA, FAA, and the Departments of Defense, Army, Navy, Air Force, Energy, Transportation, and Homeland Security, the General Accounting Office, and NATO. He has been presented the National Medal of Technology, has five times been awarded the Department of Defense's highest civilian decoration, the Distinguished Service Medal, and has received the Joint Chiefs of Staff Distinguished Public Service Medal among numerous other government

service medals. Mr. Augustine received both his bachelor's and master's degrees in aeronautical engineering from Princeton University.

CHRISTINE K. CASSEL, MD, MACP, became President and CEO of the American Board of Internal Medicine and ABIM Foundation in Philadelphia, in July 2003, after recently serving as Dean of the School of Medicine and Vice President for Medical Affairs at Oregon Health & Science University in Portland, Oregon. Dr. Cassel is a leading expert in geriatric medicine, medical ethics and quality of care. Among her many professional associations, Dr. Cassel is immediate Past-Chair of the ABIM Foundation Board of Trustees and is currently Chair of the Board of the Greenwall Foundation, which supports work in bioethics; President of the American Federation for Aging Research; member of the Advisory Committee to the Director at the National Institutes of Health. Dr. Cassel was recently elected to the Institute of Medicine Governing Council. She served on previous IOM committees responsible for influential reports on quality of care and medical errors, chaired a recent report on end-of-life care, and co-chaired a report on public health. Earlier, Dr. Cassel served on the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry (1997-98). An active scholar and lecturer, Dr. Cassel publishes extensively in professional journals, books, editorials and special reports. She is currently concerned with quality improvement in health care, health-professional education, biomedical ethics, geriatric medicine, palliative care, healthcare policy, and healthy aging. Nationally prominent as chief editor of a seminal textbook, *Geriatric Medicine* (Fourth Edition), Dr. Cassel also edited *A Practical Guide to Aging* (1997), co-authored *Ethical Dimensions in the Health Professions* (1993), and co-edited *Ethical Patient Care* (2000), *Approaching Death* (1997), *Encyclopedia of Bioethics* (1995), and *Nuclear Weapons and Nuclear War* (1984). Her new book, *Medicare Matters: Older Americans and the Future of Medicare*, is currently in press. Dr. Cassel was formerly Chair of the Department of Geriatrics and Adult Development and Professor of Geriatrics and Medicine at Mount Sinai School of Medicine in New York City. During ten years at the University of Chicago, Pritzker School of Medicine, Dr. Cassel was Chief of the Section of General Internal Medicine, Professor of Geriatrics and Medicine, Founding Director of the Robert Wood Johnson Clinical Scholars Program, and Founding Director of the Center for Health Policy Research. Dr. Cassel received her medical degree from the University of Massachusetts and completed her residency in internal medicine at Children's Hospital and the University of California at San Francisco, with subsequent fellowships in bioethics and geriatrics at San Francisco and Portland, Oregon.

THOMAS H. MURRAY, PH.D. is President of The Hastings Center, an independent non-profit, non-partisan research institute devoted to ethical issues in health and medicine and the life sciences. Dr. Murray was formerly the Director of the Center for Biomedical Ethics in the School of Medicine at Case Western Reserve University in Cleveland, Ohio, where he was also the Susan E. Watson Professor of Bioethics. Dr. Murray's research interests cover a wide range of ethical issues in medicine and science, including genetics, children, organ donation, and health policy. Among Dr. Murray's current activities, he directs a research project on conflicts of interest in biomedical research. He is a founding editor of the journal *Medical Humanities Review*, and is on the editorial boards of *Human Gene Therapy*, *Politics and the Life Sciences*, *Cloning, Science, and Policy*, *Medscape General Medicine*, *Teaching Ethics* and the *Journal of Law, Medicine & Ethics*. He is also editor, with Maxwell J. Mehlman, of the *Encyclopedia of Ethical, Legal and Policy Issues in Biotechnology*, (John Wiley & Sons, 2000). He served as a

presidential appointee to the National Bioethics Advisory Commission from 1996 – 2001 where he served as chair of the subcommittee on genetics. He served as a member of the Committee on Ethics of the American College of Obstetrics and Gynecology and is former Chair of the Social Issues Committee of the American Society for Human Genetics. He is currently a member of the Ethics Committee of the Human Genome Organization. He is a past member and founder of the Working Group on Ethical, Legal and Social Issues to the National Institutes of Health Center for Human Genome Research, and chaired its Task Force on Genetics and Insurance. He is Past President of the Society for Health and Human Values. From 1999 to 2000 he served as the President of the American Society for Bioethics and Humanities. Dr. Murray also served as a member of the AAMC Task Force on Conflicts of Interest from 2001-2002 and is currently a member of the Center for Strategic & International Studies' Council on Biotechnology Research, Innovation and Public Policy. He also serves on the Advisory Committee for the Genomics Institute at the Wadsworth Center, is an Affiliated Scholar of the Institute for Bioethics, Health Policy and Law at the University of Louisville and is a member of the Food and Drug Administration's Biological Response Modifiers Advisory Committee. He is the author of more than 200 publications. His most recent books are *The Worth of a Child*, published by the University of California Press, and *Healthcare Ethics and Human Values: An Introductory Text with Readings and Case Studies*, Blackwell Publishers, which he edited with Bill Fulford and Donna Dickenson.

PHILIP A. PIZZO, M.D. became Dean of the School of Medicine at Stanford University in April, 2001 leaving his previous position as the Physician-in-Chief and Chair of the Department of Medicine at Children's Hospital, Boston and the Thomas Morgan Rotch Professor and Chair of Pediatrics at Harvard Medical School. Prior to that, Dr. Pizzo served sequentially as a Senior Investigator, Chief of the Infectious Disease Section, and Chief of Pediatrics, at the National Cancer Institute. He received his B.A. from Fordham College, graduating Phi Beta Kappa and cum laude in 1966. He received his M.D. degree with Honors and Distinction in Research in 1970 from the University of Rochester School of Medicine. After completing his residency in Pediatrics at Children's Hospital, Boston, in 1973, Dr. Pizzo joined the Pediatric Oncology Branch of the National Cancer Institute (NCI) as a clinical associate, and then served as a pediatric oncology investigator at the National Institutes of Health (NIH), where he trained in both pediatric oncology and infectious diseases. In 1981 Dr. Pizzo was appointed chief of Pediatrics at NCI, and in 1995 was named Acting Scientific Director of NCI's Division of Clinical Sciences. He was also the director of the Infectious Disease Section at NCI. Dr. Pizzo also was professor of Pediatrics at the Uniformed Services University of the Health Sciences in Bethesda, MD. Dr. Pizzo's research efforts have focused on the treatment of childhood cancers and on the diagnosis, management, and prevention of infectious complications in immunocompromised hosts. He and his colleagues also developed new treatments for children with symptomatic HIV infection. The author of over 500 articles and editor of 13 books, Dr. Pizzo also serves on numerous national and international advisory and editorial boards and has received many honors and awards for his scientific work. He is a member of numerous distinguished societies, including the Institute of Medicine of the National Academy of Sciences.

STEPHEN D. POTTS, J.D. is Chairman of the Fellows Program of the Ethics Resource Center (ERC), a non-profit organization focused on organizational ethics, a position he has held since

September 2000. He will become Chairman of the Board of ERC on June 15, 2004. Prior to joining ERC, Mr. Potts served for 10 years (1990-2000), under two Presidents, as Director of the U.S. Office of Government Ethics. Prior to that time, Mr. Potts was a Partner at Shaw, Pittman, Potts & Trowbridge from 1961 until 1990. He also held the position of Vice President of Cherokee Life Insurance Company from 1959 to 1961, and was an Associate Attorney at Farris, Evans & Evans in Nashville, Tennessee from 1957 to 1959. In addition, Mr. Potts served as a 1st Lieutenant in the U.S. Army, Judge Advocate General's Corps. Mr. Potts served as Interim President of the Ethics Resource Center until February 2002. He also serves on the organization's Board of Directors. Other business activities include serving as a Member, Board of Directors, Fairways Corporation, 1972 – 1990; Member, Board of Directors, Wood River Capital Corporation, 1985 – 1988; Member, Board of Directors, Marline Oil Corporation, 1978 – 1985; Agency Vice President, Cherokee Life Insurance Company, 1959-1961; American Bar Association; District of Columbia Bar Association; and Tennessee Bar Association. Other civic activities he has been affiliated with include the Board of Advisors, University of Kentucky. Mr. Potts earned his bachelors degree in Political Science from Vanderbilt University, and an L.L.B. from Vanderbilt Law School.

DOROTHY K. ROBINSON, J.D. is Vice President and General Counsel of Yale University, where she has served as chief legal counsel for nineteen years, and as an officer of the University for almost as long. Previously, she held positions as Deputy General Counsel, Director of Federal Relations and Associate General Counsel of Yale University. Before coming to Yale in 1978, she practiced law with the firm of Hughes Hubbard & Reed in New York City. She received her B.A. from Swarthmore College, with Honors, and Phi Beta Kappa in 1972. She received her J. D. in 1975 from the University of California School of Law (Boalt Hall), where she served on the California Law Review. She is a member of the bar of the states of Connecticut, New York and California, and of various federal courts. Ms. Robinson has served as a director of the National Association of College and University Attorneys, and on committees, task forces and advisory boards of numerous other national organizations concerned with higher education. Among these, she served on the Association of American Universities Task Force on Research Accountability, and on the Association of American Medical Colleges Task Force on Financial Conflicts of Interest in Biomedical Research. She has also served on boards of trustees for a variety of other educational, charitable and community organizations.

LAWRENCE B. SADWIN is a business and community leader. He is a strong advocate for health education, conducting effective community service programs to encourage personal behavior change, and increasing funding for biomedical research. Sadwin's 20-year commitment to non-profit leadership at the local, regional, and national levels is rooted in his personal victory over heart disease, coupled with an extensive family history of cardiovascular disease. He was the 2001-2002 Chairman of the Board of the American Heart Association, the chief volunteer executive officer responsible for the overall administration of the association's business affairs, public relations and development. He is committed to furthering the cause of illness prevention and cure by putting a face to heart disease. This was demonstrated most uniquely when Sadwin was the model for an interpretive sculpture called "A Fine Line Between Hope and Despair", by the internationally known artist, Christianne Corbat, whose work explores the relationship between art, medicine, and healing. Sadwin is also a member of the National Leadership Council of Research!America, an organization dedicated to increasing

funding for medical research. His business career began as a senior in college, when he took over his family's textile manufacturing business after the untimely death of his father to heart disease. Sadwin served as the company's CEO for the next 30 years. As a local community leader, Sadwin has assisted in the development of more than \$25 million in urban renewal projects and has raised millions of dollars for local and national philanthropic and religious organizations. He currently serves as Chairman of the Board of Landmark Medical Center, Woonsocket, Rhode Island and is a member of the Public Advisory Board of the Joint Commission on Accreditation of Health Care Organizations. Sadwin also holds an Honorable Discharge as a First Lieutenant in the United States Army Reserve. Sadwin and his wife, Joan, are the proud parents of two wonderful children and four extraordinary grandchildren.

JAMES N. SIEDOW, PH.D. received his BA from the University of Texas at Austin in 1969 and completed his Ph.D. in plant biochemistry from Indiana University in 1972. He did postdoctoral research at the University of Michigan and Rice University before joining the Duke University faculty as an Assistant Professor of Botany in 1976. He became a Full Professor of Botany in 1987 and a Professor of Biology in 2000. He was a recipient of the Trinity College Distinguished Teaching Award in 1984. Past service at Duke includes election to the Executive Committee of the Academic Council (1992-93) and as Chair of the Academic Council (1994-96). He also served as the Dean of Faculty Development in Arts and Sciences from 1997-99. He became Vice Provost for Research in January, 2001. Professionally, Siedow has held numerous positions in the American Society of Plant Physiologists, including President, Chair of the Board of Trustees, Secretary, and Chair of the Public Affairs Committee. He spent a year as a Program Director of the Cellular Biochemistry Program at the National Science Foundation in 1998-99. He has served as an Associate Editor of the journal *Plant Physiology* and Editor of *Plant Science* and is currently an Associate Editor of *Plant Molecular Biology* and on the Editorial Boards of the *Journal of Biological Chemistry*, *Current Opinion in Plant Biology* and *Genome Biology*. Siedow's research has involved the study of oxidative processes in higher plants with an emphasis on those processes related to plant respiration. A long-term project in his laboratory has involved characterizing the structural and regulatory features of the unusual cyanide-resistant oxidase found in all plant mitochondria. A second, long-term collaboration with a group at North Carolina State University led to elucidation of the molecular mode of action of a toxin associated with the fungus responsible for the Southern Corn Leaf Blight.

REED V. TUCKSON, M.D. currently serves as the Senior Vice President for Consumer Health and Medical Care Advancement at UnitedHealth Group, a for profit health care company that encompasses several related companies that are engaged in a broad range of health related activities. A graduate of Howard University and Georgetown University School of Medicine, he has served as Senior Vice President, Professional Standards, for the American Medical Association, and is former President of the Charles R. Drew University of Medicine and Science in Los Angeles. Dr. Tuckson has served as Senior Vice President for Programs of the March of Dimes Birth Defects Foundation and as Commissioner of Public Health for the District of Columbia. In his position at UnitedHealth Group, Dr. Tuckson is interested in basic and clinical research, involved in the translation of new knowledge into clinical practice, and is an active user of health and preventive services research. His work necessarily involves him in pharmaceutical industry issues, the conduct of clinical trials, technology assessment, evaluation of clinical care, data and information systems, and advocacy for a robust research enterprise among other

activities. He is a former member of the Baxter Board of Directors. Dr. Tuckson is a member of the Institute of Medicine and serves as member of the Secretary of Health and Human Services' Advisory Committee on Genetics, Health and Society. He has held a number of other federal appointments, including cabinet level advisory committees on health reform, infant mortality, children's health, violence, and radiation testing.

Appendix C: Meetings and Speakers

March 1-2, 2004

Jordan J. Cohen, M.D., President, Association of American Medical Colleges
 Robert Hosenfeld, Director, NIH Office of Human Resources
 Holli Beckerman Jaffe, J.D., NIH Ethics Officer and OD Ethics Coordinator,
 NIH Ethics Office, Office of the Director, NIH
 Raynard Kington, M.D., Ph.D., Deputy Director, NIH
 Barbara McGarey, J.D., NIH Legal Advisor, NIH Branch, Public Health Division, Office of the
 General Counsel, HHS
 Stuart D. Rick, J.D., Deputy General Counsel, Office of General Counsel & Legal Policy, Office
 of Government Ethics
 LaVerne Stringfield, Director, Office of Federal Advisory Committee Policy, Office of the
 Director, NIH
 Edgar M. Swindell, J.D., Associate General Counsel and Designated Agency Ethics Official,
 Office of the General Counsel, HHS
 Elias A. Zerhouni, M.D., Director, National Institutes of Health (NIH)

March 12, 2004

Duane Alexander, M.D., Director, National Institute on Child Health and Human Development,
 NIH
 Jack Bennink, Ph.D., Senior Investigator, Viral Immunology Section, National Institute of
 Allergy and Infectious Diseases, NIH
 Jeremy Berg, Ph.D., Director, National Institute of General Medical Sciences, NIH
 Michael Gottesman, M.D., Deputy Director for Intramural Research, Office of the Director, NIH
 Lee Helman, M.D., Chief, Pediatric Oncology Branch; Deputy Director, Center for Cancer
 Research, National Cancer Institute, NIH
 Holli Beckerman Jaffe, J.D., NIH Ethics Officer and OD Ethics Coordinator,
 NIH Ethics Office, Office of the Director, NIH
 Raynard S. Kington, M.D., Ph.D., Deputy Director, NIH
 Allan Kirk, M.D., Ph.D., Chief, Transplant Surgery Section, Transplantation and Autoimmunity
 Branch, National Institute of Diabetes, Digestive, and Kidney Diseases, NIH
 Lance Liotta, M.D., Ph.D., Chief, Laboratory of Pathology, National Cancer Institute, NIH
 Mitchell Max, M.D., Chief, Clinical Trials Unit, Pain and Sensory Mechanisms Branch, National
 Institute of Dental and Craniofacial Research, NIH

Draft**Appendices**

Connie Noguchi, Ph.D., Chief, Molecular Cell Biology Section, Laboratory of Chemical Biology, National Institute of Diabetes and Digestive and Kidney Diseases, NIH

Robert Nussbaum, M.D., Chief of the Laboratory of Genetics Disease Research, National Human Genome Research Institute, NIH

Harold Varmus, M.D., President and Chief Executive Officer, Sloan-Kettering Memorial Cancer Center

Danny Weinberger, M.D., Director, Genes, Cognition, and Psychosis Program, Clinical Brain Disorders Branch, National Institute on Mental Health, NIH

April 2, 2004

Andrea Abati, M.D., Staff Clinician, Laboratory of Pathology, National Cancer Institute, NIH

Duane Alexander, M.D., Director, National Institute on Child Health and Human Development, NIH

William Fitzsimmons, Executive Officer, National Institute of Mental Health

Marilyn L. Glynn, J.D., Acting Director, U.S. Office of Government Ethics

Richard Hodes, M.D., Director, National Institute on Aging, NIH

Joseph Mindell, M.D., Ph.D., Investigator, Membrane Transport Biophysics Unit, National Institute of Neurological Disorders and Stroke, NIH

John Park, M.D., Ph.D., Investigator, Surgical and Molecular Neuro-Oncology Unit, National Institute of Neurological Disorders and Stroke, NIH

Appendix D

Questions to NIH Staff About Outside Activities and Conflict of Interest

As part of the National Institutes' of Health (NIH) ongoing efforts to examine the guidelines governing consulting activities of its scientists, the NIH established a Web site to collect NIH staff views on outside activities. This effort was launched as part of the NIH's Blue Ribbon Panel on Conflict of Interest Policies, a working group of the Advisory Committee to the Director, NIH.

The charge of the Blue Ribbon Panel is to review the existing laws, regulations, policies, and procedures under which NIH currently operates regarding: (1) real and apparent financial conflict of interest of NIH staff where compensation or financial benefit from outside sources is received, including consulting arrangements and outside awards, and (2) requirements and policies for the reporting of NIH staff's financial interests, including which interests are subject to public disclosure, and what portion of NIH staff file public disclosures. The Panel is also charged with making recommendations for improving existing laws, regulations, policies, and procedures, as appropriate.

To accomplish these goals, the Blue Ribbon Panel posed the following questions to NIH staff:

- Should NIH staff be allowed to consult for compensation and/or engage in other compensated outside activities? If so,
 - What compensated activities should they be allowed to engage in and why?
 - What limits should be put in place?
 - Which compensated activities or types of compensation should they be prohibited and why?
- What would be the impact on the NIH mission if NIH prohibited all compensated outside activities for its employees? What data or other information do you have to support your views?
- What information concerning compensated outside activities do you think should be disclosed to the public? Who should be required to disclose in this way?
- What other advice would you give to the Blue Ribbon Panel as they address their charge?

NIH staff members were invited to submit responses to the questions from March 4 by April 15, 2004.

Appendix E
OGE Form 450

INSTRUCTIONS FOR
OGE FORM 450,
CONFIDENTIAL FINANCIAL
DISCLOSURE REPORT

A. Why You Must File

This report is a safeguard for you as well as the Government. It provides a mechanism for disclosing and managing potential conflicts of interest and potential financial responsibilities and your private interests and activities. This allows you and your agency to fashion appropriate protections against such conflicts.

B. Who Must File

Agencies are required to designate positions at or below GS-15, O-6, or comparable pay rates, in which the nature of duties may involve a potential conflict of interest. Examples include contracting, procurement, administering grants and licenses, regulating/auditing non-Federal entities, other activities having a substantial economic effect on non-Federal entities, or law enforcement.

All special Government employees (SGEs) must file, unless exempted by their agency or subject to the public reporting system. Agencies may also require certain employees in positions above GS-15, O-6, or a comparable pay rate to file.

C. When To File

New entrant reports: Due within 30 days of assuming a position designated for filing, unless your agency requests a later position. No report is required if you left another filing position within 30 days prior to assuming the new position. (SGEs must file new reports upon each reappointment or redesignation, at the time specified by the agency.)

Annual reports: Due not later than October 31, unless extended by your agency.

D. Reporting Periods

New entrant reports: The reporting period is the preceding twelve months from the date of filing.

Annual reports: The reporting period covers October 1 through September 30 (or that portion not covered by a new entrant report). However, no report is required if you performed the duties of your position for less than 61 days during that twelve-month period. (All reappointed or redesignated SGEs file reports, regardless of the number of days worked.)

E. Where To File

With ethics officials at the agency in which you serve or will serve, or in accordance with their procedures.

F. Definitions

Dependent child - means your son, daughter, stepson, or stepdaughter if such person is either:

- (1) unmarried, under age 21, and living in
- (2) a "dependent" of yours for Federal income tax purposes. See 26 U.S.C. 152.

Honoraria - means payments (direct or indirect) of money or anything of value to you or your spouse for an appearance, speech or article, excluding necessary travel expenses. Also included are payments to charities in lieu of honoraria.

Special Government Employee (SGE) - is defined in 18 U.S.C. 202(a) as an officer or employee of an agency who performs temporary duties, with or without compensation, for not more than 130 days in a period of 365 days, either on a full-time or intermittent basis.

G. General Instructions

- 1. Filers must provide sufficient information about outside interests and activities so that ethics officials can

make an informed judgment as to compliance with applicable conflict of interest laws and standards of conduct regulations.

2. This form consists of five parts, which require identification of certain specific outside interests and activities. **NEW ENTRANT REPORTS OR ANNUAL REPORTS: DISCLOSE ALL SOURCES OF INCOME, ASSETS, AND DEPENDENT CHILDREN. YOU MUST COMPLETE EACH PART EXCEPT AS NOTED FOR PART V AND SIGN THE REPORT.** If you have information to report in any part or do not meet the threshold values for reporting, check the "None" box. New entrants and SGEs are not required to complete Part V.

3. You must include information applicable to yourself, your spouse, and dependent children on Parts I, II and V. This is required because their financial interests are attributed to you under ethics rules in determining conflicts of interest. Information about your spouse is not required in the case of divorce, permanent separation, or temporary separation with the intention of terminating the marriage or permanently separating. Parts II and IV require disclosures about yourself only.

4. You may distinguish any entry for a family member by preceding it with S for spouse, DC for dependent child, or L for family held.

Part I: Assets & Income

Assets:

- 1. Report all assets held for investment or for the production of income by you, your spouse, and dependent children, with a value greater than \$1,000 at the end of the reporting period or which produced more than \$200 in income during the reporting period.

Salary and Earned Income:

- 1. **For yourself:** report all sources of salary and earned income greater than \$200 during the reporting period.
- 2. **For your spouse:** report all sources of salary and earned income greater than \$1,000 (for honoraria, if greater than \$200).

<p>3. For dependent children: no earned income needs to be reported.</p> <p>Examples of Assets:</p> <ul style="list-style-type: none"> - Stocks - Tax Shelters - Investment Real Estate - Mutual Funds - Annuities - IRAs/401(k) Holdings - Trust Holdings - Commodity Futures - Trades & Businesses - Partnership Interests - Investment Life Insurance - Collectibles held for Investment <p>Examples of Income:</p> <p>Investment Income</p> <ul style="list-style-type: none"> - Dividends - Rents and Royalties - Interest - Capital Gains <p>Earned/Other Income</p> <ul style="list-style-type: none"> - Fees - Salaries - Commissions - Retirement Benefits - Honoraria 	<p>Do Not Report:</p> <ol style="list-style-type: none"> 1. Your personal residence, unless you rent it out; 2. Federal Government salary or retirement benefits such as the Thrift Savings Plan; 3. Social Security benefits; 4. Money owed to you, your spouse, or dependent child by a spouse, parent, sibling or child; 5. Accounts including certificates of deposit, savings accounts, interest-bearing checking accounts, or any other forms of deposit in a bank, savings and loan association, credit union or similar financial institution; 6. Money market mutual funds and money market accounts; 7. U.S. Government obligations (including Treasury bonds, bills, notes and savings bonds); 8. Government securities issued by U.S. Government agencies or Government-sponsored corporations, such as TVA, GNMA, FNMA; and 9. The underlying holdings of a trust that: 1) was not created by you, your spouse, or dependent children, and 2) the holdings or sources of income on which you, your spouse, and dependent children are to receive payments are not disclosed. An example is a trust created by a relative, from which you receive periodic income but have no knowledge about its assets. Just identify the trust by name and date of creation. 	<p>Do Not Report:</p> <ol style="list-style-type: none"> 1. Mortgages on your personal residence unless you rent it out; 2. Personal liabilities owed to a spouse, or the parent, sibling, or child of you, your spouse, or dependent child; 3. Loans for personal automobiles, household furnishings, or appliances, where the loan does not exceed the purchase price; and 4. Revolving charge accounts where the outstanding liability does not exceed \$10,000 at the end of the reporting period.
<p>Part III: Outside Positions</p>		
<p>Report for Yourself:</p> <ol style="list-style-type: none"> 1. All positions outside the U.S. Government held at any time during the reporting period (including positions no longer held), whether or not paid. <p>Positions include an officer, director, trustee, general partner, proprietor, representative, executor, employee, or consultant of any of the following:</p> <ol style="list-style-type: none"> 1. A corporation, company, firm, partnership, trust, or other business enterprise; 2. A non-profit organization; 3. A labor organization; and 4. An educational or other institution outside the Federal Government. 		
<p>Part II: Liabilities</p>		
<p>Report for Yourself, Spouse, and Dependent Children:</p> <ol style="list-style-type: none"> 1. Liabilities over \$10,000 owed to any creditor at any time during the reporting period. 		
<p>Do Not Report:</p> <ol style="list-style-type: none"> 1. Positions held in any religious, social, fraternal, or political entity; 2. Positions solely of an honorary nature; and 3. Positions held by a spouse or dependent child. 		

Part IV: Agreements or Arrangements

Report Your Agreements or Arrangements for:

1. Current or future employment;

2. A leave of absence from private or other non-Federal employment;

3. Continuation of payment by a former employer other than the Federal Government (including severance payments); and

4. Continuing participation in an employee pension or benefit plan maintained by a former employer other than the Federal Government.

Do Not Report:

1. A spouse or dependent child's agreements or arrangements.

Part V: Gifts and Travel Reimbursements

Note: Part V is not applicable to new entrants and SCEs.

Report for You, Your Spouse, and Dependent Children:

1. Travel-related cash reimbursements received from one source during the reporting period totaling more than \$285.

2. Any other gifts totaling more than \$285 from any one source. A "gift" is defined as anything of value, unless you give something of equal or greater value to the donor. This includes tangible items and intangibles such as transportation, food, lodging, and entertainment.

Note: Gifts or reimbursements valued at \$114 or less need not be included in determining the over \$285 reporting threshold.

Do Not Report:

1. Anything received from relatives, the U.S. Government, D.C., State, or local governments;

2. Bequests and other forms of inheritance;

3. Gifts and travel reimbursements given to your agency in connection with your official travel;

4. Gifts of hospitality (food, lodging, entertainment) at the donor's residence or personal premises; and

5. Gifts or reimbursements received by a spouse or dependent child totally independent of the relationship to the filer (Example: a spouse's reimbursement in connection with private employment).

Privacy Act Statement

Title I of the Ethics in Government Act of 1978 (5 U.S.C. App.), Executive Order 12674, and 5 CFR Part 2634, Subpart I, of the Office of Government Ethics regulations require the reporting of this information. The primary use of the information on this form is for review by Government officials of your agency, to determine compliance with applicable Federal conflict of interest laws and regulations. Additional disclosures of the information on this report may be made: (1) to a Federal, State or local law enforcement agency if the disclosing agency becomes aware of a violation or potential violation of law or regulation; (2) to a court or party in a court or Federal administrative proceeding if the Government is a party or in order to comply with a judge-issued subpoena; (3) to a source when necessary to obtain information relevant to a conflict of interest investigation or decision; (4) to the National Archives and Records Administration or the General Services Administration for records management purposes; (5) to the Office of Management and Budget for legislative coordination purposes; and (6) in response to a request for discovery or for the appearance of a witness in a judicial or administrative proceeding, if the information is relevant to the subject matter. This confidential report will not be disclosed to any requesting person unless authorized by law. See also the OGE/GOVT-2 executive branchwide Privacy Act system of records.

Penalties

Falsification of information or failure to file or report information required to be reported may subject you to disciplinary action by your employing agency or other authority. Knowing and willful falsification of information required to be reported may also subject you to criminal prosecution.

Public Burden Information

This collection of information is estimated to take an average of one and a half hours per response, including time for reviewing the instructions, gathering the data needed, and completing the form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Service, Paperwork Project Director, U.S. Office of Government Ethics, Suite 500, 1201 New York Avenue NW, Washington, DC 20005-3917. Do not send your completed OGE Form 450 to this address. See Section E for where to file.

Pursuant to the Paperwork Reduction Act, as amended, an agency may not conduct or sponsor, and no person is required to respond to, a collection of information unless it displays a currently valid OMB control number (that number, 3209-0006, is displayed here and in the upper right-hand corner of the first page of this OGE Form 450).

Mere disclosure of the required information does not authorize holdings, income, or affiliations, or provide a basis for any action, which are otherwise prohibited by law, Executive order, or regulation.

If you need assistance in completing this form, contact the ethics officials in the agency in which you serve or will serve.

Executive Branch CONFIDENTIAL FINANCIAL DISCLOSURE REPORT

Employee's Name (Last, first, middle initial)		Position/Title		Grade		Reporting Status: <input type="checkbox"/> New entrant <input type="checkbox"/> Annual	
Agency		Branch/Unit and Address		Work Phone		If New Entrant, Date of Appointment	
Check box if special Government employee (SGE) <input type="checkbox"/>		If an SGE, Home Address (Number, Street, City, State and ZIP Code)		Signature of Employee		Date	
I certify that the statements I have made on this form and all attached statements are true, complete, and correct to the best of my knowledge.							
Date Received by Agency		Signature and Title of Supervisor/Other Intermediate Reviewer (If agency requires)		Date			
Signature of Agency's Final Reviewing Official and Title		Date		Comments of Reviewing Officials		(Check box if continued on reverse)	

Part I: Assets and Income

None ☐

Identify, for you, your spouse, and dependent children, all assets and income exceeding the reporting threshold of \$1,000 at the close of the reporting period or producing income over \$200, and 2) sources of earned income such as salaries, fees, honoraria (other than U.S. Government salary or retirement benefits, such as for members of Congress or the Supreme Court), or income during the reporting period. Earned income sources of your spouse must be reported if greater than \$1,000 (greater than \$200 for honoraria). No earned income needs to be reported for dependent children. Assets include (but are not limited to): stocks, bonds, tax-shelters, real estate, mutual funds, pensions, annuities, IRAs, trusts, commodity futures, trades and businesses, and partnership interests. Exclude your personal residence, unless you rent it out, and deposit accounts in financial institutions. See instructions for additional exclusions.

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OGE Form 450, 5 CFR Part 2634, Subpart 1
U.S. Office of Government Ethics (9/02)
(Replaces 459 edition)

Executive Branch CONFIDENTIAL FINANCIAL DISCLOSURE REPORT

Employee's Name (Last, first, middle initial)				Page Number
Assets and Income Sources (Identify specific employer, business, stock, bond, mutual fund, type/location of real estate, etc.)		(X) If no longer held	Nature of income over \$200 (Rent, interest, dividends, capital gains, salary, etc.)	Date (Only for income)
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				

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OGE Form 450, 5 CFR Part 2634, Subpart I
U.S. Office of Government Ethics (902)
(Replaces 459 edition)

Employee's Name (Last, first, middle initial)		Page Number
Work Phone		

Part II: Liabilities

None ☐

Report for you, your spouse, and dependent children liabilities over \$10,000 owed at any time during the reporting period (over \$10,000 in the case of the period if involving a joint liability). Do not report liabilities for joint ownership of real estate, or for joint ownership of personal property, such as household furniture or appliances, and liabilities owed to certain family members (see instructions).

Creditor (Name and address)	Type of liability (Mortgage, promissory note, etc.)
Example: First Alaska Bank, Anchorage, Alaska	Mortgage on rental property in Anchorage, AK
1	
2	
3	

Part III: Outside Positions

None ☐

Report any position, whether or not compensated, which you hold outside the U.S. during the reporting period. Positions include (but are not limited to) an employee of a foreign government, officer or director of a foreign corporation, officer, director, or consultant for a business, nonprofit or labor organization, or educational institution. Do not report positions held by you or your spouse or dependent children on their behalf of an honorary nature. You need not report any position of your spouse or dependent children.

Organization (Name and address)	Type of Organization	Position	(X) Is spouse?
Example: Doe, Jones & Smith, Hometown, USA	Law Firm	Associate	X
1			
2			
3			
4			

Part IV: Agreements or Arrangements

None ☐

Report your agreements or arrangements for current or future compensation (including salary, honoraria, or other payments), or continuing participation in an employee payment by a former employer (including severance pay), or any other arrangement for compensation or other means of your spouse or dependent children.

Terms of Any Agreement or Arrangement (For example, independent managed, fully funded, defined contribution plan)	Payee	Date
Example: Doe, Jones & Smith, Hometown, USA	Doe, Jones & Smith, Hometown, USA	2/99
1		
2		
3		

Part V: Gifts and Travel Reimbursements

Do not complete this part if you are a new arrival in official government service. None ☐

Report for you, your spouse, and dependent children gifts or travel reimbursements you have received from one source totaling more than \$25. Exclude anything received from a source that is a relative or from the U.S. government, or from a source with whom you have a relationship with your official travel, and food, lodging, or entertainment received as personal hospitality at the donor's residence or premises.

Source	Description (For travel-related items, include itinerary)	Date
Example: Doe, Jones & Smith, Hometown, USA	Leather briefcase as a departing gift	2/99
1		
2		
3		
4		

Appendix F
Standard Form (SF) 278

Standard Form 278
Executive Branch Personnel
PUBLIC FINANCIAL
DISCLOSURE REPORT

Instructions for Completing SF 278

I. Introduction

Reporting Periods

Incumbents: Complete Schedules A, B, C, and Part I of D. The reporting period is the preceding calendar year, except Part II of Schedule C and Part I of Schedule D where you must also include any positions held and agreements or arrangements made from the beginning of the filing year until the date you file. Schedule B need not include transactions made, or gifts or reimbursements received, during a period when the filer was not a Federal employee.

Termination Filers: Complete Schedules A, B, C, and Part I of D. The reporting period begins at the end of the period covered by your previous filing and ends at the date of termination of Government employment in the position.

Nominees, New Entrants and Candidates for President and Vice President: Complete Schedules A, C, and D (candidates do not file Part II of Schedule D), as follows:

- **Schedule A.** The reporting period for income (BLOCK C) is the preceding calendar year and the current calendar year up to the date of filing. Value assets in BLOCK B as of any date you choose that is less than 31 days before the date of filing.

- **Schedule C, Part I (Liabilities)** - The reporting period is the preceding calendar year and the current calendar year up to any date you choose that is less than 31 days before the date of filing.

- **Schedule C, Part II (Agreements or Arrangements)** - Show any agreements or arrangements as of the date of filing.

- **Schedule D** - The reporting period is the preceding two calendar years and the current calendar year up to the date of filing.

Scope of Disclosure

The extent of the reporting requirement is noted in each schedule. The various schedules of this form require reporting of your financial interests and activities, both in the U.S. and abroad, except as otherwise noted. In addition to your individual financial information, you are required to report information concerning your spouse and dependent children in several schedules of the form. However, no report is required with respect to your spouse if he or she is living separate and apart from you with the intention of terminating the marriage or providing for permanent separation. In addition, no report is required with respect to any income or obligations of an individual arising from the dissolution of marriage or permanent separation from a spouse. There are other exceptions to the reporting of assets and income, transactions, and liabilities of a spouse or dependent child which are discussed in the instructions applicable to those subjects.

A basic premise of the statutory financial disclosure requirements is that those having responsibility for review of reports filed pursuant to the Ethics in Government Act or permitted public access to reports must be given sufficient information by reporting individuals concerning the nature of their outside interests and activities so that an informed judgment can be made with respect to compliance with applicable conflict of interest laws and standards of conduct regulations. Therefore, it is important that you carefully complete the attached form. This report is a safeguard for you as well as the Government, in that it provides a mechanism for determining actual or potential conflicts between your public responsibilities and your private interests and activities and allows you and your agency to fashion appropriate protections against such conflicts when they first appear.

A Presidential nominee to a position requiring the advice and consent of the Senate shall file with the Senate committee considering the nomination an amendment to the initial report, which shall update all items of earned income and honoraria through the period ending no earlier than 5 days before the scheduled date of the Senate committee hearing on the nomination. This update shall be provided in the manner requested by the Senate committee considering the nomination. Copies shall be provided to OGE and your agency ethics official.

Definition of Terms

• **Category of Amount**

Reportable financial interests are disclosed either by actual amount or by category of amount, depending on the interest, as specified by the form. You may, but you are not required to, indicate an actual amount where the form provides for a category of amount or value.

• **Dependent Child**

The term "dependent child" means your son, daughter, stepson, or stepdaughter if such person is either: (1) unmarried, under age 21, and living in your household, or (2) a "dependent" of yours within the meaning of section 152 of the Internal Revenue Code of 1986.

• **Excepted Investment Fund**

An excepted investment fund is a mutual fund, common trust fund of a bank, pension or deferred compensation plan, or any other investment fund, which is widely held, publicly traded (or available) or widely diversified, and under circumstances where you neither exercise control over nor have the ability to exercise control over the financial interests held by the fund. A fund is widely diversified when it holds no more than 5% of the value of its portfolio in the securities of any one issuer (other than the U.S. Government) and no more than 20% in any particular economic or geographic sector.

<ul style="list-style-type: none"> • Gifts <p>See instructions for Schedule B, Part II.B.</p> <ul style="list-style-type: none"> • Honoraria <p>The term "honoraria" means payments of money or anything of value to you or your spouse for an appearance, speech, or article, excluding necessary travel expenses. See 5 U.S.C. app. § 505(3).</p> <ul style="list-style-type: none"> • Personal Savings Account <p>The term "personal savings account" includes a certificate of deposit, a money market account, or any other form of deposit in a bank, savings and loan association, credit union, or similar financial institution.</p> <ul style="list-style-type: none"> • Trusts ("Qualified" and "Excepted") <p>See instructions for Schedule A, Part II.B., and 5 C.F.R. Part 2634, Subpart D.</p> <ul style="list-style-type: none"> • Value <p>You may use any one of the methods described below, in determining fair market value:</p> <p>Option 1 - any good faith estimate of the value of the property if the exact value is unknown or not easily obtainable;</p> <p>Option 2 - value based upon a recent appraisal of the property interest;</p> <p>Option 3 - the purchase price of your property interest, or estimated retail price of a gift;</p> <p>Option 4 - the assessed value of the property for tax purposes, adjusted to reflect current market value if the tax assessment is computed at less than 100% of current value;</p>	<p>Option 5 - the year-end book value of non-publicly traded stock or the year-end exchange value of corporate stocks, or the face value of corporate bonds or comparable securities;</p> <p>Option 6 - the net worth of your interest (as in a business partnership or other jointly held business interest);</p> <p>Option 7 - the equity value of your interest (as in a solely owned business or commercial enterprise); or</p> <p>Option 8 - exact value (e.g., personal savings accounts) or any other recognized indication of value (such as last sale on a stock exchange).</p>	<ul style="list-style-type: none"> • Officers or employees in any other positions determined by the Director of the Office of Government Ethics to be of equal classification to above GS-15; • Administrative law judges; • Employees in the excepted service in positions which are of a confidential or policy-making character, unless by regulation their positions have been excluded by the Director of the Office of Government Ethics; • The Postmaster General, the Deputy Postmaster General, each Governor of the Board of Governors of the U.S. Postal Service and officers or employees of the U.S. Postal Service or Postal Rate Commission in positions for which the rate of basic pay is equal to or greater than 120% of the minimum rate of basic pay for GS-15 of the General Schedule; • The Director of the Office of Government Ethics and each designated agency ethics official; and • Civilian employees in the Executive Office of the President (other than special Government employees) who hold commissions of appointment from the President. <p>d. Incumbent officials holding positions referred to in section I.c. of these instructions if they have served 61 days or more in the position during the preceding calendar year.</p> <p>e. Officials who have terminated employment after having served 61 days or more in a calendar year in a position referred to in section I.c. and have not accepted another such position within 30 days thereafter.</p>
<p>III. When to File</p> <p>a. Within 30 days after becoming a candidate for nomination or election to the office of President or Vice</p>		

- President, or by May 15 of that calendar year, whichever is later, but at least 30 days before the election, and on or before May 15 of each succeeding year an individual continues to be a candidate.
- b. At any time after the President or President-elect has publicly announced an intention to nominate an individual referred to in section II.b. of these instructions, but no later than 5 days after the President transmits the nomination to the Senate.
- c. Within 30 days after assuming a position described in section II.c. unless such an individual has left another such position within 30 days prior to assuming the new position, or has already filed a report with respect to nomination for the new position (section II.b.) or as a candidate for the position (section II.a.).
- d. No later than May 15th annually, in the case of those in a position described in section II.d.
- e. In the event an individual terminates employment in the position and does not accept another position described in section II.c. within 30 days, the report must be filed no later than the 30th day after termination.
- f. **Extensions.** An employing agency may grant an extension of time of up to 45 days to a filer to file any report under sections III, c.-e. above (the FEC for any report under section III, a. above). OGE may grant an additional extension of time up to 45 days to file any such report.
- g. **Fee for Late Filing.** Any individual who is required to file this report and does so more than 30 days after the date the report is required to be filed, or, if an extension is granted, more than 30 days after the last day of the filing extension period, shall be subject to a \$200 late filing fee. A report is considered to be filed when it is received by the agency. Unless waived by OGE, such fee will be collected by the filer's agency, for deposit with the U.S. Treasury.

IV. Where to File

- a. Candidates for President and Vice President, with the Federal Election Commission.
- b. The President and Vice President, with the Office of Government Ethics.
- c. Members of a uniformed service, with the Service Secretary concerned.

b. The information to be disclosed is only that which the Ethics in Government Act of 1978, as amended (the Act) and 5 C.F.R. Part 2634 specifically require. You may, however, include any additional information, beyond those requirements, that you wish to disclose for purposes of clarification. Disclosure of information does not authorize any holdings, income, honoraria, liabilities, transactions, gifts, reimbursements, affiliations or positions otherwise prohibited by law, Executive order, rule or regulation.

c. Combine on one form the information applicable to yourself, your spouse and dependent children; or if more convenient, use separate schedules to report the required information applicable to family members. You may, if you desire, distinguish any entry for a family member by preceding the entry with an (S) if it is for a spouse or a (DC) if it pertains to a dependent child. Joint assets may be indicated by a (J). See 5 C.F.R. Part 2634, Subpart C, for exclusions in the case of separation or divorce.

V. General Instructions

- a. This form consists of the front page and four Schedules. If possible, use a black ink pen or typewriter to fill out your report. You must complete each Part of all Schedules as required. If you have no information to report in any Part of a Schedule, you should indicate "None." If you are not required to complete Schedule B or Part II of Schedule D, you should leave it blank. Schedule A combines a report of income items with the disclosure of certain property interests. Schedule B deals with transactions in real property or certain other assets, as well as gifts and reimbursements. Schedules C and D relate to liabilities and employment relationships. After completing the first page and each Part of the Schedules (including extra sheets of any Schedule where continuation pages are required for any Part), consecutively number all pages.

d. Definitions of the various terms used in these instructions and detailed information as to what is required to be disclosed are contained in 5 C.F.R. Part 2634.

e. In the case of references to entities which are operating trades or businesses which do not have listed securities, you must provide sufficient information about these private entities to give the reviewers of your disclosure report an adequate basis for the conflicts analysis required by the Act. Thus, you must disclose the location and primary trade or business of private entities, as well as attributed interests and activities not solely incidental to such a primary trade or business. For instance, if your family swimming pool services corporation incurs a liability to purchase an apartment house for investment in addition to its pool services business, you will have to report the apartment house investment as part of the nature of the business of the family corporation.

f. In the case of references to entities which are investment funds such as mutual or pension funds (whether public or private), you must disclose the portfolio holdings and all other items such as transactions and liabilities to the extent otherwise required for reportable interests, unless the entity is an "excepted investment fund." See Definition of Terms above.

g. If you need assistance in completing this form, contact the designated agency ethics official of the agency in which you serve, will serve, or have served.

Schedule A

I. General Instructions

Two of the general disclosure requirements of the Act concern certain interests in property (generally referred to here as assets) and items of income. Schedule A is designed to enable you to meet both of these reporting requirements. Generally a description of your, your spouse's, and your dependent child's assets and sources of income is required to be listed in BLOCK A of the Schedule. Reading from left to right across the page from each description of the asset or income source, you will be able to report in BLOCK B the value of each asset, and in BLOCK C the type and amount of income generated by that asset or received from the non-asset source.

On Schedule A are four examples which are representative of the reporting scheme of this Schedule. The first example represents the proper method of reporting stock of Central Airlines Company held at the end of the reporting period which then had a value of \$75,000. The individual had also received dividends of \$1,500, reported in BLOCK C. If the Central Airlines stock had been sold, there would be a check in the "None (or less than \$1,001)" column in BLOCK B if the individual no longer owned any of the stock at the end of the reporting period, and there would be an entry for capital gains as well as dividends in BLOCK C if they were realized

during the period. The second example represents the proper method of reporting the source of \$130,000 of earned income from private law practice, as well as \$18,500 the reporting individual maintained in the capital account in the law firm at the end of the reporting period.

The third example represents acceptable reporting of an investment fund which is widely held, widely diversified (or publicly traded) and independently managed. Because it meets these requirements, no individual assets of the fund need to be reported, and the type of income does not need to be broken into dividends, interest, or capital gains as long as the column for "excepted investment fund" is marked. The fourth example reports a mutual fund held in an IRA from which the filer has accrued dividends of \$10,000.

Normally you will have to list an item only once in BLOCK A with all other value and income information associated with that item shown on the same line to the right. However, when you have a number of different kinds of financial arrangements and income involving one entity, a full disclosure of all the required information for that entity may require more than one line. You may always use more than one line for clarification if you choose.

II. Property Interests and Assets

(BLOCKS A and B)

A. Items to Report

Report the identity and category of valuation of any interest in property (real or personal) held by you, your spouse or dependent child in a trade or business, or for investment or the production of income which has a fair market value which exceeds \$1,000 as of the close of the reporting period. These interests include, but are not limited to, stocks, bonds, pension interests and annuities, futures contracts, mutual funds, IRA assets, tax shelters, beneficial interests in trusts, personal savings or other

bank accounts, real estate, commercial crops, livestock, accounts or other funds receivable, and collectible items held for resale or investment. **Exceptions:** Exclude your personal residence (unless rented out) and any personal liability owed to you, your spouse or dependent child by a spouse or dependent child, or by a parent, brother, sister or child of you, your spouse, or dependent child. Exclude any retirement benefits (including the Thrift Savings Plan) from Federal Government employment and any social security benefits. Exclude also any deposits aggregating \$5,000 or less in personal savings accounts in a single financial institution.

With respect to assets of a spouse or a dependent child, do not report items:

- (1) which represent your spouse's or dependent child's sole financial interest or responsibility and of which you have no knowledge;
- (2) which are not in any way, past or present, derived from your income, assets, or activities; and
- (3) from which you neither derive, nor expect to derive, any financial or economic benefit.

Note: It is very difficult for most individuals to meet all three parts of this test, especially (3). For instance, if you file a joint tax return with your spouse, you derive a financial or economic benefit from the items involved and you are charged with knowledge of those items. A trust for the education of your minor child would also convey a financial benefit to you. Therefore, those asset and income items do not fit the test.

A personal residence held for investment or production of income, such as a summer home rented during parts of the year, must be reported.

Intermittent sales from personal property such as collections of antiques or art holdings demonstrate that the items are held for investment or the production of income and should therefore be reported.

B. What to Show on the Form

Enter the identity of the asset in BLOCK A and then show the value in BLOCK B. **Only the category of value, rather than the actual value of the property interest or asset,** must be shown. You need not disclose which valuation methods you used.

For assets such as stocks, bonds, and securities, report any holdings directly held or attributable to you, your spouse or dependent child from one source totaling more than \$1,000 in value. **Identify the holding and show the category of value.** If you hold different types of securities of the same corporation (e.g., bonds and stocks of "X" Corporation), these holdings should be considered as being from the same source for purposes of determining whether the aggregate value of the interest is below or above the \$1,000 threshold value. Report personal savings accounts only if they aggregate more than \$5,000 in a single financial institution.

If you have an interest in an investment fund or pool which is an "excepted investment fund" (see Definition of Terms above), you need only identify the interest by giving the complete name of the fund, rather than identifying the underlying assets as well.

To report interests of you, your spouse, or dependent child in a business, a partnership, or joint venture, or the ownership of property held for investment or the production of income, identify the character of the ownership interest, and the nature and location of the business or interest, unless it is a publicly traded security. For example, the entry for a holding of farm land might show, under BLOCK A, "...sole ownership of 100 acres of unimproved dairy farmland on Rural Route #1 at Pine Bluff, Madison County, Wisconsin."

You must disclose the primary trade or business of non-public entities, as well as interests and activities not solely incidental to such a trade or business. For

example, if your family is involved in a private real estate investment business but as a side interest buys stock through the business in a bank, you must disclose that in addition to real estate (by type and general location), the family business holds an interest in a bank.

For an IRA (Individual Retirement Account), indicate the value of each underlying asset, as well as the income derived therefrom (even though deferred for Federal tax purposes) in accordance with section IV below, to enable the reviewer to evaluate compliance with applicable laws and regulations. If the IRA were invested solely in a mutual fund such as "Templeton World Fund, Inc." and the investment property disclosed in Schedule A, that would be sufficient identification of the asset, since for most reporting individuals that fund would be an "excepted investment fund." If, however, the IRA had an individual or privately managed portfolio, detailed disclosure of the portfolio would be required on Schedule A in the same amount of detail as if each investment were directly held.

With respect to trusts in which a vested beneficial interest in principal or income is held, or as to which you serve as trustee, report trust interests and trust assets which had a value in excess of \$1,000. See 5 C.F.R. Part 2634 for more information about vested interests.

You need not report the identity of assets of a trust of which you, your spouse or dependent children are the beneficiaries if the interest is:

1. a "qualified blind trust" or "qualified diversified trust," which has been certified by the Office of Government Ethics, in accordance with 5 C.F.R. Part 2634, Subpart D, or

2. an "excepted trust," that is, one which

A. was not created by you or your spouse or dependent children, and

B. has holdings or sources of income of which you, your spouse and dependent children have no knowledge.

In the case of these special types of trusts, you should show in BLOCK A the identity of the trust, including the date of creation, and next to BLOCK C, the classification of the trust as a "qualified trust" or an "excepted trust."

You should also report in BLOCK B the category of the total cash value of the interest in a qualified blind or qualified diversified trust, unless the trust instrument was executed prior to July 24, 1995, and precludes the beneficiary from receiving information on the total cash value of any interest therein. (The category of amount of the trust income, if it exceeded \$200, must also be reported in BLOCK C, in accordance with section IV below.)

Note: You are not permitted by the statute to "create" an excepted trust by instructing a trustee not to divulge information or otherwise avoiding previous sources of knowledge upon entering Government service.

Do not report a trust of which your spouse or dependent child is a beneficiary that meets the three part test set forth in the second paragraph under II.A. A trust that does not fit that exception may still be an excepted trust under this section; in such case, it must be reported, but the assets need not be identified.

Except for the special trusts or funds referred to above, you must identify each individual investment held by a trust or fund, which had a value in excess of \$1,000. For example, in BLOCK A an entry such as "trust held by First National Bank (Boston, MA) consisting of ITT stock, U.S. Treasury certificates, and Dallas Municipal Bonds" might be made. In BLOCK B the applicable value of each trust asset would be entered. (As described under IV.B.6. Trust Income, below, the income from each asset would be entered in BLOCK C as well as income from assets of the trust sold during the reporting period.)

III. Earned and Other Non-Investment Income
(BLOCKS A and C)

A. Items to Report

For yourself, report the identity of the source in BLOCK A and the type and **actual** amount in BLOCK C of non-investment income **exceeding \$200** from any one source. Such income includes fees, salaries, commissions, compensation for personal services, retirement benefits, and honoraria. Report these items on the same line as related interests in property, if any.

For your spouse, report the source, but not the amount, of non-investment income exceeding \$1,000 and the source, amount and date of honoraria exceeding \$200 from any one source. No report of the earned or other non-investment income of your dependent children is required.

Exclude for yourself and spouse income from employment by the United States Government and from any retirement system of the United States (including the Thrift Savings Plan) or from social security.

B. What to Show on the Form

1. HONORARIA. For you or your spouse, show the honoraria aggregating more than \$200 from any one source. Report the identity of the source in BLOCK A, the source, the services performed and actual amount in BLOCK C. List each honorarium separately. For example, if, prior to your Government service, you received \$1,500 for a speech before the Chicago Civic Club on March 19, 1999 of which \$200 was actually spent for round-trip travel, and \$200 went to the agency who made the speaking arrangement, on your new entrant report you would enter in BLOCK A, "Chicago Civic Club, 18 Lakeshore Dr., Chicago, IL," in BLOCK C under Other (specify type, "honorarium"); for

ACTUAL AMOUNT... "\$1.00," and under DATE... "3/19/99," Honoraria received and donated to charity must be reported, but a notation explaining that fact may be included in reporting such items. The source, date and amount of payments made or to be made directly to a charitable organization in lieu of honoraria must also be disclosed.

2. 2. EARNED AND OTHER NON-INVESTMENT INCOME - Include all income, exclusive of honoraria, from non-investment sources including fees, commissions, salaries, and income from personal services or retirement. Report the **identity of the source** and **give the actual amount of such income exceeding \$250 from any one source**. For example, if you earned \$450

If your spouse has earned income in excess of \$1,000 (other than honoraria) from any one source, **identify the source but show nothing under amount.** If your spouse is self-employed in a business or profession, for example as a practicing psychologist who earned \$1,050 during the year, you need only show under BLOCK A... "practicing psychologist."

IV. Investment Income

(BLOCKS A and C)

Report items of investment income on the same line of Schedule A as the related property interest or other asset from which income is derived. Note that some property interests or other assets will not have a related item of income. In such a case, check "None (or less than \$201)" in BLOCK C under category of amount.

A. Items to Report

Report the identity in BLOCK A and the type and value in BLOCK C of any investment income over \$200 from any one source received by or accrued to the benefit of **you, your spouse or dependent child** during the reporting period. For purposes of determining whether you meet the over \$200 threshold from any one source, you must aggregate all types of investment income from that same source. For your spouse or dependent child such income is only required to be reported if the asset source meets the reporting threshold in section II above.

Investment income includes, but is not limited to, income derived from dealings in property, interest, rents, royalties, dividends, capital gains, income from annuities, the investment portion of life insurance contracts, or endowment contracts; your distributive share of partnership or joint venture income, gross business income, and income from an interest in an estate or trust. You need not show the actual dollar amount of dividends, rents and royalties, interest, capital gains, or income from qualified trusts, excepted investments, or other specified investments. For these specific types of income, you need only check the category of amount of the item reported. For all "other investment income" as described in item 7 below, you will have to report the actual dollar amount of income from each source, and indicate the type of income marked "Other Income (Specify Type & Actual Amount)" in BLOCK C.

B. What to Show on the Form

Check all applicable classifications of income and corresponding categories of amounts. If more than one type of income is derived from the same asset, check all relevant types (unless an excepted investment fund) and categories of amount. Categories of amount may be distinguished by using the abbreviations D, R, I and CG in the boxes, in lieu of checks, to represent dividends, rents/royalties, interest or capital gains.

1. DIVIDENDS. Show in BLOCK C the amount you, your spouse or dependent child accrued or received as dividends from investment sources including common and preferred securities and underlying assets of pensions and mutual funds (unless an excepted investment fund). **Identify the source of such income and check the category of amount.** For example, if cash dividends of \$950 were received for shares of common stock of IBM, enter in BLOCK A... "IBM common" and in BLOCK C check that dividend income was received and check the appropriate category of amount.

2. RENTS AND ROYALTIES. Show income accrued or received by you, your spouse or dependent child as rental or lease payments for occupancy or use of personal or real property in which any one of you has an interest. In addition, show payments accrued or received from such interests as copyrights, royalties, inventions, patents, and mineral leases or other interests. **Identify the source of such income and check the category of amount.** For example, if you received \$2,000 as rental income from an apartment building in Miami, Florida, enter in BLOCK A... "apartment building at 5802 Biscayne Blvd., Miami, FL," and in BLOCK C check that rental income was received and check the appropriate category of amount.

3. INTEREST. Identify the source and the category of amount of any interest accrued or received by you, your spouse or dependent child as income from investment holdings including bills and notes, loans, personal savings accounts, annuity funds, bonds, and other securities. For example, if you earned \$300 in interest during the calendar year on a Savings Certificate with Federal Savings and Loan, enter in BLOCK A... "Federal Savings and Loan (Baltimore, MD)-Savings Certificate," and in BLOCK C check that interest income was received and check the appropriate category of amount.

4. CAPITAL GAINS. Report income from capital gains realized by you, your spouse or dependent child from sales or exchanges of property, business interests, partnership interests or securities. **Identify the source**

and check the category of amount of the gain. An example of an entry in BLOCK A might be "sale of one-third interest in 100-acre farm in Hamilton County, Iowa," and in BLOCK C check that capital gains were received and check the appropriate category of amount.

5. INVESTMENT FUND INCOME. Identify the fund and the category of amount and the type(s) of income from investment funds such as mutual or pension funds for you, your spouse or dependent child. This may include dividends, capital gains and interest for a single fund or income from an excepted investment fund. Income from each individual asset of the fund must also be listed, unless it is an excepted investment fund, in which case income from individual assets is not required to be listed. See Definition of Terms above for discussion of excepted investment funds.

6. TRUST INCOME. Report the category of amount and the type of income accrued or received from any trust. Whenever you are required to identify the source of trust income, either for yourself or for a spouse or dependent child, it is not enough simply to say "John Jones Trust." Generally, the investment holdings of the trust, discussed above under "Property Interests and Assets," and the income derived from each holding must be identified to the same extent as if held directly. However, if the trust is a qualified trust or an excepted trust, in BLOCK A show only the identity of the trust including the date of creation, in BLOCK B the category of the total cash value of your interest (if a qualified trust), next to BLOCK C check the classification of the trust interest as a "qualified trust" or "excepted trust," and in BLOCK C show the category of amount of income attributable to you, your spouse or dependent child.

7. OTHER INVESTMENT INCOME. Report any other items of investment income exceeding \$200 and not described above, along with the specific type and actual amount, such as gross income from business interests, endowment or annuity contract payments, estate income, or a distributive share of a partnership or joint business venture income. To identify the sources of

other investment income, either for you, your spouse, or a dependent child, briefly characterize in BLOCK A the nature of the business or investment interest and, when applicable, the location; for example... "one-third ownership in a retail furniture store at 1010 Grand Ave., Chicago, IL." In BLOCK C under OTHER, specify the applicable type of income, for example... "distributive share" from a partnership or "gross income" from a proprietorship, and under ACTUAL AMOUNT the actual amount of such income which was received during the reporting period. Where the asset is listed because of a value of greater than \$1,000 in BLOCK B, but it does not produce more than \$200 in income for the reporting period, check "None (or less than \$201)" instead of listing the actual amount.

Schedule B

I. Part I - Transactions

A. General Instructions and Items to Report

This part is to be completed by incumbents and termination filers only. Give a description, the date, and the category of amount of any purchase, sale, or exchange of any real property, stocks, bonds, commodity futures, excepted investment fund shares, and other securities by you, your spouse or dependent child when the amount involved in the transaction exceeded \$1,000. Also, indicate whether sales were made pursuant to a certificate of divestiture previously issued by OGE to permit delayed recognition of capital gain. (For more information on certificates of divestiture, see 5 C.F.R. Part 2634, Subpart 1.) This includes reporting any sale or exchange of an asset involving an amount exceeding \$1,000 when the sold or exchanged asset did not yield income of more than \$200 (and therefore was not reported on Schedule A), or reporting the purchase of an asset involving an amount exceeding \$1,000 but at the end of the reporting period having a value of \$1,000 or less and earning income of \$200 or less during the reporting period (and therefore not appearing on

- Schedule A). The example on the form shows the proper way to disclose Central Airlines common stock the reporting individual purchased for \$75,000 on 2/1/99. Note that on Schedule A there is an entry for the stock as well since it was still held at the end of the reporting period.

You need not report a transaction involving (1) your personal residence (unless rented out); (2) a money market account or personal savings account; (3) an asset of your spouse or dependent child if the asset meets the three-part test set forth under the instructions for Schedule A, at I.A.; (4) a holding of a "qualified blind trust," a "qualified diversified trust," or an "excepted trust"; (5) U.S. Treasury bills, notes, and bonds; (6) transactions which occurred prior to your Federal Government employment; or (7) transactions solely by and between the reporting individual, spouse, or dependent child.

You will need to report any transactions made by a non-public business or commercial enterprise, investment pool, or other entity in which you, your spouse or dependent child have a direct proprietary, general partnership or other interest unless (1) the entity is an "excepted investment fund," or (2) the transaction is incidental to the primary trade or business of the entity as indicated by you on Schedule A. (See also sections V.e. and I of the General Instructions preceding those for Schedule A.)

B. What to Show on the Form

Under identification of assets, identify the property or securities involved in the purchase, sale or exchange, and give the date of the transaction. For example, under IDENTIFICATION OF ASSETS... "GMC common stock", under TYPE OF TRANSACTION, check type; under DATE... enter date transaction occurred; under AMOUNT OF TRANSACTION... check the category of value of the sale price, purchase price, or exchange value of the property involved in the transaction. You must also indicate whether an item was sold pursuant

2. Anything received from "relatives." The term "relatives" means an individual who is your father, mother, son, daughter, brother, sister, uncle, aunt, great uncle, great aunt, first cousin, nephew, niece, husband, wife, grandfather, grandmother, grandson, granddaughter, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, stepfather, stepmother, stepson, stepdaughter, stepbrother, stepsister, half brother, half sister, your spouse's grandfather or grandmother, or your fiancé or fiancée;

3. Requests and other forms of inheritance;

4. Suitable mementos of a function honoring the reporting individual;

5. Food, lodging, transportation, and entertainment or reimbursements provided by a foreign government within a foreign country or by the United States Government, or D.C., State or local governments;

6. Food and beverages not consumed in connection with a gift of overnight lodging;

7. Anything given to a spouse or dependent child totally independent of the relationship to you;

8. Gift items in the nature of communications to your office, such as subscriptions to newspapers and periodicals;

9. Gifts of hospitality (food, lodging, entertainment) on the donor's personal or family premises, as defined in 5 C.F.R. Part 2634;

10. Gifts and reimbursements received during non-Federal employment periods; and

11. Reimbursements you received for political trips which were required to be reported under section 304 of the Federal Election Campaign Act of 1971 (2 U.S.C. § 434).

- to a certificate of divestiture issued by the Office of Government Ethics under 5 C.F.R. Part 2634, Subpart 1, to permit delayed recognition of capital gain.

Where multiple transactions have occurred which involve the same asset, you may list the item once, check purchase and/or sale, and indicate... "biweekly," "throughout year," or other appropriate frequency, and the aggregate amount of the sales and purchases. Reporting an exchange generally requires reporting two items since one item is exchanged for another.
- II. Part II - Gifts, Reimbursements, and Travel Expenses**

A. General Instructions

This Part is to be completed by incumbents and termination filers only. The Act requires you to disclose the receipt of certain gifts, in-kind travel expenses, and travel-related cash reimbursements by you, your spouse or dependent child from any one source other than the U.S. Government. This reporting requirement applies to gifts and reimbursements received by your spouse or dependent child to the extent the gift was not given to him or her totally independent of the relationship to you.

B. Items to Report

Report gifts received by you, your spouse or dependent child from any one source during the reporting period aggregating more than \$260, such as tangible items, or food, lodging, transportation, or entertainment; and travel-related cash reimbursements aggregating more than \$260 from any one source. A "gift" means any payment, forbearance, advance, rendering or deposit of money, or anything of value, unless consideration of equal or greater value is received by the donor. In determining which gifts and reimbursements must be reported or aggregated, exclude these items:

1. Anything having a value of \$104 or less;

sections V a. and f. of the General Instructions preceding those for Schedule A.)

C. What to Show on the Form

Under CREDITORS (NAME AND ADDRESS), show the name and address of the actual creditor unless the reporting individual is only able to identify a fiduciary and certifies in the report that he has made a good faith effort to determine who the actual creditor is and was unable to do so, or upon his certification that such determination is otherwise impracticable. Under TYPE OF LIABILITY, briefly indicate the nature of the liability. Under DATE, enter date loan incurred; under INTEREST RATE, note the set rate or, if a variable one, the formula used to vary the rate, i.e. prime +2%; and under TERM, show the duration of the loan. Check the category of value for the highest amount owed during the reporting period.

II. Part II - Agreements or Arrangements

A. General Instructions and Items to Report

Provide information regarding any agreements or arrangements you have concerning (1) future employment; (2) a leave of absence during your period of Government service; (3) continuation of payments by a former employer other than the United States Government; and (4) continuing participation in an employee welfare or benefit plan maintained by a former employer other than United States Government retirement benefits. This includes any agreements or arrangements with a future employer entered into by a termination filer. The example on the form shows the severance agreement under which the reporting individual expects to receive a lump sum payment from the law firm he has left in order to enter the Government. (Also note the related asset and income reported in the second example on Schedule A of the form.)

For purposes of public disclosure, you must disclose any negotiations for future employment from the point you and a potential non-Federal employer have agreed to your future employment by that employer whether or not you have settled all of the terms, such as salary, title, benefits, and date employment is to begin. Your agency may require internal disclosure of negotiations much earlier and you should seek guidance before conducting any negotiations with persons with whom you do business. A criminal statute, 18 U.S.C. § 208, applies to official actions you may take while negotiating future employment.

B. What to Show on the Form

Under STATUS AND TERMS, describe the agreement or arrangement with appropriate specificity. Under PARTIES, show the name of the organization, or entity, and (if applicable) the name and title of the official, corporate officer, or principal person responsible for carrying out the terms of the agreement or arrangement.

Under DATE, show the date of any such arrangement. No report is required regarding any agreement or arrangement entered into by a spouse or dependent child.

Schedule D

I. Part I - Outside Positions

A. Items to Report

Report all outside positions held at any time during the reporting period, as well as those positions you currently hold as an officer, director, trustee, general partner, proprietor, representative employee or consultant of (1) any corporation, company, firm, partnership, trust, or other business enterprise; (2) any non-profit organization; (3) any labor organization; (4) any educational institution; or (5) any organization other than the United States Government. Exclude positions held in any

religious, social, fraternal, or political entity, and any positions solely of an honorary nature. Be sure to report on Schedule A any income over \$200 that you received from acting in any of these positions. No report is required regarding any positions held by your spouse or dependent child.

B. What to Show on the Form

Give the name, address and brief description (type) of the organization, the title or other brief functional description of the position, and the dates you held the position. If you currently hold the position, in the entry block under TO, note "Present."

II. Part II - Compensation in Excess of \$5,000 Paid by One Source

A. General Instructions

This Part is to be completed by nominees and new entrants only. You must disclose your sources of compensation in excess of \$5,000 and the nature of the duties you provided. This includes not only the source of your salary or other fees, but the disclosure of clients for whom you personally provided more than \$5,000 in services even though the clients' payments were made to your employer, firm or other business affiliation. The examples on the form show the proper way to disclose the business affiliation which paid the reporting individual's compensation, in this case a law firm, and a client of the firm for which the reporting individual personally provided over \$5,000 worth of services. This Part does not require you to disclose the value of the compensation for these services; it does require a brief description of the services you provided. When a source has paid you directly, you should have a corresponding entry on Schedule A, if the payment was within the reporting period for Schedule A. A client who paid your business affiliation more than \$5,000 for your services will appear only in this Part.

B. Items to Report

Report the nature of the duties performed or services rendered for any person (other than the United States Government) from which compensation in excess of \$5,000 in either of the two preceding calendar years or the present calendar year was received by you or an entity which billed for your services (business affiliation). **Exclude:** (1) information to the extent that it is considered confidential as a result of a privileged relationship established by law, or (2) information about persons for whom services were provided by a business affiliation of which you were a member, partner or employee unless you were directly involved in the provision of the services. The name of a client of a law firm is not generally considered confidential. **No report is required regarding compensation paid to your spouse or a dependent child.**

C. What to Show on the Form

Under SOURCE, give the name and address of the person to whom services were provided, for example, "Newark Real Estate Co. (Newark, NJ)"; and under BRIEF DESCRIPTION, the title or other brief functional description of the services rendered, for example: "tax matters researched for above firm while an associate with Quinn and Ouspensky."

Privacy Act Statement

Title I of the Ethics in Government Act of 1978, as amended (the Act), 5 U.S.C. app. § 101 et seq., and 5 C.F.R. Part 2634 of the Office of Government Ethics regulations require the reporting of this information. The primary use of the information on this report is for review by Government officials to determine compliance with applicable Federal laws and regulations. This report may

also be disclosed upon request to any requesting person pursuant to section 105 of the Act or as otherwise authorized by law. You may inspect applications for public access of your own form upon request. Additional disclosures of the information on this report may be made: (1) to a Federal, State, or local law enforcement agency if the disclosing agency becomes aware of a violation or potential violation of law or regulation; (2) to a court or party in a court or Federal administrative proceeding if the Government is a party or in order to comply with a judge-issued subpoena; (3) to a source when necessary to obtain information relevant to a conflict of interest investigation or decision; (4) to the National Archives and Records Administration or the General Services Administration in records management inspections; (5) to the Office of Management and Budget (OMB) during legislative coordination on private relief legislation; and (6) in response to a request for discovery or for the appearance of a witness in a pending judicial or administrative proceeding, if the information is relevant to the subject matter. See also the OGE/GOVT-1 executive branchwide Privacy Act system of records. Knowing and willful falsification of information, or failure to file or report information required to be reported by section 102 of the Act, may subject you to a civil monetary penalty and to disciplinary action by your employing agency or other appropriate authority under section 104 of the Act. Knowing and willful falsification of information required to be filed by section 102 of the Act may also subject you to criminal prosecution.

Public Burden Information

This collection of information is estimated to take an average of three hours per response, including time for reviewing the instructions, gathering the data needed, and completing the form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Associate Director for Administration,

U.S. Office of Government Ethics (OGE), Suite 500, 1201 New York Avenue, NW., Washington, DC 20005-3917. **Do not** file financial disclosure reports at this address; submit them as indicated in "Where to File" on page 3.

Pursuant to the Paperwork Reduction Act, as amended, an agency may not conduct or sponsor, and no person is required to respond to, a collection of information unless it displays a currently valid OMB control number (that number, 3209-0001, is displayed here and in the upper right-hand corner of the first page of this Standard Form 278).

Important Note on Reporting of Higher-Value Category Items on Schedules A, B and C of the SF 278:

For assets, income, transactions and liabilities of over \$1,000,000 in value that are held solely by your spouse or dependent children, just mark the over \$1,000,000 column. For such items which you as the filer hold, either singly or jointly with your spouse or dependent children, you must mark the other higher categories of value, as appropriate. For assets, transactions and liabilities, the higher categories are \$1,000,001 to \$5,000,000; \$5,000,001 to \$25,000,000; \$25,000,001 to \$50,000,000; and over \$50,000,000. For income, the higher categories are \$1,000,001 to \$5,000,000; and over \$5,000,000. Asterisked notes on Schedules A, B, and C explain these higher-value category reporting requirements.

Executive Branch Personnel PUBLIC FINANCIAL DISCLOSURE REPORT

Reporting Individual's Name	Reporting Status (Check Appropriate) Last Name	Incumbent <input type="checkbox"/>	Calendar Year Covered by Report	New Entrant, Nominee, or Candidate <input type="checkbox"/>	Termination Date (Month, Day, Year) Filer <input type="checkbox"/>	Termination Date (Month, Day, Year) Filer <input type="checkbox"/>	Fee for Late Filing Any individual who is required to file this report and does so more than 30 days after the due date shall be subject to a fee of \$250. If an extension is granted, more than 30 days after the last day of the filing extension period, shall be subject to a \$250 fee.
Position for Which Filing	Title of Position	Department or Agency (If Applicable)					
Location of Present Office (or forwarding address) Position(s) held with the Federal Government during the reporting period (12 Months, if not same as above)	Address (Number, Street, City, State, and ZIP Code) Telephone No. (Include Area Code)						
Presidential Nominee Subject to Senate Confirmation	Title of Position(s) and State(s) Held Do You Intend to Create a Qualified Diversified Trust? Yes <input type="checkbox"/> No <input type="checkbox"/>						
Certification I CERTIFY that the statements I have made are true, complete and correct to the best of my knowledge.	Signature of Reporting Individual Date (Month, Day, Year)						
Other Reviewer (Identified by agency)	Signature of Other Reviewer Date (Month, Day, Year)						
Agency Ethics Official's Opinion On the basis of information contained in this report, I conclude that the filer is in compliance with applicable law and regulations (subject to any comments on this basis).	Signature of Designated Agency Ethics Official/Reviewing Official Date (Month, Day, Year)						
Office of Government Ethics Use Only	Signature Date (Month, Day, Year)						
Comments of Reviewing Officials (If additional space is required, use the reverse side of this sheet) (Check box if filing extension granted & indicate number of days) <input type="checkbox"/>							
Agency Use Only							
OGE Use Only							

Page Number

Income: type and amount. If "None (or less than \$201)" is checked, no other entry is needed in Block C for that item.

This category applies only if the asset/income is solely that of the filer's spouse or dependent children. If the asset/income is either that of the filer or jointly held by the filer with the spouse or dependent children, mark the other higher category of value, as appropriate.

Editor Editions Cannot Be Used.

SE 278 (Rev. 05/2/00)
U.S. Office of Government Ethics

Do not complete Schedule B if you are a new entrant, nominee, or Vice Presidential or Presidential Candidate

Reporting Individual's Name

Page Number

Part I: Transactions

Report any purchase, sale, or exchange by you, your spouse, or dependent children during the reporting period of any real property, stocks, bonds, commodity contracts, or other assets if the aggregate amount of the transaction exceeded \$1,000. Include transactions that resulted in a loss.

Do not report a transaction involving property used solely as your personal residence, or a transaction solely between you, your spouse, or dependent child. Check the box if the transaction is a block certificate of divestiture from OGE.

None ☐

Transaction Type (check one)

Gift ☐ Sale ☐ Purchase ☐

Date (Mo., Day, Yr.)

2/1/99

Amount of Transaction (\$)

\$1,000.001
\$100,000
\$250,000
\$500,000
\$1,000,000
\$500,000
\$250,000
\$100,000
\$50,000
\$15,001
\$15,000
\$5,001
\$5,000
\$1,000.000
\$1,000.001
\$5,000,000
\$10,000,000
\$50,000,000
\$100,000,000
Over \$50,000,000

Certificate of Divestiture of Assets

Part II: Gifts, Reimbursements, and Travel Expenses

For you, your spouse and dependent children, report the source, a brief description, and the value of (1) gifts (such as tangible items, transportation, lodging, food, or entertainment) received from one source totaling more than \$260, and (2) travel-related cash reimbursements received from one source totaling more than \$260. For conflict analysis, it is helpful to indicate a basis for receipt, such as "Personal friend," "Agency approval under 5 U.S.C. § 4111," or "Other statutory authority." Exclude gifts and reimbursements received from your agency, dates, and the nature of expenses provided. Exclude anything given to you by the U.S. Government given to your agency in connection with official travel; received from relatives; received by your spouse or dependent child totally independent of their relationship to you; or provided as personal hospitality at the donor's residence. Also, for purposes of aggregating gifts to determine the total value from one source, exclude items worth \$104 or less. See instructions for other exclusions.

None ☐

Source (Name and Address)

Brief Description

Value

Examples: Nat'L Assn of Book Collectors, NY, NY
Frank Jones, San Francisco, CA

Airline ticket, hotel room & meals incident to national conference 6/15/99 (personal activity unrelated to duty)

\$500

1

2

3

4

5

Prior Editions Cannot Be Used

SC-278 (Rev. 05/2000)
SCEA Form 278-1
U.S. Office of Government Ethics

Do not complete Schedule B if you are a new entrant, nominee, or Vice Presidential or Presidential Candidate

Reporting Individual's Name

SCHEDULE B continued
(Use only if needed)

Page Number

Part I: Transactions

Identification of Assets

Transaction Type (a)

Date (Mo., Day, Yr.)

Amount of Transaction (c)

Classification of Disposition

1

2

3

4

5

6

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15

16

*This category applies only if the underlying asset is solely that of the filer's spouse or dependent children. If the underlying asset is either held by the filer or jointly held by the filer with the spouse or dependent children, use the other higher categories of value, as appropriate.

Prior Editions Cannot Be Used

SE 728 (Rev. 03/01/2000)
5 U.S.C.F.R. Part 2634
U.S. Office of Government Ethics

Page Number

SCHEDULE D

Reporting Individual's Name

Part I: Positions Held Outside U.S. Government
Report any positions held during the applicable reporting period, whether compensated or not. Positions include but are not limited to those of an officer, director, trustee, general partner, proprietor, representative, employee, or consultant of any corporation, firm, partnership, or other business enterprise or any non-profit organization or educational institution. Exclude positions with religious, social, fraternal, or political entities and those solely of an honorary nature.
None ☐

Examples	Organization (Name and Address) Next State of Residence, City, State Doe Jones & Smith, Hometown, State	Type of Organization Non-profit educational Law firm	Position Held President Partner	From (Mo., Yr.) To (Mo., Yr.) 7/83 1/90
1				
2				
3				
4				
5				
6				

Part II: Compensation in Excess of \$5,000 Paid by One Source
Report sources of more than \$5,000 compensation received by you or your business affiliation for services provided directly by you during any one year of the reporting period. Do not report compensation received from the U.S. Government, corporation, firm, partnership, or other business enterprise, or any other non-profit organization when Incumbent, Termination Filer, or Vice Presidential or Presidential Candidate. You need not report the U.S. Government as a source.
None ☐

Examples	Source (Name and Address) Doe Jones & Smith, Hometown, State Hometown University (client of Doe Jones & Smith), Hometown, State	Legal Services Legal services in connection with university construction	Brief Description of Duties
1			
2			
3			
4			
5			
6			

Print Edition Cannot Be Used.

NIH — Spreadsheets

IC	Name (Last, First)	Current Employ Y/N	NIH Position Title	List of Consulting Arrangements for IC Employees (past/current) for the period 01/01/99 to 12/31/03						Pharma or Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stocks & Stock Options
				Consult			Y/N					Start	End		
				Intral 278/ 450/ None	Extra 450/ None	Admin	None	Y	N						
NCCAM	Kresel, Jane	Y	Associate Dir. Science Policy Operations	E	450	N				P	Service on Boards or Committees	9/1/02	-	\$306 YTD expenses of stock options future est expenses future est \$1200 est total 1506 shares of stock.	40K shares of stock options YTD future est 20K more shares of stock.
NCCAM	Quen, Michael	Y	Chief, Diabetes Unit	I	450	Y				B	Consulting	9/14/98	-	\$3K comp YTD, future est comp \$8K, total 12K	

List of Ongoing Consulting Arrangements for IC Employees

IC	Name (Last, First)	Current Employ. Y/N	NIH Position Title	Intra/ Extra/ Admin	278/ 450/ None	Consult. Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
										Start	End		
NIAAA	Pacher, Pal	Y	Research Fellow	Intra	None	N	Proctor and Gamble Consultant	Pharma	pharmaceuticals work and Loop model development, data acquisition and analysis consultation and training (consulting)	1/2/03	indefinite	received \$7,144 in 2003; will receive less than \$10,000 in 2004	none
NIAAA	Salem, Norman	Y	Chief, LMBB	Intra	450	N	Discovery International-panel member	Pharma	answers questions on DHA supplements for infant nutrition	12/5/03	indefinite	2003-\$4,000 2004-\$8,000 expect Yearly income for life of project will be \$4,000 year	none
NIAAA	Salem, Norman	Y	Chief, LMB	Intra	450	N	Hoffman LaRoche- editorial board member	Pharma	PUFA newsletter scientific reviewer	12/1/97	indefinite	\$3,000 yearly	none
NIAAA	Salem, Norman	Y	Chief, LMB	Intra	450	N	Martek Corp- consulting services	Biotech	consults on issues regarding essential fatty acids in nutrition including study design consults on potential vitamin supplements; also serves as member of "Bayer Consumer Care Nutrition Advisory Board"	4/9/01	indefinite	\$3,000 yearly	none
NIAAA	Salem, Norman	Y	Chief, LMB	Intra	450	N	Bayer Corp- consulting services	Pharma		3/27/03	indefinite	2003-\$16,000 2004 and beyond- anticipate \$2,000 yearly	none

IC	Name (Last, First)	Current Employ. Y/N	NIH Position Title	Intra/ Extra/ Admin	278/ 450/ None	Consult. Y/N	Outside Organization & Organization	Pharma or Biotech	Nature of Activity	Activity Period		Monetary		Stock & Options
										Start	End	Comp.		
NIAID	Nabel, Gary	Y	Director, VRC	I	450 N		Trivium Capital Management Suntory Pharmaceuticals Res. Lab, LLC	Biotech	Member	11/3/2003	11/3/2003	11/3/05 to Present: Fee - \$15,000; Travel - \$0; Future: Fee - \$20,000; Travel Est - \$2000		N
NIAID	Paul, William	Y	Laboratory Chief	I	450 Y			Pharmac eutical	Member	5/1/2000	11/11/2011	5/1/00 to Present: Fee - \$280,000; Travel \$6400; Future: Fee - \$350,000; Travel - \$8000		N
NIAID	Paul, William	Y	Laboratory Chief	I	450 Y		Novartis Pharma AG Science Board	Pharmac eutical	Member	2/1/2001	11/11/2011	2/1/01 to Present: Fee: \$100,000; Travel - \$40,000; Future \$120,000/5 yrs; Travel/Expenses - \$40,000		N
NIAID	Shevach, Ethan	Y	Section Chief	I	450 Y		Tanox Biosystems, Inc	Biotech	Member	5/1/1998	4/30/2004	5/1/98 to Present: Fee - \$49,500; Travel - \$1413; Future: Fee \$15,000/yr; Exercised Stock Option - \$517,981		Y
NIAID	Shevach, Ethan	Y	Section Chief	I	450 Y		Vaccinex, L.P.	Biotech	Member	7/1/1998	11/11/2011	7/1/98 to present: Fee - \$6000; Travel - \$75; Future \$2500/yr; Stock - \$2400		Y
NIAID	Singh, Sanjay	Y	Staff Scientist	I	450 Y		Emcure Pharmaceuticals	Pharmac eutical	Consultant	4/1/2004	3/31/2005	4/1/03 to Present: Fee - \$0; Travel - \$0; Stock Options 25,000	Fee - \$20,000; Travel/Expenses \$4800	N
NIAID	Sirovsky, Michael	Y	Section Chief	I	450 Y		Adenosine Therapeutics, LLC	Pharmac eutical	Member/Co nsult	4/1/2003	11/11/2011	11/3/02 to present: Fee - \$4000; Travel - \$420; Future: \$0	Fee - \$0; Travel - \$0	Y
NIAID	Sirober, Warren	Y	Laboratory Chief	I	450 Y		Biocsek, Inc.	Biotech	Member	11/3/2002	12/31/2008	11/3/02 to present: Fee - \$6700; Travel - \$7; Future: Fee - 5000 (UK pounds/yr)	Fee - \$4000; Travel - \$420; Future: \$0	Y
NIAID	Yewdell, Jonathan		Section Chief	I	450 N		Biovex	Biotech	Member	6/1/2002	11/11/2011	4/19/02 to Present: Fee - \$5000/yr; Travel - \$3000; Future: Fee - \$5000/yr; Travel - \$1000/yr	Fee - \$6700; Travel - \$7; Future: Fee - 5000 (UK pounds/yr)	N
NIAID	Yewdell, Jonathan		Section Chief	I	450 Y		Genecor Intl	Biotech	Consultant	4/19/2002	11/11/2011		Fee - \$5000/yr; Travel - \$1000/yr	N

List of Ongoing Consulting Arrangements for IC Employees

IC	Name (Last, First)	Current Employ. Y/N	NIH Position Title	Intra/ Extra/ Admin	278/ 450/ None	Consult. Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
										Start	End		
					None			Biotech	Biomet will ask for advice in choosing a technology to commercialize in the future	9/22/03	Continuing	Fee: \$5,000/year; \$1,125 received so far	None
NAMS	Tuan, Rocky	Y	Chief, Cartilage Biology and Orthopaedics branch	Intra/	450	yes	Biomet, Inc	Biotech	Serve as a consultant to develop a protocol of cyclical mastalgia/fibrocystic breast disease.			Fee: \$13,000; Travel: \$3,000	None
NAMS	Adler, Deborah	Y	Program Director, Behavioral and Prevention Research	Extra/	450	yes	Abbott Laboratories	Pharma		9/15/03	12/15/05		None

List of Ongoing Consulting Arrangements for IC Employees

IC	Name (Last, First)	Current Employ Y/N	NIH Position Title	Intra/ Extra/ Admin	278/ 450/ None	Y/N	Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
										Start	End		
NIDCR	Bugge, Thomas	Y	Tenure Track Investigator	Intra/ Admin	450	Y	Combo A/S, Consultant	Pharma	Consult and render advisory services with respect to protease inhibitor discovery	11/1/03	11/1/05	\$1200/year (2003, \$1200, 2004, \$1200, 2005, \$1200)	
NIDCR	Park, Myung Hee	Y	Senior Investigator	Intra/ Admin	None	Y	Rexahn Corporation, Consultant	Biotech	Will provide technical and scientific advice on research and development of various small molecule chemical anti-cancer drugs	4/10/03	4/19/06		stock option (can be exercised as the end of 3 year service
NIDCR	Siraganian, Reuben	Y	Senior Investigator	Intra/ Admin	450	Y	Boehringer Ingelheim Pharmaceutical	Pharma	Member of the Pulmonary Research Advisory Board	10/5/03	10/5/04	\$27000 (2003, \$13,500 (\$7,500 fee/\$6,000 approximate travel expenses - everything was pre- paid), 2004, \$13,500 (\$7,500 fee/\$6000 travel expenses -	

IC	Name (Last, First)	Current Employ Y/N	NIH Position Title	Intra/ Extra/ Admin	Z78/ 450/ None	Consult Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech P/B	Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
										Start	End		
NIDCR	Sreenath, Taduru	Y	Staff Scientist	Intra/	None	N	Bioreliance Corporation	P/B	Evaluate the coded slides for chromosomal aberrations and micronuclei formation and recording data on score sheets provided by BioReliance	2/1/98	7/1/05	\$ 60/melaphase for chromosome aberration analysis and \$10/slide for micronucleus analysis - 1999, \$25,342.40; 2000, \$268,16.80; 2001, \$50,880; 2002, \$60,229.20; 2003, \$62,344; 2004, \$48,000; 2005, \$24,000. Total compensation is divided between Dr. Sreenath and his non-government partner.	

List of Ongoing Consulting Arrangements for IC Employees							Stock & Stock Options
IC	Name (Last, First)	NIH Position Title	Outside Organization Position Held with Organization	Activity Period		Monetary Comp.	
				Start	End		
NIDDK	BAX, ADRIAAN	SR. INVESTIGATOR	WYETH-AYERST	10/1/1995	Cont.	1995 \$3,000 Fee, \$400 Travel; 1996 \$3,000 Fee, \$400 Travel; 1997 \$3,000 Fee; \$400 Travel; 1998 \$3,000 Fee; \$400 Travel; 1999 \$3,000 Fee; \$400 Travel; 2000 \$3,000 Fee, \$400 Travel; 2001 \$3,000 Fee, \$400 Travel; 2002 \$3,000 Fee, \$400 Travel; 2003 \$3,000 Fee, \$400 Travel	N
NIDDK	BAX, ADRIAAN	SR. INVESTIGATOR	PFIZER, INC., PFIZER RESEARCH & DEVELOPMENT	11/1/2003	11/1/2004	2003 \$2,000 Fee	N
NIDDK	FELSENFELD, GARY	SR. INVESTIGATOR	REGULOME CORPORATION	06/01/01	6/1/04	2001 \$1,000 Stock, \$500 Travel; 2002 \$1,000 Stock, \$500 Travel; 2003 \$1,000 Stock, \$500 Travel	Y
NIDDK	FELSENFELD, GARY	SR. INVESTIGATOR	Stazione Zoologica	5/23/2004	5/26/04	2004 \$1,200 Travel; \$600 Hotel; \$300 Meals	
NIDDK	KOVAC, PAVOL	SR. INVESTIGATOR	TELTECH EXPERT NETWORK	08/15/00	5/1/05	2000 \$700 Fee; 2001 \$700 Fee; 2002 \$700 Fee; 2003 \$700 Fee	N
NIDDK	LEROITH, DEREK	SR. INVESTIGATOR	COUNCIL FOR THE ADVANCEMENT OF DIABETES RESEARCH	01/01/02	12/31/2006	2002 \$31,800 Honoraria; \$1,200 Airfare (in kind); \$400 Lodging (in kind); \$200 Cabs & Meals (in kind); 2003 \$31,500 Honoraria; \$1,200 Airfare (in kind); \$400 Lodgings (in kind); \$200 Cabs & Meals (in kind)	N
NIDDK	LEROITH, DEREK	SR. INVESTIGATOR	WARBURG PINCUS LLC	06/01/03	5/31/2004	2003 \$2,250 Honorarium (No expenses)	N
NIDDK	LEVINE, MARK	SR. INVESTIGATOR	Red Bull GmbH (Client of Arent Fox law firm)) (Fee)	09/11/03	8/24/2004	2003 \$0.00	N
NIDDK	LIANG, JAKE	SR. INVESTIGATOR	XTL BIOPHARMACEUTICALS LIMITED, ISRAEL	07/01/99	6/30/2006	FY 2000 \$20,000 Fee; \$2,000 Expenses; FY 2001 \$20,000 Fee; \$2,000 Expenses; FY 2002 \$20,000 Fee; \$1,500 Expenses; FY 2003 \$20,000 Fee; \$1,000 Expenses; FY 2004 (half year to 3/1/04) \$10,000 Fee	Y

IC	Name (Last, First)	NIH Position Title	Outside Organization & Position Held with Organization	Activity Period		Monetary Comp.	Stock & Stock Options
				Start	End		
NIDDK	LIANG, JAKE	SR. INVESTIGATOR	GILEAD SCIENCES	10/01/01	12/31/2004	2001 - \$0.00; 2002 \$3000 Per Diem (2 days); \$1,000 Expenses; 2003 - \$1,500 Per Diem (1 day); Expenses \$1,000	N
NIDDK	RICE, KENNER	SR. INVESTIGATOR	ENTREMED, INC.	8/15/1995	12/31/2010	1995 - \$0.00; 1996 - \$0.00; 1997 - \$0.00; 1998 - \$0.00; 1999 - \$12,000 Per Annum; 2000 - \$12,000 Per Annum; 2001 - \$12,000 Per Annum; 2002 - \$12,000 Per Annum; 2003 - \$12,000 Per Annum	N
NIDDK	SHILOACH, JOSEPH	SR. INVESTIGATOR	ADVANCED BIOSYSTEMS, INC.	07/01/00	12/31/2004	2000 \$2,800 Fee; 2001 \$7,000 Fee; 2002 \$4,000 Fee; 2003 \$1,500 Fee; No monies so far in 2004.	N

List of Ongoing Consulting Arrangements for IC Employees

IC	Name (Last, First)	Current Employ. Y/N	NIH Position Title	Intra/ Extra/ Admin Intra	276/ 450/ None 276	Consult. Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
NIEHS	Blackshear, Perry	Yes	Director of Clinical Research	Intra	276	Yes	Consultant - Trellis Biotechnologies	Sci: Advisory Bd. Member & consult		Start 9/1/03	End 9/1/05	Fees \$12,000 Travel \$2,000	Option to purchase 20,000 shares of each
NIEHS	Korach, Kenneth	Yes	Chief, Lab. Reproductive & Dev. Tox.	Intra	450	Yes	Consultant - Schering AG	Biotech	Consult on biochemical & pharmacological actions of estrogens	11/04	12/31/04	Fees \$52,500 Travel - \$25,000	

List of Ongoing Consulting Arrangements for IC Employees

IC	Name (Last, First)	Current Employ. Y/N	NH Position Title	Intra/ Extra/ Admin	276 Adm. None	Consult. Y/N	Outside Organization Position Held with Organization	Pharma or Biotech	Names of Activity	Activity Period Start End	Monetary Comp.	Stock & Stock Options
NEI	Carpi Rachel	Y	Chief, Immunoregulation Section	Intra/	NONE	N	Teleogenics, Inc./ Scientific Advisor	Biotech	Member-Scientific Advisory Board	Jan. 2002 Indefinite	N/A	5000 shares @ \$3.00*
NEI	Nussenblatt Robert	Y	Chief, Laboratory of Immunology	Intra/	YES	Y	Enzon Pharmaceuticals/Scientific Advisor	Pharma	Member-Scientific Advisory Board	Dec. 2003 Dec. 2004	\$5K + meals and travel	
NEI	Nussenblatt	Y	Chief, Laboratory of Immunology	Intra/	YES	N	Teleogenics, Inc./ Scientific Advisor	Biotech	Member-Scientific Advisory Board	Jan. 2002 Indefinite	N/A	5000 shares @ \$3.00*

END

* Stock Options

IC	LNAME	FNAME	CURRENT EMPLOY. - Y/N	NH POSITION TITLE	Intra/ Extra Admin.	278/ 450/ NONE	CONSULT Y/N	OUTSIDE ORG	POSITION HELD	Pharm or Biotech	TYPE OF ACT	NATURE OF ACTIVITY	START DATE	END DATE	MONEY COMP.	STOCK & STOCK OPTIONS
NHLBI	Brewer	H. Bryan	Y	Chief, Molecular Disease	I	450	Y	Eli Lilly & Company	Consultant	X	B1	Consulting with remuneration	3/11/2004	3/12/2004	2004 - \$2,000 fee, \$500 travel exp One Time Activity	N
NHLBI	Brewer	H. Bryan	Y	Chief, Molecular Disease Branch	I	450	Y	Novartis Pharmaceuticals Corporation	Consultant	X	B1	Consulting with remuneration	11/19/2003	11/30/2007	2003 - \$2,000 fee, \$3,000 travel exp Future - \$6,000 fee, \$2,500 travel exp/yr	N
NHLBI	Brewer	H. Bryan	Y	Chief, Molecular Disease Branch	I	450	Y	Pfizer	Member	X	B1	Consulting with remuneration	6/29/2002	6/28/2006	2001 - \$19,000 fee, \$2,600 travel exp 2002 - \$16,500 fee, \$3,400 travel exp 2003 - \$20,000 fee, \$2,400 travel exp Future - \$18,000 fee, \$4,000 travel exp/yr	N
NHLBI	Brewer	H. Bryan	Y	Chief, Molecular Disease Branch	I	450	Y	AstraZeneca	Member	X	E1	Service on Advisory Board/Committee with remuneration	3/14/2002	11/11/2111	2001 - \$6,000 fee, \$1,000 travel exp 2002 - \$10,000 fee, \$3,000 travel exp 2003 - \$15,000 fee, \$2,975 travel exp Future - \$8,000 fee, \$3,000 travel exp/yr	N
NHLBI	Brewer	H. Bryan	Y	Chief, Molecular Disease Branch	I	450	Y	Lipid Sciences	Consultant	X	E1	Service on Advisory Board/Committee with remuneration	4/4/2001	11/11/2111	2002 - \$5,000 fee, \$1,800 travel exp 2003 - \$78,000 fee, \$4,765 travel exp Future - \$50,000 fee, \$7,500 travel exp/yr	Y
NHLBI	Childs	Richard	Y	Chief, Tumor Immunology Section and	I	450	Y	Kirin Brewery Company (Pharmaceutical Division)	Member	X	A1	Teaching/Presenting with remuneration	3/21/2004	3/27/2004	2004 - \$3,750 fee, \$6,747 travel exp One Time Activity	N
NHLBI	Childs	Richard	Y	Chief, Tumor Immunology	I	450	Y	Armstrong, Donohue, Ceppos &	Practitioner	X	B1	Consulting with remuneration	2/28/2004	11/11/2111	Future - \$1,800 fee/yr Activity Just Started	N

IC	LNAME	FNAME	CURRENT EMPLOY- Y/N	NH POSITION TITLE	Intra/ Extra Admin	278/ 450/ NONE	CONSULT Y/N	OUTSIDE ORG	POSITION HELD	Pharm or Biotech	TYPE OF ACT	NATURE OF ACTIVITY	START DATE	END DATE	MONETARY COMP	STOCK & STOCK OPTIONS
NHLBI	Chids	Richard	Y	Chief, Tumor Immunology Section and	I	450	Y	MedDigma	Other	X	A1	Teaching/Pre- senting with remuneration	2/25/2004	2/27/2004	2004 - \$2,500 fee, \$1,453 travel exp One Time Activity	N
NHLBI	Chung	Jay	Y	Senior Research Investigator	I	999	Y	ISU Chemical Company	Member	X	E1	Service on Advisory Board/Comm ittee with	2/15/2002	12/30/2004	2002 - \$15,000 fee 2003 - \$15,000 fee Future - \$10,000 fee/yr	N
NHLBI	Domanski	Michael	Y	Leader, Clinical Trials SRG	E	450	Y	Wharton Levin Ehmantraut & Klein (case involves pharmaceutical)	Consultant	X	B1	Consulting with remuneration	9/24/2003	9/20/2005	2003 - \$15,400 fee 2004 - \$15,400 fee 2005 - \$15,400 fee Future - \$15,400 fee/yr	N
NHLBI	Dunbar	Cynthia	Y	Chief, Molecular Hematopole sis Section	I	450	Y	MolMed	Presenter	X	B1	Consulting with remuneration	4/6/2003	4/8/2006	2003 - \$1,370 fee, \$3,630 travel exp Future - \$1,500 fee, \$3,500 travel exp/yr	N
NHLBI	Levy	Daniel	Y	Leader, Framingha m Research Unit	E	450	Y	Hypertension Online (supported by unrestricted grant from Merck)	Presenter	X	I1	Editor/Editori al Board without remuneration	5/15/2001	11/11/2111	2001 - none 2002 - none 2003 - \$7,000 hon Future - est less than \$10,000 hon/yr	N
NHLBI	Manganiello	Vincent	Y	Chief, Biochemical Physiology Section	I	450	Y	Williams & Connolly	Consultant	X	B1	Consulting with remuneration	8/1/2002	11/11/2111	2002 - none 2003 - \$2,675 fee, \$2,040 travel exp Future - future income unknown, no current ongoing services	N
NHLBI	Manganiello	Vincent	Y	Chief, Biochemical Physiology Section	I	450	Y	GlaxoSmithKin e and Bayer	Writer/Editor	X	A1	Teaching/Pre- senting with remuneration	6/10/2002	11/11/2111	2002 - \$3,000 fee, \$950 travel exp 2003 - \$2,000, \$50 travel exp Future - \$2,000 fee, \$1,000 travel exp/yr	N

IC	LNAME	FNAME	CURRENT EMPLOY. Y/N	NH POSITION TITLE	Intra/ Extra Admin	278/ 450/ NONE	CONSULT Y/N	OUTSIDE ORG	POSITION HELD W/ORG	Pharm or Biotech	TYPE OF ACT	NATURE OF ACTIVITY	START DATE	END DATE	MONEY COMP	STOCK & STOCK OPTIONS
NHLBI	Nabel	Elizabeth	Y	Scientific Director for Clinical Research; Chief, Vascular Biology Section	I	450	Y	Boston Scientific Corp	Practitioner	X	B1	Consulting with remuneration	9/7/1999	11/11/2111	1999 - \$23,333 fee, \$750 travel exp 2000 - \$70,000 fee 2001 - \$70,000 fee 2002 - \$60,000 fee, \$945 travel exp 2003 - \$50,000 fee, \$800 travel exp 2004 - est \$50,000 fee, \$1,000 travel exp Future - \$50,000 - \$60,000 fee, \$1,000 - \$4,000 travel exp/yr	Y Stock ownership separate from 520 activity
NHLBI	Peterson	Charles	Y	Director, DBDR	E	450	Y	LightTouch Medical	Member	X	G1	Holding Office with remuneration	10/1/1997	11/11/2111	Stock options, current value \$20,000	Y
NHLBI	Piehn	Jonathan	Y	Staff Clinician	I	NONE	Y	Paimieri, Tyler, Wiener, Wilhelm & Ortho Biotech Products	Faculty	X	B1	Consulting with remuneration	4/18/2003	11/11/2111	2003 - \$13,000 fee Future - \$20,000 fee/yr	N
NHLBI	Sloand	Elaine	Y	Medical Officer	I	450	Y		Consultant	X	E1	Service on Advisory Board/Committee with remuneration	12/5/2002	11/11/2111	1999 - \$1,200 fee 2000 - \$1,200 fee 2001 - \$1,200 fee 2002 - \$1,200 fee 2003 - \$1,200 fee Future - \$8,000 fee/yr	N
NHLBI	Young	Neal	Y	Chief, Hematology Branch	I	450	Y	AstraZeneca	Consultant	X	B1	Consulting with remuneration	9/25/2003	11/11/2111	2003 - none Future - \$1000 fee/yr (final fee not yet negotiated, activity 2 3 hrs annually)	N

List of Ongoing Consulting Arrangements for IC Employees														
IC	Name (Last, First)	Current Employ. Y/N	NIH Position Title	Intra/ Extra/ Admin	278/ 450/ None	Consult. Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech		Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
								Start	End					
NHGRI	Wilfond, Benjamin	Y	Staff Clinician	Intra	450	N	Wyeth Research - Member, Bioethics Board			Provides advice regarding clinical research consent forms.	2002	Ongoing (Waiting for approval for 2004)	Fees for 2002: \$5,000 (Cash); Fees for 2003: \$2,500 (Cash) Expenses for 2002: \$800 (Cash); Expenses for 2003: \$400 (Cash)	
NHGRI	Green, Eric	Y	Scientific Director	Intra	278 (As of 2004)	Y	Monsanto Company - Consultant	Biotech	Serves as an advisor in the area of plant genetics and genomics.	2000	Ongoing	Honoraria for 2000: \$18,500 (Cash); Honoraria for 2001: \$36,000 (Cash); Honoraria for 2002: \$24,000 (Cash); Honoraria for 2003: \$23,000 (Cash); Honoraria for 2004: \$5,000 (Cash) Expenses for 2000: \$7,596.96 (in-kind & cash); Expenses for 2001: \$1,396.25 (in-kind & cash); Expenses for 2002: None; Expenses for 2003: \$1,334.57 (in-kind & cash); Expenses for 2004: \$631 (in- kind & cash)		

List of Ongoing Consulting Arrangements for NIDA Employees

IC	Name (Last, First)	Current Employ. Y/N	NIH Position Title	Intra/ Extra/ Admin	278/ 490/ None	Consult. Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period		Monetary Comp. \$	Stock Options
										Start	End		
NIDA	Hoffer, Barry	Y	Scientific Director	Intra	450	Y	Merck Research Laboratories, Consultant	P	Follow-up report on studies initiated when Dr Hoffer was at the U of Colorado in 1995/1996	8/1/03	10/1/04	2003 Travel expenses = (\$2,789) + Fees (\$3,000) = Total \$5,789; 2004 Travel expenses (\$10,000) + Fees (\$6,000) = \$16,000	N/A
NIDA	Rothman, Richard	Y	Chief, Clinical Psychopharmacology Section	Intra	450	Y	Sedgwick, Delert, Moran, & Arnold-consultant (Bristol Myers)	P	Medical Consultative Services	1/9/03	11/1/05	2003 Fee = \$16,167; 2004 Est Fee = \$2,500	N/A
NIDA	Rothman, Richard	Y	Chief, Clinical Psychopharmacology Section	Intra	450	Y	McKenna Long & Aldridge LLP-Consultant (Eon Labs)	P	Medical Consultative Services	4/4/03	11/1/05	2003 = \$0; 2004 Est Fee = \$2500	N/A
NIDA	Rothman, Richard	Y	Chief, Clinical Psychopharmacology Section	Intra	450	Y	Orrick, Herrington, and Sutcliffe, LLP-Consultant (Hoffman LaRoche)	P	Medical Consultative Services	4/4/03	4/1/05	2003 = \$0; 2004 Est Fee = \$2500	N/A
NIDA	Rothman, Richard	Y	Chief, Clinical Psychopharmacology Section	Intra	450	Y	Orrick, Herrington, and Sutcliffe, LLP-Consultant (Abbott)	P	Medical Consultative Services	4/4/03	4/1/05	2003 Fee = \$27,075; 2004 Est Fee = \$0	N/A

List of Ongoing Consulting Arrangements for IC Employees

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List of Ongoing Consulting Arrangements with biotechnology and pharmaceutical companies for IC Employees

IC	Name (Last, First)	Current Employ. Y/N	NIH Position Title	Intra/ Extra/ Admin	278/ 450/ None	Consult Y/N	Outside Organization	Pharma or Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
										Start	End		
NIMH	Brownstein, Michael	yes	Chief, Lab of Genetics	ip	450	yes	N-Gene Research Laboratories	Biotech	member of board of Directors, and scientific advisory board	9/1/98	ongoing	no fees paid in past 5 years; between 1999-2000 paid \$3,000 in fees and \$400 in travel expenses	earned stock that is not publicly traded and is valued by the company at \$30,000
NIMH	Brownstein, Michael	yes	Chief, Lab of Genetics	ip	450	yes	Serenix	Biotech	scientific advisory board member	5/1/97	ongoing	no fees; no expenses	owns 7% of company in equity that is not publicly traded; company values it at \$100,000
NIMH	Brownstein, Michael	yes	Chief, Lab of Genetics	ip	450	yes	Neurocrine Biosciences, Inc.	Biotech	member of board of directors and scientific advisory board member	1/1/92	ongoing	fee is currently \$1500/day plus expenses- earned 9,000 in consulting fees in 2003 and approximately \$3000 in fees in each of the previous 4 years- plus approx. \$3,000 for in-kind tickets, room and meals (\$1000-\$1500/trip)	earned stock options which vested - now owns approx. 30,000 shares; stock is trading at \$57.64/share
NIMH	Brownstein, Michael	yes	Chief, Lab of Genetics	ip	450	yes	Thyrees Corporation	Biotech	originally member of board of directors and scientific advisory board since its incorporation; company is dominant and now exists only to hold intellectual property	1/1/96	ongoing	no fees; no expenses	Dr. Brownstein has invested his own money in the company and received equity in return; he owns about 50% of the company which might be valued at \$100,000
NIMH	Charney, Dennis	yes	Chief, Mood and Anxiety Disorder Research Program	ip	450	yes	Cyberonics, Inc.	Pharma/ Biotech	advise on investigation of VNS (vagus nerve stimulation) therapy as a potential long- term treatment for chronic and recurrent depression	March 2003	ongoing	received fees approx. \$7,000 (for 2003) and \$1500/expenses; fees paid at rate of \$500/hr.; may work 20 hours/yr.	none

IC	Name (Last, First)	Current Employ Y/N	NIH Position Title	Intra/ Extra/ Admin	278/ 450/ None	Consult Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
										Start	End		
NIMH	Charney, Dennis	yes	Chief, Mood and Anxiety Disorder Research Program	irp	450	ongoing	Abbott Laboratories	Pharma	Chairman of data monitoring committee for study of the mood stabilizer Depakote as used in a multicenter clinical trial of children and adolescents with bipolar disorder to company	January, 2004	ongoing	no fees or expenses received to date; fee is paid at a rate of \$350/hour or \$3500 per day with a maximum not to exceed 70 hours or \$25,000. Dr. Charney estimates that this activity will involve some 20 hrs/year. Estimate for 2004 - \$4,000 in fees.	none
NIMH	Desimone, Robert	yes	Scientific Director, Section on Neuroimaging in Mood and Anxiety Disorders	irp	278	beginning	Neuroscience Solutions Corporation	biotech	developing computer software and behavioral training to improve the cognitive functioning of elderly adults with cognitive impairments	approval pending	approval pending	no fee; expenses estimated at \$1000 for travel/hotel and meals	1000 stock options valued at \$.50 per share (\$1,000)
NIMH	Drevets, Wayne	yes	Chief, Molecular Imaging Branch	irp	450	yes	Pfizer, Inc.	Pharma	participate in Zipsadone advisory board meeting (one day)	March 28-29, 2004	March 28-29, 2004	\$3500/fee plus in-kind expenses - airfare, hotel, meals	none
NIMH	Innis, Robert	yes	Chief, Molecular Imaging Branch	irp	450	yes	Imanet, a subsidiary of Amersham	Pharma	provides services to pharmaceutical companies			no fees or expenses in 2001; \$20,520 honorarium and \$8,362 expenses in 2002; \$5,000 fee and no expenses in 2003; estimate \$22,500 fee in 2004 plus travel expenses	none
NIMH	Innis, Robert	yes	Chief, Molecular Imaging Branch	irp	450	advised	Amersham	Pharma	consulting on PET imaging to extend technology to the private sector	10/1/01	ongoing	earned fees 2001 \$3,018, expenses \$7,932; fees in 2002 \$15,682, expenses \$8,094; fees in 2003 \$13,250, expenses \$3,001, expects to earn \$22,500/year plus travel expenses in 2004	none

IC	Name (Last, First)	Current Employ Y/N	NIH Position Title	Intra/ Extra/ Adm/ n	278/ 450/ Y/N	Consult Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
										Start	End		
	Ichise, NIMH Masanori	yes	senior staff physician, PET imaging section, Molecular Imaging Branch Section on Developmental Psychopathology, Division of Mental Disorders, Behavioral Research, and AIDS	irp	450	ongoing	Guilford Pharmaceuticals	Pharma	member of the data monitoring board of a Phase II study to evaluate a new drug to treat Parkinson's disease	21/04	ongoing	fee is \$250/hour, estimate \$2,500-\$3,000/year; there has been one meeting and Dr. Ichise has billed \$1500, but has not been paid yet; no expenses since meetings are local	none
	James, Regina NIMH	yes	Chief, Laboratory of Molecular Pathophysiology	irp	450	yes	Burroughs Health Care Management Group acting for the McNeil Pharmaceutical company	Pharma	participate as an advisor to an African American Advisory Board on ADHD (attention deficit/hyperactivity disorder) addressing concerns about cultural barriers to the treatment of ADHD	meeting Aug 22- 23 2003 and meeting 12/12-14 2003	ongoing but no meeting set for 2004	meeting 8/22-23/03 fee paid \$1500, plus \$93 expenses and in-kind airplane ticket; meeting 12/12-14/03 fee paid \$2,000 plus \$90 expenses and in-kind air ticket	none
	Merrill, Hussein NIMH	yes	Chief, Section of Biochemical Genetics	irp	450	yes	Pfizer, Inc.	Pharma	meeting on the pathophysiology of bipolar disease	3/23- 24/2004	3/23- 24/2004	fee is \$2000; expenses include airfare, hotel, meals, local travel fees received: 2000- \$10,000; 2003-\$10,000; no fees in 2001 or 2002; no expenses because no travel; fee will be \$10,000/yr	stock options received valued at \$14,000; none offered for the future year term
	Merrill, Carl NIMH	yes	Chief, Section of Biochemical Genetics	irp	450	yes	Panacea Pharmaceuticals	Pharma	chairman of the scientific advisory board	10/1/00	ongoing	\$2,250 received to date of service will (for 2003); company pays at rate of \$125/hour to earn between \$2,000- \$4,000/yr.	for a year term of service will receive 6,000 stock options valued at \$59/share
	Merrill, Carl NIMH	yes	Chief, Section of Biochemical Genetics	irp	450	yes	Genzyme Inc.	Pharma	consultant - advise on planning studies for childhood onset conditions; advising on selections of diagnostic and behavioral rating instruments, reviewing preliminary data	6/1/03	ongoing	no consulting assignments to date and no fees earned; fee is rated at \$450/Hr/NT \$3,000; expense estimated at \$1500/event	none
	Rapoport, Judith NIMH	yes	Chief, Child Psychiatry Branch	irp	450	yes	Pfizer, Inc.	Pharma	reviewing preliminary data	10/6/03	12/31/03		none

List of Ongoing Consulting Arrangements for NLM Employees

IC	Name (Last, First)	Current Employ. Y/N	NIH Position Title	Intra/ Extra/	278/ 450/ Admin	Consult Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stock Options
										Start	End		
NLM	Altschul, Stephen	Y	Senior Investigator	Intra	None	Y	None	Pharm	Consulting	Feb '02	Ongoing	2002 Fee \$4000 2002 Travel \$2475.86	9576 Vested Shares 4992 Shares will vest from 03/01/2004 to 02/28/2005
							Plexicon Pharmaceuticals Scientific Advisory Board					2003 Fee \$6000 2003 Travel \$1821.68 2004 Projected Fee \$8000 2004 Projected Travel \$2000	4576 Shares will vest from 03/01/2005 to 02/28/2006 440 Will vest on 03/01/2006
NLM	Landsman, David	Y	Senior Investigator	Intra	450	Y	Cambrex Bioscience (Formerly BioWhittaker) - Consultant	Biotech	Consulting	May '02	Ongoing	2002 Fee \$600 2003 Fee \$2700 2004 Fee \$800	N/A
NLM	Sirotkin, Karl	Y	Staff Scientist	Intra	450	Y	Avalon Pharmaceuticals - Consultant	Pharm	Consulting	June '00	Ongoing	2000 Fee \$24, 750.00 2001 Fee \$76,140.75 2002 Fee \$79,040.50 2003 Fee \$70,661.40 2004 Projected Fee Unknown due to Company's Financial Difficulties	6000 Stock Options Vested 4000 Shares left to purchase per vesting schedule

List of Ongoing Consulting Arrangements for IC Employees

IC	Name (Last, First)	Current Employ. Y/N	NIH Position Title	Intra/ Extra/ Admin	278/ 450/ None	Consult Y/N	Position Held with Organization & Outside Organization	Pharma Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
										Start	End		
CC	Alter, Harvey	Y	DTM	Intra/	450	Y	Laboratoire Francais Du Fractionnement Et Des Biotechnologies (LFB), Paris, France	Biotech	Serve on International Scientific Advisory Committee (ISAC) for LFB.	6/1/2001	5/31/04	Honorarium of \$2,000 per meeting 2001-\$2,000; 2002-\$2,000; 2003-\$2,000; 2004-\$2,000 totalling \$8,000. Actual travel expenses in kind.	
CC	Alter, Harvey	Y	DTM	Intra/	450	Y	CHIRON, Emeryville, CA	Biotech	Serve on Blood Testing Scientific Advisory Cmte.	8/1/2003	8/1/05	\$1,500 fee per meeting. 2003-\$1,500 Actual travel expenses in kind.	
CC	Alter, Harvey	Y	DTM	Intra/	450	Y	Gen-Probe, Inc.	Biotech	Serve on Scientific Advisory Board.	8/1/2003	8/1/04	Fee is \$5,000 per meeting. Total for 2003-\$5,000 fee. Actual travel expenses in kind.	
CC	Alter, Harvey	Y	DTM	Intra/	450	Y	Roche Molecular Systems, Parsippany, CA	Biotech	Serve on Global Advisory Board (GAB).	4/1/2002	4/1/04	Honorarium is \$1,000 per meeting or \$3,000 per annum. Honoraria for 2002 -\$3,000; 2003-\$3,000 totalling \$6,000. Actual travel expenses in kind.	
CC	Alter, Harvey	Y	DTM	Intra/	450	Y		Biotech	Member of Scientific Advisory Cmte. BSF.	Feb-01	2/1/04	2001-\$2,000; 2002-\$2,500; 2003-\$2,500 Total compensation by honoraria since inception \$7,500. Actual travel expenses in kind.	
CC	Alter, Harvey	Y	DTM	Intra/	450	Y	Blood Systems, Inc., Scottsdale, AZ	Biotech	Member of Acrometric Scientific Advisory Board.	10/1/2001	10/31/06	Fee \$2,000 per meeting, but beginning in 2003 compensation was changed to \$200/hr for up to 10 hrs/year. Fee for 2001-\$2,000; 2002-\$2,000; 2003-\$2,000 totalling \$6,000. Actual travel expenses in kind.	
CC	Klein, Harvey	Y	DTM	Intra/	450	Y	Acrometric, Benicia, CA	Biotech	Medical and scientific advisory board for industrial cold processing and use.	11/1/95	11/1/06	\$10,000 per year, \$5000 per meeting, \$500 per conference call. Actual expenses, coach class, taxi, meals. Past Compensation 1999-\$3,000; 2000-\$14,000 2001-\$32,000; 2002-\$22,700; 2003-\$18, 600.	20,000 stock options in 2000, 3,000 stock options in 2003.
CC	Klein, Harvey	Y	DTM	Intra/	450	Y	Navant (previously Viacord) Gambro BCT, Lakewood, CO	Biotech	Medical advisory board for pathogen inactivation of blood.	12/1/00	11/7/07	\$1,500 per meeting and actual expenses, coach class taxi, meals. Past compensation: \$5,000 in 2000, \$3,000 in 2001, \$5,000 in 2002, \$7,000 in 2003.	
CC	Klein, Harvey	Y	DTM	Intra/	450	Y	Haemonetics Corp., Braintree, MA	Biotech	Outside Director on Haemonetics Board of Directors	10/1/98	10/1/08	\$24,000 per annum, \$1,500 per meeting Stock options as granted: Past compensation \$20,000 and stock options in 1999, \$10,000 and stock options in 2000, \$10,000 and stock options in 2001, \$10,000 and stock options in 2002, \$10,000 in 2003 One time grant of stock options, \$3,000 travel reimbursement per year (Actual expenses, coach class, taxi, meals). No other compensation.	Stock Options as granted: 6,000 in 1999, 9,000 in 2000, 9,000 in 2001, 9,000 in 2002, 9,000 in 2003.
CC	Klein, Harvey	Y	DTM	Intra/	450	Y	Sangart, Inc. San Diego, CA	Biotech	Science Advisory Board for blood substitutes	8/1/99	8/8/08		20,000 in 1999

IC	Name (Last, First)	Current Employ. Y/N	NH Position Title	Intra/ Extra/ Admin	278/ 450/ None	Consult Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period Start End	Monetary Comp.	Stock & Stock Options
CC	Klein, Harvey	Y	DTM	Intra/	450	Y	Verax Biomedical Inc., Worcester, MA	Biotech	Medical Advisory Board for phlebot technology	5/1/02 5/7/07	Fee and one time grant of stock options \$1,500 per meeting and actual expenses, coach, class, taxi, meals. Past compensation \$3,000	
CC	Klein, Harvey	Y	DTM	Intra/	450	Y	Baxter Healthcare, Transfusion Therapies, Round Lake, IL	Biotech	Outside data and safety monitoring board for licensed pathogen reduction product used in Europe	6/1/03 6/1/06	\$1,000 per meeting, \$250 for travel per day. Actual expenses, coach class, taxi, meals. No compensation in 2003, \$1,500 pending.	
CC	Klein, Harvey	Y	DTM	Intra/	450	Y	ZymeQuest, Beverly, MA	Biotech	Medical Advisory Board	10/1/95 10/1/08	Fee per annum \$6,000 per year, \$1,000 per meeting and actual expenses, coach class, taxi, meals. Past compensation \$7,000 in 1999, \$10,000 in 2000, \$10,000 in 2001, \$10,000 in 2002, \$7,500 in 2003	

List of Ongoing Consulting Arrangements for IC Employees

IC	Name (Last, First)	Current Employer Y/N	NH Position Title	Initial Contract Adverse None	218 Contract Y/N	Outside Organization Position Held with Organization	Pharma Biotech	Name of Activity	Activity Period		Monthly Comp	Stock & Stock Options
									Start	End		
CSR	Barker, Lawrence	Y/N	Scientific Review Administrator	Extra	450 Y	Biogen Incorporated	Biotech	Analysis of clinical studies	8/1/07	7/31/09	\$4000/fee	No

List of Ongoing Consulting Arrangements for IC Employees

IC	Name (Last, First)	Current Employ. Y/N	NH Position Title	Intra/ Extra/ Admin	278/ 450/ Y/N	Consult. Y/N	Outside Organization	Pharm or Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
										Start	End		
N/A	Abernethy, Darrell	Y	Chief, Laboratory of Clinical Investigation	Intra	450 Y		Expert, Gray Cary	P	Expert witness in litigation in patent dispute involving client Cobalt Pharmaceuticals	12/10/2003	11/30/2006	\$9,375.00 Fee, \$625 Travel Expenses \$7,500.00	No
N/A	Abernethy, Darrell	Y	Chief, Lab of Clin Invest	Intra	450 Y		Consultation - Genozor	P	Consultant	4/1/5/03	4/14/06	\$500.00 Travel Expenses \$500.00	No
N/A	Abernethy, Darrell	Y	Chief, Lab of Clin Invest	Intra	450 Y		Member, Perwest Pharmaceuticals Co.	P	Scientific Advisory Board Member	5/1/03	4/30/08	\$200.00 Fee, \$10,000 Expenses	No
N/A	Abernethy, Darrell	Y	Chief, Lab of Clin Invest	Intra	450 Y		Expert Witness, Kirkland and Ellis	P	Expert Witness for client Boston Scientific and SomaLife Systems	6/1/03	5/31/06	\$1,250 Travel Expenses	No
N/A	Fenucci, Luigi	Y	Chief, Longitudinal Studies section	Intra	450 Y		Consultation, Ortho Biotech	B	Consultant - research on anemia	12/6/2003	12/31/2004	\$2418.00 Travel Expenses \$2500.00	No
N/A	Gurathik, Jack	Y	Medical Officer	Intra	450 Y		Consultation, Ortho Biotech	B	Consultant - advice re general issues concerning the epidemiology, methods and approaches to research on elderly	5/15/2003	5/14/2006	\$119,322.7 Travel Expenses \$2,267.74	No
	Kliner-Triolo, Melissa	Y	Research Psychologist	Intra	None	Y	Expert Consultant, Wyeth Pharmaceuticals		Consultant	11/20/01	12/31/04	Travel Expenses	No
N/A	Ko, Minoru	Y	Chief, Developmental Genomics & Aging section	Intra	450 Y		Consultation, Daiichi Pharmaceutical Co	P	Consultant - advice on genomics and developmental biology for drug target discovery program	4/7/2003	4/6/2005	\$11,200.00 Travel Expenses	No
N/A	Ko, Minoru	Y	Chief, Developmental Genomics & Aging section	Intra	450 Y		Consultation, Neo-Morgan Lab, Inc.	B	Consultant - biological research	1/1/2004	12/31/2004	\$10,000.00 Fee	No
N/A	Rao, Mahendra	Y	Section Chief, Stem Cells	Intra	450 Y		Consultation, Toucan Capital (Theradigm/Cancer Co)	B	Consultant - advice on cell replacement therapy	9/1/2003	Indef	\$10,000 Fee	Yes
N/A	Rao, Mahendra	Y	Section Chief, Stem Cells	Intra	450 Y		Consultation, Cua Therapeutics	B	Consult - advice on company's stem cell research	8/1/2002	Indef	\$2500.00 Travel Expenses	Yes
N/A	Rao, Mahendra	Y	Section Chief, Stem Cells	Intra	450 Y		Consultation, Amelica, Inc	B	Consultant - advice re ceramics as a bone substitute	7/1/2001	Indef	Travel Expenses	Yes
N/A	Rapoport, Stanley	Y	Section Chief, Brain Physiology and Metabolism	Intra	450 Y		Expert, Faegre & Benson	P	Expert Witness in litigation involving Invenor for Amelica Pasteur, Inc.	11/12/2000	Indef	\$17,985 Travel Expenses	No
N/A	Rapoport, Stanley	Y	Section Chief, Brain Physiology and Metabolism	Intra	450 Y		Consultation, Best Practice	P	Consultant - advice re how to evaluate efficacy of drugs for human brain disorders	3/1/2003	Indef	\$3750.00 Fee, \$250.00 Travel Expenses	No

IC	Name (Last, First)	Current Employ. Y/N	NIH Position Title	Intra/ Extra/ Admin	218/ 450/ N/A	Consult Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
										Start	End		
N/A	Schlessinger, David	Y	Chief, Lab of Genetics	Intra	450 Y		Member, Via Genomics	B	Scientific Advisory Board member for genetics based company	6/14/2001	12/31/2004	\$1,000 Research In \$394,680 Travel Expenses	No
N/A	Schlessinger, David	Y	Chief, Lab of Genetics	Intra	450 Y		Member, International Genomics Inc	B	Scientific Advisory Board member for genetics based company	3/15/2002	3/25/2005	\$4000.00 Research In \$315,000 Travel Expenses	Yes
N/A	Tash, Dennis	Y	Investigator	Intra	450 Y		Member, S.H. Biomedical Corporation	B	Scientific Advisory Board member to provide service on clinical immunology	6/1/2002	6/30/2005	\$275.00 Travel Expenses	Yes

List of Ongoing Consulting Arrangements for IC Employees												
IC	Name (Last, First)	Current Employ. Y/N	NH Position Title	Intra/ Extra/ Admin	772/ 450/ None	Consult. Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period Start End	Monetary Comp.	Stock & Options Stock
NCI	Aditya, Sankar	Y	Senior Investigator	Intra	450	Y	Genzyme, Inc. - SAB	Yes	Consulting w/\$	5/1/03 open	\$2,000/yr for 3 yrs	\$3,000 Stock
NCI	Ashwell, Jonathan	Y	Medical Officer (Research)	Intra	450	Y	PLIVA 25 - SAB	Yes	Consulting w/\$	10/1/08 9/30/07	\$200/day for 4 days	\$3,428
NCI	Bates, Susan	Y	Lead Clinical Investigator	Intra	450	Y	3M Pharma	Yes	Consulting w/\$	7/27/03 8/30/05	\$2,000 honor. And \$1,428 Expenses	
NCI	Bates, Susan	Y	Lead Clinical Investigator	Intra	450	Y	Pfizer - Review a technology related to drug resistance in cancer and to give Lecture	Yes	Consulting w/o \$	3/1/04 2/28/05	\$1,428 Expenses	
NCI	Berzofsky, Jay A.	Y	Medical Officer	Intra	450	Y	Cytologizer/Therapeutic Devices Consult on co's approach to treat cancer by removing inhibitors of inflammatory cytokines.	Yes	Consulting w/\$	12/21/01 1/1/06	\$3,000/day to date 15,000.	\$ 2,375 S. O.
NCI	Berzofsky, Jay A.	Y	Medical Officer	Intra	450	Y	Genzyme Int'l - Consult on protocols for clinical testing of hepatitis B vaccine	Yes	Consulting w/\$	7/21/03 8/11/06	\$200/day for 4 days total \$800	
NCI	Berzofsky, Jay A.	Y	Medical Officer	Intra	450	Y	TransForm Pharm. - consult on vaccine formulation and product development	Yes	Consulting w/\$	12/11/02 1/30/06	\$3,000 for 02 & 03 (\$1,500/per day)	\$25,000 per year 100,000 to date
NCI	Berzofsky, Jay A.	Y	Medical Officer	Intra	450	Y	Celera Genomics - consult on antigen processing much Exp. Invol. Papill-family proteases	Yes	Consulting w/\$	9/23/02 10/1/06	\$5,000 yr/15K cumulative for hours worked 1000/yr total of 1040/00	2,500 Shares
NCI	Berzofsky, Jay A.	Y	Medical Officer	Intra	450	Y	Pharmadine Inc. - to consult and develop immunopants to treat viral & bacterial diseases	Yes	Consulting w/\$	10/6/97 12/31/06	\$5K per annum, but not received	
NCI	Berzofsky, Jay A.	Y	Medical Officer	Intra	450	Y	Exp. on trans approaches for developing vaccines for TB as well as design of experiments & interpretations of results.	Yes	Consulting w/\$	10/31/00 11/30/06	\$5,000 yr/15K cumulative for hours worked 1000/yr total of 1040/00	2,500 Shares
NCI	Copeland, Neil G	Y	Senior Investigator	Intra	450	Y	Lexicon Genetics - consult/focused on use of patented gene knockout tech (targeting & trapping) to alter DNA of specific genes in mouse embryonic stem cells.	Yes	Consulting w/\$	5/17/01 open	\$20,000 since 2001	
NCI	Court, Donald L	Y	Senior Investigator	Intra	450	Y	Genzyme, Inc. - SAB	Yes	Consulting w/\$	12/03 2/15/08	\$1,500 Per Year/ \$2,000 Per Year/ 188,608 Cum Travel=15,250; Proj 04 Fee=24,000; Travel=3,000; 9,950 Per year since 2000/ no 04 as yet for a total of 2,000 and 2,000 and 2,000-36,000.	
NCI	Erment-Buck, Michael	Y	Clinical Investigator	Intra	450	Y	Microcycle Pathotechnology - Form xtn business/provide pathology resources to research community	Yes	Consulting w/Law Firms or other prof. w/\$	2/1/00 open	\$20,000	Owns company
NCI	Friedman, Fred K	Y	Research Chemist	Intra	450	Y	AstraZeneca LP - Case discussions, education re: cancer related topics to health practitioners/support groups	Yes	Consulting w/\$	8/13/01 open	\$1,500 Per Year/ \$2,000 Per Year/ 188,608 Cum Travel=15,250; Proj 04 Fee=24,000; Travel=3,000; 9,950 Per year since 2000/ no 04 as yet for a total of 2,000 and 2,000 and 2,000-36,000.	
NCI	Gulley, James L	Y	Staff Clinician	Intra	450	Y	Schering-Plough/Canil - Gene Therapy Adv Panel and to advise regarding safety issues assoc. w/gene therapy	Yes	Consulting w/\$	9/23/02 open	\$1,500 Per Year/ \$2,000 Per Year/ 188,608 Cum Travel=15,250; Proj 04 Fee=24,000; Travel=3,000; 9,950 Per year since 2000/ no 04 as yet for a total of 2,000 and 2,000 and 2,000-36,000.	
NCI	Harris, Curtis	Y	Senior Investigator	Intra	450	Y	LG Chemical Res Park/Cosmetic R&D Ctr - Critique ongoing research to develop & improve skin care by additives.	Yes	Consulting w/\$	2/9/98 open	\$1,500 Per Year/ \$2,000 Per Year/ 188,608 Cum Travel=15,250; Proj 04 Fee=24,000; Travel=3,000; 9,950 Per year since 2000/ no 04 as yet for a total of 2,000 and 2,000 and 2,000-36,000.	
NCI	Hearing Jr, Vincent J	Y	Research Biologist	Intra	450	Y	Procter & Gamble - Lecture & Critique research program	Yes	Consulting w/\$	4/12/00 open	\$600.00 Expenses 2003-36,000.	
NCI	Hearing Jr, Vincent J	Y	Research Biologist	Intra	450	Y	R-Tech Demo, Ltd. - Research Prog.	Yes	Consulting w/\$	11/1/03 9/30/04	\$600.00 Expenses 2003-36,000.	

V. : 12/16/03

List of Ongoing Consulting Arrangements for IC Employees												
IC	Name (Last, First)	Current Employ. YN	NH Position Title	Intra/ Extra/ Admin	276/ 460/ None	Consult YN	Outside Organization & Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period Start End	Monetary Comp.	Stock & Options
NCI	Hodge, David R.	Y	Budget	Intra	450	Y	Aphion Lab of Molecular Med.	Yes	Consulting w/\$	4/1/03	\$1,000	
NCI	Hughes, Stephen H.	Y	Senior Investigator	Intra	450	Y	Virologic - Advise re: development & interpretation of assays for HIV-1 quasi-species evolution	Yes	Consulting w/\$	11/2/99	Paid \$20,815 from Virologic/partly for expenses since 1999	\$12,000.00 shares
NCI	Jenkins Copeland, Nancy	Y	Senior Investigator	Intra	450	Y	Lexicon Genetics	Yes	Consulting w/\$	5/17/01	open	\$15,000
NCI	Jenkins Copeland, Nancy	Y	Senior Investigator	Intra	450	Y	Eli Lilly Ltd	Yes	Consulting w/\$	3/1/03	open	
NCI	Ji, Xiaohua	Y	Senior Investigator	Intra	450	Y	Unilever Technologies Inc. - Foundation of Dir	Yes	Consulting w/\$	10/15/93	open	\$0
NCI	Jin, Hong	Y	Medical Technologist	Intra	None	Y	Genologic Co - Histology Consulting	Yes	Consulting w/\$	11/7/03	9/1/04	24,000
NCI	Kim, Seong Jin	Y	Senior Investigator	Intra	450	Y	TissueGene Inc - Bcl Ngu/Ad Hoc Research	Yes	Consulting w/\$	10/1/99	9/30/05	\$60,000 Cum. Cum: 37,000; 104=5,00
NCI	Lanza, Elaine	Y	Nutritionist	Intra	450	Y	Cytosix - Research/Develop	Yes	Consulting w/\$	7/1/99	2/7/05	
NCI	Libutti, Steven K.	Y	Senior Investigator	Intra	450	Y	Peregrine Pharma, Inc. - Asst Peregrine in development of anti-P-6 monoclonal antibody program	Yes	Consulting w/\$	9/23/03	9/22/04	\$11,000 to date/\$22,000 yearly date/\$10,100 to date; potentially \$5,000 per month and \$60,000 per year \$320/mo \$39,000 to date
NCI	Libutti, Steven K.	Y	Senior Investigator	Intra	450	Y	Therapio Consulting - Asst w/Dev. Of Rehab programs which would provide outpatient svcs for patients	Yes	Consulting w/\$	4/22/03	4/21/04	
NCI	Lotta, Lance A.	Y	Lab Chief	Intra	450	Y	Biospect Inc - Advice on public domain diagnostic testing methods	Yes	Consulting w/\$	10/21/02	3/1/05	
NCI	Passan, Ira H.	Y	Senior Investigator	Intra	450	Y	AKG Pharma - review program treat & Diagnose breast cancer/dysplasia gen. test	Yes	Consulting w/\$	6/1/01	5/1/06	\$1,000 for Fees. Up to \$1,000 expenses S. O.
NCI	Passan, Ira H.	Y	Senior Investigator	Intra	450	Y	Glycomimetics Inc. - SAB	Yes	Consulting w/\$	1/12/04	1/2/07	\$1000 Plus/Exp
NCI	Passan, Ira H.	Y	Senior Investigator	Intra	450	Y	Glycomimetics Inc - Consult w/members of SAB and scientific staff	Yes	Consulting w/\$	1/12/04	3/4/07	\$150/hr to \$1000 per plus expenses S.O. on 7,000 shares stock
NCI	Pavakis, George N.	Y	Senior Investigator	Intra	450	Y	Marine Polymer Technologies Inc. - Advise co on medical uses of hemostatic polymers/review & evaluate some research projects.	Yes	Consulting w/\$	2/1/03	5/1/07	\$40,000 to date and possible \$120,000 for 3 years. Trav: 2,462 to date and possible 73,086) Company provided Hotel/Travel;
NCI	Pavakis, George N.	Y	Senior Investigator	Intra	450	Y	Kenyon & Kenyon Intellectual Prop Law - Consult and testify as fact witness, case involving human growth hormone. US District Court/Wilmington, DE	Yes	Consulting w/\$	1/13/03	12/30/04	Possible income \$2000-6000;
NCI	Restifo, Nicholas P.	Y	Senior Investigator	Intra	450	Y	Purdue Pharma, LP	Yes	Consulting w/\$	2/23/04	2/23/05	\$10,000 to date/103= 7,500. And \$996.00 expenses)
NCI	Restifo, Nicholas P.	Y	Senior Investigator	Intra	450	Y	Genlinc, LLC - Perform as a Scientific Advisor to Co.	Yes	Consulting w/\$	2/25/03	open	

Ve. r12/16/03

List of Ongoing Consulting Arrangements for IC Employees													
IC	Name (Last, First)	Current Employ. Y/N	NIH Position Title	Intra/ Extra/ Admin	27% Admin	Consult. Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period Start End	Monetary Comp.	Stock & Stock Options	
NCI	Ried, Thomas	Y	Senior Investigator	Intra	450	Y	AvalonTherapeutic Genomics - Consulting re: cancer genomics Immatics Biotechnologies -Consult. W/Co re Peptides as active pharma. Ingredients/Critical review of e.g. scf strategies and approaches, clinical development plans and results from pre- clinical testing & clinical trial	Yes	Consulting w/\$	5/1/00 4/30/05	\$30,000/yr '00- '03=120,000 and 20,000 to date in '04. Total of \$140,000	Stock	
NCI	Rosenberg, Steven A	Y	Medical Officer	Intra	450	Y		Yes	Svc on Bds or Comm with \$/Consulting	9/27/03 9/26/04	\$25,000/yr		
NCI	Schneider, Thomas D	Y	Research Biologist	Intra	450	Y	Physiogenetic Labs Inc. -SAB Becker & Assoc. - Consult on medical device development	Yes	Svc on Bds or Comm with \$/Consulting	9/4/95 8/31/10	\$0		
NCI	Simon, Richard	Y	Suprvy Statistician (math)	Extra	450	Y		Yes	Consulting w/\$	1/27/03 12/31/06	to date, 10,625.00		
NCI	Singer, Alfred	Y	Senior Investigator	Intra	450	Y	Hematech, Inc. -SAB	Yes	Svc on Bds or Comm with \$/Consulting	9/1/00 open	100=2500.701=5,000 102=5,000/03=6,500 0 TRV 00=\$80. And 02 50.00 Total travel is 130. And total Fees \$19,000. 15,000 shares/SO Fees: 02=11,250 103=15,000; EXP 102= 2,127. 03 2,710		
NCI	Topalian, Suzanne L	Y	Medical Officer	Intra	450	Y	Cetus Corp. -SAB	Yes	Svc on Bds or Comm with \$/Consulting	2/1/02 open	Fees to date \$125,000 and \$5000 expenses to date. Is to receive 35,000 peryear fees and \$1,000 travel expenses per year.		
NCI	Wiedmann, Thomas	Y	Medical Officer	Intra	450	Y	Health Case Ventures -SAB	Yes	Consulting w/\$	4/2/98 open	To date: 2,100. And is to receive @2,500 per mg/2x yr/expense of \$700/mg.	S. O.	
NCI	Weinstein, John N	Y	Senior Investigator	Intra	450	Y	ACLARA Biosciences Inc. -membership board/guidance on relevance, quality & direction of research/participate in mtgs/phone calls re:research program	Yes	Consulting w/\$	11/20/03 open	Cum. Expenses \$1,290. 103=50.00; 102=250.00; 101=0.00;	250,000 Shares	
NCI	Young, Howard A	Y	Head, CMS, LEI Microbiologist	Intra	450	Y	Adv. Viral Res. Corp. -SAB to develop a unique immunomodulator. Product R/pt into clinical trials	Yes	Svc on Bds or Comm with \$/Consulting	3/25/02 3/24/05			
NCI	Yuspa, Stuart H	Y	Senior Investigator	Intra	450	Y	Demigen - Adv on Toxicology Studies/Refer business regarding tox. Studies	Yes	Consulting w/\$	12/1/90 open			

Vei 4/2/19/03

List of Ongoing Consulting Arrangements for IC Employees													
IC	Name (Last, First)	Current Employ. Y/N	NIH Position Title	Intra/ Extra/ Admin	278/ 450/ None	Consult. Y/N	Outside Organization & Position Held with Organization	Pharma or Biotech	Nature of Activity	Activity Period		Monetary Comp.	Stock & Stock Options
										Start	End		
												99.01 \$0.0; 02= 21.98 and 03=2,576, 250 Per hour x 32 hrs =8,000/yr. \$500- 600 per trip expenses/2 trips yr total of 9,200/yr.	
NCI	Yuspa, Stuart H	Y	Senior Investigator	Intra	450	Y	Gillette Co -Consult in area of regulation of hair growth and appl of emerging tech.	Yes	Consulting w/\$	2/2002	open		02 only= \$2,830 (99-01/03 are \$0.0) \$2000/day NTE 8,000 yr. For earnings and travel
NCI	Yuspa, Stuart H	Y	Senior Investigator	Intra	450	Y	Proctor & Gamble -Consulting re: hair growth control	Yes	Consulting w/\$	2/1/02	open	\$2,830	

NIH ETHICS CONCERNS: CONSULTING ARRANGEMENTS AND OUTSIDE AWARDS

TUESDAY, MAY 18, 2004

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2322 Rayburn House Office Building, Hon. James C. Greenwood (chairman) presiding.

Members present: Representatives Greenwood, Stearns, Walden, Ferguson, Barton (ex officio), DeGette, and Waxman.

Staff present: Alan Slobodin, majority counsel; Bud Albright, staff director; Ann Washington, majority counsel; Casey Hemard, majority counsel; William Carty, legislative clerk; William Harvard, legislative clerk; David Nelson, minority investigator and economist; and Jessica McNeice, minority staff assistant.

Mr. GREENWOOD. A quorum being present, this hearing of the Oversight and Investigations Subcommittee will come to order. The Chair recognizes himself for purposes of making an opening statement. Good morning to everyone.

In this hearing the subcommittee turns from last week's focus on the lofty aims of the NIH Blue Ribbon Panel on Conflict of Interest Policies to the ignoble case specific realities of how ethics issues have been handled at the NIH. We will look mostly at what led to the weaknesses in the NIH ethics program and what can be learned from this examination to increase the chances for success and improving NIH's ethics program. This examination will highlight two cases illustrating conflicts of interest, concerns rising from consulting agreements and election reports.

Consider the case of Correlogic Systems, a small bioscience company in Bethesda, Maryland, developing diagnostic disease tests. Although a small company, Correlogic attracted the partnership of the Food and Drug Administration, the National Cancer Institute, to develop a test by Correlogic based on an innovative way that attempts to detect diseases by looking at patterns of proteins in the blood as opposed to single biomarkers, the conventional method used by researchers.

Correlogic's test takes a single drop of blood from a patient and scans for patterns of protein fragments through a mass spectrometer. The test was able to detect ovarian cancer in 50 of 50 patients who participated in the study, 100 percent, including patients with earliest stage cancers. Ovarian cancer is the fifth leading cause of

cancer deaths of U.S. women but the survival rate is near 95 percent when ovarian cancer is detected in stage one.

The data produced in this study was a joint effort of Correlogic, the FDA, and the NCI through the FDI, NCI clinical proteomics program. Correlogic's partners were Dr. Emanuel Petricoin of the FDA and Dr. Lance Liotta of the NCI.

In light of these encouraging results in April 2002 the joint effort of Correlogic and the FDA and NCI was converted into a cooperative research and development agreement called a CRDA involving the NCI, the FDA, and Correlogic. A CRDA is an agreement that allows the Government to collaborate with outside organizations on research and development. Dr. Liotta and Dr. Petricoin became the co-principal investigators of CRDA. This was a research created to allow Dr. Liotta and Dr. Petricoin to test Correlogic's software.

One of the purposes of this joint collaboration was to develop technology and develop a strategy that would lead to the prompt commercialization of protein pattern recognition tests first for ovarian cancer patients. Now, at this point, this could have been a great public health story.

A public/private partnership saving the lives of ovarian cancer patients by expediting development of these diagnostic tests. Unfortunately, this story took a different path. Sometime in the spring of 2002 NCI decided to unilaterally sponsor clinical trials on the ovarian cancer test instead of executing a clinical research CRDA with Correlogic.

Since the time that NCI has wanted to unilaterally pursue clinical trials, Correlogic and NCI have been engaged in negotiations for about 2 years now over whether to pursue the clinical trial CRDA.

In the fall of 2002 a company called Biospect recruited Dr. Liotta and Dr. Petricoin to consult for them. Biospect is a competitor of Correlogic. Its mission statement, "Development technology for identifying and assaying protein biomarker pattern," is virtually identical to Correlogic's.

At this time Dr. Richard Clausner, former Director of NCI, was a board member of Biospect. Dr. Carol Dahl, former Chief of the Office of Technology and Industrial Relations at NCI, served as Vice President for Strategic Partnerships. In addition to hiring Liotta and Petricoin, the two co-principal investigators on the Correlogic CRDA and co-inventors of Correlogic's test, Biospect also hired the technology transfer officer from NCI and the person with whom Correlogic had to negotiate its CRDA.

FDA scientists like Dr. Petricoin are subject to stricter ethics regulations than NIH scientists because the FDA is a regulatory agency and would be prohibited from consulting with biotechnology companies. Nonetheless, Dr. Petricoin's request to consult with Biospect was approved in October 2002. Dr. Liotta's request was approved in December 2002. His consulting agreement covered the areas of diagnostic devices, serum handling, and microfluidics but not areas involving data pattern analysis.

Sometime in 2003 Correlogic learned that Liotta and Petricoin were consulting for Biospect. In July 2003 a representative for Correlogic raised concerns that Dr. Anna Barker, the Deputy Director of NCI, about Dr. Liotta's consulting arrangement with

Biospect. As a result of this complaint, the NCI re-reviewed Dr. Liotta's consulting arrangement and reapproved it.

NCI recognized that Biospect and Correlogic did business in the same area, but Dr. Carol Barret, Liotta's supervisor, determined that the consulting was limited to areas that did not overlap with Liotta's official duties.

In the days before this hearing Dr. Petricoin and Dr. Liotta have ceased their consulting arrangements with Biospect but the damage has been done to a promising partnership. Dr. Zerhouni has stated that all public/private partnerships such as cooperative research and development agreements must be transparent but the Correlogic case proves that such transparency can be a fiction.

The NIH and the FDA allowed Government scientists who are co-inventors and creative partners with Correlogic to secretly provide consulting services without the knowledge or consent of Correlogic to Correlogic's competitor which had already hired the NCI tech transfer specialist from the CRDA. What happened to the public trust?

Every day private companies negotiate provisions in business contracts to protect themselves from employees or consultants who might later try to work for a competitor. Indeed, there was such a provision in the Biospect consulting agreement with Dr. Liotta. Yet, in a case like Correlogic a private company entering into a CRDA with NIH cannot protect itself. It risks its Government partners taking the insight, knowledge, and prestige gained from the CRDA to consult with the competition and all under the cover of an ethics approval.

Even under the so-called limited consulting agreement with Biospect, Dr. Liotta was permitted to advise Biospect on what seemed to be commercialization strategies, the very heart at what CRDA was all about. There are a few situations more destructive of public/private partnerships than this one. What company will want to enter a CRDA with NIH if this is the way conflict of interest issues are managed? This isn't transparency. This is an outrage.

In addition to the Correlogic case, the subcommittee will look at the strange story of how NIH officials got to live under a permissive policy for receiving cash gift awards from entities doing business with their institutes. In 1996 Dr. Richard Clausner, who was the Director of the NCI, was notified by the University of Pittsburgh that he had been awarded the Dixon Prize of Medicine associated with a \$30,000 cash gift.

However, ethics officials at the NIH advised him that he could not accept the prize. There were three reasons for this advice. (1) an ongoing lawsuit by famous cancer researcher Dr. Bernard Fisher against the University of Pittsburgh, the NCI, and other co-defendants; (2) an ongoing contract dispute between Pittsburgh and NCI; and (3) the University of Pittsburgh status as a major entity doing business with the NCI, receiving and seeking substantial funding for grants, contracts, and agreements.

In giving this advice, one of the NIH ethics officials conferred with an attorney at the Office of Government Ethics who supported the advice and indicated that Dr. Clausner still could not accept

the award even if he disqualified himself from all matters involving Pittsburgh.

On August 27, 1997, Dr. Fisher and the defendants announced a settlement of the lawsuit which involved a \$2.7 million payment from Pittsburgh to Fisher. However, most of this \$2.7 million actually came from other defendants, not Pittsburgh. One of those defendants was the NCI and available evidence indicates that Dr. Clausner orally approved a \$300,000 payment from the Government as a contribution to the settlement.

At about the same time, the Dixon Prize Awards Committee made up of faculty members of the University of Pittsburgh, decided to recommend Dr. Clausner again for the award. This time the cash gift was increased from \$30,000 to \$40,000. Although the rules for the prize state that the award should be given to the individual who made the most progress in medicine for the year in question, Dr. Clausner was honored for achievements that occurred prior to becoming NCI director in 1995.

Giving the prize to Dr. Clausner in 1997 was like giving the Academy Award to a well-liked actor who just didn't happen to make any movies that year. Within days after the settlement, Harriet Robb, the HHS General Counsel and Presidential appointee, asked Edward Swindell, the Acting Director of the Ethics Division, to see if there was a way Dr. Clausner, Presidential appointee, could receive the prize from Pittsburgh now that the litigation was settled.

Notwithstanding the past guidance from OGE and the concerns raised by the NCI ethics advisor, Mr. Swindell wrote the legal opinion that interpreted the ethics regulations to allow an NIH official to receive a cash gift award from a grantee as long as there wasn't a pending matter in the official's in-box at the time the award was tendered. This interpretation has bound HHS and NIH to this day preventing Dr. Zerhouni from taking immediate steps to place restrictions on awards.

I am pleased that the Office of Government Ethics recognizes in its testimony for this hearing that the HHS interpretation was overly permissive. Although the University of Pittsburgh insist that Dr. Clausner was selected on his merits, serious appearance questions are raised because of the timing and the circumstances of the award.

In addition, it is amazing that the highest ranking ethics official at HHS ignored these appearance questions, disregarded OGE's advice, and may have provided a permissible but incorrect interpretation of ethics regulations to please political appointees.

We invited both Dr. Clausner and Dr. Michael Lotts of the University of Pittsburgh who chaired the awards committee at the time to testify at this hearing. Both indicated that they would be unable to testify. We also invited the NCI's ethics advisor Dr. Maureen Wilson to testify but she had a long-standing personal commitment that prevented her from appearing today. We may have her as a witness at a future hearing.

The subcommittee will hear from two panels of witnesses today. The first panel includes representatives from OGE, HHS, NIH, an ethnics specialist, Congressional Research Service, and Dr. Harold Varmus, the former director of the NIH. The second panel features

witnesses from the NCI, the FDA to discuss the Correlogic case study.

Through this hearing it is my hope we will learn about the problems of day-to-day implementation of NIH ethics issues and in so doing understand what must be done to assure that the good intentions of Dr. Zerhouni are actually carried out.

The Chair welcomes these witnesses and looks forward to their testimony and recognizes the gentlelady from Colorado for an opening statement.

Ms. DEGETTE. Mr. Chairman, I would ask unanimous consent that Mr. Waxman be recognized out of order. He has an obligation on the Senate side.

Mr. GREENWOOD. Without objection, Mr. Waxman is recognized for an opening statement.

Mr. WAXMAN. Thank you very much.

Mr. GREENWOOD. Try to keep it as brief as mine was.

Mr. WAXMAN. If I did, Mr. Chairman, I would forget about my obligation on the Senate side completely. I thank both of you for allowing me to make this statement. Last week the subcommittee held its first hearing on revelations that dozens of NIH scientists had accepted large consulting fees from drug companies. Not only were NIH officials accepting money from companies where interest might have been in conflict, but many of these arrangements were being kept secret from the public.

NIH has a long and proud tradition of scientific independence and integrity. Because NIH is the source of some of our Nation's most important biomedical research, it is essential that America and the world continue to feel confident that NIH's grant decisions and research results are not biased in any way.

Today we will hear from the Government agencies and others directly responsible for enforcing department and Government-wide conflict of interest rules. I am deeply troubled that these groups in whom we have placed responsibility for ensuring the highest ethical conduct from public servants are the very people who sanctioned the loose ethical rules that resulted in the questionable financial relationships we have uncovered.

This subcommittee's investigation has revealed a series of actions by the Office of Government Ethics and by HHS ethics advisors that seem designed not to protect against conflicts of interest but to ease the way for such conflicts. It was the Office of Government Ethics which advised Dr. Varmus in 1995 that NIH was free to lift existing caps on the amounts that NIH scientists could receive from drug companies. As a result of that advice, there is no limit on the amount of money NIH scientists can accept from drug companies.

It was the Office of Government Ethics that drafted the legal opinion concluding that scientists hired under Title 42, including those in senior positions, could not be required to publicly disclose their financial dealings with drug companies. It was HHS ethics advisors who signed off on the huge consulting fees paid to high-ranking NIH officials that triggered this investigation in the first place.

These decisions are the opposite of what people have the right to expect from our Government ethics officials. Unfortunately these

decisions appear to be part of the dubious pattern of covering up conflicts of interest rather than trying to avoid them. This is a pattern also reflected in HHS' highly questionable decision to permit Tom Scully, the head of CMS, to continue to negotiate the Medicare drug benefit legislation while at the same time looking for a new job with the very interest most affected by that legislation.

I want to close on a positive note. Last week I expressed in my statement in the record a particular concern that under the Blue Ribbon Panel's proposal some NIH scientists would still have no obligation to disclose financial relationships with drug companies. NIH testified that despite the agency's own desire for a full disclosure, it had been advised by Federal ethics officials that full disclosure could not be required.

This week I have learned that Dr. Zerhouni has decided to seek new rules to require public disclosure of potential conflicts of interest for all NIH employees. I applaud Dr. Zerhouni for his insistence on full disclosure. Only with full disclosure can we continue to ensure public confidence in the work of NIH. I hope that we hear from today's witnesses that they will not throw up any barriers to Dr. Zerhouni's very appropriate decision. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and ask unanimous consent to enter into the record a letter dated May 17 to Ms. Dara Corrigan, Esq., Acting Principal Deputy Inspector General at the Department of Health and Human Services. This is a bipartisan letter signed by Chairman Barton, ranking member Dingell and myself and the ranking member of this subcommittee Mr. Deutsch asking for a review of the Petricoin case mentioned in my opening statement. Without objection it will be entered into the record.

The Chair recognizes and welcomes the chairman of the full committee for his opening statement, Mr. Barton.

Chairman BARTON. Thank you, Mr. Chairman. This is a very important hearing. I am glad to be a part of it and I appreciate you holding it.

As I said last week, this committee will get the information that it needs to do its oversight. Last week because of the failure of the HHS Department and NIH to produce certain information that this committee had requested on consulting agreements we had to announce that we would seek it from the drug companies.

I am pleased to learn that immediately after our hearing last week the NIH director suddenly discovered the ability to get that information. This committee is now getting the information and we will continue to do so. Let us hope that HHS and NIH have learned that it is absolutely pointless not to provide information and force this committee to force them to cooperate, as I said last week, coercively.

This hearing today will show that the committee is doing more than getting information. We are starting to achieve positive changes in NIH ethics policy both for consulting and for awards. For example, because of the committee's investigation HHS has ordered all of its agencies, including the NIH, to collect an amount of information as part of the approval process for outside activities.

Because of this committee's investigation, the Office of Government ethics is now providing additional guidance on the issue of awards. Finally, the committee has already played a role in spurring efforts by HHS and the Office of Government Ethics to expand the number of NIH employees that will be covered by public financial disclosure requirements. Much more needs to be done, quite frankly, but the committee has played an important role in getting the process moving.

We are also exposing abuses and questionable practices. This subcommittee will examine a remarkable case today in which the NIH and FDA scientists who were collaborating with a private company on a joint invention under a public/private partnership which we call a CRDA were secretly consulting with their private partners competitor.

Incredibly the FDA scientist who worked at the FDA Center for Biologics was allowed to consult with this competitor which was about technology company. Such consultations are prohibited under the stricter supplemental regulations that apply to the FDA but did not apply to NIH. As a result of these secret deals, progress appears to have slowed on a public/private partnership that could lead to prompt commercialization of a lifesaving ovarian cancer diagnostic test. Public trust has been damaged.

In another astonishing case that we will go into today, a permissive HHS policy allowed an NIH director to collect cash gift awards for major grantees under very questionable circumstances. In 1997 Richard Clausner, who was then the NCI director, appeared to be personally involved in approving a \$300,000 payment from the Government to settle a lawsuit filed against both U.S. Government and the grantee with great financial benefit to the grantee.

The grantee almost at the same time offered Dr. Clausner a \$40,000 cash prize. Yet, the official for overseeing the HHS ethics program did not even address the appearance issue and disregarded advice from the Office of Government Ethics. Instead, this official wrote a legal interpretation that would allow Dr. Clausner to accept the prize.

It will be a hallmark of my chairmanship, at least I hope it will be, that we are going to hold agencies responsible for their actions and produce better results in Government ethics and better services and better policies for the American people. That is the purpose of oversight. We will continue to look at NIH. We will also focus our efforts on the FDA.

I want to congratulate Chairman Greenwood for his work on this investigation. I want to thank the ranking members on the minority side for their participation and the staffs on both sides. We are doing this on a bipartisan basis and we are beginning to see results. I look forward to having a productive hearing today, Mr. Chairman. I yield back the balance of my time.

Mr. GREENWOOD. Thank you, Mr. Chairman. The Chair recognizes the gentlelady from Colorado, Ms. DeGette, for an opening statement.

Ms. DEGETTE. Thank you, Mr. Chairman. Before I make my opening statement, I would ask unanimous consent that Mr. Dingell's opening statement and the rest of the opening statements of the committee be made part of the record.

Mr. GREENWOOD. Without objection.

Ms. DEGETTE. Thank you for holding this hearing, Mr. Chairman. I found the hearing last week to be very illuminating and I think this issue is so important and has such ramifications for the integrity of medical research and public health. I am glad that you are having a series of indepth hearings on this issue.

I want to begin by reiterating the statement that I strongly expressed at the last hearing which is I have grave concerns about the Blue Ribbon Panel recommendations. I believe, Mr. Chairman, that we need to consider not only full disclosure and limits on outside compensation, but also even a blanket restriction on outside compensation because of the serious conflicts of interest and the appearance of conflicts of interest.

At last week's hearing we heard the same argument being made over and over by the witnesses. That view is that allowing lucrative contracting agreements between NIH scientists and outside companies in addition to allowing the acceptance of awards that come with a hefty amount of cash attached to them, to name two examples, are key to recruiting and retaining quality scientists and researchers.

Now, a fact that everybody knows but no one really talked about too much is that the current rules did not always exist. The caps on outside compensation were lifted in the mid-1990's, something I think Dr. Varmus will talk to us about.

Up to that point there were monetary restrictions on what these Federal employees could receive from outside groups, for example, and there was certainly more public disclosure in this regard. I think what we really need is more information about the situation at NIH before the restrictions were done away with. Did the NIH have serious problems with recruiting and retaining high-level talent? Was the NIH a lower quality institute before 1995 due to this problem? If so, was the problem because of the outside compensation?

If that is the case, I would like to get some factual evidence to support this because it has been repeatedly given as the reason that this is so important to the integrity of the NIH. We also need to see if limitations on outside compensation and awards, as well as disclosure, will go far enough to prevent the kinds of conflicts that the Chairman himself highlighted in his opening statement.

One of the things that has been reported on, and was also included in the Blue Ribbon Panel Report, is that many employees including senior level scientists at the NIH are increasing demoralized by the scrutiny and criticism that this issue has cost lately.

In addition, it has been alleged that the confusing nature of the current rules is also confusing and dispiriting to staff. I think this is really too bad because these staff members are simply trying to wade through the rules and do what the rules allow them to do. However, I think that there is an implication in the report that somehow it is the media and congressional examination that is the problem rather than the issue itself.

It is not the fault of the scientists that they are under a cloud of suspicion as it is characterized in the report but it is the system that has created this situation. There has also been a lot of talk about perceptions of conflicts of interest and how it has been a mo-

rare problem at the NIH. The fact of the matter is there are serious conflicts of interest issues. We heard this last week. We are going to hear it again today. Those conflicts of interest must be scrutinized for everyone's sake including, and perhaps most importantly, the NIH scientists that they apply to.

The resolution of this problem, which means completely cleaning up what is currently happening, is to preserve the reputation of the NIH and the integrity of everybody who works there.

Now, there is one solution that from our perspective would be really simple. If we completely banned outside compensation there would be a bright line and the confusion would disappear. In the absence of persuasive evidence that this policy would seriously hamper the science, I believe we should seriously consider this option.

I also want to say one thing that won't help the situation is if we keep layering onto the current system and revamp it in a way that causes even more confusion, especially for the scientist, and making changes that will surely allow for future transgressions will not help either.

For example, if as proposed by the Blue Ribbon Panel certain restrictions on consulting fees are instituted for certain employees but there is no change as to regulations regarding receipt of bona fide cash awards, then surely what we will see, and we see this with campaign finance reform all the time, is a shift to more and larger cash awards in other places like for prizes. The money influx won't change. It will just shift around and it will be very confusing for all involved.

I think what we need to do is try to get a grip on this and we need to challenge all of our assumptions including the assumptions that we simply can't get good people without these large amounts of outside compensation. I think that is the nub of the issue and I really look forward to hearing all of our witness' view on this.

Again, Mr. Chairman, thank you for holding this hearing and I look forward to hearing the testimony.

Mr. GREENWOOD. Thank the gentlelady. I recognize the gentleman from New Jersey, Mr. Ferguson.

Mr. FERGUSON. Thank you, Mr. Chairman. Thank you for holding this hearing and for your diligence in pursuing this investigation of possible conflicts of interest at NIH.

NIH provides our country and the world with world-class research done by the best scientists and doctors our country and the world has to offer. Although it is important that NIH attract and retain the best and the brightest in the fields of medical research, we must be assured that the professionals at NIH are conducting themselves according to the highest standards.

Last week we heard from Dr. Zerhouni and the members of the Blue Ribbon Panel about the recommendations to establish policies against conflicts of interest. I look forward to hearing from today's witnesses concerning two examples where the line may have been crossed and the best interest of medicine may have been compromised. This committee and Congress must do all that it can to ensure that NIH maintain a spotless reputation free from any question as to the mission and goals of the professionals at NIH.

Just before I close, I just had a group of advocates for ALS research in my office. They are fanning out across Capitol Hill today and making a very persuasive argument for increased NIH funding for ALS research. Clearly it is something that needs to be done and we in the Congress want to advocate for that.

But whether it is the hearings we had some months ago about, frankly, scientifically dubious grants that are awarded sometimes by NIH, frankly, sometimes morally objectionable grants that are sometimes made by NIH, or whether it is a conflict of interest issues that we are dealing with now, it is extremely important that NIH maintain its stellar reputation and its spotless reputation for doing research and for conducting itself with the highest standards possible.

People's lives depend on it. The lives of our children, our grandchildren, and their grandchildren depend on the research that you do. The only way you are going to be able to continue to do that important research is to keep folks like us out of your hair. We can only stay out of your hair if we know for certain that you are doing your job in a way that we don't need to be getting involved in your business.

That is one of the reasons I feel so strongly about these hearings and one of the reasons I appreciate the Chairman and the ranking member of the full committee and the subcommittee for encouraging this investigation.

We are big fans, I anyway am, and I know we all are fans of NIH and the research and the important work that NIH does. That is why it is so important for NIH to maintain its reputation for integrity. Thank you, Mr. Chairman. I yield back.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentleman from Florida, Mr. Stearns, for an opening statement.

Mr. STEARNS. Good morning and thank you, Mr. Chairman. Obviously this is a very important hearing and I appreciate your calling it. I think last week we sort of looked at this from a helicopter and I guess we could say we are looking at it this morning perhaps on the ground. We are trying to understand some of the details about this.

We talk about the field of science being one inherently cooperative and collaborative. Scientists and physicians and researchers need to share and study alongside one another. I think we all understand that. Of course, we saw in the 1980's and 1990's and that we were losing good researchers to the private sector. For the Federal Government obviously to compete for these scientists we provided some financial incentive so Congress took the step to try and create some competition and allow us to keep these scientists.

Perhaps, as we see today, Mr. Chairman, the pendulum has swung too far. We hear different exploits about arrangements between NIH and high-level researchers and industry. I am concerned about perhaps some of the smaller universities or the mid-level universities not getting an opportunity to participate in NIH grants because they can't get their foot in the door because of the ties of maybe these prestigious universities or scientists are not directing or not allowing some of these mid-level or small colleges to get involved with some of the grants.

All this calls into question what can we do here in Congress. Can we allow this continuing incentive for scientists to remain in place? At the same time, obviously, like my colleague from New Jersey, we have supported increased funding for NIH and we think it is important in the long run to get this ground breaking detection on ovarian cancer. I think all of us are a little disturbed about this and that is why I think this hearing will get to the bottom of it and will bring out some good examples of things it will show us that we probably need some action. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. MICHAEL BILIRAKIS, A REPRESENTATIVE IN
CONGRESS FROM THE STATE OF FLORIDA

Thank you, Mr. Chairman. I appreciate all the work that you and your staff have done to examine these two specific cases of consultation fees and outside awards before us today. Last week's hearing focused on what the NIH is doing to create greater oversight of this important matter, and I think that we can all agree that Dr. Zerhouni's creation of the Blue Ribbon Panel is a step in the right direction. However, I don't know that it is enough. While I am not interested in laying blame today, I am glad to having the opportunity to discuss these two specific cases, and find out how severe this problem was.

I appreciate both panels of witnesses taking the time to come here today, even though I'm sure you all will be asked some difficult questions. I'd like to extend a special thanks to Dr. Harold Varmus, former Director of NIH, for his testimony today. Dr. Varmus has testified before my subcommittee several times, and I am anxious to hear his thoughts.

The ethical concerns being raised today in this hearing are worrisome to me. However, during this discussion, I also believe it is critical we remember that the NIH is the world's leader in conducting important research that will unlock critical information and lead to discoveries beneficial to patients suffering from many diseases. We don't want to hinder those efforts. But because of the tradition of excellence, the NIH is also held up to a certain standard. That standard should not be tainted by the thought that the research conducted at NIH is influenced by private companies giving money to institute directors.

My Subcommittee on Health has held four hearings during the 108th Congress to highlight research activities at the NIH and educate Members and others about the work that the NIH is doing so we can better assess how to help NIH better meet its stated mission. One of the reasons my Subcommittee has held these hearings is that, while NIH does exemplary research, their transparency and accountability in the approval process of investigator-driven grants at the NIH could be improved. Many times it is difficult for Members of Congress to get a quick answer about research activities, let alone the general public.

The lack of transparency of the NIH processes could be one of the reasons that we are holding this hearing today. If there were more transparency with respect to these consulting fees and awards, such as making the information public, then maybe there wouldn't be the need for a high level of concern.

As I said last week, the fact that some NIH officials have received cash, stock, and stock options from consulting arrangements with drug or biotechnology companies really gives me pause. While I understand that there is importance in allowing scientists the opportunity to pursue their independent work, I have concerns with tying the financial success of an individual to a particular company's stock. If outside consultation fees and award grants in any way affect the grant approval process and the budget priority setting at NIH, then that taints the entire NIH process, including the research.

I am glad that we have this forum today to speak to officials from NIH, and hear the comments of other agencies, such as the Food and Drug Administration (FDA) and Ethics offices. I am curious to hear how the NIH has managed possible conflicts of interest, and the degree that they have been effective.

Thank you, Mr. Chairman. I yield back the balance of my time.

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF MICHIGAN

Mr. Chairman, again let me commend you for conducting this investigation and holding this hearing, as well as the one last week, into conflicts of interest at the National Institutes of Health (NIH). The scientists at the NIH campus, and the grantees that use NIH funds for their biomedical research, are critical to this Nation's fight against disease. These hearings are being held because several NIH researchers have decided to supplement their taxpayer-funded salary with monies provided by drug and biotech companies, firms whose vital interests are tied to the research performed at the NIH.

Today we will hear from Dr. Harold Varmus, a Nobel laureate and a former Director of NIH. He was the responsible official in 1995 when all effective administrative controls were lifted from the consulting practices of NIH employees and public disclosure was virtually removed as well. Dr. Varmus has much to account for, as does the current NIH leadership and the Department of Health and Human Services (HHS) lawyers who have systematically undermined the application of any meaningful ethical standards to the consulting arrangements of NIH employees.

As a direct result of this investigation and one conducted by the *Los Angeles Times*, some changes have been made or have been agreed to by the current Director. This is a good thing, but not nearly enough. Last week, Dr. Zerhouni and the co-chairs of the so-called Blue Ribbon Panel testified that, except for the highest level employees and those administering grants, all other NIH researchers would be free to continue to serve two masters provided that they received the approval of something called the NIH Ethics Advisory Council (the NEAC). This Council was supposed to apply the most rigorous standards to its review of outside consulting arrangements.

All NIH employees with current outside arrangements with drug or biotech firms were supposed to suspend those arrangements in February and reapply to the NEAC. While over half the NIH employees engaged in these apparent conflicts chose not to reapply, about 120 did. Several NIH researchers have been approved by NEAC to receive payments from companies that had agreed to pay them hundreds of thousands of dollars (one researcher had received almost \$2 million from biotech firms in recent years). This is not acceptable.

Finally, I cannot help but note an even worse case of an ethical violation approved by the Department. One of the witnesses scheduled to appear today is an employee not of the NIH, but the Food and Drug Administration (FDA). He signed a contract to receive thousands of dollars from a biotech company whose products could be regulated by his employer, the Center for Biologic Evaluation and Research. This appears to be in direct conflict with the Supplemental Regulations for FDA that forbid receipt of monies by any employee from any regulated entity.

Ethics officials at FDA and/or HHS apparently approved this "outside employment." FDA has told the Subcommittee staff that any approval was an error without precedent elsewhere in that Agency. I certainly hope that is the case but intend to join with you, Mr. Chairman, in asking for an expedited review of all outside employment by FDA employees as well as the HHS and FDA review of the consulting arrangement that we will discuss today.

Thank you again for holding this hearing, and for the bipartisan manner in which this entire inquiry has been handled.

Mr. GREENWOOD. The Chair thanks the witnesses for your patience for half an hour of opening statements, 15 minutes of which was mine, I think. We welcome each and every one of you. Let me introduce our first panel.

Ms. Marilyn L. Glynn is the Acting Director of the U.S. Office of Government Ethics. Welcome and thanks for being with us this morning.

Mr. Edgar M. Swindell, Associate General Counsel, Ethics Division, Department of Health and Human Services. Good morning, sir.

Dr. Raynard S. Kington, Deputy Director of the National Institutes of Health. Good morning, sir. Thank you for joining us.

Mr. Jack Maskell is with the American Law Division of the Congressional Research Service. Thank you for your service.

And, finally, Dr. Harold Varmus, M.D., Former Director of the National Institutes of Health and is currently the President and Chief Executive Officer of the Memorial Sloan-Kettering Cancer Center in New York. Good morning, sir. Welcome to all of you.

It is the custom and practice of this committee to take testimony under oath so I would begin by asking if any of you object to giving your testimony under oath. Seeing no objection, it is then my responsibility to inform you that you are entitled to be represented by counsel if you wish. Do any of you choose to be represented by counsel this morning? Okay. In that case, if you would rise and raise your right hands, I will give you the oath.

[Witnesses sworn.]

Mr. GREENWOOD. You are under oath. Ms. Glynn, we will begin with you and you are recognized for 5 minutes for your opening statement.

TESTIMONY OF MARILYN L. GLYNN, ACTING DIRECTOR, U.S. OFFICE OF GOVERNMENT ETHICS; EDGAR M. SWINDELL, ASSOCIATE GENERAL COUNSEL, ETHICS DIVISION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; RAYNARD S. KINGTON, DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH; JACK MASKELL, AMERICAN LAW DIVISION, CONGRESSIONAL RESEARCH SERVICE; HAROLD VARMUS, FORMER DIRECTOR, NIH, PRESIDENT AND CHIEF EXECUTIVE OFFICER, MEMORIAL SLOAN-KETTERING CANCER CENTER

Ms. GLYNN. Thank you for the opportunity to appear today to discuss executive branch ethics rules relating to consulting activities and awards. Mr. Chairman, you asked that I particularly address these issues, consulting and awards, as they pertain to the situation at NIH.

By way of brief background, let me explain that my office, the Office of Government Ethics, or OGE as it is called, is the executive branch agency responsible for directing policies relating to the prevention of conflicts of interest on the part of executive branch employees.

Of particular relevance to the issue before the subcommittee today are OGE's standards of conduct regulations. Pursuant to an Executive Order issued by the first President Bush, these standards of conduct are intended to be a uniform set of ethics rules for the entire executive branch. However, agencies may add special provisions to address any agency specific needs. My office must approve these so-called supplemental agency regulations.

First I would like to say a few things about the awards issue. The OGE standards of conduct contain a provision authorizing employees to accept certain bona fide awards for meritorious public service or public achievement. This awards rule is an exception to the usual prohibition of acceptance of gifts from prohibited sources or gifts given because of your official position.

There are two key questions about this rule that have a bearing on the issues you are examining today. First, what are the permissible sources of these awards, particularly where the award recipient is the head of an agency or the head of an office or a large com-

ponent in an agency. And, second, how do you distinguish between real awards and mere speaker's fees.

In my written statement I have set out in some detail how OGE would analyze both of these questions and I would be happy to answer any questions you might have about those tests we set out.

The second issue you asked me to speak about concerns rules governing outside activities such as consulting for compensation. The rules are designed to be reasonably flexible and they reflect a balance between the rights of employees to have a life outside of work with the need for the Government to demand the highest ethical standards from its employees.

Generally speaking, the rules permit compensated consulting unless the activity would require recusal from matters center or critical to the employee's position, or if the activity would violate a particular statute or regulation such as the OGE rules prohibiting the use of public office for private gain.

There are essentially two approaches that an agency can take to implement this rule. First, an agency can review outside activities of each individual employee on a case-by-case basis in light of the general standards found in the OGE rules. Or an agency can seek approval from OGE to issue a so-called supplemental regulation restricting certain specific outside activities for all employees at that agency or certain groups of employees.

Since 1995 NIH has followed the case-by-case approach. However, though, recent accounts in the media and elsewhere about NIH consulting activities raise concerns about the nature and extent of consulting arrangements that have been approved under the case-by-case approach. I think it becomes clear that either the system for reviewing the proposed activities on this case-by-case approach should be strengthened by NIH or NIH should develop specific supplemental regulations tailored to the circumstances of NIH.

We have received the report of the Blue Ribbon Panel on conflicts of interest policies and note that it recommends the adoption of some additional restrictions. OGE is ready to help NIH and its parent, HHS, implement whatever restrictions they think would be necessary to ensure public confidence in the important work of NIH.

My written statement provides further details concerning these rules relating to outside activities and I would be happy to answer any questions you may have.

[The prepared statement of Marilyn L. Glynn follows:]

PREPARED STATEMENT OF MARILYN L. GLYNN, ACTING DIRECTOR, OFFICE OF
GOVERNMENT ETHICS

Mr. Chairman and members of the subcommittee: Thank you for the opportunity to appear today to discuss Executive Branch ethics rules pertaining to consulting activities and awards from outside sources. Mr. Chairman, you asked in particular that I address issues that have arisen at the National Institutes of Health with respect to employees' consulting activities and outside awards. I will discuss these subjects and provide OGE's views on the general legal questions. Before discussing these specific topics, I want to provide the Subcommittee with background information about OGE and its role in the Executive Branch ethics program.

THE EXECUTIVE BRANCH ETHICS PROGRAM AND OGE'S ROLE

Established by the Ethics in Government Act of 1978, OGE is the executive branch agency responsible for directing policies relating to the prevention of con-

licts of interest on the part of Federal executive branch officers and employees. OGE develops rules relating to ethics and conflicts of interests, establishes the framework for the public and confidential financial disclosure systems, develops training and education programs for use by executive branch ethics officials and employees, and supports and reviews individual agency ethics programs to ensure they are functioning properly.

As the supervising ethics office of the executive branch, OGE has developed and issued various executive branch-wide regulations in Title 5 of the Code of Federal Regulations, including the Standards of Ethical Conduct for Employees of the Executive Branch (Part 2635), rules that implement the financial reporting requirements in the Ethics in Government Act (Part 2634), and rules that implement criminal conflict of interest laws (Parts 2635, 2637, 2640 and 2641). Pursuant to the Ethics in Government Act and Executive Order 12674 (as modified by E.O. 12731), regulations interpreting the provisions of sections 207, 208, and 209 may be promulgated only with the concurrence of the Attorney General, while regulations establishing a single set of executive branch standards of conduct and a system of nonpublic financial disclosure are promulgated in consultation with the Attorney General and the Office of Personnel Management."

Many of the rules bearing on the issues of concern to the Subcommittee today are found in OGE's Standards of Ethical Conduct. OGE issued these rules originally in 1992, pursuant to the order of the first President Bush to "establish a single, comprehensive and clear set of executive-branch standards of conduct that shall be objective, reasonable, and enforceable." E.O. 12674, § 201(a). In keeping with the President's goal of promoting uniformity in the application of ethics requirements across the executive branch, the OGE standards were to supercede any agency-specific standards, unless an agency sought and obtained approval from OGE to issue supplemental regulations "of special applicability to the particular functions and activities of that agency." *Id.* at § 301(a).

While OGE provides direction and overall leadership to the executive branch ethics program, the head of each agency has primary responsibility for the ethics program at his agency. Each agency head appoints a Designated Agency Ethics Official (DAEO) to manage the ethics program and act as a liaison to OGE. The DAEO and his staff ensure that the required ethics program elements are accomplished. Basic elements and responsibilities of an agency ethics program include effective collection and review of financial disclosure reports; ethics training that meets the requirements of OGE's training regulations; an employee counseling program; and prompt and effective action for violations of the ethics rules. With respect to the issues of concern to the Subcommittee today, I would note that the duties of agency officials also include the approval of certain kinds of outside awards and the review and approval of certain outside activities.

OGE provides training and guidance to agency ethics officials in numerous ways. Among other things, OGE: publishes advisory opinions and issues memoranda to ethics officials; conducts periodic national and regional training courses; communicates regularly with ethics officials through an electronic list service; provides consultative services to agency officials through the OGE desk officer system and through telephonic and written advice from OGE legal staff.

OGE also monitors and evaluates the executive branch ethics program through periodic reviews of the ethics programs at each agency. The purpose of these reviews is to ensure that agencies have developed effective ethics systems and procedures, in compliance with OGE regulations, to prevent conflicts of interest and other violations of ethics laws and regulations. Typically, the focus of these reviews is on agency systems, rather than instances of misconduct by individual employees. Individual misconduct by employees is investigated by the Office of Inspector General responsible for each agency.

AWARDS

OGE understands that the Committee has two primary questions about the receipt of outside awards by employees. The first question pertains to the permissible sources of such awards, and the second question pertains to the distinction between an award and an honorarium for giving a lecture. In order to address these questions, it is first necessary to set out the purpose and requirements of OGE's awards rule.

The awards rule, 5 C.F.R. § 2635.204(d), is actually an exception to certain statutory and regulatory gift prohibitions. See 5 U.S.C. § 7353; 5 C.F.R. part 2635, subpart B. Generally, employees are prohibited from receiving gifts from certain prohibited sources and gifts given because of an employee's official position. Prohibited sources include any person who: (1) is seeking official action by the employee's agen-

cy; (2) does business or seeks to do business with the employee's agency; (3) conducts activities regulated by the employee's agency; (4) has interests that may be substantially affected by performance or nonperformance of the employee's official duties; or (5) is an organization a majority of whose members are such persons. 5 C.F.R. § 2635.203(d).

The awards rule provides an exception to these gift prohibitions where the gift is a "a bona fide award or incident to a bona fide award that is given for meritorious public service or achievement." An important limitation on the exception is that the donor must not be a particular type of "prohibited source," i.e., a person who has interests that may be substantially affected by the employee's duties (or an association or organization in which the majority of members have such interests). Moreover, if the gift has an aggregate value in excess of \$200 or is in the nature of cash or an investment interest, an agency ethics official must make a prior written determination that the award is part of an "established program of recognition" that meets additional criteria specified in the rule.

1. *The source limitation*

One question that has been raised is whether the head of an office, such as the Director of one of the Institutes at NIH, may receive an award from an entity that has grants, contracts or other business with the same office. In other words, is someone doing business with a particular office always going to be a person who has interests that may be substantially affected by the duties of the head of that office, even if the head of the office has delegated the relevant functions to subordinates and does not currently have any personal involvement in matters affecting that source?

OGE has not issued written guidance on this question. One possible reading of the regulation might be that the head of an office "may" have duties that could affect any person doing business with that office. The theory would be that the head of the office has authority over every matter pending in his office and therefore has the power, whether exercised or not in any given instance, to intervene in any such matter. Regardless of any delegations or other attenuating circumstances, the office head always "may" still perform the duties that would affect the source.

While this may be a reasonable interpretation, OGE declines to adopt such a broad reading. For one thing, we think it important that the source limitation uses terms such as "performance" and "duties," which suggests that some actual involvement by the employee must at least be reasonably foreseeable. Other ethics provisions expressly cover matters that are merely under an employee's "official responsibility," and we could have used such language in the awards rule, but did not. *See, e.g.,* 5 C.F.R. § 2637.202(b)(2) (all matters pending in agency are under official responsibility of agency head). Moreover, since the awards rule intentionally carves out only a particularly problematic subset of prohibited sources, it would be somewhat peculiar to say that the agency head and other senior management essentially may never receive an award from anyone involved with the agency; again, we have drafted other rules that expressly apply special provisions to agency heads and other senior officials, but that was not the course chosen in the awards rule. *See, e.g.,* 5 C.F.R. §§ 2635.102(b) (conduct of agency head); 2635.807(a)(2)(i)(E)(3) (activities of high level political appointees).

Perhaps most important, we think the broad interpretation would lead to unreasonable results. Under this interpretation, virtually every person doing business with an office would be an impermissible award source for the office head, regardless of the size of the office or the nature or importance of the business. For example, a relatively autonomous component of a very large agency might make a significant number of modest grants to various associations, universities, and other nonprofits to fund meetings or other informational events on a wide range of non-controversial topics, with such grants being handled routinely by employees several levels below the agency head and without any foreseeable intervention by higher level officials. Under these circumstances, we do not believe it would make sense to say that an association whose sole connection to the agency is one of these lower level grants would be an impermissible source for an otherwise legitimate award to the agency head. The broad interpretation of the source limitation could produce even more extreme results. For example, a component of an agency may procure paper products from a supplier; even though the head of the agency may have the legal authority to participate in this purchase, there is very little likelihood that the agency head would become involved in such matters, and it would seem unreasonable to say that the paper supplier would be an impermissible source for an award.

At the same time, however, we do not believe it is necessary or desirable to limit the reach of the source restriction to those situations where the donor currently has matters before the head of an office personally. Nor do we think the restriction can

be avoided merely because the head of an office usually or normally leaves such matters to subordinates. In our view, the word “may” in the source limitation does not mean that it must be “more likely than not” that the office head will intervene in a matter substantially affecting the source. If there is at least a reasonable prospect that the office head may become involved in a matter, we do not believe that a donor who could be substantially affected by such involvement should be allowed to grant an award, possibly with the hope of building good will with the office head in the event that his intervention may be needed or desired.

The approach we would follow, therefore, is one of reasonableness: is it reasonable to assume that the office head may become involved in a matter substantially affecting the interests of the donor, or is the chance of such intervention simply a remote and speculative possibility? To assist agency ethics officials in making such determinations, we have identified several factors they should consider, in light of the totality of the circumstances:

- How have such matters been handled historically by the office? For example, is there precedent for the office head becoming involved in matters of this type and/or matters involving this particular donor in the past?
- Are matters of this type typically handled at a level far below the office head, or are they handled at an intermediate level somewhat closer to the agency head?
- How large is the office for which the employee is responsible?
- Is there a multitude of similar matters pending somewhere in the office at any given time, such that the matter affecting the donor may be less likely to have any particular prominence?
- How important or sensitive is the matter? For example, does the matter involve a significant dollar amount or is there any particular controversy or novelty? On the other hand, is the matter relatively routine and one that does not call for the exercise of significant discretion?
- Is the office head typically apprised of such pending matters and any attendant issues, for example, through status reports that identify the affected source?
- Can it be said that the donor is a regular “constituent” or “stakeholder” with respect to the programs and operations of the office? For example, does the particular donor have a number of matters pending in the office or does the donor regularly seek business or official action from the office?

The foregoing list of factors is not intended to be exhaustive, and ethics officials should consider any information indicating that it is more or less foreseeable that an office head would be in a position to exercise duties substantially affecting a particular donor.

Finally, OGE wants to emphasize that the awards exception is subject to the same general limits as all the other gift exceptions in the OGE standards of ethical conduct. Among those limitations is the caveat that employees may not “[a]ccept gifts from the same or different sources on a basis so frequent that a reasonable person would be led to believe the employee is using his public office for private gain.” 5 C.F.R. § 2635.202(c)(3). Although it is not feasible to specify a bright line test for frequency of awards, we do think that ethics officials should be cautious where high level employees have a history of accepting awards of significant monetary value, as such circumstances can increase the risk that an official may appear to be using public office for private gain.

2. *Awards vs. compensation for services*

A second issue pertains to the relationship between the awards exception and other ethical limitations concerning the receipt of earned income and compensation. In particular, questions have been raised about whether certain “lectureships” or “lecture awards” are permissible awards, or more appropriately should be treated as outside earned income or compensation for speaking. In certain instances, there have been concerns that impermissible outside earned income or compensation for speaking related to the employee’s official duties may have been misidentified as permissible awards. OGE shares these concerns and recognizes that agency officials must exercise judgment to distinguish true awards from what are essentially speaking fees.

Quite apart from the rules pertaining to awards and other gifts, there are ethical restrictions that focus on the receipt of earned income or compensation in certain situations. Certain Presidential appointees are prohibited from receiving “any earned income for any outside employment or activity performed during” their Presidential appointment. Executive Order 12731, § 102. Similarly, a provision in the Ethics in Government Act limits the annual amount of outside earned income that certain high level political appointees, such as noncareer members of the Senior Executive Service, may receive to 15 percent of the annual rate of basic pay for level II of the Executive Schedule. For these purposes, earned income generally means

“compensation for services.” 5 C.F.R. § 2636.303(b). This includes compensation for an employee’s services as a speaker, such as “honoraria.” *Id.* Earned income does not, however, include items that may be accepted from a prohibited source under the gift rules in the Standards of Ethical Conduct. § 2636.303(b)(1).

There is another restriction that focuses specifically on compensation for speaking. Under 5 C.F.R. § 2635.807(a), all employees—not just Presidential appointees or other noncareer personnel—are prohibited from accepting compensation for speaking that is related to their official duties. Like the restrictions on earned income discussed above, section 2635.807(a) covers payments for an individual’s activities or services, specifically “any form of consideration, remuneration or income . . . given for or in connection with the employee’s teaching, speaking or writing activities.” § 2635.807(a)(2)(iii). Similar to the definition of earned income, the definition of “compensation” in section 2635.807(a)(2)(iii)(A) does not include “items that could be accepted from a prohibited source under Subpart B” of the Standards of Ethical Conduct.

It should be apparent from this discussion that the rules governing awards and the rules governing compensation or earned income serve different purposes and have different requirements. On the one hand, a bona fide award for meritorious public service or achievement is a gift, which may be received notwithstanding the gift prohibitions, under certain circumstances. Payments for speaking activities, on the other hand, are not considered gifts but compensation for a service or activity, and the permissibility of such compensation is judged by different standards than those governing the receipt of gifts. The exclusion of certain gifts governed by Subpart B of the Standards of Ethical Conduct from the definitions of earned income and compensation underscores the distinct treatment of gifts and compensation or earned income.

Nevertheless, OGE recognizes that it may not always be immediately apparent to employees and agency officials whether a particular offer from an outside source should be viewed as a gift subject to the awards exception or as compensation for a speaking activity. This is especially true where an employee is offered something of value in connection with a “lectureship” or “lecture award” sponsored by an outside organization. In some instances, it may not be clear whether the real intent of the payment is to honor the employee for meritorious public service or achievement, or to compensate the employee for providing a speech on a subject of interest to the sponsor or the intended audience.

The question is further complicated by the fact that even clearly bona fide awards programs sometimes involve the recipient giving a substantive speech, i.e., not merely a brief “thank you” or acceptance remarks. For example, recipients of the Nobel Prize for Medicine—which is cited specifically in the OGE rule as an example of a bona fide award—deliver a “Nobel Lecture” which can be of significant duration and scientific content. *E.g.*, www.nobel.se/medicine/laureates/2002/horvitz-lecture.html (one of three co-recipients in 2002 delivered 51 minute lecture, complete with data and graphs). Plainly, the delivery of a speech by an award winner is not, in and of itself, enough to convert an award into earned income or compensation for speaking, for purposes of the ethical restrictions discussed above.

By the same token, invitations to engage in speaking activities often are motivated by the speaker’s past accomplishments. The fact that the sponsor of a lectureship extends an offer of compensation based on the prospective speaker’s curriculum vitae does not, in and of itself, mean that the lectureship is an award as opposed to a compensated speaking engagement. Even if the lectureship itself carries a certain prestige within a particular profession or discipline, the primary intent of the sponsor still may be to obtain the services of a well-qualified speaker for an event.

OGE has not had occasion to issue written guidance on this question, but we believe that the appropriate approach to such questions is to determine whether the primary purpose of the arrangement is to honor the employee for meritorious public service or achievement, or to compensate the employee for services as a speaker. In a somewhat analogous area of federal income taxation, we note that authorities have focused on whether an award is “intended primarily to provide gratuitous honorific recognition of achievement” or instead is “primarily compensatory in nature.” *Rogallo v. United States*, 475 F.2d 1, 2, 5 (4th Cir. 1973); see generally Kogan, *The Taxation of Prizes and Awards: Tax Policy Winners and Losers*, 63 Wash. L. Rev. 257 (1988) (historic concern for awards as disguised compensation). Given the range of award and lecture programs, this analysis inevitably involves a case-by-case consideration of any factors bearing on the purpose or intent of the particular program.

OGE has identified several factors that can be relevant to such determinations. The list that follows is by no means intended to be exhaustive. Moreover, in many

cases, no one factor will be determinative, and agencies will have to discern the primary purpose of the program from the totality of the circumstances.

- How has the sponsor historically characterized the program? It would be relevant, for example, if the sponsor's written materials traditionally have referred to the program as "an award" or, alternatively, as a "lecture series."

- How is the event promoted by the sponsor? For example, extensive publicity by the sponsor advertising the speech as the draw for attendance at an event could indicate that the speaker was invited primarily to attract an audience for a lecture. Of particular concern would be publicity by the sponsor in which the event is portrayed as an opportunity for the audience to receive specialized information or unique insights from the speaker.

- Is it the policy of the sponsor to make the delivery of a speech a condition of receiving the award? If the award winner has the discretion to accept the full award but decline to make a speech, then the arrangement almost certainly would be an award rather than a compensated speaking activity. As noted above, however, the fact that an award winner may be expected to make a speech does not necessarily mean that the award is primarily intended as compensation for speaking.

- What is the nature of the expected speech? If the speech consists of little more than brief acceptance remarks, the award can hardly be characterized as compensation for speaking. It also may be relevant whether the anticipated speech would convey new or previously unpublished information, or focus in significant part on new or ongoing work of the speaker; this could suggest an intent to compensate the recipient for the content of the speech rather than to honor the recipient for past work. On the other hand, a speech merely reviewing the past work for which the speaker is being honored could well be consistent with a purpose to honor the recipient gratuitously for past achievement.

CONSULTING ACTIVITIES

One of the major areas that can give rise to conflict of interest questions is outside activities. Two basic issues must be addressed when an employee proposes to engage in an outside activity: whether the employee may participate in the outside activity at all, and, if so, what limitations apply to such participation.

a. Conflicting Outside Activities and Appearance Problems

OGE's Standards of Ethical Conduct for Employees of the Executive Branch prohibit an employee from engaging in an outside activity that conflicts with his official duties. 5 C.F.R. § 2625.802. An outside activity will conflict with an employee's official duties if it is prohibited by statute or an agency supplemental regulation, or if the disqualification required to avoid a conflict of interest is so central or critical to the performance of the employee's official duties that his ability to perform his job is materially impaired.

There are two substantive provisions that may require disqualification or recusal. A criminal statute, 18 U.S.C. § 208, prohibits employees from participating in certain matters affecting their personal and imputed financial interests. An OGE regulation, 5 C.F.R. § 2635.502, provides for employees and agency officials to consider recusal from matters involving persons with whom the employee has certain business and personal relationships. When an employee wishes to participate in an outside activity that will require recusal under either of these provisions, agency officials must exercise informed judgment to determine whether the scope of any recusal will materially impair that employee's ability to do his job. Such management determinations take into account a variety of factors, including the nature of the employee's duties, the needs of the office, and the ability to reassign projects in the office.

Even if an outside activity is not prohibited under this standard, it may nonetheless violate other principles or standards and therefore be prohibited. One important standard is that employees may not use their public office for their own private gain or the private gain of others with whom they have certain relationships. 5 C.F.R. § 2635.702. Certain outside activities may be prohibited under this standard, whether or not the activity would require the employee to recuse from matters that are central or critical to the position. For example, even if the head of an office reasonably can recuse from a matter affecting an entity with which he has a consulting arrangement, there still could be an appearance that the entity is benefiting from the employee's official position: depending on the circumstances, one might reasonably question, for instance, whether subordinates involved in the matter would feel subtle pressure to favor the entity with which their supervisor has a substantial business relationship. Moreover, some outside consulting relationships may involve a subject matter that is so closely related to an employee's official work that the overlap would give rise to an appearance that the employee took advantage of his

official position to obtain the outside consulting opportunity or that the employee is providing insights obtained on the job only to those willing to pay.

The Standards provide that whether “particular circumstances create an appearance that the law or these standards have been violated shall be determined from the perspective of a reasonable person with knowledge of the relevant facts.” 5 C.F.R. § 2635.101(b)(14). Agencies are undoubtedly in the best position to determine if an outside activity is permissible under these Standards generally, and with respect to appearances in particular. Some things that an agency should consider in making a decision about whether participation in an outside activity will create the appearance that an employee is using public office for private gain are the level of the employee’s position and the nature of his duties; the subject of the outside work and its relation to agency programs and operations; the identity of the outside employer and its relationship to the agency, including whether it receives grants or contracts; and the timing of the offer of employment.

Although the standards mentioned so far generally require a case-by-case consideration of the proposed outside activity, the OGE Standards also permit agencies to promulgate blanket prohibitions on certain outside activities. These prohibitions, called supplemental agency regulations, must be approved by OGE, pursuant to an Executive Order requiring OGE concurrence in any departures from or additions to the uniform standards of conduct applicable to the entire executive branch. The Department of Health and Human Services, in fact, has promulgated certain supplemental prohibitions on outside activities. 5 C.F.R. part 5501.

We note that a 1995 OGE review of the NIH ethics program discovered that NIH had a series of restrictions on outside consulting that were not promulgated in accordance with the procedures prescribed in the Executive Order. OGE directed that NIH either remove these restrictions or propose them for inclusion in the HHS supplemental regulation. At that time, NIH chose to remove the restrictions and did not propose any additional outside activity restrictions in the HHS supplemental regulation. As we understand it, NIH decided to rely on case-by-case evaluations, under the general standards applicable to all executive branch employees.

Subsequently, questions have arisen concerning the current NIH system and the need for more specific restrictions on certain kinds of outside activities. In this connection, we understand that NIH now is considering recommendations from the Blue Ribbon Panel on Conflict of Interest Policies, which panel is a Working Group of the Advisory Committee to the Director, which was appointed by the Director of NIH. The Panel report makes numerous recommendations, including proposals for supplemental regulations governing certain outside activities, such as consulting. OGE has received a copy of this report and is in the process of reviewing it. If the Department of Health and Human Services decides to request amendments to its supplemental regulation, in response to any recommendations of the Panel, OGE stands ready to assist the Department and act expeditiously on any request.

b. Limitations When an Outside Activity Is Undertaken

The Standards of Ethical Conduct provide that an employee who is engaged in an outside activity must comply with all applicable provisions set forth in the ethics rules and statutes. This includes rules that prohibit the misuse of official title, authority, resources, information, and time in connection with outside activities. There are also important restrictions on representing others before the Government and serving as an expert witness in matters affecting the Government. Additionally, certain noncareer employees are subject to limitations on outside earned income, compensated service on boards of directors, and involvement with entities providing professional services of a fiduciary nature.

Particularly relevant in the context of the present inquiry are the rules that require employees not to participate in certain Government matters when their own interests, or the interests of certain others, are affected by such matters. As mentioned above, disqualification or recusal from certain matters may be required under 18 U.S.C. § 208 or 5 C.F.R. § 2635.502. The obligation to recuse when necessary and to ensure that a disqualification is observed always remains the personal responsibility of the individual employee subject to the disqualification. An employee should notify his supervisor when he becomes aware of the need to disqualify himself from certain matters because of a potential conflict of interest. Once it is determined that the outside activity is permissible, the employee’s supervisor has a responsibility to facilitate the disqualification by ensuring that the employee is not assigned to work on matters from which he is disqualified. Agency ethics officials obviously have an important role through direct counseling to, and education of, employees and supervisors to ensure that they understand when a recusal is required and how to effectively implement a required recusal.

OGE PROGRAM REVIEWS AT NIH

As I stated earlier, OGE conducts systemic reviews of all executive branch department and agency ethics programs to determine whether agencies have developed effective ethics systems and procedures, in compliance with OGE's regulations, to prevent conflicts of interests. OGE typically has conducted reviews of approximately 35 agencies annually, with major agencies being reviewed approximately every 5 to 6 years. Agencies are selected for review based on the length of time since their last review, OGE staff concerns about an agency's program, and news media reports of ethical concerns.

These reviews generally focus on several ethics program elements, including the structure and staffing of the ethics program, the financial disclosure systems, the ethics education and training program, the advice and counseling services, the outside activity approval process, ethics systems for advisory committees, acceptance of travel payments from non-Federal sources under 31 U.S.C. § 1353, ethics staff relations with the Office of Inspector General, and ethics issues unique to that agency. In large agencies or departments, OGE may look at how the ethics program is managed in its individual components rather than the entire agency. The reviews do not typically look at individual employee cases of conflict. On occasion concerns about an individual employee will arise in the course of a review, and OGE will consider the facts giving rise to the concern and make appropriate recommendations.

Since 1990, OGE has completed three program reviews at NIH. These prior reviews focused on, among other issues, NIH practices and policies pertaining to teaching, speaking, writing and other outside activities. OGE has initiated a 2004 review of the NIH ethics program. This review is being performed at the Office of the Director, NCI, NIAID, and the Clinical Center. The focus of the current review is on the structure and staffing of NIH's ethics program, the public and confidential financial disclosure systems, the criteria and process for approving outside activities, and the criteria and process for approving the acceptance of awards. The review is ongoing.

CONCLUSION

In closing, I would like to emphasize that OGE stands ready to work with you, the Committee, HHS, and NIH to ensure that the public has the highest confidence in the important work of all the components at NIH.

I would be happy to answer any questions you may have.

Mr. GREENWOOD. Thank you very much, Ms. Glynn.
Mr. Swindell.

TESTIMONY OF EDGAR M. SWINDELL

Mr. SWINDELL. Mr. Chairman and members of the subcommittee, thank you for inviting me to speak with you today. I also have a prepared statement that I will submit for the record.

I am the Assistant General Counsel for Ethics at the Department of Health and Human Services and as such my principal role is to provide legal advice to the Secretary and the General Counsel on Government ethics and related issues. In addition, I serve as the designated agency ethics official for HHS under the Secretary's direct appointment.

Today I was the primary point of contact with the Office of Government Ethics and we have a program within HHS that is decentralized. There are deputy ethics counselors that run ethics programs within the Department.

Based upon these qualifications I am here today to speak to the committee. I would first like to emphasize to the committee that the goal of ensuring public confidence and the integrity of NIH is one that the Department shares very much with the committee and a goal which we can work together to accomplish.

As NIH moves forward with the help of the Department to address areas of concern, the Department values the committee's in-

formed views. Secretary Thompson has a goal of making HHS the leading cabinet agency on ethics matters.

However, I understand that concerns have been raised by the committee about a perceived lack of the responsiveness on the part of the Department or on the part of the Office of General Counsel within the Department with particular attention to information requested by the committee regarding outside consulting arrangements involving NIH employees.

I would like to assure you that the Department is fully committed to cooperating with the committee. In response to the NIH's request to ask employees for information regarding outside compensation. The Department through OGC has worked extensively to identify and resolve legal issues that are relevant to pertaining this information.

When the committee first asked NIH to obtain amounts of compensation for outside activities, these amounts were unavailable for those individuals who file a confidential OGE 450 financial disclosure form or who do not file any financial disclosure form at all. This is because OGE has historically viewed the form as serving a conflicts of interest purpose rather than a disclosure purpose. The conflicts analysis for reviewing potential outside activities has historically focused Government-wide on the type and source of compensation rather than the amount.

HHS strove to help NIH find a way to collect the information and was successful in doing so. This information is critically important and so I have taken steps consistent with the privacy act to obtain this data in the future for all outside activity requests.

HHS advised NIH about the privacy act and its requirement that collection and maintenance of identifiable information be for purposes authorized by statutes, regulations, or executive order. Although the interest of Congress alone would not be a sufficient legal basis to collect and maintain the information, an agency interest pursuant to statutes, regulations, or executive order would be an appropriate basis. Accordingly, the Department sought to identify such a legal basis.

On January 27, 2004, I issued a directive informing the DEC's, the ethics counselors, that in the context of any agency evaluation, of any previously approved ongoing outside activity for continued compliance with existing law, and in order to request prior approval for any new outside activity employees would be required to provide both retrospective, if applicable, and prospective compensation information. Such amounts were to be noted on the HHS 520 and this allowed NIH to collect compensation amounts for all ongoing outside activities.

I would note that the form we have been using is from 1982 and we have canvassed other departments and agencies and found out that of the other cabinet departments about nine of them don't even have such forms that we have. Then five of them have forms and they don't ask for this type of amount of information either. We are going to be working to make sure that our form is the best possible form for dealing with outside activities that we have.

HHS explained to the committee staff the potential difficulties in collecting information pertaining to completed and closed outside activities. Referencing these discussions in its February 25 letter to

the Department, the committee said, "The Department is attempting in good faith to assist the committee."

In addition, HHS continued to work to develop an interpretation of the Ethics in Government Act that would support the collection of information for completed outside activities. In so doing, we discussed the legitimate and important need for NIH to collect the information NIH and OGC felt was important for the agency to collect.

As a result, OGE agreed with us that the Ethics in Government Act and its implementing regulations providing the DAEO, and therefore the Agency, with authority to evaluate the agency's supplemental ethics regulations to determine their continued adequacy and effectiveness in relation to current agency responsibilities. This determination supported the collection of information regarding completed and closed activities with pharmaceutical and biotechnology companies.

As a result of these efforts, Dr. Zerhouni was able to write to the committee on March 12, 2004, that "We consider this collection [of information] authorized by the Ethics in Government Act of 1978 and Executive orders mentioned above." It is my understanding that NIH decided to manage litigation risk from NIH employees who might not wish to comply with a required collection of information by first attempting to collect the information on a voluntary basis.

However, I understand that Dr. Zerhouni is now going to instruct all NIH employees who had consulting arrangements since January 1, 1999 to report the compensation amounts received pursuant to the consulting as a requirement and condition of their employment subject to discipline.

The Department has also worked with NIH and the committee to facilitate an appropriate and timely response to other aspects of the committee's investigation. The issue of appropriate ethical oversight is critically important to the Secretary. In fact, under the Secretary's and the General Counsel's leadership the ethics division that I head has undertaken a series of efforts to enhance its functions but particularly to institute systematic oversight of components ethics programs, review of financial disclosure forms, and training to employees.

Our staff has been small. We have a large agency. It has operated decent programs. We have had little ability to be able to know what is going on absent situations that come up like this or the OGE reviews that occur every 4 to 6 years. We are going to do what we can to make sure that we have internally the knowledge to know what is going on.

Our staffing will more than double from 11 in my office to 25. This, to my knowledge, will make us the largest single legal office devoted exclusively to Government ethics outside of OGE. The steps we are undertaking will enhance the Department's operations and work on behalf of the public. Therefore, the Department will continue to cooperate with the committee as it addresses these important issues. In this manner working together our two branches of Government can achieve our collective goal of ensuring public confidence in agency programs and operations through whatever means that will best accomplish that objective.

I will be pleased to answer any questions you have.
[The prepared statement of Edgar M. Swindell follows:]

PREPARED STATEMENT OF EDGAR M. SWINDELL, ASSOCIATE GENERAL COUNSEL FOR ETHICS, OFFICE OF THE GENERAL COUNSEL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, Mr. Deutsch, and members of the subcommittee: Thank you for inviting me to speak with you today to discuss the ethics issues relating to the National Institutes of Health (NIH).

The goal of ensuring public confidence in the integrity of NIH is one that the Department very much shares with the Committee B and a goal which we can best accomplish together. The Committee's oversight in this area has been edifying and helpful in identifying areas of concern. As NIH moves forward, with the help of the Department, to address those concerns, the Department values the Committee's informed views and welcomes the Committee's suggestions regarding steps that can be taken to ensure that the tremendous trust that the Congress and the public place in NIH is as unquestioned as the vast contributions NIH has made towards advancing the nation's health and the promise it holds to continue doing so. To this end, we believe the recommendations of the Blue Ribbon Panel provide an important perspective and serve as a helpful starting point.

As Associate General Counsel for Ethics, my principal role is to advise the Secretary and the General Counsel on government ethics, restrictions on political activity by federal government employees, and related issues. Concurrently, under an appointment directly from the Secretary, I serve as the Designated Agency Ethics Official (DAEO) for the Department. The DAEO is the point of contact with the Director of the Office of Government Ethics (OGE). That office sets ethics policy for the entire executive branch under an Executive Order issued by the first President Bush replacing a system of individual agency regulation of employee conduct.

I understand that concerns have been raised by the Committee about the role of the Office of General Counsel, within the Department, in responding to the Committee's oversight, with particular attention to information requested by the Committee regarding payments, expenses, and stock options paid to NIH employees for consulting arrangements since January 1, 1999. NIH proposed asking employees for information regarding compensation for outside activities. Accordingly, the Department, working through OGC, has worked extensively with NIH and the Committee's staff, as well as other federal agencies, to identify and resolve legal issues relevant to obtaining this information.

When the Committee first asked NIH to obtain amounts of compensation for outside activities, these amounts were unavailable for those individuals who file the confidential OGE 450 financial disclosure form or who do not file any financial disclosure form. This is because OGE has historically viewed the form as serving a conflicts of interest purpose rather than a disclosure purpose. And the conflicts analysis for reviewing potential outside activities has historically focused, governmentwide, on the type and source of compensation rather than the amount. For the same reason, the HHS 520 form, used for review of potential outside activities, did not, until my January 27, 2004 memorandum, request the amount of compensation. Historically, OGE has advised that it did not view the dollar amount as normally relevant to the outside activity conflicts analysis.

HHS strove to help NIH find a way to collect the information and was successful in doing so. This information is critically important and so we have taken steps, consistent with the Privacy Act, to obtain this data in the future for all outside activity requests.

HHS advised NIH about the Privacy Act, and its requirement that collection and maintenance of identifiable information be for purposes authorized by statutes, regulations, or Executive Order, and that such authority must be cited in the Privacy Act statement accompanying the request for information. Although the interest of Congress alone would not be a sufficient legal basis to collect and maintain the information, an agency interest pursuant to statutes, regulations, or Executive Order, would be an appropriate basis. At first, we hoped that the Ethics in Government Act, administered by OGE, could serve such a basis. The difficulty was that OGE did not historically believe that amounts of compensation were normally relevant to conflicts analyses.

OGC worked with OGE to devise an interpretation of the authorities provided in the Ethics in Government Act that would support the collection of compensation amount information for ongoing activities as well as activities being reviewed for compliance with the relevant rules. At that time, OGE did not believe that the au-

thorities in the Ethics in Government Act could support the collection of compensation amount for completed and closed outside activities.

On January 27, 2004, I issued a directive informing Deputy Ethics Counselors [DECs] that in the context of any agency evaluation of any previously approved, ongoing outside activity for continued compliance with existing law and in order to request prior approval for any new outside activity, employees would be required to provide both retrospective (if applicable) and prospective compensation information. Such amounts were to be noted on the HHS 520. This allowed NIH to collect compensation amounts for all ongoing outside activities.

HHS explained to Committee staff the potential difficulties in collecting information pertaining to completed and closed outside activities. Referencing these discussions in its February 25, 2004 letter to the Department, the Committee said "the Department is attempting in good faith to assist the Committee."

In addition, HHS continued to work to develop an interpretation of the Ethics in Government Act that would support the collection of information for completed outside activities. In so doing, we discussed the legitimate and important need for NIH to collect the information NIH and OGC felt was important for the agency to collect. As a result, OGE agreed that, in this case, the Ethics in Government Act and its implementing regulations providing the DAEO with authority to evaluate the agency's supplemental standards to determine their continued adequacy and effectiveness in relation to current agency responsibilities, supported the collection of information regarding completed and closed activities with pharmaceutical and biotechnology companies. OGC further applied the same reasoning to all for-profit entities.

As a result of these efforts, Dr. Zerhouni was able to write to the Committee on March 12, 2004, that "We consider this collection [of information] authorized by the Ethics in Government Act of 1978 and Executive orders mentioned above." It is my understanding that NIH decided to manage litigation risk from NIH employees who might not wish to comply with a required collection of information by first attempting to collect the information on a voluntary basis.

However, because of inadequate response, I believe that Dr. Zerhouni is now going to instruct all NIH employees who had consulting arrangements since January 1, 1999 that are now closed to report the compensation amounts received pursuant to the consulting as a requirement and condition of their employment.

Background. HHS has a workforce of more than 60,000 individuals, of which approximately 1,000 file public financial disclosure reports and 25,000 file confidential financial disclosure reports and receive annual ethics training. These 60,000 employees safeguard the nation's health and provide essential human services through myriad programs, policies, and initiatives that affect countless stakeholders and a large part of the American economy. Whether in allocating grant funds, awarding contracts, entering into public-private partnerships, approving lifesaving drugs, protecting patient privacy, or reducing health care costs, our employees must address the concerns of the many while avoiding the appearance or fact of undue influence by the few. To assist those who bear that responsibility, the Ethics Division advises on how to ensure these duties are carried out impartially and unimpeachably. This is largely accomplished through legal advice to agency decision-makers and ethics officials, guidance to employees, education of the workforce, development of guidance documents, and, when necessary, liaison with OGE.

In HHS, as in most large Cabinet Departments, the DAEO oversees and coordinates a decentralized Departmental ethics program. As DAEO, I appoint Deputy Ethics Counselors (DECs) chosen by each operating division, such as the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and NIH. Each of these DECs, along with agency heads and management in each component, are responsible for running ethics programs tailored to the needs of extensive, geographically dispersed workforces composed of many professionally trained employees with varied responsibilities that range from insuring the health care needs of the elderly and disadvantaged to ensuring the safety and efficacy of drugs and medical devices.

The DECs are senior management officials within each component, and they have staff who assist them in carrying out the ethics functions, either as collateral duties or as members of an ethics program office. NIH in particular has such an office under its DEC. As managers closest to day to day operations, they are equipped and responsible for identifying and evaluating the relevant ethics issues in their component. Additionally, the DECs and their staff possess the scientific and technical expertise necessary to identify and resolve ethics issues in situations involving science, medicine, and other complex fields. Within their respective operating divisions, the DECs are responsible for establishing a system for reviewing public and confidential financial disclosure forms, considering outside activity requests, providing ethics ad-

vice to individual employees, initiating ethics education and training programs, and ensuring that violations of the conflicts statutes or the conduct standards are reported to investigatory authorities and where appropriate, seeing that disciplinary action is taken. Individual employees are, of course, ultimately responsible for their own actions.

In addition, the Ethics Division has responsibilities similar to those of a DEC but for the Office of the Secretary and with respect to political appointees. Staff lawyers within the Ethics Division provide legal advice to the DEC's to assist them in their role in making ethics decisions. Furthermore, we conduct training such as an all day DEC workshop each year to keep DEC's current on ethics law, and approximately thirty ethics officials from across the Department attend the annual OGE conference and its various break-out sessions or classes conducted on a wide variety of ethics topics. OGE's periodic program reviews or audits provide us with a sense of how well the Department's components meet their ethics responsibilities. In these reviews, OGE has recognized that the Ethics Division provides sound guidance and instruction and that a clear "road map" is in place.

Ethics Initiative. Based upon a process begun by the General Counsel in December, the Ethics Division has undertaken a series of efforts to intensify our ability to scrutinize and oversee the Department's ethics activities. We are dedicating additional resources to enhance the Ethics Division. As part of this initiative, the Department will institute systematic oversight of the ethics programs within the various operating divisions of the Department through regularized compliance auditing and program review, as well as dramatically strengthen our ability to provide guidance to these programs and their officials. The initiative will increase component accountability for ethics program implementation, augment financial disclosure review and training development, and enhance the capabilities of the Ethics Division and the authority of the DAEO. Our staffing will more than double from 11 to 25. To my knowledge, this will make us the largest single legal office devoted exclusively to government ethics, outside of OGE. We will create two units within the Ethics Division: the Advice and Financial Disclosure Branch and the Education and Program Review Branch. These branches will be staffed by a mix of attorneys, paralegals, computer/training developers, legal resource analysts, auditors, and support staff.

The steps we are undertaking will enhance the Department's operations and work on behalf of the public. Specifically, this initiative will strengthen the Department's identification and prevention of employee actions that would or would appear to be motivated by private, pecuniary, or associational interests, rather than an impartial assessment of the public interest.

Historical Context. To provide further background to the Committee in connection with its review of these issues, following is an understanding of how we came to where we are on the issues of financial disclosure, outside consulting arrangements, and awards at NIH.

a. *Financial Disclosure.* The degree to which the public may have access to the personal financial information of employees at NIH is governed by federal law and OGE regulations. The Ethics in Government Act and implementing regulations in 5 C.F.R. part 2634 provide for two types of financial reporting: (1) public disclosure of detailed information about assets, income, liabilities, and outside affiliations on a report form called the SF 278; and (2) a less intrusive, confidential version known as the OGE 450. On the SF 278, filers must disclose income amounts and asset values within broad categories, by checking, for example, a block indicating a figure between \$1,001 and \$15,000, and so on. The OGE 450 does not ask for any disclosure of amounts, only the identity of holdings and income sources, in other words, the information necessary at a minimum to assess conflicts.

By statute, the public SF 278 filing requirement is reserved exclusively for highly paid, senior employees, such as Senate confirmed Presidential appointees, non-career and career members of the Senior Executive Service, Schedule C political appointees in the General Schedule, uniformed service officers in the Public Health Service Commissioned Corps at pay grade O-7 or above, Administrative Law Judges, and employees in other pay systems if the lowest rate of basic pay for that pay plan exceeds \$104,927 per year. The confidential OGE 450 basically is filed by career employees in the General Schedule, generally at grade levels 12 or above, and by special Government employees who do not serve beyond 60 days. Under current law, increased public disclosure can occur only through a process of demonstrating to OGE that the duties of a particular position B that would not ordinarily be required to file publicly under the existing rules B is nevertheless equivalent to the positions that do file. This process is required because many of the alternative pay systems at NIH do not have minimum rates of basic pay that exceed the threshold.

In 1997, the Ethics Division wrote to the Director of OGE asking for an interpretation of the law to require employees hired under the authority of Title 42, Section 237, establishing the Senior Biomedical Research Service (SBRS), to file SF 278s if the actual annual salary received by the employee was equal to or above 120% of the rate of basic pay for GS-15, Step 1. The letter urged that these employees be required to file public financial disclosure forms and argued that not doing so would be “inconsistent with what would seem to be the prevailing rule in the post-employment context [and] appears contrary to the purpose of the public financial disclosure requirement. Conceivably an...employee with a salary equivalent to an Assistant Secretary would not be required to file a Public Financial Disclosure Report...[A]ll SBRS employees with such salary above 120% of the GS-15, step 1, level should be automatically required to file a Public Financial Disclosure Report.”

On February 11, 1998, the Director of the OGE declined that request and responded that for purposes of the public financial disclosure requirement, the term “rate of basic pay” was defined as “the lowest level of pay authorized for a position’s pay grade.” Director Potts opined that the definition of “rate of basic pay” for SBRS employees is the lowest step or entry level pay authorized for a particular pay grade or range. Thus, since the entry level minimum pay authorized for SBRS positions is set by statute as the minimum rate payable for GS-15, and since that will always be less than the Ethics in Government Act SF 278 threshold of 120% of GS-15, Step 1, the SBRS employees would not be required by the Ethics in Government Act to file public financial disclosure reports. Like the SBRS employees hired under the authority of Section 237, the employees hired under the authority of section 209(f) (who do not have any fixed rate of basic pay) have a “rate of basic pay” that is less than the statutory SF 278 threshold.

Although, for the reasons stated above, “Title 42” employees are not statutorily defined as SF 278 public financial disclosure report filers, it is our understanding that all of the NIH Institute and Center Directors who were appointed under section 209(f) continued to file public financial disclosure form SF 278s even during the time they were not required to do so. To ensure that this continues to be the case, as well as to increase transparency with respect to the next level of senior employees identified by NIH, we have been successful in securing an OGE equivalency determination for 93 positions that requires, as of February 6, 2004, the Directors, Deputy Directors, Scientific Directors, and Clinical Directors within each NIH Institute and Center to file publicly available SF 278s. This determination was in response to our letter of January 12, 2004. Following our request that NIH identify other positions with equivalent authority and responsibilities that meet the statutory test, we recently forwarded to OGE a list of another 506 positions for this special classification.

b. *Outside Consulting and Financial Interests.* HHS employees currently are required by an agency supplemental regulation to seek prior approval only for professional or consultative activities, teaching, speaking, or writing, and board service. They submit an HHS Form 520 that solicits detailed information about the proposed activity, and each operating division may specify various levels of review, which may start with the supervisor and end with the DEC.

The HHS Form 520, which was designed in 1982 and has since remained virtually unchanged. It does not require the applicant to specify the amount of compensation to be received in connection with the outside activity. Until recently, it was not understood that this information would be relevant to the outside activity approval process because the requisite legal analysis focuses on the identity of the payor and the nature of the outside activity. This information is critically important and so I have taken steps, as DAEO, consistent with the Privacy Act, to obtain this data in the future for all outside activity requests.

Approval requires an assessment of whether the proposed outside activity violates any statute or regulation, including the OGE Standards of Ethical Conduct for Employees of the Executive Branch or the HHS supplemental ethics regulation. Included in the OGE Standards is the requirement that the proposed activity cannot create an actual or apparent conflict that would result in recusals that would materially impair an employee’s ability to do his job.

In evaluating conflicts, the reviewer must address two provisions that form the core of Federal ethics law. A criminal statute, 18 U.S.C. § 208, deals with an “actual conflict” due to the employee’s own or imputed financial interest in the resolution of a government matter. A regulatory provision in the OGE Standards, 5 C.F.R. § 2635.502, principally addresses disqualifications called for when an “appearance of a conflict” arises from a “covered relationship.”

Under section 208 of the criminal code, to avoid a conflict of interest that results, for example, from stock ownership or outside employment, a federal employee must not participate personally and substantially in a particular matter that, to his

knowledge, directly and predictably affects his own financial interest or that of his outside employer. To prevent an “appearance of a conflict” that results from serving in a role short of employment, for example, as an advisor, consultant, or other type of independent contractor compensated with fees and expenses, a different rule applies [6 CFR 2635.502].

Both sections are disqualification provisions in that they do not prohibit the acquisition of an asset or relationship, rather they bar actual “participation” in a potentially conflicting matter, either personally or through the direct and active supervision of the participation of a subordinate. However, neither section is triggered by mere knowledge of, or official responsibility for, a particular matter. In short, under 5 C.F.R. § 5501.106(d)(4), prior approval to engage in an outside activity “shall be granted,” provided there are no other statutory or regulatory impediments.

In addition, a number of statutes and regulations do preclude certain outside activities. For example, if an employee sought approval to be a lobbyist, the anti-representation statutes, 18 U.S.C. §§ 203 and 205, would be implicated. If the activity were clearly one that should be done as an official duty, then approval would be denied, under 18 U.S.C. § 209, as an improper salary supplementation. Another regulation prohibits the use of public office for private gain 5 CFR 2635.702.

Another regulation, 5 C.F.R. § 2635.807, precludes compensation, subject to certain exceptions, if an employee wants to teach a course, deliver a speech, or write a book that relates to his official duties. (Consulting, technically, is not covered by this section, but the analysis does provide guidance in evaluating many outside activities.) For career employees, compensation is precluded if, among other things, the teaching, speaking, or writing deals in significant part with any current assignment (or one completed within the last year) or any ongoing policy, program, or operation of the agency. However, the provision contains an important explanatory note. A career employee may receive compensation for “teaching, speaking, or writing on a subject within the employee’s discipline or inherent area of expertise based on his educational background or experience even though the [activity] deals generally with a subject within the agency’s areas of responsibility.”

Finally, there are also special ethical restrictions that focus on the receipt of earned income by political appointees. Under Executive Order 12,731, issued by the first President Bush and modifying Executive Order 12,674, certain Presidential appointees may not receive “any earned income for any outside employment or activity performed during” their Presidential appointment. Similarly, the Ethics in Government Act limits the annual amount of outside earned income, including honoraria, that highlevel political appointees such as noncareer members of the Senior Executive Service may receive. This year, that limit is \$23,715.

As noted earlier, outside activities must also comply with applicable provisions governing the avoidance of actions creating an appearance of violating the ethical standards, including the prohibition against use of official position for an employee’s private gain or for the private gain of any person with whom the employee has employment or business relations or is otherwise affiliated in a non-governmental capacity.

As can readily be seen, supervisors, ethics program officers, and the DEC’s, in particular, have difficult assessments to make when reviewing outside activity requests. For example, at NIH, review of the requests often necessitates an ability to analyze the relationship between technically complex official scientific duties and similarly complex outside activities, both of which might be in the same general field of expertise. Even when the activities are approved, individual employees remain personally responsible for abiding by their recusal obligations and avoiding violations of any other applicable provisions. These responsibilities are exacerbated by mergers, acquisitions, joint ventures, partnerships, and even name changes, within industry that, on any given day, may make it difficult to know whether one has a conflict to avoid.

As outlined in the Blue Ribbon Panel report, prior to 1995, NIH had stringent internal policies that barred certain outside activities, limited the amount of outside compensation, capped the number of hours that could be spent in outside work, and precluded the receipt of stock or stock options as compensation. However, during a program review conducted in 1995, OGE notified NIH that its requirements went beyond the 1993 executive-branch wide Standards of Ethical Conduct. By Executive Order, OGE was required to ensure uniformity within the executive branch with respect to the core ethics requirements. OGE did not permit agencies unilaterally to impose ethics requirements or policies that were more restrictive than the OGE Standards, absent the submission to OGE for its approval a supplemental regulation with adequate justification. The then NIH Director did not pursue that option, and the internal policies at NIH were changed to conform to the case-by-case evaluation process prescribed in the OGE regulations.

Therefore, whether NIH employees can hold “drug or biotech” stocks or consult with companies in these industries is governed by the application of OGE regulations. Currently, conflicting stock holdings are subject to a de minimis exception that allows employees to work on specific party matters as long as the value of the affected stock does not exceed \$15,000 and on a general matter if the value of any one affected holding does not exceed \$25,000, subject to a \$50,000 cap when cumulating all affected interests. Also, NIH employees can consult with various companies involved in scientific research, if the legal requirements are satisfied.

c. *Awards.* Another important issue is whether NIH employees should be allowed to receive bona fide awards from outside entities with interests affected by NIH programs and operations. Depending upon the resolution of these questions, it is conceivable that the NIH Director might be barred from receiving the Nobel Prize in Physiology or Medicine because, as we understand, the awarding entity on behalf of the Nobel Committee is the Karolinska Institute, which collaborates in research matters with NIH.

Bona fide awards for meritorious public service or achievement are conceptualized as gifts. Gifts to executive branch employees are governed by 5 U.S.C. § 7353, which bars the solicitation or acceptance of anything of value from persons or entities defined as prohibited sources, subject to such reasonable exceptions as the supervising ethics office for the executive branch, by regulation, deems appropriate. OGE implemented this statute in the Standards of Ethical Conduct for Employees of the Executive Branch at 5 C.F.R. Part 2635, Subpart B. These rules expressly permit employees to accept bona fide awards and cash incident thereto from most prohibited sources, e.g., contractors, grantees, regulated entities, applicants for governmental action, etc., including organizations a majority of whose members are of the enumerated type, provided that the award is determined by agency ethics officials to be part of an established program of recognition, as defined in regulatory criteria. Specifically, under 5 C.F.R. § 2635.204(d)(1), the reviewer must ascertain whether the award is made as part of an established program of recognition for meritorious public service or achievement:

- (1) Under which awards have been made on a regular basis or which is funded, wholly or in part, to ensure its continuation on a regular basis; and
- (2) Under which selection of award recipients is made pursuant to written standards.

This exception to the prohibited gifts rule is unavailable, however, if the awarding entity is a special type of prohibited source, i.e., a person or entity who “has interests that may be substantially affected by the performance or nonperformance of the [award recipient’s] official duties.”

As OGE notes in their testimony today, “one possible reading” of this phrase could be to bar an agency official from receiving an award from any entity that has matters pending under that individual’s official responsibility, i.e., from any entity or person doing business with the recipient’s office, or it could specify a “situational” approach predicated on the interpretive assumption that the use of terms such as “performance” and “duties” suggests that some actual involvement by the official must at least be reasonably foreseeable. Included with the Committee’s initial inquiry on this subject was an opinion of the Congressional Research Service that suggests the former interpretation. When NIH asked for help in preparing a response to the Committee’s inquiry and the Congressional Research Service analysis, I drafted a White Paper describing the existing policy and its derivation.

That paper pointed out that, because the above-quoted phrase appears in OGE’s regulation, the phrase’s meaning is ultimately a matter for OGE deliberation, that OGE has not formally opined on it, and that OGE may well choose a different approach than that of the Department. Furthermore, the paper observed an alternative to OGE clarification: that AFederal departments and agencies were authorized to issue, jointly with OGE approval, supplemental ethics regulations to establish prior approval procedures for outside activities, to impose prohibited financial holdings requirements, and to address ethics issues unique to the programs and operations of the respective agencies.®

Today, the Acting Director of OGE provides in her statement the first definitive written guidance on the subject. OGE’s analysis articulated in her testimony today does not adopt a bright line. Moreover, some of the factors relied upon by HHS are factors she has articulated. We are required to implement the OGE interpretation, of course, absent a change in law, OGE regulation, or, one other important possibility. As mentioned in the White Paper provided to NIH and, in turn, to the Committee last July, agencies are “authorized to issue, jointly with OGE approval, supplemental ethics regulations to . . . address ethics issues unique to the programs and operations of the respective agencies.” Therefore, if NIH policymakers decided to go so far as to outright prohibit the receipt by all or certain NIH officials or employees

of all or some awards from outside entities with which NIH interacts, a request for such a provision could be included in a supplemental regulation submitted for OGE approval.

In addressing the issue of awards, it is necessary to guard against monetary awards and prizes that may appear to be little more than a payment for delivering a speech. As noted earlier, federal employees cannot receive compensation for speaking that relates to their official duties within the meaning of a very detailed regulation, 5 C.F.R. § 2635.807. Moreover, a criminal statute, 18 U.S.C. § 209, bars federal employees from receiving a supplementation of salary for performing their official duties, and another, 18 U.S.C. § 201, proscribes illegal gratuities tied to an official act. But a bona fide award for meritorious public service or achievement and any money that is associated with the honor are considered gifts, rather than compensation. As you can readily see, there is a continuum between the permitted activity on the one hand B accepting a prestigious award with the prize money and then delivering the speech that is routinely expected of the honoree at the award presentation B and the prohibited activity on the other B accepting money to deliver a speech in the guise of receiving an award.

Unfortunately, the ethics rules do not provide us much guidance in distinguishing between the two scenarios. Fortunately, the Acting Director of OGE in her written statement submitted today has endeavored to tackle these issues and has even sent us in the direction of tax law for help in determining whether an award is "intended primarily to provide gratuitous honorific recognition of achievement" or is instead "primarily compensatory in nature." I am grateful to Director Glynn and her staff for providing this valuable assistance.

It must be considered that even though particular conduct may be permitted under the applicable statutes and regulations, and even where employees sincerely believe there is no appearance of impropriety in the conduct, there may be instances where employees should exercise common sense and prudence to abstain from the conduct. However, ethics officials are not empowered to compel that abstention.

In conclusion, the Blue Ribbon Panel's recommendations are certainly a helpful starting point. But we remain open-minded and interested to hear from NIH regarding its evaluation of the recommendations. As the Department moves forward with respect to the recommendations and requests from NIH, we will carefully consider what steps should be taken. At the same time, HHS, and, in particular, the expanded Ethics Division [of the Office of General Counsel], will continue accelerating and implementing our plans to independently audit ethics programs in the Department's components, ensure extensive education and training, increase transparency in the form of thorough and accurate disclosure, and provide advice and ethics counsel to the nation's premier professionals in the ever-changing field of biomedical research.

We would also very much welcome hearing from the Committee about what changes it believes are required to strengthen the ethics rules, policies, and procedures at NIH. HHS will continue to cooperate with the Committee as the Committee addresses these important issues. In this manner, working together, our two branches of government can achieve our collective goal of ensuring public confidence in agency programs and operations through whatever means will best accomplish that objective. The objective is especially meaningful and important because so too is the mission of NIH to generate knowledge which will advance our ability to care for human ailments and improve the lives of all Americans.

Thank you for the opportunity to speak with you today. I would be pleased to answer any questions that you may have.

Mr. GREENWOOD. Thank you, Mr. Swindell.

Dr. Kingston, good morning.

TESTIMONY OF RAYNARD S. KINGTON

Mr. KINGTON. Good morning. Mr. Chairman, members of the subcommittee, I am the Deputy Director of the National Institutes of Health. I am also the Deputy Ethics Counselor at NIH as well as co-chair of the NIH Ethics Advisory Committee.

The Director of NIH appointed me as the DEC, Deputy Ethics Counselor, on January 12, 2004. At the time of my appointment the Director expanded the role of the DEC's jurisdiction over the immediate senior staff and institute and center directors to include

institute and center deputy directors, scientific directors, clinical directors, extramural program directors.

In regard to this group of the most senior managers at NIH, I am directly responsible for reviewing and approving applications to permit various outside activities pursuant to the ethic regulations. As Dr. Zerhouni testified before this subcommittee last week, he created the NIH Ethics Advisory Committee, or NEAC, in the Office of the Director to provide independent peer review of activities involving outside organizations.

The NEAC, which conducted its first meeting on January 20 of this year advises the NIH Deputy Ethics Counselor on conflicts of interest and helps to ensure the activities involving acceptance of compensation from outside sources receive uniform oversight at the NIH.

NEAC reviewed applications for proposed activities with outside organizations that stand the greatest chance of posing risks to NIH's objectivity or appearances thereof including where an award is valued at \$2,500 or more, where total income from an activity from an outside organization exceeds \$10,000 or is unknown, where outside compensation is in the form of equity, or when the activity involves a drug or biotech company or where the activity involves any senior NIH leadership such as scientific or clinical directors.

The committee is co-chaired by myself and the Deputy Director for Intramural Research, Dr. Michael Gottesman. It consist of 10 rotating members and two ex officio ethics advisors all of whom are full-time Federal employees. The rotating members are nominated by the institute and center directors and appointed by myself and Dr. Gottesman.

Membership represents the categories of employees submitting proposals to the NEAC including two IC directors, deputy directors, scientific directors, clinical directors, extramural directors, and other OD, Office of the Director, senior staff. During the centralized NIH review committee members review each proposed activity to assess whether it creates an actual or an apparent conflict of interest. The committee reviews the proposals based on criteria set forth and the standards of ethical conduct for employees of the executive branch promulgated by the U.S. Office of Government Ethics and the Department of Health and Human Services Regulations.

To ensure oversight activities that had already been approved prior to the creation of NEAC. We also instructed that all existing consulting relationships with pharmaceutical or biotechnology firms be stopped and resubmitted to the NEAC for its review and input before they could be reapproved and, if appropriate, continued by the NIH ethics counselor.

I am pleased to answer any additional questions you might have about the current NIH ethic program. Thank you.

Mr. GREENWOOD. Thank you, Dr. Kington.

Mr. Maskell.

TESTIMONY OF JACK MASKELL

Mr. MASKELL. Mr. Chairman and members of the subcommittee, thank you for the invitation to present testimony in this matter today. I am a legislative attorney with the American Law Division

in CRS and have worked there on legal and legislative issues concerning ethics and Government for about 30 years.

I began working with the subcommittee staff a year ago concerning the legal issues of large cash awards or prizes being given by private laboratories or clinics for the directors of the Institutes of NIH. In the course of that work the scenario that developed was as follows:

An agency of the Federal Government makes grants for research or clinical studies to a private facility totaling millions of dollars a year. That private facility then gives a substantial cash award or prize of several thousand dollars to the Director of the very Federal agency making those grants.

One does not need to have an intricately detailed knowledge of Federal law and regulations on ethics to see the obvious appearance problems and potentials for more serious consequences in that scenario. Beyond any mere appearance problem, however, this scenario raised specific questions of violations of Federal ethics regulations, and the statutes underlying them.

I prepared a fairly detailed analysis of some of the legal and ethics issues involved for the subcommittee, and with the subcommittee's permission, I have appended that analysis to my statement today.

Simply put, it appears that an agency head, with administrative and operational authority over all aspects of that agency's functions and programs, should not under Federal law and regulation be accepting cash gifts, awards or prizes from a private grantee of his own agency, that is, a private source that is dependant upon and so interested in the official duties, responsibilities and powers of that administrator.

The regulatory exception to the general gift ban for bona fide awards or prizes for meritorious service applies only when the donor of the award is a sufficiently independent source. The standard is that the donor may not "have interest that may be substantially affected by the performance or nonperformance of the employee's official duties." The example specifically given in the Office of Government Ethics regulations of a permissible award is an NIH official receiving the Nobel Prize. The Department of Justice, analyzing the awards issue under a related criminal statute, explained that acceptable bona fide awards must come from donors who are "detached from and disinterested in the performance of the public official's duties."

I believe it would strain credibility to argue that a grantee regularly receiving millions of dollars in grants from a Federal agency is "detached from" or "disinterested in" or "independent of" the duties, powers, and responsibilities of the Director of that agency.

Even when the agency head or other supervisory personnel are not directly participating in the award of a grant, or actually participating in certifying the private entity as a "comprehensive" treatment facility, the actual authority over those subordinate employees making the decisions, promotion, pay and work assignments and other things, the inherent influence of supervisors and agency heads over such subordinate employees, and the natural inclination of employees to want to please their superiors, all counsel

against such agency heads and management personnel receiving cash awards from these private grantees under the regulation.

While there certainly may be some leeway in the interpretation of the language of the regulation, the Supreme Court, in a unanimous decision authored by Justice Scalia in 1999, has given some guidance by explaining fairly clearly that a private entity has interests that “may be substantially affected by the performance of” an official’s public duties when that official “has the capacity to exercise governmental power or influence in the donor’s favor,” regardless of whether there is any specific, particular matter on the desk of the official relating to that private entity.

In fact, if there is a particular matter pending before the official relating to the private entity at the time of the cash payments, questions of both the application of criminal laws as well as ethics violations could be implicated.

That Supreme Court decision, known as the Sun-Diamond case, related to criminal charges concerning the then Secretary of Agriculture for accepting gifts of travel and entertainment from private entities regulated by his Department. The indictment charged the parties secretary with the giving of “illegal gratuities” under the Federal bribery statute. There were no allegations that the Secretary ever did any official act for the donors, or that any specifically identified official matter was pending before the Secretary involving those donors.

The Independent Counsel argued before the Court that the mere position of the Secretary, and the authority and power of the Secretary to affect the interests of the donor were enough to invoke the felony “illegal gratuities” prohibition upon making or accepting gifts or payments from them.

The Supreme Court, however, disagreed with the Independent Counsel, and Justice Scalia, writing for a unanimous Court explained in dicta that there is a multi-layered web of ethics laws and regulations in place for Federal officials, and that while such so-called “status gifts” are not necessarily “illegal gratuities” (because they can not be tied to any specific, identified official act), they do violate the language of the express regulation that we are discussing today, that is, they are gifts from a donor who has interests that may be substantially affected by the public duties of the official because the public official “is in the position to act favorably to the giver’s interest,” that is, the official has the “capacity to exercise governmental power or influence in the donor’s favor.”

It is obvious that a Director of a Federal agency has the official capacity, position and authority to exercise governmental power or influence which may affect the fortunes and interests of a grantee of that agency. Merely because a Director might have “delegated” certain grant functions to subordinates does not relieve or divest the officer of his official authority and responsibility. This is how the levels of responsibility and accountability are constructed in the Federal service.

If we are to err on the side of caution, the overall public interest would seem to dictate broadly prohibiting those ultimately responsible for grant decisions from personally benefiting from cash prizes, awards, or other such gifts given by grateful recipients of those Federal grants.

Thank you and I am willing to answer questions that you may have.

[The prepared statement of Jack Maskell follows:]

PREPARED STATEMENT OF JACK MASKELL, LEGISLATIVE ATTORNEY, CONGRESSIONAL RESEARCH SERVICE

Mr. Chairman and Members of the Subcommittee: Thank you for the invitation to speak to you today on the matter of "awards" from private sources. My name is Jack Maskell, and I am a legislative attorney with the American law Division of the Congressional Research Service. I began working with the subcommittee staff a little more than a year ago concerning the legal issues of private cash "awards" or "prizes" being given to the directors of the Institutes of the National Institutes of Health from private laboratories or clinics. In the course of that work, the scenario that developed was as follows:

An agency of the Federal Government makes grants for research or clinical studies to a private laboratory/ clinic in the sum of tens of millions of dollars a year. That private laboratory/clinic then gives a cash "award" or "prize" of several thousand dollars to the *Director* of the very federal agency making those grants.

One does not need to have an intricately detailed knowledge of federal law and regulations on ethics to see the obvious "appearance" problems and potentials for more serious consequences in that scenario. In fact, preventing appearances of impropriety and increasing confidence in the public's perception of the fairness of the administration of federal programs is one of the principal purposes behind federal ethics regulations and laws. *Crandon v. United States*, 494 U.S. 152, 164-165 (1990); H.R. Rpt. No. 748, 87th Cong., 1st Sess. 4-6 (1961); 5 C.F.R. 2635.101(a).

Upon further research and analysis it became clear that even beyond any mere "appearance" problem, however, this scenario raised specific questions of violations of federal ethics regulations, and the statutes underlying them. I prepared a fairly detailed analysis of some of the legal and ethics issues involved for the subcommittee, and with the subcommittee's permission, I have appended that analysis to my statement today.

Simply put, it appears that an agency head, with administrative and operational authority over all aspects of that agency's functions and programs, should not under federal law and regulation be accepting cash gifts, "awards" or "prizes" from a private grantee of his own agency, that is, a private source that is dependant upon and so interested in the official duties, responsibilities and powers of that administrator. This is particularly the case with certain private clinics and laboratories which have a continuing "certification," as well as a substantial and continuing grant, relationship with the agency.

As a brief background, federal law now prohibits the receipt of "gifts" by federal officials from "interested parties," or what are also called "prohibited sources." In the executive branch there are two general categories of interested parties. The first are those that are prohibited sources agency-wide, that is, for everyone in the agency, and includes those private entities seeking official action from, doing business with, or that are regulated by one's agency. 5 U.S.C. §7353(a)(1); 5 C.F.R. §2635.203(1)-(3). The second category are those that are prohibited sources for a particular officer or employee in question, that is, a restriction which is *personal* to the particular official—and that includes those "whose interests may be substantially affected by the performance or nonperformance of the individual's official duties." 5 U.S.C. §7353(a)(2); 5 C.F.R. §2635.203(4).

While most gifts may not be accepted from either category of interested parties (agency-wide or personal), there is a specific exception in executive branch regulations for the receipt of a *bona fide* award or prize for meritorious public service, when the donor of the award is a sufficiently *independent* source. Specifically, the awards exception allows an official to accept a *bona fide* award under certain circumstances from someone who is not in that second, "personal" category of interested parties, that is, an entity which does not have "interests that may be substantially affected by the performance or nonperformance of the employee's official duties." 5 C.F.R. 2635.204(d)(1). The example specifically given in the Office of Government Ethics regulations, is an NIH official receiving the Nobel Prize. 5 C.F.R. 2635.204(d), *note*. The Department of Justice, analyzing the "awards" issue under a related criminal statute, explained that acceptable *bona fide* awards must come from donors who are "detached from and disinterested in the performance of the public official's duties." 8 Op. O.L.C. 143, 144 (1984).

It would strain credibility to argue that a grantee regularly receiving millions of dollars in grants from a federal agency is “detached from” or “disinterested in” or “independent of” the duties, powers, and responsibilities of the Director of that agency. Even when the agency head or other supervisory personnel are not directly participating in the award of a grant, or actually participating in certifying the private entity as a “comprehensive” treatment facility, the *actual* authority over those subordinate employees making the decisions, the inherent influence of supervisors and agency heads over such subordinate employees, and the natural inclination of employees to want to please their superiors, all counsel against such agency heads and management personnel receiving cash awards from these private grantees under the regulation.

While there certainly may be some leeway in the interpretation of the language of the regulation, the Supreme Court, in a unanimous decision authored by Justice Scalia in 1999, has given some guidance by explaining fairly clearly that a private entity has interests that “may be substantially affected by the performance of” an official’s public duties when that official “has the capacity to exercise governmental power or influence in the donor’s favor,” regardless of whether there is any specific, particular matter on the desk of the official relating to that private entity. *United States v. Sun-Diamond Growers of California*, 526 U.S. 398, 405-511 (1999). In fact, if there is a particular matter pending before the official relating to the private entity at the time of the cash payments, questions of both the application of criminal laws as well as ethics violations could be implicated.

That Supreme Court decision, known as the *Sun-Diamond* case, involved a 31-count criminal indictment against the then Secretary of Agriculture for accepting gifts of travel and entertainment from private entities regulated by his Department. The indictment charged the Secretary with the acceptance of “illegal gratuities” under the federal bribery statute. There were *no* allegations that the Secretary ever did any official act for the donors, or that any specifically identified official matter was pending before the Secretary involving those donors. The Independent Counsel argued before the Court that the mere position of the Secretary, and the authority and power of the Secretary to affect the interests of the donor were enough to invoke the felony “illegal gratuities” prohibition upon accepting gifts or payments from them. The Supreme Court, however, disagreed with the Independent Counsel, and Justice Scalia, writing for a unanimous Court explained in *dicta* that there is a multi-layered web of ethics laws and regulations in place for federal officials, and that while such so-called “status gifts” are not necessarily “illegal gratuities” (because they can not be tied to any specific, identified official act), they *do* violate the language of the express regulation that we are discussing today, that is, they are gifts from a donor who *has interests that may be substantially affected* by the public duties of the official because the public official “is in the position to act favorably to the giver’s interest,” that is, the official has the “capacity to exercise governmental power or influence in the donor’s favor...” *Sun-Diamond, supra* at 408, 411.

It is obvious that a Director of a federal agency has the official capacity, position and authority to exercise governmental power or influence which may affect the fortunes and interests of a grantee of that agency. Merely because a Director might have “delegated” certain grant functions to subordinates does not relieve or divest the officer of his official authority and responsibility. As noted by the United States Court of Appeals, the head of an agency who delegated authority to a subordinate official Adid not, however, divest...himself of the power to exercise his authority or relieve him of his responsibility for action taken pursuant to the delegation.” *Skokomish Indian Tribe v. G.S.A.*, 587 F.2d 428, 432 (9th Cir. 1978), *see NLRB v. Duval Jewelry Co.*, 357 U.S. 1, 7-8 (1958). As stated simply by Professor Bayless Manning, one of the drafters of the model federal conflict of interest laws in the 1960’s: “[T]he head of a department or agency would have ‘under his official responsibility’ all matters in the department or agency.” Manning, *Federal Conflict of Interest Law*, at 207-208 (Harvard University Press 1964). That is how the system of responsibility and accountability is constructed in the federal service. Because of the actual authority over subordinate employees and their promotions and pay, the inherent influence of supervisors and agency heads over such subordinate employees, and the natural inclination to please one’s superiors, it would appear that the reasons behind the ethics rule do not necessitate the actual or the reasonably foreseeable active participation in a specific matter by such supervisory personnel for them to fall outside of the narrow “awards” exception.

Financial disclosure. The framework of the public financial disclosure issues is that certain personnel in the Institutes earning up to \$200,000 a year in federal salary are seen as exempt from the statutory requirements for public financial disclosure. This has apparently come about by virtue of the Institute’s authority under 42 U.S.C. § 209(f) and (g) to hire “special consultants” and experts without regard

to civil service rules. The pay established by the agency for such positions ranges from \$38,000 to \$200,000. Under this authority the Institutes have reportedly hired high-level administrative personnel, including apparently directors, but since the “pay range” under this authority begins at \$38,000, below the statutory threshold for disclosure, the agency has exempted those hired under this authority from public financial disclosure. *Report of the National Institutes of Health Blue Ribbon Panel on Conflicts of Interest Policies*, Draft of May 5, 2004 at 20, 29-31.

The exemption from filing for those in a “pay range,” when the lowest amount in the range is below the statutory threshold, is not *necessarily* required by the language of the federal law, but is rather an interpretation of the law by the Office of Government Ethics. The federal law merely says in relevant part that public disclosure is required from:

each officer or employee in the executive branch...who occupies a position..., in the case of positions not under the General Schedule, for which the rate of basic pay is equal to or greater than 120 percent of the minimum rate of basic pay payable for GS-15 of the General Schedule...5 U.S.C. appendix, § 101(f)(3).

The law itself does not specifically say anything about pay bands, or the lowest level in any given pay range. The Office of Government Ethics has determined, however, that the statutory language and intent of the law means that the “basic pay” for a “position” is the lowest possible pay, that is, the so-called entry level or beginning pay, for any particular pay range, rather than the pay actually received by a particular incumbent in that position.

It should be mentioned here that in the legislative branch we do not follow OGE’s particular interpretation of the law (with respect to similar language) applying to legislative branch employees, and that when an employee in the legislative branch reaches the *actual* annual rate of pay that is comparable to the statutory threshold (120% of a GS-15), then that employee must file a public disclosure, regardless of any minimum pay possible for that “pay band” or “pay range.”

The Office of Government Ethics has explained that the intent of the disclosure law was to cover a “position” rather than a particular employee, and that the coverage of the disclosure law “is determined by the employee’s level of responsibility” and that the lowest level of pay possible defines that responsibility (OGE Letter to DAEO’s, No. 98 x 2). In most cases, this is perfectly logical and effective, particularly where there may be a number of “positions” in an occupational series, and several corresponding pay bands to which an employee may be progressively promoted or appointed. The pay ranges may then be fairly correlative to responsibility and, of course, “level of pay” is a more easily determined and definable standard than is “level of responsibility.” However, where there is merely an authority to hire and no positions and pay statutorily defined, or merely a maximum rate of pay, then the lowest permissible pay rate may not fairly describe the responsibility of those in the upper echelons of pay and authority. In some cases a rigid application of the “lowest possible pay” interpretation does not conform to the actual facts on the ground. Under their title 42 authority, for example, it has been explained that the Institutes hire managers, supervisors and even directors. Clearly, their positions and levels of responsibilities are significantly different from and greater than “consultants” and advisors at the lower end of that possible pay range.

Policy makers must, of course, balance the interest of full disclosure for public officials with the privacy interests of federal employees and officials, and the possible “nuisance” factors of public disclosure and its effect on recruitment and retention of qualified personnel. However, these policy decisions should not be confused with any constitutional “rights to privacy” of public employees with regard to financial matters. The federal courts examining the issue of privacy rights have determined that an implied right to privacy exists under several possible provisions of the Constitution when there is involved “intimate” family and personal relationships and decisions, such as the decision concerning procreation and child-rearing. *Whalen v. Roe*, 429 U.S. 589 (1977). The courts have not, as of yet, expressly extended any constitutional right to privacy, however, to a public official’s *financial* matters or interests, noting that “[f]inancial privacy is not within the autonomy branch of the right to privacy,” that is, it is not within the Asphere of family life constitutionally protected by the right of privacy.” *Duplantier v. United States*, 606 F.2d 654, 669 (5th Cir. 1979), *cert. denied* 449 U.S. 1076 (1981) [upholding the federal Ethics in Government Act public disclosures for federal judges], *citing Plante v. Gonzalez*, 575 F.2d 1119, 1132 (5th Cir. 1978), *cert. denied* 439 U.S. 1129 (1979).

Memorandum December 4, 2003

TO: House Committee on Energy and Commerce, Attention: Alan Slobodin

FROM: American Law Division

SUBJECT: Cash “Awards” and “Prizes” to Agency Heads from Grantees of the Agency

This memorandum is prepared in response to the Committee’s request, as discussed with counsel Alan Slobodin. The American Law Division previously provided a legal analysis to your Committee, dated May 20, 2003, discussing federal law and interpretation concerning the receipt of cash gifts, including “awards,” by an agency head from a grantee of that official’s agency. In response to the Committee’s subsequent inquiry to that agency, the Committee received an unsigned memorandum (or “white paper”) from the Department of Health and Human Services, dated July 11, 2003, which attempted to justify the receipt of cash awards by the head of an agency in the Department, the National Cancer Institute of the National Institutes of Health, based on a particular exemption to the executive branch gifts regulation. The Committee has asked for a legal analysis of the HHS response.

The Department memorandum would construe the gifts restriction, and the narrow exemption in it for *bona fide* “awards” to federal officials from disinterested sources, in such a permissive manner as to condone the personal enrichment of the Director of an agency directly from a source receiving significant grant funding from his agency. The reasoning employed by the Department obscures and overlooks the obvious and serious ethical implications in this scenario. On its face, allowing the top administrator and final decision maker of an agency to receive cash “awards” or “prizes” from those private entities concerning whom the agency must make determinations involving millions of dollars in grant funds implicates the precise conflicts of interest and ethical issues that are addressed in various criminal laws, statutes on gifts, and standards of conduct regulations. As developed below, under the common understanding of the language used in the gift regulations and exemptions, and under relevant administrative rulings and examples, as well as legal interpretations by the Supreme Court,—a private grantee of the Federal Government clearly “has interests that may be substantially affected” by the official powers and duties of the Director of the grantor federal agency, and as such, may not be the source of substantial gifts of cash, even in the form of “awards,” given to that particular Government official.¹

Background. The limitations and restrictions on gifts, and the prohibitions on private salary supplementation of federal employees are, as noted by the Office of Government Ethics, “aimed at preventing the Government employee from becoming beholden to anyone in the private sector who might affect the independence or judgment of that employee.”² There is, of course, a grave concern that official decisions may actually be influenced, even subtly influenced, when a private recipient of federal largess “awards” the responsible federal official with cash in appreciation of his public duties.³ Such conduct not only provides a potential lucrative reward for those *past* decisions favorable to the grantee, but also provides an opportunity for a potentially generous “incentive” for *future* official conduct favorable to the grantee by that official and other agency officials who are possible future recipients of such “awards.” In addition to actual influence over official decision-making, however, there is an extended concern that permitting such conduct diminishes the confidence of the public in the independent, impartial and even-handed administration of federal programs.⁴ The Supreme Court has noted the important interest of the Government in adopting rules to avoid even “potential conflicts of interest in the perform-

¹ 5 U.S.C. § 7353(a)(2); 5 C.F.R. §§ 2635.202, 2635.203(d), 2635.204(d); 8 Op. O.L.C. 143, 144 (1984); Office of Government Ethics [OGE] Advisory Opinions Nos. 83 x 11 (July 26, 1983), and 92 x 7 (February 26, 1992); see *United States v. Sun-Diamond Growers of California*, 526 U.S. 398, 405-411 (1999).

² Office of Government Ethics, Opinion 81 X 31, October 2, 1981, in *Informal Advisory Letters and Formal Opinions*, 1979-1988, at 210; Paul H. Douglas, *Ethics in Government*, at 45-49 (Harvard University Press 1952); Roswell B. Perkins, “The New Federal Conflict of Interest Law,” 76 *Harvard Law Review* 1113, 1137 (1963), discussing 18 U.S.C. § 209.

³ *Id.*; the late Senator Paul Douglas, explained in his treatise *Ethics in Government*, *supra* at 44, that often “the corruption of public officials by private interests takes a more subtle form” than outright bribes, through indirect financial support which may “put the public official under such a feeling of personal obligation that the latter gradually loses his sense of mission to the public...” Douglas noted that sometimes subtle “shifting loyalties” from the community to narrow private interests may lead an official to make decisions favorable to “his private benefactors and patrons” while all the time “the official will claim—and may indeed believe—that there is no causal relationship between the favors he received and the decisions which he makes.”

⁴ “The proper operation of a democratic government requires that officials be independent and impartial;... and that the public have confidence in the integrity of its government.” H. R. Rpt. No. 748, 87th Congress, 1st Session, 4-6, House Judiciary Committee (1961). The Office of Government Ethics has recognized the imperative to “ensure that every citizen can have complete confidence in the integrity of the Federal Government...” 5 C.F.R. 2635.101(a).

ance of governmental service” to “maintain[] the public’s confidence in the integrity of the federal service.”⁵

To address the ethical issues inherent in the receipt of things of value by federal officials from private sources when there exists any “nexus” between the interests of the donor entity and the official duties and responsibilities of the recipient federal official, there has developed in the Federal Government a multi-layered structure of criminal laws, general statutes, and standards of conduct regulations which seek to regulate these situations. The criminal laws include the federal bribery statute which provides criminal penalties for any federal official who receives something of value “in return for” being influenced in the performance of an official act; the “illegal gratuities” clause of the same bribery statute which prohibits the receipt of things of value that are connected to official duties in particular ways,—received “for or because of” a particular official act performed or to be performed by the officer or employee; and a criminal conflict of interest provision which prohibits federal employees in the executive branch from working on or being involved “personally and substantially” in any official particular matter in which they have a personal or imputed financial interest.⁶ In addition to these provisions of criminal law, it should be noted that a specific criminal provision of federal law also prohibits the receipt of money or things of value intended as private “compensation,” or as a salary supplementation, for one’s official duties performed for the United States Government.⁷ Under this latter provision, 18 U.S.C. § 209, there has been developed and recognized by the Department of Justice an exemption from the criminal law for *bona fide* awards to federal officials for their public service from sources “detached from” and “disinterested in” the area of responsibilities of the recipient federal official.⁸

Statute and General Regulations on Gifts. In addition to the provisions of federal criminal law noted above, there are non-criminal statutes of general applicability, as well as administrative regulations governing the acceptance of gifts and other “self-enriching” activities of federal officials.⁹ The principal statutory provision in federal law regarding gifts from private sources was adopted as part of the Ethics Reform Act of 1989,¹⁰ codifying for the most part somewhat similar ethical rules and limitations on the receipt of gifts by federal employees which had been in effect for the executive branch since 1965 by way of Executive Order and agency regulations.¹¹

The current law on gifts from outside sources, codified at 5 U.S.C. § 7353, prohibits the receipt of “anything of value” by a federal official from what have come to be known as “prohibited sources.” In the current gifts law, the “prohibited sources” are expressly set out in two separate categories of persons or entities, to include those persons:

- (1) seeking official action from, doing business with, or (in the case of executive branch officers and employees) conducting activities regulated by, the individual’s employing entity; [5 U.S.C. § 7353(a)(1)] or
- (2) whose interests may be substantially affected by the performance or non-performance of the individual’s official duties. [5 U.S.C. § 7353(a)(2)]

Under the gifts statute, the supervisory ethics offices for particular employees and officials may issue regulations detailing the gift limitations and providing reasonable exceptions to the general prohibitions.¹² The Office of Government Ethics has issued gift regulations under this statutory provision for the executive branch of Government, setting out numerous restrictions and exemptions to the general prohibition. Under the regulations, the Office of Government Ethics sets out the categories of what constitutes a “prohibited source” from whom things of value may not be received as follows at 5 C.F.R. § 2635.203:

(d) *Prohibited source* means any person who:

- (1) Is seeking official action by the employee’s agency;
- (2) Does business or seeks to do business with the employee’s agency;
- (3) Conducts activities regulated by the employee’s agency;

⁵ *Crandon v. United States*, 494 U.S. 152, 164-165 (1990).

⁶ 18 U.S.C. § 201(c)(1)(B); 18 U.S.C. § 201(b)(2); 18 U.S.C. § 208.

⁷ 18 U.S.C. § 209.

⁸ 8 Op. O.L.C. 143, 144 (1984).

⁹ As noted by the Supreme Court there is now “an intricate web of regulations... governing the acceptance of gifts and other self-enriching actions by public officials.” *United States v. Sundiamond Growers of California*, 526 U.S. 398, 409 (1999).

¹⁰ P.L. 101-194, Sec. 303, November 30, 1989, 103 Stat. 1746.

¹¹ See Executive Order No. 11222, Section 201, May 8, 1965 (now superseded by E.O. 12674, April 12, 1989), and former regulations, 30 F.R. 12529, October 1, 1965, 5 C.F.R. § 735.202.

¹² 5 U.S.C. § 7353(b).

- (4) Has interests that may be substantially affected by performance or non-performance of the employee's official duties; or
- (5) Is an organization a majority of whose members are described in paragraphs (d)(1) through (4) of this section.¹³

Regulatory Exemption for Certain Bona Fide Awards. Based on the guidance and principles developed in the Department of Justice's exemption for bona fide awards under 18 U.S.C. § 209, the Office of Government Ethics promulgated an exception from the gifts prohibitions for certain "bona fide awards" for meritorious public service given by certain entities to federal officials when the recipient federal officials are not in positions to affect the interests of the donor of the award or prize. The current regulatory exemption provides as follows, at 5 C.F.R. § 2635.204:

(d) *Awards and honorary degrees.* (1) An employee may accept gifts, other than cash or an investment interest, with an aggregate market value of \$200 or less if such gifts are a bona fide award that is given for meritorious public service or achievement by a person who does not have interests that may be substantially affected by the performance or nonperformance of the employee's official duties or by an association or other organization the majority of whose members do not have such interests. Gifts with an aggregate market value in excess of \$200 and awards of cash or investment interests offered by such persons as awards or incidents of awards that are given for these purposes may be accepted upon a written determination by an agency ethics official that the award is made as part of an established program of recognition:

- (i) Under which awards have been made on a regular basis or which is funded, wholly or in part, to ensure its continuation on a regular basis; and
- (ii) Under which selection of award recipients is made pursuant to written standards.

The examples given by the Office of Government Ethics and the rulings by that agency, as well as the Department of Justice interpretations under § 209, have demonstrated that a *bona fide* award, to fit the exemption, must (among other qualifications for a cash award) come from a person, group, or entity that is to a certain degree "independent" of the recipient public official, in the sense that the public official is not in a position to act favorably to the giver's interests. The Department of Justice has expressly stated that the exemption from the criminal statute at 18 U.S.C. § 209 that it has recognized for *bona fide* awards to federal officials from outside sources, must come from donors who are "detached from and disinterested in the performance of the public official's duties."¹⁴

The example expressly provided in the published regulations of the Office of Government Ethics uses the Nobel Prize to illustrate the type of "award" from independent sources that may be received by a federal official:

Example 1: Based on a determination by an agency ethics official that the prize meets the criteria set forth in § 2635.204(d)(1), an employee of the National Institutes of Health may accept the Nobel Prize for Medicine, including the cash award which accompanies the prize, even though the prize was conferred on the basis of laboratory work performed at NIH.¹⁵

Similarly, an advisory ruling from the Office of Government Ethics provided another example of when the receipt of a *bona fide* award by a particular official would not raise ethics and conflict of interest concerns, that is, again, when the recipient/awardee is not in a position to exercise official duties or responsibilities that may substantially affect the interests of the donor:

A nonprofit organization presents its annual award consisting of \$5,000 and a medallion for "Greatest Public Service Performed by an Elected or Appointed Official" to an employee of the Bureau of Prisons. The organization applied long-standing written criteria in judging all of the candidates. *The organization has no relationship with the Bureau of Prisons.* Because it is a *bona fide* award for public service, it is not intended to compensate the employee for his services to the Bureau of Prisons and would not violate section 209.¹⁶

Where there existed apparent or potential conflicts of interest for employees of an agency with respect to the donor entity, however, because those employees worked in a subject "area" of interest to the donor, the Office of Government Ethics, in applying an earlier version of the exemption, found that the requisite independence

¹³ 5 C.F.R. § 2635.203(d).

¹⁴ 8 Op. O.L.C. 143, 144 (1984).

¹⁵ 5 C.F.R. § 2635.204(d), note.

¹⁶ OGE, Memorandum, DO-02-016, "18 U.S.C. § 209 Guidelines," July 1, 2002, *see* OGE Advisory Letter 83 x 10. Emphasis added.

or disinterestedness of the donor was not present, and that the awards could not be accepted.¹⁷

The Office of Government Ethics has not published an interpretation specifically addressing the issue of the head of an agency receiving cash “awards” from a grantee of that agency. There is, however, no ruling from the Office of Government Ethics which interprets this narrow exception from the general gifts prohibition for *bona fide* “awards” in such a manner as to allow the personal enrichment of a federal official, such as an agency Director, from any entity, such as a grantee of the Director’s agency, which is so vitally concerned with and connected to the area of official responsibilities and powers of the intended recipient. Under the general principles of the administrative and regulatory exemptions, a grantee of an agency can hardly be said to be “detached from”¹⁸ or “disinterested in” the official duties and responsibilities of the Director of the grantor federal agency. As explained below, such conduct not only raises general ethics and conflict of interest concerns and appearances, it appears to specifically violate the express prohibition on gifts from interested parties.

Meaning of Phrase “Interests That May Be Substantially Affected” by the Officer’s Duties. The regulatory exception for bona fide awards thus does not allow, for obvious ethics and conflict of interest reasons, a public official to receive an award from an entity which is in the “fourth category” of regulatory “prohibited sources,” that is, from an entity that “has interests that may be substantially affected” by the performance or nonperformance of that official’s public duties. The Memorandum from the Department of Health and Human Services admits its confusion and lack of understanding of the plain language of this category of “prohibited sources” in the OGE regulations.¹⁸ The Department “white paper” speculates that this fourth category in the regulations could not mean “grantees” of the agency because, it argues, such entities are already covered by the regulations in another category of prohibited sources, that is, those doing business with the agency. Such an interpretation, the Department “white paper” argues, would create a meaningless “tautology” that an employee could “accept an award from a “prohibited source” provided that it is not a ‘prohibited source,’”¹⁹ and the Department eventually concludes that the provision does not limit an award to the agency’s director merely because the donor is a grantee of that agency.

The Department’s expressed confusion concerning the categories of “prohibited sources” may be substantially clarified, in the first instance, by looking at the explanations of the Office of Government Ethics in its advisory opinions and rulings. OGE has explained that the first three categories of “prohibited sources” in its regulations (which correspond to the first category of prohibited sources in the statute, 5 U.S.C. § 7353(a)(1)) are intended as “agency-wide” prohibited sources of gifts.²⁰ That is, that such entities in the first three categories are “prohibited sources” from whom gifts may not be received by *everyone* employed in the particular agency, regardless of the employee’s duties, responsibilities or functions. The “fourth category” of prohibited sources in the OGE regulations (which corresponds to the second, separate category in the statute, 5 U.S.C. § 7353(a)(2)), however, is not merely a repetitious statement of, or another, agency-wide limitation, but rather is intended to be a restriction which is *personal* for the particular public official in question, and is dependant upon the incumbent’s official authority, powers and duties.

Thus, an entity such as a research laboratory and treatment facility which receives grants from a federal agency and has a continuing relationship with that agency,²¹ would be a “prohibited source” of “gifts” generally for every officer and employee in the agency under one of the first three regulatory categories of prohibited sources (those seeking action from, doing business with, or regulated by the agency). However, that laboratory would also be a “prohibited source” under the *fourth* category of the regulations, and thus a “prohibited source” even of “awards,” only if the particular officer in question were in a position to exercise governmental author-

¹⁷ OGE Opinion 83 x 11, July 26, 1983.

¹⁸ “Analysis of Ethics and Related Issues Concerning the Receipt of Lecture Awards by National Institutes of Health Employees,” 2-3, July 11, 2003.

¹⁹ *Id.* at 3.

²⁰ OGE Opinion 94 x 5, February 7, 1994.

²¹ In the facts provided by the Committee, one grantee facility which gave the agency Director a several thousand dollar “lecture award,” the Arizona Cancer Center of the University of Arizona, advertizes itself as a “National Cancer Institute-Designated Comprehensive Cancer Center” (<http://www.azcc.arizona.edu>). In the relevant time period, in Fiscal Year 1999, for example, the University of Arizona received grants from the National Cancer Institute in the amount of \$22,193,000, and contracts in the amount of \$237,000; and in Fiscal Year 2000 received grants from NCI in the amount of \$25,249,000 and contracts in the amount of \$486,000. *Fact Book*, National Cancer Institute, 1999, at E-12; *Fact Book*, National Cancer Institute, 2000, at E-11.

ity which could substantially affect the interests of that grantee.²² Clearly, a laboratory/facility which is a “grantee” of a particular agency may be a “prohibited source” for general “gifts” for every officer and employee of the agency (merely because of the laboratory’s status as an agency “grantee”) and, at the same time, may also be a “prohibited source” for the Director of that agency for an “award,” because the Director’s general supervisory, administrative and operating authority relative to all of his agency’s decisions may, obviously, have a substantial effect on the interests of the laboratory/facility. It is thus the “status” of the position that the intended recipient holds, and the incumbent’s ability or capacity to exercise governmental authority affecting the donor entity, that is the relevant measure of the application of the fourth “prohibited source” category.

In further clarification of the phrase used in the regulatory exemption, the Supreme Court of the United States clearly explained that for a particular public official, this “fourth category” of “prohibited sources” in the Office of Government Ethics regulations, from whom things of value may not be received because the donor has “interests that may be substantially affected” by the duties of the official, relates to those situations where the public official “is in a position to act favorably to the giver’s interests,” that is, where the public official has the “capacity to exercise governmental power or influence in the donor’s favor,” regardless of whether there is a particular, identifiable matter immediately before the official.²³ The clause in the ethics regulation thus clearly is directed at the powers and responsibilities of the office of the incumbent recipient, rather than the immediacy of any particular matter and, in the case of a grantee of a federal agency, would obviously be applicable to the Director of the agency who has final statutory, administrative and operational authority over the agency decision-making vitally affecting the interests of the donor entity.

In *United States v. Sun-Diamond*, the Supreme Court analyzed a prosecution of a federal official, the Secretary of Agriculture, under the “illegal gratuities” clause of the bribery statute for his receipt of various gifts from business entities which could be affected by the exercise of the Secretary’s official duties because they had businesses that were regulated by the Department. It should be noted that for a number of years, in several federal circuits, so-called “status gifts” were successfully prosecuted as “illegal gratuities.”²⁴ Status gifts were things of value received by an official which were given because of that employee’s official position in the Government, that is, given to an officer or employee who “was in a position to benefit” the private donor entity. The United States Government in *Sun-Diamond* argued unsuccessfully for that specific interpretation in the case of the Secretary of Agriculture:

The Independent Counsel asserts that “section 201(c)(1)(A) reaches any effort to buy favor or generalized goodwill from an official who either has been, is, or may at some unknown, specified later time, be *in a position to act* favorably to the giver’s interests.” Brief for United States 22 [Court’s emphasis]. The Solicitor General contends that § 201(c)(1)(A) requires only a showing that a “gift was motivated, at least in part, by the recipient’s *capacity to exercise governmental power or influence* in the donor’s favor” without necessarily showing that it was connected to a particular official act. Brief for United States Dept. of Justice as *Amicus Curiae* 17 [Court’s emphasis].²⁵

The Supreme Court, however, found that for a violation of the “illegal gratuities” provision, there must be some particular, identifiable “official act” to which the gift is connected.²⁶ The Supreme Court noted in *Sun-Diamond* that so-called “status gifts,” that is, gifts to a federal official which were prohibited “by reason of the recipient’s mere tenure in office” because they were in a position to act favorably on the donor’s behalf,²⁷ were not necessarily “illegal gratuities,” but rather would come within, be regulated by, and would violate the OGE regulations on gifts. Specifically,

²² Employees in the agency who are in jobs that do not involve the making, evaluation, approval, or oversight of grants to that laboratory/facility, nor supervising those who have such responsibilities, would still be prohibited from receiving “gifts” from that facility (merely because of its status as a grantee of the agency), but would not be prohibited from receiving a *bona fide* award from that laboratory/facility because their particular responsibilities do not affect its interests.

²³ *United States v. Sun-Diamond Growers of California*, 526 U.S. 398, 405-411 (1999).

²⁴ *United States v. Niederberger*, 580 F.2d 63, 69 (3rd Cir. 1978), *cert. denied*, 439 U.S. 980 (1978) (golfing trips for I.R.S. officer paid for by Gulf Oil Corp. when officer was merely “in a position to use his authority in a manner which could affect the gift-giver”); *United States v. Alessio*, 528 F.2d 1079, 1082 (9th Cir. 1976), *cert. denied*, 426 U.S. 94 (1976) (gift to prison administrator).

²⁵ 526 U.S. at 405-406.

²⁶ 526 U.S. at 406.

²⁷ 526 U.S. at 408.

the unanimous court found such gifts, that is, things of value given to a public official who has the capacity to act favorably on the donor's behalf at some time, to be gifts which would violate the regulations expressly prohibiting the receipt of gifts from anyone who "has interests that may be substantially affected by performance or nonperformance of the employee's official duties:"

[I]t is interesting to consider the provisions of 5 C.F.R. § 2635.202 (1999), issued by the Office of Government Ethics... The first subsection of that provision, entitled 'General prohibitions,' makes unlawful approximately (if not precisely) what the Government asserts [the statute] makes unlawful: acceptance of a gift "[f]rom a prohibited source" (defined to include any person who "[h]as interests that may be substantially affected by performance or nonperformance of the employee's official duties..."²⁸

The Supreme Court in *Sun-Diamond* thus explicitly explained that the prohibition in the executive branch regulation on accepting gifts from one who "has interests that may be substantially affected by the performance or nonperformance of the employee's official duties," is a prohibition on receiving things of value from private sources by a federal official who is merely "in a position to act favorably to the giver's interests," that is, that the recipient public official has the "capacity to exercise governmental power or influence in the donor's favor."²⁹ There need not be any identifiable, particular governmental matter currently before, or "on the desk of," the official to violate this provision of ethics regulation under the Supreme Court explanation. In fact, if there is a particular, identifiable matter involving the donor-entirety immediately before the Government official who is at the same time receiving significant cash "awards" or other gifts from that entity, there may very well be more than merely an "ethics" violation of the gift regulation, but rather potential felony violations of federal criminal law.³⁰

Authority of Agency Director. As a general matter, it is obvious and beyond reasoned argument that a Director of a federal agency has the official capacity and authority to exercise governmental power or influence which could have a favorable or unfavorable impact on the interests of a grantee of that agency, particularly an entity with a continuous grantee and certification relationship with that federal agency. In fact, under federal law, the Director of the agency in question, the National Cancer Institute, has *express* administrative control and statutory authority over all of the relevant functions of the Institute,³¹ and thus oversees the grant functions, administration and oversight of grantee programs.³²

One may not convincingly argue, under either general or conflict-of-interest-specific legal principles, that an agency grantee has no interests which may be substantially affected by the official authority, duties and responsibilities of that agency's Director merely because the Director has "delegated" certain functions regarding

²⁸ 526 U.S. at 411, citing to the gifts regulations at 5 C.F.R. § 2635.203(d)(4).

²⁹ 526 U.S. at 405, 411.

³⁰ The timing of the offer and receipt of things of value, in relation to a particular official matter actually pending before a recipient Government official is a relevant circumstantial consideration in determining the requisite "intent" needed for an "illegal gratuity," that is, the intent to be rewarded or compensated for a particular official act. *United States v. Biaggi*, 853 F.2d 89, 99-100 (2nd Cir. 1988), *cert. denied* 489 U.S. 1052 (1989), evidence of required intent to reward may be inferred from the size of gift, and "the nature and sequences of events"; *United States v. Jennings*, 160 F.3d 1006, 1014, 1017-1018 (4th Cir. 1998), (referring to federal bribery law at 18 U.S.C. § 201 and similar language at 18 U.S.C. § 666, regarding bribery and gratuities in federally funded programs): "Direct evidence of intent is not necessary," but may be inferred from circumstances including timing and sequences of gifts and acts. *Note* also 18 U.S.C. § 209, where donor's interest in immediate official matter, although clearly not necessary for a violation, may arguably provide further evidence of "intent to compensate" and "appearance of a conflict of interest... sufficient to violate § 209." *United States v. Moore*, 765 F.Supp. 1251, 1254 (E.D.Va. 1991). The law at § 209 has been described as a conflict of interest statute "in the strictest sense," that is, an "employee does not have to do anything improper in his office to violate the statute," but rather his special status as a government employee "makes an unexceptionable act wrongful—wrongful because of the potential dangers in serving two paymasters." Association of the Bar of the City of New York, Special Committee on the Federal Conflict of Interest Laws, *Conflict of Interest and Federal Service*, at 55-56 (Harvard University Press 1960). There may also be other considerations of felony violations when a public official actually participates "personally and substantially" in a particular agency matter in which the official has his own personal, financial interest. 18 U.S.C. § 208.

³¹ 42 U.S.C. §§ 285a-1, 285a-2.

³² According to the NCI web-site (<http://www3.cancer.gov/mab/hnc1.htm>), the Office of the Director "(1) Serves as the focal point for the National Cancer Program; (2) develops a National Cancer Plan and monitors implementation of the plan; (3) directs and coordinates the Institute's programs and activities; and (4) develops and provides policy guidance and staff direction to the Institute's programs in areas such as program coordination, program planning, clinical care and administrative management."

grants to subordinate officials. A delegation of authority by a federal official is *not* a divestiture of official authority or responsibility.³³ As noted by the United States Court of Appeals, the head of an agency who delegated authority to a subordinate official “did not, however, divest . . . himself of the power to exercise his authority or relieve him of his responsibility for action taken pursuant to the delegation.”³⁴ In fact, the Supreme Court has found that an official may not administratively divest himself of statutory authority.³⁵

A superior thus clearly has “official responsibility” for, as well as “official authority” over, the actions of those subordinate officials in the chain of authority and command in his federal agency.³⁶ The assignment, review, oversight, and supervision of official actions of subordinate employees, as well as the express authority retained by that official to direct the overall functions and programs of the agency, are all among the official responsibilities and duties of a federal officer such as an agency Director. In explaining the conflict of interest principles in the concept of the “official responsibilities” of a federal officer, Professor Manning expressly noted that: “[T]he head of a department or agency would have ‘under his official responsibility’ all matters in the department or agency.”³⁷

It should be emphasized that there is *not* a requirement under the gifts prohibition/“award” restriction that the recipient official must actually participate “personally and substantially” in any current governmental matter affecting the donor/grantee for the prohibition on awards to apply, as there is under several *criminal* conflict of interest laws.³⁸ As noted, the restrictions on awards from interested parties is concerned, for obvious ethical and conflict of interest reasons, with the power to exercise governmental authority in the donor’s favor, that is, it is concerned with the status of the recipient official *vis-a-vis* the donor, and not with whether such authority is actually exercised in a particular, identifiable matter. Like many conflict of interest rules, this regulation does *not* require actual corruption, loss by the Government, or wrongful official acts, but rather is preventative and prophylactic in nature, and thus is, as the Supreme Court noted concerning another conflict of interest law, “directed not only at dishonor, but also at conduct that tempts dishonor.”³⁹ Under the relevant legal and administrative interpretations of, and the plain meaning of the language employed in the gifts/“award” limitations, therefore, an entity such as a cancer research and treatment facility which has a continuing grant and certification relationship with a federal agency such as the National Cancer Institute, clearly has interests that may be substantially affected by the actual, statutory operational, administrative and supervisory duties, responsibilities and authorities of the Director of that agency, and may thus not be a source of cash “awards” to that Director.

SUMMARY/CONCLUSION

1. A federal official in the executive branch may not, under federal ethics regulations, receive a cash “award” or “prize,” even a “*bona fide* award,” from a donor

³³*Skokomish Indian Tribe v. General Services Administration*, 587 F.2d 428, 432 (9th Cir. 1978).

³⁴*Skokomish Indian Tribe*, *supra* at 432. For conflict of interest purposes it may be noted that the act, decision and discretion of delegating certain authority or not delegating authority, to whom such authority is delegated, and the nature—reviewability, timing, extent—of such delegation may involve, in themselves, the exercises of official duties that may substantially affect a grantee.

³⁵*NLRB v. Duval Jewelry Company*, 357 U.S. 1, 7-8 (1958); *Equal Employment Opportunity Commission v. Exchange Security Bank*, 529 F.2d 1214, 1218-19 (5th Cir. 1976).

³⁶*See*, for example, definition of “official responsibility” for purposes of certain criminal conflict of interest laws as including “direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct Government action.” 18 U.S.C. § 202(b). Emphasis added.

³⁷Bayless Manning, *Federal Conflict of Interest Law*, at 207-208 (Harvard University Press 1964).

³⁸While not requiring “personal and substantial” participation in a particular governmental matter affecting the donor to incur the prohibition on “awards,” even that much stricter criminal standard of responsibility and duties would not, as discussed by Roswell Perkins, “create a loophole for the lazy executive in the chain of command who may not have bothered to dig into the substance” of a particular matter. Roswell Perkins, “The New Federal Conflict of Interest Law,” 76 *Harvard Law Review* 1113, 1128 (1963).

³⁹*United States v. Mississippi Valley Generating Co.*, 364 U.S. 520, 549 (1960). The language of the regulatory limitation prohibiting an “award” when the donor entity has interests that “may be” influenced by the official duties of the recipient indicates a focus on potential performance or influence. The Supreme Court noted in another ethics context, that the Government “appropriately enacts prophylactic rules that are intended to prevent even the appearance of wrongdoing . . .” *Crandon v. United States*, 494 U.S. 152, 164 (1990).

- which has interests that may be substantially affected by the performance or nonperformance of the official's governmental duties.⁴⁰
2. An entity is not a "disinterested" nor "detached" source, and specifically *has* interests that "may be" substantially affected by the performance or nonperformance of the official duties of a federal officer when that officer is "in a position to act favorably to the giver's interests," that is, when he has the "capacity to exercise governmental power or influence in the donor's favor."⁴¹
 3. The Director of a federal agency has the official authority, responsibility and duty to direct, oversee, manage and supervise the agency decisions regarding the making of grants and the continued certification of certain grantee entities, may not divest himself of such authority and responsibility by way of delegation, and thus, obviously, has significant federal authority, power, capacity and official responsibilities that may substantially affect the interests of such a grantee of that agency.⁴²
 4. The federal gift restrictions, therefore, prohibit the Director of a federal agency such as the National Cancer Institute from personally enriching himself by accepting large cash "awards" or "prizes" from grantees of his own agency.

Mr. GREENWOOD. We thank you very much, Mr. Maskell.
Dr. Varmus.

TESTIMONY OF HAROLD VARMUS

Mr. VARMUS. Thank you, Mr. Greenwood. Thank you and your colleagues for holding this hearing and giving me an opportunity to speak. I agree with you that if there are concerns about ethics practices of the NIH that the vit unshanum on those practices will be useful to maintain the integrity and utility of the NIH.

I have been asked to speak about some historical matters so I will be addressing some of the questions Ms. DeGette raised in her opening statement and not the specific cases that you mentioned in your opening comments, Mr. Chairman.

What I would like to do is give you a brief historical review of the situation, comment a bit on the evolution of views about management of conflict of interest and ethics matters, and comment on the current status of issues at the NIH.

My current opinions are based on three phases of my career. First, as a faculty member at the university of California during the 1970's and 1980's; second, as Director of the NIH from 1993 to 1999; and, finally, in my current capacity as the head of an academic health center in New York.

Some brief history. During the 1970's and 1980's biomedical research was profoundly transformed by the birth of the biotechnology industry. This enterprise, as you know, has generated some remarkable products, hepatitis B vaccines, human insulin, hormones that we use to protect patients undergoing chemotherapy, major advances the public welcomes.

The growth of this industry was also remarkable because it depended heavily on an unusually intimate relationship between industry and the nonprofit sector, especially scientists and academic

⁴⁰ 5 U.S.C. § 7353(a)(2); 5 C.F.R. §§ 2635.202, 2635.203(d), 2635.204(d).

⁴¹ *United States v. Sun-Diamond Growers of California*, 526 U.S. 398, 405-411 (1999); 8 Op. O.L.C. 143, 144 (1984); OGE Advisory Opinions Nos. 83 x 11 (July 26, 1983), and 92 x 7 (February 26, 1992). There need not be a particular identifiable matter before or "on the desk of" the official for the regulation to apply, and if there is such an official matter immediately before the officer while he is receiving things of value, gifts and cash from that entity, then other, more serious criminal violations may be implicated.

⁴² 42 U.S.C. §§ 285a-1, 285a-2. *NLRB v. Duval Jewelry Company*, 357 U.S. 1, 7-8 (1958); *Skokomish Indian Tribe v. General Services Administration*, 587 F.2d 428 (9th Cir. 1978). An official need not have "personal and substantial" participation in a particular matter for the regulation to apply (Compare to 18 U.S.C. § 208).

institutions. These scientists are largely supported by Federal funds. They are often in State universities, receive public salaries. They are nearly always beneficiaries of Federal research grants.

They were not simply the authors of information that was used by the biotech industry. They were also intimately involved in the development of that industry as founders, consultants, board members, collaborators, and the source of newly trained employees.

Now, in that period there was no uniformity of practice with respect to how academic institutions managed the many potential conflicts and outside activities conducted by their employees. Government scientists, especially those working as bench scientists in the intramural program of the NIH were subject to much more severe limitations.

Despite the fact that they are neither regulators of non-Government research nor responsible as bench scientists in the intramural program for awarding grants and contracts in distinction to scientists of the NIH who work in the extramural program that awards grants and contracts.

In fact, you could argue that Government scientists in the intramural program have position descriptions very similar to those of academic scientists at universities and health centers.

Now, when I came to the NIH as director in the fall of 1993, it was quite clear from a number of sources that the intramural research program was held in relatively low esteem by outside scientists and morale was low. That is well documented by a long article that appeared in *Science Magazine* in August 1993 and other pieces of evidence that included the inability to recruit scientists from the outside. Nearly all recruits were people who had been trained within the NIH, and it was also apparent from the well-documented loss of many of the most prominent scientists at the NIH to academic or industrial sectors.

This was not simply due, in my view, to the restrictions on outside activity interactions but that certainly was a component, both the limitations on industrial interactions and restrictions on other outside activities including bans and honoraria and so forth. One of the things that I did when I came to the NIH was to try to restore the NIH, especially the intramural program, to its former high regard.

We brought together a distinguished group, our own Blue Ribbon Panel, to look at issues of management, evaluation procedures, facilities.

Then in 1995 when we were advised by the Office of Government Ethics that NIH had dramatically improved its oversight of outside activities which had been critically reviewed several years earlier, and that we were advised that NIH had come into compliance with less restrictive policies employed by other Federal agencies, I lifted the restrictions as another step toward making the NIH intramural program more welcoming to outside scientists.

Included in that lifting of restrictions was the explicit directive that all outside activities would be carefully reviewed by ethics officers to ensure they did not interfere with the conduct of official duties.

Later I also sought permission from the Department to expand the use of alternative pay scales, again as part of a multi-factored

approach to improving the intramural research programs assigned to equality.

I believe that in the aggregate those steps have been successful. The intramural program does have the very high regard in these scientific communities that it had 20 years ago. It competes effectively with academic institutions for outstanding job candidates at the junior level. Many of its current leaders have been brought to the NIH in the last decade in the extramural community.

It is difficult to know how much to ascribe that to changes in compensation, policies governing outside activities, to new buildings, to the altered reputation itself, or to improved management practices. But to give you one example, the vaccine research center, a brand new entity on the campus, has successfully recruited 10 new outstanding staff to conduct research in the pursuit of an AIDS vaccine and the director of the vaccine research center advises me that if he did not have the salary capabilities conferred by Title 42 and the ability to offer the possibility of outside activities, that he would have had a very difficult time in making those recruitments.

There have been many changes in the approach that the extramural community has made; that is, the academic community has made to issues of outside activities over the last 4½ years since I left the NIH. A number of important cases and meetings have brought to the attention of this community the need for clear definitions of what conflicts of interest are when they pertain to individuals and institutions.

More attention has been given to conflicts of commitment; that is, situations in which excessive reimbursement or unusual amounts of time given to an outside activity may deflect attention to the prime interest of an academic scientist. We are paying more attention to appearance of conflict of interest. Complicated cases are now reviewed by conflict of interest committees composed of scientists, administrators, lawyers, and many informed lay persons.

I have testified, of course, to Dr. Zerhouni's Blue Ribbon Panel. I agree largely with the recommendations the Blue Ribbon Panel has made. I have emphasized the continued importance of allowing participation in outside activities including consulting for industry to maintain the vibrancy of the intramural research program to ensure that the talents of its members are fully utilized for the benefit of society, and to provide the tools necessary for effective recruitment and retention of outstanding scientists.

I have also argued in contrast to the policies we have put in place in the mid-1990's that rules of engagement now need to be more explicit, more restrictive. We have learned something over the last several years. Some reasonable limits in the number of hours devoted to and the amount of compensation received from an outside activity.

I have suggested that senior personnel such as institute and center directors who are responsible for the award of grants in the development of programs be barred from certain activities. I have applauded Dr. Zerhouni's creation of his trans-NIH committee, the so-called DEAC. I commend him for trying to enlarge the group of intramural scientists who must provide full general disclosure. I believe in disclosure.

Final actions by the Director of NIH on these and other matters addressed in the panel's report should take into consideration your deliberations here, public comments on the report, the views of NIH employees and others. I appreciate the efforts you are making, Mr. Chairman, to study these complex issues and I will be pleased to respond to any questions you might have. Thank you for indulging me with my slightly overlong presentation.

[The prepared statement of Harold Varmus follows:]

PREPARED STATEMENT OF HAROLD VARMUS, PRESIDENT, MEMORIAL SLOAN-KETTERING CANCER CENTER

Mr. Chairman and Members of the Committee: Thank you for an opportunity to speak with you about rules governing the outside activities of scientists employed by the National Institutes of Health (NIH) and about my views of the recommendations recently made to the NIH Director by the panel he established to review practices related to conflicts of interest. I welcome the public discussion of these topics, because the NIH is of such importance to the future of biomedical research and health care, and the conduct and management of its research program are therefore matters of general concern.

My current opinions about the complex issues being addressed at your hearing today are based on my experiences in three phases of my career—first, as a faculty member at the University of California, San Francisco, Medical School from 1971 to 1993; second, as the Director of the NIH, from 1993 to the end of 1999; and, third, as the current head of the Memorial Sloan-Kettering Cancer Center (MSKCC) in New York City. Each of these phases offered lessons that are pertinent to our important discussion here today.

Phase 1: Birth of the biotechnology industry

It helps to begin with some history. During the 1970's and 1980's, biomedical research was transformed by advances in molecular biology and genetics that led to the development of recombinant DNA technology. Once the government and the scientific community reached agreement about reasonable means to monitor the safety of these new methods, an industry based on them—the biotechnology industry—was born and grew rapidly, especially in the Bay Area, where I was working. Soon this new enterprise generated and began to manufacture some of its now numerous products—such as human insulin, hepatitis B virus vaccine, and hormones that protect the bone marrow after cancer chemotherapy—major advances in health care that help to justify to the public the major investment that our country has made in basic biomedical sciences.

The growth of the biotechnology industry was also remarkable because it depended heavily on an unusually intimate relationship between the industry and the non-profit sector, especially scientists in academic institutions. These academic scientists, largely supported by public funds (often salaried by state universities and nearly always beneficiaries of Federal research grants), were not only the authors of the published knowledge on which the biotechnology industry was built; they were also the founders, the consultants, the board members, the collaborators, and the sources of newly trained employees for the companies. Different academic institutions displayed a wide range of attitudes towards these activities, without consensus on the nature or seriousness of any potential conflicts and often without clear guidelines for preventing or governing them.

One indisputable feature of this change was the enhanced fertility and frequency of relationships between the academic and industrial sectors. In contrast, government scientists, such as those working in the intramural program (IRP) of the National Institutes of Health, were more likely to be subject to limitations to their participation in these productive and interesting interactions, despite the fact that they were neither regulators of non-government research nor responsible for awarding grants and contracts. In fact, in most ways, the government scientists in the IRP could be viewed as having position descriptions very similar to those of academic scientists at universities, health centers, and research institutes: to perform not-for-profit research, largely with public funds, with the intention that the findings will be useful for the control of disease. (The major differences between IRP and academic scientists are related to funding mechanisms, review procedures, and the speed of the IRP's response to new health threats.)

Phase 2: Strengthening the NIH IRP

The governmental restrictions, however, on industrial interactions and other “outside activities” (such as bans on honoraria for speaking, editing, and writing), combined with less generous salary scales and many concerns about the management of research activities in the Federal agency, contributed to the relatively low esteem in which the IRP was held by outside scientists and to the low morale in the program when I arrived at the NIH as Director in the fall of 1993. Worrisome consequences of these attitudes included ineffective recruiting of new staff from the external scientific community (it was reported that 70% of recently recruited staff had been trained in NIH laboratories) and the recent loss of some of NIH’s most prominent scientists to the academic or industrial sectors. (Some of these issues are discussed in a lengthy news article that appeared in *Science* magazine in August, 1993; J.Cohen, “Is NIH’s Crown Jewel Losing Luster,” *Science* 261: 1120, 1993.)

As a proud product of the NIH intramural training program in the late 1960’s, when it was considered to be in an extraordinarily productive phase, I was intent on trying to return the IRP to its earlier stature in my new position. To achieve this, my colleagues and I energetically and successfully followed the recommendations made by a panel of distinguished investigators that we convened to address concerns about management, evaluation procedures, and facilities in the IRP (Report of the External Advisory Committee of the Director’s Advisory Committee and Implementation Plan and Progress Report, November 17, 1994). I sought permission from the DHHS, again successfully, to expand the use of alternative pay scales, including the Senior Biomedical Research Series, and alternative hiring authorities, such as Titles 38 and 42. When advised by the Office of Government Ethics in 1995 that NIH had dramatically improved its oversight of outside activities, following a critical appraisal in 1991, and should come into compliance with the less restrictive policies employed at other Federal agencies, I lifted the restrictions as another step towards making the NIH IRP more welcoming to outstanding scientists, with the explicit understanding that all outside activities would be carefully reviewed by ethics officers to insure that they did not interfere with the conduct of official duties.

In my estimation—and, I believe, in the estimation of most of the scientific community—the IRP has largely regained its stature and its productivity. It competes effectively with academic institutions for outstanding job candidates at the junior level, and many of its current leaders have been brought to the NIH campus in the past decade from the extramural community. It is difficult, of course, to know how much to attribute the improved status of the IRP to changes in compensation, policies governing outside activities, new buildings, altered reputation, or improved management practices. But, to offer one example, the Director of the new Vaccine Research Center (VRC) has told me that he would have been unable to recruit most of the seven junior and three senior scientists he has hired at the VRC since his arrival in 1999 if he did not have Title 42 authorities to offer salaries competitive with those provided at outside institutions; furthermore, while his new staff members fully understand the need for careful review of their outside activities for conflicts of interest and commitment, they would have been discouraged from coming to the NIH if it were considered unethical to use their general knowledge to advance the practical use of new information by consulting for industry.

Phase 3: Growing sophistication of approaches to outside activities

During the nearly four and a half years since I left the NIH for MSKCC, I have closely observed and participated in the evolution of attitudes at academic health centers towards outside activities, particularly those that involve the for-profit, industrial sector. In view of the dangers posed by conflicts of interest in clinical research, many academic health centers—acting alone and through their associations—have re-examined their rules for the conduct of clinical research. They have also sought clear definitions of conflicts of interest that affect individual investigators or entire institutions, and they have applied them to the conduct of basic laboratory research as well as clinical research. As a by-product of these deliberations, more attention is now also given to the conflicts of commitment that result from the devotion of relatively extensive time to, or the receipt of relatively generous reimbursement from, an outside activity. Furthermore, academic institutions increasingly appreciate the importance of even the appearance of conflicts of interest or commitment, since a perceived potential for conflict can undermine public confidence in medical research.

Importantly, the accumulated experience with a wide variety of outside activities undertaken by employees at many non-profit research institutions indicates that complicated cases are generally uncommon, but difficult to judge by a simple rule book. For this reason, many academic centers, including our own at MSKCC, have established conflict of interest committees, composed of scientists, administrators,

lawyers, and informed laypersons, to review unusual and complex situations on a case-by-case basis and make recommendations to institutional leaders for the management of those cases.

Advice to the Blue Ribbon Panel

These more sophisticated approaches to management of outside activities in academia should also be applied to the NIH IRP, as I maintained when I testified before the Blue Ribbon Panel that Elias Zerhouni, Director of the NIH, recently assembled to advise him about conflict of interest policies. More specifically, I emphasized the continued importance of outside activities, including consulting for industry, to maintain the vibrancy of the IRP, to ensure that the talents of its members are fully utilized for the benefit of society, and to provide the tools necessary for effective recruitment and retention of outstanding scientists. I also argued that rules of engagement need to be more explicit and frequently revisited—and revised if necessary—while remaining consistent with the cardinal principle of non-interference with the performance of official duties. I applauded Dr. Zerhouni's creation of a trans-NIH conflict of interest committee and his already successful efforts to enlarge the group of IRP scientists required to provide full public disclosure, not just internal disclosure, of their compensated outside activities. I also argued that some reasonable limits should be placed on the number of hours devoted to and/or the amount of compensation received from an outside activity. Finally I recommended that senior NIH personnel, such as Institute and Center Directors, who are responsible for the award of grants or the development of extramural programs and who are unable to recuse themselves in favor of an appropriate superior should not be permitted to engage in outside activities involving potential or actual beneficiaries. (I also proposed some of these policy changes in written testimony submitted to the Labor-HHS Subcommittee of the Senate Appropriations Committee on January 15, 2004.)

In general, I agree with the Blue Ribbon Panel's recommendations, as presented to your Committee last week by Bruce Alberts and Norman Augustine, with a few qualifications. I believe that exclusion of senior Institute and Center personnel from consulting for industry or academia should be based on function (namely, formulation or funding of extramural programs as opposed to direction of intramural research), rather than seniority or title. I also believe that exemptions should be permitted from the ban on reimbursement with equities if reviewed favorably by the trans-NIH conflict of interest committee. Final actions by the NIH Director on these and other matters addressed in the Panel's report should take into consideration public comments on the report, the views of NIH employees and grantees, and the opinions formed by this Committee and the Congress as a consequence of these hearings.

I appreciate the efforts you and your colleagues are making, Mr. Chairman, to study these complex issues by holding this series of hearings. Your actions and views can have important consequences for one of the world's most esteemed research organizations.

I would now be pleased to respond to any questions you might have.

Mr. GREENWOOD. That is quite all right. Thank you, Dr. Varmus.

The Chair would recognize the Chair of the full committee, Mr. Barton, for purposes of inquiry for 10 minutes.

Chairman BARTON. Thank you, Mr. Chairman. I may not have 10 minutes of questions but I do have a few. I want to start with Ms. Glynn. On page 4 of your testimony you say, and I am quoting from it, "It would be somewhat peculiar to say that the agency had and other senior management essentially may never receive an award from anyone involved with the agency." Well, I am not sure I think that is so peculiar so why would it be peculiar if we just had a blanket categorization that you couldn't receive a cash award?

Ms. GLYNN. I think you have to remember that the rule we are talking about, the one promulgated by my office, is an executive branch-wide rule so it would have similar applicability at DOD, for example, and NIH. We are very concerned when we promulgate these rules that we don't go overboard while trying to address the issues that are present at one particular agency.

For example, at DOD you would have to assume that virtually every company in the country would be a prohibited source for Secretary Rumfeld to receive an award from because virtually every major corporation in the country——

Chairman BARTON. I may be misinterpreting your testimony but I am talking about cash awards. I am not talking about getting a plaque for good guy of the year.

Ms. GLYNN. That is right, sir.

Chairman BARTON. Where there is a cash stipend that goes with it.

Ms. GLYNN. Yes, sir. I understand that. That is the reason we came up with this test that affords at least a small modicum of flexibility. Frankly, I would say, for example, in the DOD example I just gave there is no way that Secretary Rumfeld would ever be approved to accept an award from Northrup Grumman or Lockheed Martin. But by contrast, Coca Cola or Disney does do business with DOD and they might conclude that any matters involving Coca Cola or Disney is far removed from any of the work that he would do.

Chairman BARTON. I am checking with the House Ethics Committee and the Congressional Research but I am not aware that a Member of Congress while he or she is in Congress can receive any kind of a cash award. It is just not done and there are 435 of us so there are 434 watchdogs. At least whatever the other party is, you know they are going to watch us like a hawk and we watch them.

Ms. GLYNN. Sure. The President in an executive order has issued an outside earned income ban for all Presidential appointees. But one exception to that ban is our regulation that allows these bona fide awards. Once again, I think the head of NIH, if he were eligible to receive a Nobel prize would probably not want to have to turn that prize down even though it involves a cash award.

Chairman BARTON. Well, not just in NIH and FDA but Government-wide how many Federal employees each year either receive or are offered cash awards? Are we talking about hundreds, thousands, tens of thousands?

Ms. GLYNN. We have no data on that, but I'll be honest, with my informal discussions with agency ethics officials in preparation for this hearing, awards at other agencies are infrequent.

Chairman BARTON. Infrequent?

Ms. GLYNN. Yes, sir.

Chairman BARTON. Could you ask your staff to compile whatever inquiries you have—is it a requirement that if one is offered a cash reward, they have to touch base with your department?

Ms. GLYNN. No, it is not a requirement but we certainly could do a sort of informal survey of major agencies.

Chairman BARTON. Should it be a requirement? Should we require by statute that any Federal employee that is offered a cash award has to have it cleared by your office or some office?

Ms. GLYNN. I hate to invite that little bit of extra work. Maybe perhaps for a certain level of employee; I am not sure that I would want every GS-9 who gets offered a cash award to have to clear it through our office.

Chairman BARTON. So under current statute someone—there is no requirement that any person offered a cash award touch base with your group?

Ms. GLYNN. No, sir.

Chairman BARTON. So it is all voluntary?

Ms. GLYNN. They have an ethics official. Remember the ethics program is a decentralized program so there is a designated ethics official at every agency. That person would normally be involved in the approval of such awards.

Chairman BARTON. But do they—

Ms. GLYNN. They are not required to consult with us, though.

Chairman BARTON. So yours is purely—

Ms. GLYNN. Anecdotal evidence.

Chairman BARTON. [continuing] a service that is available if they want to use it.

Ms. GLYNN. Yes.

Chairman BARTON. It is not mandatory.

Ms. GLYNN. Yes, sir.

Chairman BARTON. Okay. Now, Mr. Swindell, you are the person, I believe, that on Dr. Clausner's request to receive the award from the University of Pittsburgh, you are the one that said that was okay. Is that right or wrong?

Mr. SWINDELL. Yes, sir. I am the one that signed that approval and it is not a decision that I look back on with fondness or pride.

Chairman BARTON. Okay.

Mr. SWINDELL. I think the situation was one where I relied too uncritically on the direction and information provided to me by General Counsel Rabb at that time. In that regard, let me provide some background of how we had to operate back in that prior administration.

We and other attorneys in the Office of General Counsel at that time had been specifically instructed to provide advice and evaluate issues based on whether any reasonable argument could be made that a particular course of action was legally supportable. The view was that the decisionmakers, the political appointees and other senior officials were to be responsible and accountable themselves for the choices that they made. To say no to anything the lawyers would have to demonstrate that was the only real possible answer.

Chairman BARTON. Now, wait a minute. That is the political guidance that came to you or that is your—

Mr. SWINDELL. I will read to you, Mr. Chairman, a copy of a note to a file that I wrote 10 years ago in 1994. I was a staff attorney in the Ethics Division at that time. I provided the committee a copy of the note. If you will permit me to quote from it because I think it is pretty interesting.

Chairman BARTON. These are your words?

Mr. SWINDELL. These are my words written to a note to the file in 1994.

Chairman BARTON. Okay.

Mr. SWINDELL. This is 3 years before the Clausner award. It said, My supervisor indicated to me that the General Counsel instructed him to confine ethics advice to purely legal answers. We are no longer to provide observations about the wisdom of particular actions or policy or how things may appear on the front

page of the Washington Post or possible political ramifications of options.

These matters are for policymakers. The General Counsel does not desire career objective view as a check on official actions. We are to decide only if there is a legal objection, i.e., whether the action or option is legally supportable under the law and regulations.

My supervisor, in turn, instructed me to carry out the General Counsel's wishes. He said that he had written a note to the file to document this instruction and advised me to do the same. There may arise situations where when we comply with these instructions and are prevented from providing full counsel—

Chairman BARTON. I have the gist of it. So what you are basically saying is as long as at some point in the past you have written a note to the file to cover your bottom, it is okay. Whatever the guys on top tell you to do, you are going to find a way to do.

Mr. SWINDELL. Well, essentially—

Chairman BARTON. Tell us your title at HHS right now.

Mr. SWINDELL. It is Associate General Counsel.

Chairman BARTON. For what?

Mr. SWINDELL. For ethics.

Chairman BARTON. For ethics?

Mr. SWINDELL. That is right. I can assure you that we do not operate under this type of advice under the current administration.

Chairman BARTON. And what was your title in 1994?

Mr. SWINDELL. I was a staff attorney in the ethics division.

Chairman BARTON. For ethics.

Mr. SWINDELL. Yes, sir.

Chairman BARTON. Okay.

Mr. SWINDELL. The problem is—

Chairman BARTON. So, as I understand that note, though, the direction is even though you are in the ethics division, you are not supposed to use any ethics. You are supposed to use your legal training to render the decision that the political higher ups ask you to render.

Mr. SWINDELL. It is a fair criticism to render the precise answer and allow the individual to take the risk of the appearance.

Chairman BARTON. Okay. Does an associate general counsel or an assistant general counsel in HHS and ethics, is it ever ethical to just resign or to say, "I can't do that," and give you what my real opinion is?

Mr. SWINDELL. Well, there was a restrain on us. I checked my bar rules to make sure. The bar rules require lawyers to provide counsel on ethics, political, social, and so forth. They also say the client waive those.

Chairman BARTON. Do you view the job of the Ethics Division as a watchdog for the integrity of the American people or as a lapdog for whoever the superiors happen to be at the time? That is a serious question.

Mr. SWINDELL. It is a very serious question. Unfortunately, I do not view it the bad way. I view it as we want to do the right thing. I have devoted a dozen years of my career to working on ethics. I was very concerned about the restraints on us. I kept being reassured that the officials would be responsible for the risk of their assessment of what people think about them.

Chairman BARTON. My time has expired. I want to ask a question of Dr. Varmus very quickly.

You were an NIH director in the mid-1990's and my briefing book says you are the one that made the decision to lift the restrictions on consulting at NIH. Is that true?

Mr. VARMUS. Yes. Of course, in consultation with other people.

Chairman BARTON. But it was your ultimate decision. In hindsight do you think the decision you made then, if you had to make it today knowing what you know now, would you make the same decision?

Mr. VARMUS. As I have indicated, I think we have learned a lot about the problems of managing this kind of—these outside activities and the difficulties of appearance of conflicts and I would do it somewhat differently as I have indicated in my testimony.

Chairman BARTON. Okay. Thank you, Mr. Chairman.

Mr. GREENWOOD. If the gentleman will yield, I want to clarify one thing. I know he has no time to yield but, Mr. Swindell, you said you received those directions from your superior. Would you identify your superior?

Mr. SWINDELL. My superior at that time, his name was Jack Kress.

Mr. GREENWOOD. Jack Kress with a C or a K?

Mr. SWINDELL. K-R-E-S-S.

Mr. GREENWOOD. And did Mr. Kress indicate to you what motivated him to render that advice to you, whether he had been chastised from someone in a superior position to him or what the genesis of that was?

Mr. SWINDELL. It was my understanding that this came after a performance review that he had. In fact, about 6 months—

Mr. GREENWOOD. And who would have been reviewing his performance?

Mr. SWINDELL. The General Counsel Harriet Rabb. In fact, about 6 months later my supervisor shared with me a criticism he had received from the General Counsel about a memorandum that I had drafted for the supervisor's signature that stated that certain conduct would not be prudent. She said that this was our old problem of giving opinions about appearances rather than just stating legal conclusions backed by law.

Mr. GREENWOOD. Did you ever have a sense of what motivated Ms. Rabb to do that, whether someone in a superior position to her had—

Mr. SWINDELL. I don't know.

Mr. GREENWOOD. Okay. The gentlelady from Colorado is recognized for 10 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman. Mr. Swindell, you had mentioned with the Chairman's example that that waiver was given under the previous administration but the waiver that was given to Tom Scully was given under this administration. Correct?

Mr. SWINDELL. Are you talking about a conflict of interest?

Ms. DEGETTE. Yes, sir.

Mr. SWINDELL. Yes, the Scully waiver.

Ms. DEGETTE. Right. That was the one on May 12, 2003. Right?

Mr. SWINDELL. I am not sure.

Ms. DEGETTE. Okay. Now, in that situation basically you recommended that HHS Secretary Thompson issue a waiver to Tom Scully who was the head of CMS—we all know him—so that he could negotiate employment with persons having matters before Mr. Scully which included lobbyist and law firms with drug companies and health care companies as their clients. Is that right?

Mr. SWINDELL. Yes, I prepared the document that the Secretary signed.

Ms. DEGETTE. Now, Mr. Scully told you in his memo, and I am quoting, “These entities are likely to have substantial interest in matters pending before the Department and Mr. Scully has responsibility for such particular matters that may affect the financial interest of the firms with which he may seek employment.” Is that correct?

Mr. SWINDELL. I will be able to explain in a moment the process.

Ms. DEGETTE. Okay. I understood but that is what he said to you in his memo. Right?

Mr. SWINDELL. I am not sure there was a memo to me.

Ms. DEGETTE. Okay. Actually, this is your memo.

Mr. SWINDELL. This is my memo to the Secretary.

Ms. DEGETTE. Right. So did you write those words?

Mr. SWINDELL. If they are in the document I wrote those words.

Ms. DEGETTE. Okay. Now—

Mr. SWINDELL. Actually, a staff attorney prepared it.

Ms. DEGETTE. The HHS regulations on post-employment restrictions state that current employees who have begun seeking or negotiating for non-Federal employment must recuse themselves from participating in any official matter that involves the perspective employer including a legislative initiative or policy initiative that affects the perspective employer as a member of a defined class. Is that right?

Mr. SWINDELL. If it is in the document, that is right.

Ms. DEGETTE. Now, have you ever given the kind of waiver you gave to Mr. Scully to a Senate confirmed official while he was the agency lead on a major piece of legislation?

Mr. SWINDELL. I don’t know about the specifics about legislation but there have been many waivers like that granted in the past including one approved by President Clinton with regard to Donna Shalala when she was head of HHS and talking to universities. Of course, universities—

Ms. DEGETTE. Well, but at this time this was right in the middle of Mr. Scully’s negotiations with Congress on the Medicare bill, right?

Mr. SWINDELL. As it turns out—

Ms. DEGETTE. May 2003.

Mr. SWINDELL. I think afterwards that was the case.

Ms. DEGETTE. Right.

Mr. SWINDELL. By the time he came to me I was not aware of what all he was involved in.

Ms. DEGETTE. He didn’t tell you he was involved in those? Didn’t your memo exactly say that he had substantial interest pending before—

Mr. SWINDELL. That is a presumption that would be the case, that there would be industries—

Ms. DEGETTE. Now, did anybody tell you to give Mr. Scully this waiver? You said before your boss told you. That was your decision?

Mr. SWINDELL. No. The manner in which we deal with conflicts of interest when someone leaves the Government, I will be happy to explain the process and why it is important.

Ms. DEGETTE. Okay. Briefly, please.

Mr. SWINDELL. Section 208 of the criminal statute and some regulations require employees to recuse from matters once they start talking about employment.

Ms. DEGETTE. Right. Did Mr. Scully recuse himself from negotiating the Medicare bill?

Mr. SWINDELL. I don't know whether he recused from negotiating the Medicare bill. The key point is there are some narrow distinctions in the law itself that talk about two types of matters, the particular matters of general applicability and particular matters involving specific parties.

The ethics concerns for the particular matters of general applicability are less than they are for a particular matter involving specific parties. The idea is if you are someone like the head of an agency and you are talking with someone in the agency that you regulate, then you are going to be recused from doing your job totally. It means that you—

Ms. DEGETTE. Well, not really. Only if you are looking for another job and there is a major bill pending before Congress that affects lots and lots of people to whom you are applying for a new job. Right?

Mr. SWINDELL. If the same situation was with Donna Schlala, the idea is that the agency head, if they start talking with someone when they are trying to leave the agency, they will have recusal obligations that are very, very extensive and basically can't do their job.

Ms. DEGETTE. Okay. Well, I understand but when Donna Shalala—I really do understand but here is the thing. Did you then as part of your waiver to Mr. Scully say, "Now, don't negotiate specific pieces of legislation with Congress in which these folks may have a financial interest."

Mr. SWINDELL. No, because a piece of legislation is a particular matter of general applicability which is what the waiver covered.

Ms. DEGETTE. So how many times have you given those types of waivers to senior government officials like the one to Mr. Scully?

Mr. SWINDELL. Well, first of all, they are issued by management, not me. These are signed by the Secretary or Assistant Secretary.

Ms. DEGETTE. Okay. So it was the Secretary.

Mr. SWINDELL. The Secretary approved it.

Ms. DEGETTE. Okay. But it was your recommendation?

Mr. SWINDELL. Sure.

Ms. DEGETTE. Okay. I am sorry. Maybe we will have another round and we can explore this further.

Mr. SWINDELL. I would be happy to provide the Congress with a statement explaining the law.

Ms. DEGETTE. That would be super. That would be great.

Now, Dr. Kington, I actually got all the different statute books that had the different ethical rules in it. It seems to me there are

lots of ethical rules, Ethics in Government Act, Privacy Act, Freedom of Information Act, the internal NIH rules. Is this causing some confusion and angst among your researchers as to what they can and can't do right now?

Mr. KINGTON. Fortunately, we have a large staff of attorneys mostly who advise us on compliance with the law. There are multiple laws involved and it is challenging to get the precise answer.

Ms. DEGETTE. Right. I am sure the attorneys love that. I used to be an attorney. My question is about the researchers. Are they feeling confused about—

Mr. KINGTON. Certainly now when we are in this period of transition, yes. We try to give them as much direction as we possibly can given what we know about the law.

Ms. DEGETTE. Okay. Dr. Varmus, when you assumed the directorship of the NIH, did you find that the institutes were populated with second-rate scientists?

Mr. VARMUS. There were some, yes. There were many reasons to believe the review processes had not been stringent enough. NIH had not been able to recruit the best people to come into these staff positions. There was much reason to believe based on both conversations and reportage that the NIH intramural program did not have the—was not held in the esteem which it was held 10 to 20 years earlier.

Ms. DEGETTE. And do you think that was mainly or solely because of the issue of outside compensation?

Mr. VARMUS. As I have indicated in my testimony and in my statement, Ms. DeGette, only partly. There are many other reasons having to do with management and review processes. It is a complex situation and we tried to deal with matters across the board.

Ms. DEGETTE. And, you know, you probably wouldn't be surprised to hear last week in our hearing some of the testimony was that the younger scientists, the people doing a lot of the basic research at NIH right now, and since you came in in the mid 1990's, morale is pretty good now. Also interestingly, most of these researchers aren't receiving this outside compensation. Would that surprise you?

Mr. VARMUS. That doesn't surprise me, no. I think the issue is not simply whether you are active in that process but whether the intramural program scientists who don't have responsibilities for regulation, for making grants, whether they have the opportunities that their equals on the outside have. I think it is a simple matter—

Ms. DEGETTE. And it is not so much for them about compensation as about research opportunities. Wouldn't that be fair to say?

Mr. VARMUS. Well, it is a mixture. What kind of atmosphere obtains the intramural program. Do people feel like they are second-class citizens. Do they not have the opportunity even if they don't use it to undertake consultations to carry out outside activities.

Remember that not all of the outside activities are concerned with industrial relations. In many cases this is just a matter of honoraria for talks and special publications. When I came to the NIH the whole intramural program was called the honorarium ban in which matters of writing special kinds of review articles or giv-

ing lectures could not be compensated as they were for people on the outside. It created an atmosphere——

Ms. DEGETTE. You know, I have got to say this happens to Members of Congress all the time. I get invited to speak to groups and they might invite somebody from private industry or something to speak and give them a cash award. When I go, I get a really nice placque. We all have rooms full of them. But for me it is the honor of going and speaking to the group. I know that someone else from a university or somewhere else might be allowed to take a cash award. Truly, most of these folks it is about the prestige of the event.

Mr. VARMUS. As a former Presidential appointee, I feel your pain about not getting awards.

Ms. DEGETTE. It is actually not painful for me.

Mr. VARMUS. We have to also recognize that an intramural scientist is very different from a legislator or very different from someone who runs an agency. It creates an atmosphere that people don't find attractive when they are making choices of jobs when they can go to a place where the world seems open to them where very similar kinds of work are being done at a university laboratory, for example, as opposed to going to the NIH. The NIH is just——

Ms. DEGETTE. I just have one more question because under this Blue Ribbon Panel recommendation, the senior appointees at the NIH would not be able to accept these kinds of awards as I understand it. It would just be the more junior researchers who aren't getting them right now. My question is why not make a more bright line rule and at least set some pretty clear standards so people wouldn't be confused about it.

Mr. VARMUS. Because I think we have to distinguish not between juniors and seniors. We have to distinguish between those who have certain kinds of functions. Every opportunity has a risk and I don't deny that there are risks. That is why we have the NIHEAC and why we have rules. I, too, now would argue that it is useful to have some guidelines that will prevent conflicts of commitment and outright conflicts of interest. I don't think it is appropriate to ban all these activities because they do have utility. It is not difficult to imagine someone saying, "Gee, it seems a shame to have all these talented people at the NIH who are unable to provide any advice."

Ms. DEGETTE. Let us be clear and then I am finished. I appreciate the Chairman's indulgence. No one is suggesting that we ban all these outside activities. What we are talking about is what we do about compensation. We can explore that further. Thank you.

Mr. GREENWOOD. If the gentlelady would yield, certainly a CRDA is a perfectly acceptable manner by which the scientists at NIH get to work collaboratively with private sector scientists to produce excellent results for the public for which there is no compensation.

Mr. VARMUS. I agree.

Mr. GREENWOOD. I have not come to the point where I am prepared to say there should be no outside compensation but I think it is important to note that even if we did, that would certainly not be an impediment to the NIH scientists working collaboratively in the private sector for the good of mankind.

Ms. DEGETTE. And reclaiming the time that I don't have, I concur with the Chairman which is I am not to the point where I think we should ban it but I think there are so many issues here and they are very complex that I think it should be a real consideration.

Mr. VARMUS. And they are concerned. Even those of us who are outside of Government now in the academic sector feel this very acutely. We have all been revising our rules, changing the way in which we monitor our investigators to avoid the same kinds of conflicts you are worried about because, indeed, many of our people are supported, almost all of them are supported with public money they receive from the NIH and many of them at public institutions like State universities have other kinds of public monies. These are major concerns.

Mr. GREENWOOD. The Chair thanks the gentlelady. The Chair would note—first, the Chair would ask unanimous consent that the document binder be incorporated into the record. Without objection it is.

The Chair would note that there is a series of votes in process right now so we are going to have to recess probably until 12:30. We apologize to the witnesses for keeping you that much longer but it will take us that long to get through the series of votes and get back here. The committee is in recess until 12:30.

[Whereupon, at 11:37 a.m. the subcommittee recessed to reconvene at 12:37 p.m.]

Mr. GREENWOOD. A quorum being present, the hearing will reconvene, and the Chair recognizes himself for 10 minutes for purposes of questions. And I am going to begin with you, Mr. Swindell.

Your testimony on page 4 states that HHS employees must address the concerns of the many while avoiding the appearance or fact of undue influence by the few. Is that correct?

Mr. SWINDELL. I don't have a copy.

Mr. GREENWOOD. And you agree that HHS employees attempt to accomplish avoiding appearance of undue influence in part through legal advice provided by your division, or, if they are political appointees, from you as the HHS designated agency ethics official. Is that correct?

Mr. SWINDELL. Yes, I am.

Mr. GREENWOOD. Okay. Well, I didn't ask you if that is who you were. I said, "And you agree that HHS employees attempt to accomplish avoiding the appearance of undue influence in part through legal advice provided by your division, or, if they are political appointees, from you as the HHS designated agency ethics official."

Mr. SWINDELL. The HHS Ethics Division—its principal clientele are the political appointees. The DEC's who run the programs within the Department do the ethics in those components, and as needed, and they consult the Ethics Division.

Mr. GREENWOOD. Okay. So, for example, in 1996 when Dr. Clausner was offered a \$30,000 award from the University of Pittsburgh, he sought advice on whether to accept this award. Is that correct?

Mr. SWINDELL. He came to the General Counsel to seek advice about that.

Mr. GREENWOOD. Okay. In 1996, the first time out.

Mr. SWINDELL. The first time out.

Mr. GREENWOOD. When the answer was no.

Mr. SWINDELL. Okay. I was not the head of the office then, but you are right, I do recall. That is right.

Mr. GREENWOOD. Okay. And the advice he was given was that he could not accept the award, is that right?

Mr. SWINDELL. That is correct.

Mr. GREENWOOD. Okay. If you go to Tab 10, that binder right in front of you there, you will see a memo by the Ethics Advisor at the National Cancer Institute, Dr. Maureen Wilson, advising Dr. Clausner to decline the award because the University of Pittsburgh was a prohibited source. Can you identify that?

Mr. SWINDELL. Yes.

Mr. GREENWOOD. Okay. Am I characterizing that document correctly?

Mr. SWINDELL. Correct.

Mr. GREENWOOD. It is a memo by Wilson advising Clausner to decline the award, because the University of Pittsburgh was a prohibited source. Okay.

Do you know who Michele Russell Einhorn is?

Mr. SWINDELL. She was an attorney in the Ethics Division at that time.

Mr. GREENWOOD. Okay. If you go to Tab 12, you will see Ms. Russell-Einhorn sent you an e-mail on October 7, 1996, that included another e-mail. Do you see that?

Mr. SWINDELL. Yes.

Mr. GREENWOOD. In the message she sent to you and others she writes about a phone call with the Office of Government Ethics and the OGE which said Dr. Clausner could not accept the award for three reasons: an ongoing lawsuit involving Pittsburgh and the National Cancer Institute, a contract dispute between Pittsburgh and the National Cancer Institute, and the fact that Pittsburgh is a grantee contractor in a cooperative group trial participant funded by the NCI. Do you see that? Okay.

Mr. SWINDELL. Yes.

Mr. GREENWOOD. So you were aware that Ms. Russell-Einhorn had consulted the Office of Government Ethics and was told that Dr. Clausner could not accept the award from the University of Pittsburgh. Is that right?

Mr. SWINDELL. I was an addressee among all of the staff members. I was not focusing on NIH issues at that time, but I obviously know about this.

Mr. GREENWOOD. I didn't ask you if you were the only one who knew about it. I was asking you if you knew about it.

Mr. SWINDELL. I would have received the message. I don't know if I would have focused on it at the time.

Mr. GREENWOOD. Would you have read it?

Mr. SWINDELL. I would assume I would have read it.

Mr. GREENWOOD. Okay. In 1997, you were aware about OGE's past advice when the University of Pittsburgh offered the award again to Dr. Clausner but this time with a \$40,000 cash gift. Is that right?

Mr. SWINDELL. Yes, I looked—asked the staff to look and to see what had happened.

Mr. GREENWOOD. Okay. Did you confer with the Office of Government Ethics regarding the 1997 Pittsburgh award?

Mr. SWINDELL. That is something I have tried to think whether we did or not. I have a visual impression in my mind that a staff member was talking to me about some aspect of the opinion, about the reasonably foreseeable language, but no one can indicate that we made any—no record that we talked with them.

Mr. GREENWOOD. What would be the routine, standard operating procedure?

Mr. SWINDELL. It varies, depending upon what the issue is, if there is confusion. Obviously, when I looked at this, I thought we were going in the right direction with the concept about what we call a bad prohibited source, something that is—there is really something going on precisely at the time, the timing—and, yes, it talks about being a grantee, but I am afraid I didn't really pick up on that.

Mr. GREENWOOD. I mean, isn't that a huge red flag?

Mr. SWINDELL. If that had been the answer—

Mr. GREENWOOD. Isn't the fact that Pittsburgh—the University of Pittsburgh was a grantee, isn't that a gigantic red flag?

Mr. SWINDELL. Of course it is. But it is an exception to the gift rules for getting gifts from grantees, to get a bona fide award.

Mr. GREENWOOD. Right.

Mr. SWINDELL. So the concept exists that one could get a bona fide award from a prohibited source. This is the crux of the issue that the General Counsel and the Acting Director of OGE has now given us guidance as to what—how we analyze this.

You know, trying to think back 7 years and what was in my mind with the General Counsel asking—there were about six lawyers working on this issue, asking questions, trying to find out about what the University of—the Dixon Prize was, its connection to the University of Pittsburgh.

If the answer had been the mere fact that it was a grantee, that would have been the end of it from—OGE could have said, "It is a grantee; that is the end of it." So in grappling—

Mr. GREENWOOD. Why was that difficult to find out?

Mr. SWINDELL. It is not difficult to find out. As I said, I am not sure whether we called or not. I just don't have any records that we did.

Mr. GREENWOOD. Were you aware that Dr. Wilson sent a memo dated October 1, 1997, to Dr. Clausner raising concerns about the Pittsburgh award? If you look at Tab 22, it might refresh your memory.

Mr. SWINDELL. I assume she is giving the results of whatever we have been finding out about the University of Pittsburgh.

Mr. GREENWOOD. Did you talk with her regarding your recommendations in the memo?

Mr. SWINDELL. I don't recall.

Mr. GREENWOOD. Did you agree with her recommendations?

Mr. SWINDELL. I guess the recommendation is that Dr. Clausner would have to assure that he didn't have matters pending in front

of him that were consistent with the opinion. So to the extent that that is the case, I would agree with it, but——

Mr. GREENWOOD. So you would agree with her?

Mr. SWINDELL. Mr. Chairman, as I explained earlier, the whole result of this opinion was very technical, trying to see. The General Counsel was obviously interested. We were under an obligation to take a look at this, and if there was no legal way to stop this award, then it was not our duty to stop it. The individual was supposed to take the heat for this kind of decision and the appearance of this kind of decision.

Mr. GREENWOOD. Wait a minute. Wait a minute. You are not allowed to take money from prohibited sources, correct?

Mr. SWINDELL. You are not allowed to receive a gift from a prohibited source.

Mr. GREENWOOD. Right. Okay. And a source becomes prohibited de facto if the source is a recipient of the entity headed by the guy who is going to take the money, right?

Mr. SWINDELL. It is a——

Mr. GREENWOOD. What is the hard part?

Mr. SWINDELL. Well, I will defer to the Office of Government Ethics to explain better than I can. But there is an exception to this idea that you can't get gifts from prohibited sources. It focuses on whether the entity is a—whether the offeror of the award is an entity that has interest that can be substantially affected by the performance or non-performance of the——

Mr. GREENWOOD. All right. Where is the cloudy part in that?

Mr. SWINDELL. Well, it doesn't say agency head. If the idea is you are going to—if that means the same thing as grantee, then it is a circuitous argument. You can't have—they can't be the same. It can't be just a grantee, because you have got an exception to a rule for grantees. So it had to mean something different.

Mr. GREENWOOD. Let me ask Mr. Maskell. Do you think there is anything cloudy about this? Maybe I am missing something. It looks like a no-brainer to me.

Mr. MASKELL. I understand I am preaching to the choir here, but no, I—the problem is you have two sets of prohibited sources. The first three you have are agency-wide prohibited sources. That is someone who does business with, is regulated by, or seeking action from the agency—everybody—that includes grantees and contractors.

But the other prohibited source, the fourth prohibited source, is personal to the individual. That is why it is not duplicative, and that is why it is not circuitous. The fourth one is personal, and it says if that source can be—has interest that can be affected by the performance and non-performance of that individual's official duties, then they cannot accept even an award from them. I thought it sounds pretty clear to me that——

Mr. GREENWOOD. I will bet it is crystal clear to you.

Mr. MASKELL. [continuing] an agency head has that authority.

Mr. GREENWOOD. And if you were told don't—if it was your job, if you had Mr. Swindell's job at the time, and you were told—I know this is hypothetical——

Mr. MASKELL. I know.

Mr. GREENWOOD. [continuing] but if you were told, "You can't say no"—even if they put this incredible restraint on you, which is, "You can't say no, if there is any legal reason—there has to—using the letter of the law is the only guidance here." Would you still find any difficulty in the letter of the law prohibiting this?

Mr. MASKELL. I can't speak to the political pressures that Mr. Swindell felt at that time. But that is—

Mr. GREENWOOD. I am not asking you to. I am just saying, is there any question—

Mr. MASKELL. That is probably another reason to have a bright line. I personally would have cited that rule, and I would have cited 18 U.S.C. Section 209 and said you are not allowed to—

Mr. GREENWOOD. Mr. Swindell, do you think there was any political pressure involved here?

Mr. SWINDELL. There was pressure, obviously, to provide the advice that—according to the instructions. Obviously, the person who renders that advice, to tell us how to give advice, obviously was a political appointee. But I don't think politics entered into it.

I think what we have—

Mr. GREENWOOD. You don't think Clausner was trying to get friends of his to give him a green light on this?

Mr. SWINDELL. That is certainly possible, but I don't have any facts to know that. I think—

Mr. GREENWOOD. Dr. Wilson wrote—let me interrupt you. She wrote, "Given that the litigation was only recently settled, the major issue to be overcome is the appearance that the NCI agreed to cooperate with Pittsburgh to settle the litigation, including the monetary payments, as well as other tangibles and intangibles, and that this award is being made as a result of that agreement." Did you see that memo?

Mr. SWINDELL. Yes, and that is what—that is the point, is that he is going to have to assess those appearance situations personally and assume those risks. I think it is very good that Jake Wilson wrote that.

Mr. GREENWOOD. Well, let me just finish here. Just a second. Whether you read this memo or not, do you agree with the NCI Ethics Advisor that there is an appearance issue to be overcome? That you got, right?

Mr. SWINDELL. I got that.

Mr. GREENWOOD. And you had it then. You knew that there was an appearance issue.

Mr. SWINDELL. Yes. I was very—a number of us were concerned about the looks of that. Sure.

Mr. GREENWOOD. Okay. As the designated agency ethics official for the Department of Health and Human Services, did you advise Dr. Clausner about the appearance of undue influence or conflict of interest in his accepting a \$40,000 cash gift from a grantee institution involved in a lawsuit with the National Cancer Institute that had recently been settled?

Mr. SWINDELL. I didn't personally give him advice other than what was in the opinion.

Mr. GREENWOOD. Do you know whether anyone said to him, "This looks like hell, but we are not going to"—

Mr. SWINDELL. The communications with Clausner were from the General Counsel. I don't know what she would have said.

Mr. GREENWOOD. Did you address the appearance issue in your memorandum to Dr. Clausner?

Mr. SWINDELL. I think it stresses in there—it is very careful. It stresses in there about the fact that he is going to have to make his determination in accordance with the limitations and what the meaning of it was.

Mr. GREENWOOD. Wait a minute. Did you address, did you say, did you indicate anything about the appearance problem?

Mr. SWINDELL. I don't recall what is in the memo precisely.

Mr. GREENWOOD. Go to Tab 23 and look at your memo there.

Mr. SWINDELL. Okay.

Mr. GREENWOOD. My question is: in your memo to Clausner, did you say—did you address the appearance issue, or did you just address the strictly legalistic—give a strictly legalistic response, pursuant to what you had been instructed to do—

Mr. SWINDELL. Right.

Mr. GREENWOOD. [continuing] by your superior, a la per the note in the file?

Mr. SWINDELL. You are correct. It doesn't look like that I really stressed that issue with him.

Mr. GREENWOOD. You weren't supposed to, right? You had just been told—you had been told—

Mr. SWINDELL. That is right. I mean, I wanted to make sure that he attested to things. I remember that was one important thing to me, that he—that we apprised him what the law was that we understood, and that he was supposed to attest to the facts, that he didn't have anything, you know, within the meaning of the rule in front of him, because I wanted to make sure that he was understanding that.

Mr. GREENWOOD. But basically you said technically—technically, the Emperor has clothes on, but the fact that you appeared to everybody else to have no clothes on, you didn't bother to incorporate that into your memo.

Mr. SWINDELL. Well, certainly, as I said, this is—I was in a difficult situation back then. I was new. I was an acting person only there for just, you know, a few months when this occurred. I agree this could have been done a lot better.

Mr. GREENWOOD. Okay. The gentlelady from Colorado is recognized.

Ms. DEGETTE. Well, I just wanted to—are you yielding to me?

Mr. GREENWOOD. No, it is your turn.

Ms. DEGETTE. Oh, great. But following up on the chairman's questions, Mr. Swindell, you have said several times that in a situation like Dr. Clausner's situation it is a personal determination. And, in fact, in your memo, after going through all of the standards, on page 5 of your memo you do say you will need to apply this interpretive guidance to your own situation. But here is—

Mr. GREENWOOD. I am sorry. I made an error.

Ms. DEGETTE. Go ahead.

Mr. GREENWOOD. Mr. Stearns has not had a first round.

Ms. DEGETTE. Okay.

Mr. GREENWOOD. So—

Ms. DEGETTE. Can I just follow up on your question just with this—on your questioning, Mr. Chairman?

Mr. GREENWOOD. In think in fairness—

Ms. DEGETTE. Okay.

Mr. GREENWOOD. [continuing] do that on your time. We will give Mr. Stearns his shot now. We will give you as much time as you would like.

The gentleman from Florida is recognized.

Mr. STEARNS. Thank you, Mr. Chairman. Are we have 5 minutes or—

Mr. GREENWOOD. Ten minutes.

Mr. STEARNS. Ten minutes. Okay, good. I have three questions.

Let me just start—I have a subcommittee that deals with oversight on financial accounting standards, and we are having a debate on whether stock options should be expensed. And I guess last week's advisory—Blue Ribbon Panel of the Advisory Committee to the Director examined the conflict of interest that NIH employees eligible to engage in compensation outside of professional activities, should they receive compensation in the form of stock options or other equities for their service.

And so, Dr. Kington and Ms. Glynn, these are questions for you. And I will start with you, Ms. Glynn. It seems to me that offering these stock options to these individuals creates some problems. The Financial Accounting Standards Board would like to expense all of these, so that the people who invest in these companies know what stock options are being provided.

And lo and behold, these have all been kept pretty silent. And so I guess my question is—the current compensation involving stock options, is that ethical? Is it protecting the stockholders, the taxpayers, the patients? I guess everybody involved.

And then for you, Dr. Kington.

Ms. GLYNN. I think the major problem in permitting acceptance of either stock or stock options as a form of compensation is that it creates a kind of continuing financial interest in the company, so that even after your consulting work is completed you continue to have a conflict of interest with anything affecting that company, because, in effect, you are sort of an owner of the company.

So from that perspective, what that means is that once your consulting concludes you must continue to be recused from matters involving the company. What we have is, then, a potential for not only recusal during the consulting period but a continuing recusal once the consulting is finished, and that is problematic.

I have heard—and, you know, from OGE's perspective we are certainly not experts on this, but I have heard that one of the problems in barring stock options or stock as compensation is that it tends to favor payers that are from bigger established organizations that can afford to pay scientists cash versus the smaller start-up types that don't have any cash to pay, and this is all they can afford.

Now, understand, I am not taking any position on that, because it sort of begs the question of whether the consulting was proper to begin with, whether it is paid in cash or stock or stock options.

Mr. STEARNS. Dr. Kington?

Mr. KINGTON. Well, NIH fully recognizes the problem with payment to employees who consult with stock options, and we were very receptive to the Blue Ribbon Panel's recommendation that that not be allowed.

Mr. STEARNS. Yes. Because, you know, these people that have the stock option then will try to promote the company. And the ways they can do it are varied and multiple, and you can't—no one knows about it.

Mr. VARMUS. Can I comment just briefly on that, Mr. Stearns?

Mr. STEARNS. Sure.

Mr. VARMUS. First of all, NIH employees are allowed to own stock.

Mr. STEARNS. Oh, no, no. Yes, they can own stock in a—

Mr. VARMUS. So if you buy stock, you become interested in—

Mr. STEARNS. Well, we are talking about stock options that are given to you.

Mr. VARMUS. I understand. I understand. But I think that the holding of stock—I am just commenting on Ms. Glynn's remark—you know, that doesn't necessarily create a conflict of interest. It just means you have an interest in—

Mr. STEARNS. But this is your own money that you make after the bottom line, after you pay taxes, you invest. This is compensation that is part of the—

Mr. VARMUS. It is an alternative means of compensation, and I think—

Mr. STEARNS. Do you disagree with these two people?

Mr. VARMUS. I do a little bit, in the sense that I think one of the reasons that the NIHEAC was established, the NIH Ethics Advisory Committee, is to look at issues of that kind, because there are instances in which companies simply don't have much capital to spend on consultants, and—

Mr. STEARNS. Well, if these people are—why should they be working for the NIH when they get—they are consulting for this company and they are getting stock options?

Mr. VARMUS. Well, if we do entertain the idea of consultation, and we think that is potentially valuable in both directions, it seems to me that the—

Mr. STEARNS. Well, let me give you a hypothetical.

Mr. VARMUS. Yes.

Mr. STEARNS. You are working for NIH, and you are under retainer with a company to advise them—Company X. And they have ground-breaking technology, and they offer you stock options. And they are paying you, and you are getting paid by NIH, and you are sharing the information from them with the NIH. Should you get stock options from them without making it public that you are getting these stock options? Is that what you are saying, it should be—

Mr. VARMUS. No, I am not.

Mr. STEARNS. [continuing] private?

Mr. VARMUS. No, I am all for disclosure—

Mr. STEARNS. I think we are talking about—

Mr. VARMUS. [continuing] and I am all for discussing each of these instances on a one-by-one basis. I think there could be conditions under which reasonable people would say that the fraction of

the total stock being held by the employee is extremely small, that the——

Mr. STEARNS. It depends upon what the stock does, whether it is small or not, and it depends upon the stock option.

Mr. VARMUS. Well, as a fraction of the total company stock issue, that—I think that——

Mr. STEARNS. I mean, if they gave them \$100,000, eventually it could be worth \$4 million. That would be quite an incentive for this person.

Mr. VARMUS. Well——

Mr. STEARNS. How does he keep his conflict of interest separate?

Mr. VARMUS. Well, the conflict of interest, of course, would arise if there were some situation in which the conflict arose. The assumption is that——

Mr. STEARNS. So you disagree with the Blue Ribbon Panel of the Advisory Committee to the Director on this.

Mr. VARMUS. I think that being cautious about stock is very appropriate, and I am just arguing for what I think we have all been arguing for in a sense, that in some cases the nature of the compensation should be a matter for, in a sense, case adjudication. And that the reason we have at all our institutions committees to look at these is to try to be sure that we don't write a blanket rule that obviates the possibility of——

Mr. STEARNS. So you think if the company gives a flat fee that is the same as stock options.

Mr. VARMUS. No, I am not saying that.

Mr. STEARNS. I mean, wouldn't a flat fee be more ethical than getting a stock option, which is based upon the performance of the company?

Mr. VARMUS. All of these—as we learn from these experiences, they are all different. And I—you know, I take your point, and I think the stock options are more problematic. But I would opt in my ideal world for a more flexible policy, that is all.

Mr. STEARNS. Have you taken stock options in a situation like I just described?

Mr. VARMUS. Not at the NIH, of course, but I did as a——

Mr. STEARNS. When you were working for NIH, did you get——

Mr. VARMUS. No, no. No, absolutely not.

Mr. STEARNS. Okay.

Mr. VARMUS. I, as a Presidential appointee, gave up everything that could remotely be considered——

Mr. STEARNS. That is my point. As a Congressman, I——

Mr. VARMUS. But I was in charge of the NIH.

Mr. STEARNS. I mean, I don't get stock options, and there is no one in this room that gets stock options. And if you are working for NIH, you are advocating they should get stock options with a company they are consulting instead of—that is what you are advocating.

Mr. VARMUS. What I am arguing is that people at NIH have different functions. The Director of NIH——

Mr. STEARNS. Well, they are Government employees, though.

Mr. VARMUS. Yes, but some—but Government employees who work in the intramural program as——

Mr. STEARNS. Well, why should we make an exception for NIH if we don't make it for the Congressmen and Senators and Presidents?

Mr. VARMUS. I think the functions are very different. This is obviously a complicated issue, but it is one that I think is important to bring up, that—

Mr. STEARNS. Well, I think you can get into conflict of interest, and I think the Blue Ribbon Panel and the Advisory Committee to the Director made that clear.

Let me move on. I just have so much time. I have to stop you.

Mr. VARMUS. They didn't say conflict of interest. They said conflict of the commitment.

Mr. STEARNS. Let me say I—the question I have now—on February 10, the NIH Office of Management Assessment forwarded a final advisory report from the HHS Office of Inspector General for review of a conflict of interest allegation concerning a Board of Scientific Counselors ad hoc reviewer.

NIH Deputy Director Michael Gutzman and NCI Director Andrew von Eschenbach were among the recipients of this report. In this report, the IG recommended that the National Cancer Institute modify its process for selecting ad hoc reviewers to allow a principal investigator to object in writing directly to the Board of Scientific Counselors' Executive Secretary if he or she believes the selected BSC ad hoc reviewer has a conflict of interest.

I guess the question is: has this recommendation been implemented? Anybody?

Mr. KINGTON. This is the first I have heard of that recommendation.

Mr. STEARNS. Okay. Another question is, based upon this report, we know that NIH intramural researchers know in advance. I think the staff has advised—probably advisable, Dr. Kington, that you should follow up in writing on this, since this was provided in writing with the recommendation. And I guess we in the Oversight Subcommittee see—think not only should you know about it, but it should be implemented.

So I guess the fact that you, one, don't know about it, is a concern of ours. And then, two, give you a chance to answer, come up to speed, and then see if you can implement it.

Mr. KINGTON. We would be happy to respond.

Mr. STEARNS. Okay. And last, Mr. Chairman, if you bear—forbearance here, based on this report we know that NIH intramural researchers know in advance who is on the list of ad hoc reviewers and who can object if they think a proposed reviewer has a conflict of interest.

This is like the preemptory challenges in courts where each side gets a chance to strike against a potential juror they don't like. Given that intramural researchers have this right, why shouldn't a private partner negotiating a CRADA with intramural researchers know if those researchers are consulting for the competition?

Let me repeat that—with intramural researchers know if those researchers are consulting for the competition. Shouldn't a private partner in the CRADA have the right to know and the right to object to a perceived conflict of interest? Dr. Kington? It is a little hard to understand the question. It is sort of laid out as—some—

times we lay these questions out to get them on the record, and that is the way this question is, so——

Mr. KINGTON. I will refrain from commenting.

Mr. STEARNS. Well, no, we are asking you to comment. You are forced to comment here.

Mr. KINGTON. Clearly, any time there is a situation in which the Government has entered into a CRADA with another private company, we have decided that is the best way that we can achieve some scientific goal. And, obviously, we should be very concerned if there is a possibility of an appearance of conflict with an employee who might be involved with a competitor. So, yes, there should be some—that is of concern.

Mr. STEARNS. I guess it is just public information that the intramural researcher knows this information, whereas a private partner in CRADA does not. And I guess we are saying that shouldn't this private partner have this right, too, so we have transparency here? Does that make sense?

Mr. KINGTON. On the face of it, yes. I mean, we absolutely want our partners to have faith that we are reasonable partners, that we are actually committed to working with them. So, yes, we would be concerned about appearance of—we should be concerned about appearance of conflict of interest.

Mr. STEARNS. And so that this private partner should be told, should have the right to know, and the opportunity to object if there is perceived conflict of interest?

Mr. KINGTON. I am not sure if that necessarily has to be—and I want to make that comment as a policy. There is no question that we should do whatever is necessary to remove the possibility of a serious conflict or appearance of conflict of interest, and we are committed to that, however we could achieve that.

Mr. STEARNS. Yes. Well, I honestly feel you are—you want to do that. So if you don't mind, you might tackle this question, too——

Mr. KINGTON. I would be happy to.

Mr. STEARNS. [continuing] in your reply, and we can look at it. I thank the chairman.

Mr. GREENWOOD. Now the gentlelady from Colorado is recognized.

Ms. DEGETTE. Thank you, Mr. Chairman.

Okay. Mr. Swindell, if you will recall, we were having this discussion about who—how we decide what standards to apply. In your memo, you had said to Dr. Clausner, “You will need to apply this interpretive guidance to your own situation.”

And I think you said in response to the chairman's questions that his interpretive guidance would be sort of how would it look to the public or would it pass the smell test? Would that be accurate?

Mr. SWINDELL. That is essentially what the General Counsel said. The smell test or The Washington Post test was something that we don't advise about.

Ms. DEGETTE. Now, at this time, Dr. Clausner was the Director of the National Cancer Institute, right?

Mr. SWINDELL. That is correct.

Ms. DEGETTE. But, you know, so one would hope he might have a press liaison to help him figure that out. But how is everyone

else going to figure that out? It seems to be a very, very nebulous standard.

Mr. SWINDELL. That is a very good point, and that is the problem with it.

Ms. DEGETTE. Right.

Mr. SWINDELL. And that is why we are not going to operate under that and haven't operated under that kind of analysis about these questions.

Ms. DEGETTE. But even under the new guidelines there seems to be a lot of personal discretion as to whether there are conflicts that I am not sure any ethics board could address.

Mr. SWINDELL. It is difficult. I mean, the idea is is that the statutes and the regulations to some extent are intended to codify what an appearance is. And we have tried to, in our advice-giving now, since the very beginning of this administration when I spoke with Governor Thompson's people when they came in and actually discussed how we would give advice in the problems we had, that what we will do is we will counsel what we believe the law means, what the regulations mean, and the regulations themselves in part—some aspects of what an appearance is, but that we will try to also give advice about what we will call perception or optics.

Ms. DEGETTE. But which is a moving target, isn't that fair to say?

Mr. SWINDELL. It is.

Ms. DEGETTE. Yes. Now, Dr. Varmus and others have talked about how employees at NIH, while public employees, are different than, say, Congressional employees. And I should add for the record it is not just Members of Congress, it is our staffs, it is all of the employees of the U.S. Government.

I wanted to ask you, Ms. Glynn, because I got to thinking, what are the ethical standards with respect to outside compensation and award, say, for the EPA employees? Because we have employees over there who are doing scientific environmental research.

Ms. GLYNN. Right. Can I address something else before I answer that question?

Ms. DEGETTE. If we have time at the end, you can address that.

Ms. GLYNN. Okay. I mentioned in my oral statement, there is one broad, bright line rule for the entire executive branch, and that is in the rule published by my office. And as far as outside employment or activities is concerned, that rule is that the outside activity can't be such a conflict with your job that it would require recusal essentially from most important aspects of your job.

But a second part of that rule is that the outside activity can't be prohibited by a statute or any other regulation, and another regulation is that it can't be an appearance of a conflict of interest. It can't be use of public office for private gain—

Ms. DEGETTE. So do researchers over at the EPA get outside income? Do you know?

Ms. GLYNN. And, remember, each agency is allowed to implement, supplement—

Ms. DEGETTE. Right.

Ms. GLYNN. [continuing] more difficult, you know, more stringent.

Ms. DEGETTE. Yes, I understand.

Ms. GLYNN. Okay. EPA, for example, does—for certain categories of employees—does have more stringent rules. It is not exactly across the board, but it does have more stringent rules.

My impression is that this is not a problem—this compensation issue is not a problem at most science agencies, however.

Ms. DEGETTE. Okay. What about the NSF or the CDC? Do you know if they have supplemental rules?

Ms. GLYNN. Mr. Swindell can speak better than I can about CDC, but NSF definitely has supplemental rules as well.

Ms. DEGETTE. And do they allow their researchers to take this type of outside compensation?

Ms. GLYNN. There is no broad prohibition on it. There are some prohibitions, but not an across-the-board prohibition. However, once again, based on my conversations—informal—with ethics officials at these agencies it is not that common to permit employees to receive compensation there.

Ms. DEGETTE. Okay. Mr. Chairman, I think it would be very helpful—maybe Mr. Maskell or someone could supplement the record by giving us the standards at all of the Government agencies about what kinds of outside compensation are allowed for the employees.

Ms. GLYNN. Sure. I mean, you can actually find them in the Code of Federal Regulations—

Ms. DEGETTE. Yes, we have got that.

Ms. GLYNN. [continuing] you have back here. But they are all listed there.

Ms. DEGETTE. That would be helpful.

Mr. VARMUS. It is important, Ms. DeGette, to note who is—

Ms. DEGETTE. Yes, sir.

Mr. VARMUS. [continuing] what functions are being performed by the agency. So the NSF, for example, makes grants but doesn't have the equivalent of an intramural research program. There are no scientists doing scientific work in the National Science Foundation. They are developing grant programs and administering grants.

Ms. DEGETTE. That is a really good point. Thank you, Dr. Varmus. But, you know, and that kind of leads into my next level of questioning, which is the researchers at NIH are primarily doing basic research. Is that right?

Mr. VARMUS. It depends what you mean by "basic." There are many who are doing clinical research, if you are contrasting laboratory and research with patients. But it is—I think we have to define the term "basic research."

Ms. DEGETTE. Well, okay, let me put it in a different way.

Mr. VARMUS. They are not doing applied research.

Ms. DEGETTE. Most of the private companies don't have a big investment in basic research.

Mr. VARMUS. Actually, many of them do now. That is a major change that actually came about during the growth of the biotechnology industry, and many fundamental findings have been made in the biotech industry. And now large pharmaceutical houses have acquired those companies, have engaged themselves in basic research. The continuum is much more complex than it was 30 years ago.

Ms. DEGETTE. You know, it is interesting because I was talking to, actually, some of the pharmaceutical representatives who said that the bulk of the basic research is still being done at NIH, and that——

Mr. VARMUS. Or with NIH dollars, because that——

Ms. DEGETTE. Or with NIH dollars, and that——

Mr. VARMUS. [continuing] over 80 percent of our money—of NIH's money goes to universities and academic health centers and colleges.

Ms. DEGETTE. Right. So I guess my question is, for some of the scientists coming in, especially the newer scientists who are the ones that theoretically these new ethical rules would apply to, I am not sure I buy the fact that these people would not be—these top flight folks would be attracted to NIH if their outside compensation were greatly constrained or even eliminated, because many of them are doing basic kinds of research and not the advanced kinds of research. Would you disagree with that?

Mr. VARMUS. Well, the choice that most are making is whether to go to the NIH intramural program to do research or to do essentially very, very similar work under somewhat different terms. And I don't mean simply financial terms, but in terms of review and response to a different kind of system of organizing research at universities, academic health centers, colleges, universities. That is the usual choice.

Ms. DEGETTE. With NIH dollars in many cases at those academic centers.

Mr. VARMUS. And salaries being set independently and different sets of rules. So it is a different environment, and it has seemed I think—and especially in the 1980's—more favorable to most to work in the extramural community as opposed to the NIH.

Ms. DEGETTE. Now, when you were—I assume you participated in trying to recruit folks to come to NIH when you——

Mr. VARMUS. Absolutely.

Ms. DEGETTE. [continuing] were there. And did these folks tell you that their decision of where to go was in part—I mean, how important was the outside compensation?

Mr. VARMUS. Very important, especially for the people I was recruiting, because I was recruiting people at the upper end of the spectrum.

Ms. DEGETTE. Right. Who now, of course, won't be entitled to that, many of them.

Mr. VARMUS. Pardon me?

Ms. DEGETTE. Now many of those folks won't be entitled to that compensation. So do you——

Mr. VARMUS. Well, but the——

Ms. DEGETTE. [continuing] think now we are going to——

Mr. VARMUS. Ms. DeGette, we have two issues on the table with respect to compensation. One is the outside activities, and we are all agreeing that for certain high-level people those should be prohibited or restricted.

Ms. DEGETTE. Right.

Mr. VARMUS. But there are also salary issues, which we are not discussing today, that are very important with respect to using pay scales such as those that are allowable under Title 42 that make

compensation more competitive with the kinds of salaries that we have talked about.

Ms. DEGETTE. You know, I used to sit on a college board, and we used to have these big debates vis-a-vis the economics department and say, "Well, you know, these people could go to private industry, and maybe we should pay the economics professors, you know, \$200,000 a year, and we should pay the classics professors \$20,000 a year."

And those were really tough discussions that we had, and I think those discussions are endemic throughout the academic world, and particularly difficult when you are talking about biotechnology and all kinds of cutting edge research.

But, you know, the problem I think we have is that, No. 1, I don't think we can make the assumption that people are simply going to the NIH because of outside compensation. And, No. 2, I think we have continuing tough, tough issues about conflicts of interest which only get murkier, not clearer, the more levels of ethics rules that we try to place, especially because of the nature of research.

And this is really, I think, what we are struggling with now. And I don't know the solution, but I just don't fundamentally agree with the premise that this outside—if we really constrain this outside compensation, so long as we continue to allow collaboration, that that is going to severely affect the quality of research scientists at NIH. That is just my view.

Mr. GREENWOOD. The Chair thanks the gentlelady.

The gentleman Mr. Walden is recognized for 10 minutes.

Mr. WALDEN. Thank you, Mr. Chairman.

Mr. Swindell, you were Acting Director of HHS Ethics Division at the time Dr. Clausner requested to receive the Dixon Prize in 1997, weren't you?

Mr. SWINDELL. That is correct.

Mr. WALDEN. Okay. And as I recall, in your testimony you said there was sort of an edict from up above about not giving anything more than just a description of the law, correct? I mean, that—

Mr. SWINDELL. That is correct.

Mr. WALDEN. [continuing] may not be the lawyerly—that is correct?

Mr. SWINDELL. That is correct.

Mr. WALDEN. Was there a reason to believe that if you didn't follow the instructions, to ignore appearance issues, that that might affect you getting a permanent appointment? Was it that kind of a feeling in the—

Mr. SWINDELL. No. At the time, there was actual concern within the whole Ethics Division that it would be dissolved and moved into another division. I had no desire to have to give any advice to the General Counsel for the purpose of personal advancement.

The Ethics Division at the time, they were going to merge it into what was called the Business and Administrative Law Division.

Mr. WALDEN. Why would they want to do that? What was the talk?

Mr. SWINDELL. Well, there were difficulties I think with my supervisor about how we gave ethics advice, which, of course, precipitated this direction of how we were supposed to get—

Mr. WALDEN. And who was your supervisor then?

Mr. SWINDELL. Jack Kress.

Mr. WALDEN. And who did Jack Kress work for?

Mr. SWINDELL. Harriet Rabb.

Mr. WALDEN. And was this coming from both Mr. Kress and Ms. Rabb?

Mr. SWINDELL. I read into the record earlier today, Congressman, that—I wrote a note to the file that indicated that my supervisor had told me that the General Counsel directed us to provide precise legal issues, that we weren't supposed to give advice about the appearances of things.

Mr. WALDEN. I mean, I just find that amazing. You know, when I get counsel, I want to know all of the potential ramifications, so I know——

Mr. SWINDELL. As I mentioned earlier——

Mr. WALDEN. With ethics, it is about appearance as much as legality in public service.

Mr. SWINDELL. Obligation, yes. And it was a difficult circumstance to be in.

Mr. WALDEN. Was Harriet Rabb the one who contacted you about the Pittsburgh award regarding Dr. Clausner?

Mr. SWINDELL. Yes.

Mr. WALDEN. And she was, what, the General Counsel?

Mr. SWINDELL. She was the General Counsel.

Mr. WALDEN. Is it standard operating procedure for the HHS General Counsel to get involved in award receipt requests of this nature?

Mr. SWINDELL. I would not normally think so.

Mr. WALDEN. Did it happen any other time with her?

Mr. SWINDELL. No, not that I can recall.

Mr. WALDEN. Do you recall any other HHS General Counsel ever getting involved in other requests of this nature?

Mr. SWINDELL. No, I don't recall another one.

Mr. WALDEN. What made this one so special, do you think, that it rose to the level of——

Mr. SWINDELL. I do not know why this was so special, but it was obviously—she wanted an answer. It was very difficult to—she was somewhat inscrutable, because she also seemed to understand that this was unseemly. But nevertheless—so I don't know what her directions were.

Mr. WALDEN. What makes you say that she seemed to understand it was unseemly?

Mr. SWINDELL. She would frown about the fact, you know, he is trying to make a big deal about getting some money. You know, I just think——

Mr. WALDEN. Mr. Clausner.

Mr. SWINDELL. Yes.

Mr. WALDEN. Dr. Clausner.

Mr. SWINDELL. Dr. Clausner.

Mr. WALDEN. Do you recall Harriet Rabb contacting you on behalf of any other official for this kind of award? Or was this just a very unique situation?

Mr. SWINDELL. I thought it was very unique, yes.

Mr. WALDEN. Did you or anyone else ever inquire as to why she was involved in this?

Mr. SWINDELL. Why she was in this? No, did not.

Mr. WALDEN. Just one of those things that came down from above, and you read the law and gave your interpretation?

Mr. SWINDELL. We had lawyers and a couple of divisions looking at it—the Public Health Division, Ethics Division—and trying to evaluate the nature of the award, because there were some issues about whether it was coming from a foundation or whether it was coming from a university, and so forth.

Mr. WALDEN. Were they under the same constraints that you were in terms of not being able to offer opinion outside of just the strict statutory reading?

Mr. SWINDELL. That was generally the way the lawyers were supposed to operate in the Office of General Counsel was we—I assumed they felt that lawyers were making policy—you know, making decisions that were left to decisionmakers.

Mr. WALDEN. And was the theory that if you put something in writing that showed there might be evidence—or it might have the appearance, let us say, of conflict, that, therefore, that would be taken into account.

Mr. SWINDELL. I think that would be a problem if we did. As I said, we had an earlier circumstance where I had drafted a memorandum where I said some conduct would not be prudent, trying to get into the appearance of it. And my supervisor was told it—I had drafted it for my supervisor's signature.

And he had come back from his performance appraisal saying that was the same old situation of us giving advice about appearances. And, you know, he was rebuked for that, and told me as well. So there was clear understanding how we were supposed to——

Mr. WALDEN. And that was Jack Kress?

Mr. SWINDELL. Yes.

Mr. WALDEN. Okay. So he was rebuked, and I assume by that he was rebuked by Harriet?

Mr. SWINDELL. Harriet Rabb.

Mr. WALDEN. Harriet Rabb. Do you think this went all the way up to the secretarial level?

Mr. SWINDELL. I can't speak to that.

Mr. WALDEN. Did you also approve Secretary Shalala's appearance in that famous milk mustache ad?

Mr. SWINDELL. That was done not only with my looking at the issue but the Public Health Division lawyers—the idea being that the Government ethics rules don't govern the conduct of an agency acting as an agency.

Mr. WALDEN. Yes.

Mr. SWINDELL. And that, therefore, this had been vetted through the agency, it was part of a joint initiative with the National Cancer Institute dealing with child and immunization diseases, and so forth. And so it came up through that vetting. The determination was that there was legal authority under the Public Health Service Act, so the Associate General Counsel for Public Health Service was also involved.

It had come up earlier in the administration—and I concurred with my boss at the time, Jack Kress—that we didn't think that it was legal for her to do it at that time.

Mr. WALDEN. Why?

Mr. SWINDELL. As I recall, the milk mustache text of the ad had some language in it that talked about health care reform at the time, and it almost was the point of lobbying with respect to pending legislation. So we had that concern.

Obviously, the appearance concerns that she would have to take, and she was advised about, that obviously people could criticize her.

Mr. WALDEN. So it was somewhat controversial in the Ethics Division?

Mr. SWINDELL. Controversial in the Ethics Division and the ethics community and the press. But bare minimum legality, the Public Health Division—the Public Health Service Act, you know, says—it says a lot of language in there about the Secretary having authority to encourage health promotion activities, you know, and it was thought that this would be a method of reaching teenagers. It was popular to make them drink milk, and, therefore, you know, have strong bones.

Mr. WALDEN. Builds bodies in seven ways.

Mr. SWINDELL. Yes.

Mr. WALDEN. Or whatever it is. Is it true that you framed the milk mustache ad and hung it on your office on your wall?

Mr. SWINDELL. It was everywhere, and it was there to remind me that that was the kind of advice that I was supposed to provide. Every day we would sit up there and see the Secretary's milk mustache.

Mr. WALDEN. Now, what do you mean by that, that it was the kind of advice you were—

Mr. SWINDELL. Well, it is a precise—it is another example of a legal determination and allowing the policymaker to take, you know, whatever responsibility for—

Mr. WALDEN. And they take the heat.

Mr. SWINDELL. [continuing] adverse perception.

Mr. WALDEN. Okay. Is that ad and picture still on your wall?

Mr. SWINDELL. Of course not.

Mr. WALDEN. When did it come down?

Mr. SWINDELL. The very first day of the new administration.

Mr. WALDEN. All right. Okay. I think that is all the questions I have at this point, Mr. Chairman. Thank you.

Mr. GREENWOOD. Milk grows strong bones, but something else has to draw—create strong backbones. There wasn't a lot of that going on.

Dr. Varmus, how did you get authorization—actually, is it—yes, it is my turn, isn't it?

Ms. DEGETTE. I guess.

Mr. GREENWOOD. Yes, okay. I get a second round.

How did you get authorization to convert NIH directors from full-time continuous positions into Title 42 special consultants?

Mr. VARMUS. I don't remember all of the details, Mr. Chairman, but there was definitely consultation with the Department to interpret the existing rules. I know that there was a fairly severe time

limit on Title 42 classification, and we couldn't work this very well on a 1-year basis, and we were given the authority from the Department to make appointments, non-tenured appointments for 5 years under Title 42.

So this was the result of discussions that I and the Office of Human Resource Management had with the Department.

Mr. GREENWOOD. Did that include the Office of General Counsel?

Mr. VARMUS. Yes.

Mr. GREENWOOD. Were you advised—

Mr. VARMUS. And presumably with the Office of Personnel Management at the Department. I don't remember exactly what conversations occurred, but we were able to make a few appointments in that category I believe as early as 1997, late 1997 or 1998.

And then I—one of my last acts before leaving was to write a letter to Kevin Therm, who was then the Deputy Secretary, asking for permission to extend the use of Title 42 for incoming people who we thought might be more easily recruited with the higher pay scale that we could pay under Title 42.

And there was a legal interpretation of whether people under Title 42 would be—could act as opposed to just being consultants, and I believe the language says “assist and consult” or “assist and advise,” and that was viewed as reason to allow—

Mr. GREENWOOD. Didn't that feel like a circumnavigation of the intent of the law to you?

Mr. VARMUS. Not to me. I thought that—and we were looking for flexibility to adapt to circumstances that were making it very difficult to—

Mr. GREENWOOD. But didn't that exist—doesn't Title 42 exist, and wasn't its origin the notion that sometimes you need to bring in specialists for a limited period of time to consult? And that is why Congress created that opportunity, and that was—it was never Congress' intent to say, “Well, the new guys come in under Title 42.” I mean, I—

Mr. VARMUS. Well, it wasn't my idea that it would be all of the new guys either. So we were trying to find—it seemed to me that the language was consistent with an interpretation that would say we were bringing in people to do high-level positions who would not be tenured, would come in perhaps for a few years, and would serve as experts. Obviously, I didn't make this decision single-handedly.

Mr. GREENWOOD. Well, what you were advised as to the position of the HHS General Counsel for widespread use of Title 42 conversion?

Mr. VARMUS. That it was a legal application of the provision.

Mr. GREENWOOD. Who advised you of that?

Mr. VARMUS. I can't remember all of the people involved, but certainly the General Counsel herself, and Kevin Therm as I recall. I don't remember specifically, and I don't want to—

Mr. GREENWOOD. Okay.

Mr. VARMUS. [continuing] since I am under oath. But I know the—

Mr. GREENWOOD. Do you have any idea how many people in NIH are under Title 42 now?

Mr. VARMUS. I am told it is a lot—it is many more than were on Title 42 when I left. I don't know the exact number.

Mr. GREENWOOD. Do you know order of magnitude?

Mr. VARMUS. It is probably in the range of several hundred or a thousand.

Mr. GREENWOOD. Would you be surprised if I told you it was more like minimally 1,400? Or, actually, 4,000?

Mr. VARMUS. I am somewhat surprised, but until I heard the circumstances I wouldn't react to it.

Mr. GREENWOOD. You wouldn't be shocked to know that the policy that you enacted on your way out has enabled 4,000 people to—

Mr. VARMUS. Well, I didn't enact the policy, Mr. Chairman. I asked for permission to enlarge—

Mr. GREENWOOD. That is what I mean. That is what I mean. I am not—we don't need to parse words here. I am just—it was your idea, correct?

Mr. VARMUS. I supported it, yes.

Mr. GREENWOOD. It wasn't your idea?

Mr. VARMUS. Well, I didn't know a lot about Title 42 to begin with. But I began to learn about it, and it looked like a reasonable mechanism for us to use in specific circumstances to recruit people who were being paid very high salaries in academia and—

Mr. GREENWOOD. I understand that. But the text of the law says special circumstances. Okay? And when I tell you that there are 4,000—we think there are 4,000 people at NIH who are now salaried, paid under special—for special—special consultants, does that seem to you—does that not strike you as something run amok?

Mr. VARMUS. I would say it is a number that surprises me. I wouldn't have thought it would be that large.

Mr. GREENWOOD. Okay. When you became the NIH Director in 1993, were you aware that NIH was collecting information on compensation amounts for outside consulting arrangements?

Mr. VARMUS. I am not sure I understand the nature of the—

Mr. GREENWOOD. When you became Director in 1993, were you aware that the NIH was collecting information on compensation amounts for outside consulting arrangements, that they were routinely gathering that information?

Mr. VARMUS. There was a limit on the amount that could be acquired, so I assume that—I don't know what you mean by the term "collection." That is what I am interested in. I assume it was being monitored because there was a restriction, especially on money from consultation from single source.

Mr. GREENWOOD. Okay. In May 1991, the scientists published a story entitled "NIH Struggling to Regulate Employees' Outside Income." The article states that at the time NIH had begun to collect followup information from scientists about what they were paid for outside activities.

The information was to be used as part of a review of the NIH salary structure to compare incomes of NIH scientists with their counterparts in the private sector. Dr. Philip Chen, then Associate Director for Intramural Affairs to NIH, stated, "We may use that information as an argument in favor of the need to modify the salary structure to become more competitive with the outside world."

NIH has been unable to provide the committee the amounts NIH employees receive from past outside activities. In fact, NIH was not collecting this information until recently, but NIH did collect this information in the past as the article discusses. NIH was using the information to determine whether salaries needed to be adjusted.

At the time, outside consulting was allowed to help make employee income competitive with the outside, although it was capped at \$25,000. Isn't it true that the consulting was viewed as compensation for the employee?

Mr. VARMUS. Yes, but not Government compensation. But yes, part of the compensation package.

Mr. GREENWOOD. And wasn't the collection of this information discontinued when the cap was lifted?

Mr. VARMUS. As far as I know, it was.

Mr. GREENWOOD. And isn't it true that NIH came up with another way to compensate employees in order to make their salaries competitive with the private sector Title 42? In other words, in the good old days, in the old days, they collected information to see how much people were making from consulting agreement, so they could show that, in fact, how needy they must be to have to go out and collect these outside—arrange this outside consulting. And then that information was then used to support the notion that we needed to use Title 42 to increase the compensation.

Mr. VARMUS. My sense was from the discussions that I had that the Title 42 pay scale was advocated in part—in greater part by comparison of NIH salaries with salaries that people were receiving in academic institutions from which we were trying to recruit them.

Mr. GREENWOOD. Well, where I am trying to go with this is the NIH gathered information about outside activity in order to bolster the argument that the scientists at NIH—the intramural scientists—were underpaid, and it did that and justified the Title 42 application.

And then the question is, so that being the case, why continue—why is it a good policy to continue with the outside consulting agreements when we have already attempted to solve the problem through Title 42?

Mr. VARMUS. Well, I see where you are going, Mr. Chairman. But to the best of my recollection, most of the arguments that we made were not based on compensation, because, in fact, a moderately small amount—number of NIH employees were engaged in consulting. What troubled me more was the difficulty of recruiting to the NIH people who were making amounts that were considerably in excess of what we could offer in the conventional GS or SES pay scales.

Mr. GREENWOOD. Now, when you were Director, did you employ retention bonuses?

Mr. VARMUS. Occasionally.

Mr. GREENWOOD. Could you describe a retention bonus and how that system works?

Mr. VARMUS. It was quite a rare phenomenon, but it usually would occur when someone was being offered a job on the outside and had a written demonstration that a job was honestly offered, not simply an idle comment. We would then apply for a retention

bonus to help retain that person, and these were usually fairly modest sums.

Mr. GREENWOOD. Give me an example.

Mr. VARMUS. Oh, it might be—I am conscious of being under oath. I can't remember the numbers exactly, but in the range of \$25 to \$50,000.

Mr. GREENWOOD. Okay. And you say it was rarely used? Could you give us an order of magnitude of the number of times that you think it was used while you were Director?

Mr. VARMUS. Well, used in situations where I would be making the appeal for the retention bonus, I don't believe it would be more than 10 to 20 times perhaps, maybe less than that.

Mr. GREENWOOD. Were you the only person at the NIH that could approve a retention bonus?

Mr. VARMUS. No. I would have to consult with my former colleagues to know whether—there were some pay scales in which a retention bonus could be given by an Institute Director. During our time at the NIH, some personnel responsibilities—some personnel authorities were delegated to Institute directors.

I mean, it is possible in some pay scales and categories that a retention bonus could be developed for an employee of an institute, and I would not have been involved.

Mr. GREENWOOD. You said that you were surprised to hear that as many as 4,000 NIH personnel could be under Title 42 now. Can you justify that? Do you think—could you make the argument today that but for Title 42 that anything like 4,000 employees at NIH would go walking away because they are underpaid?

Mr. VARMUS. Well, I would have to look—I would have to hear more about how and why it was done, and whether the pay ranges are actually different from what people would have been assigned if they were in the regular GS series. I don't know the full particulars. I have been away for—

Mr. GREENWOOD. Why else would they be under Title 42 if it weren't for salary—

Mr. VARMUS. I don't know, Mr. Chairman. I know I would—having heard the number, I will be interested to find out. But I honestly can't tell you I have heard the—

Mr. GREENWOOD. And you said that you had set up the policy so that new hires could come in under Section 42. Did you—was it your idea that people would be able to convert their status to Title 42?

Mr. VARMUS. That was a possibility, sure.

Mr. GREENWOOD. Pardon me?

Mr. VARMUS. That would be a possibility, if someone were being promoted, for example, or doing exemplary work or being lured away as a retention mechanism. It would seem to me to be a possible use of the Title 42.

Mr. GREENWOOD. If I told you 21 out of 27 Institute directors converted to Title 42, would that seem like a reasonable occurrence to you?

Mr. VARMUS. I am less surprised by that than I am by the number itself, because Title 42 is particularly useful in the higher ranges of the institution.

Mr. GREENWOOD. Okay. Final question for you, Mr. Swindell. When did you—you were acting in your position for 3 years. Is that correct?

Mr. SWINDELL. Yes, sir.

Mr. GREENWOOD. Did you find that extraordinary, to be in an acting mode for all of that time? I mean, didn't you feel like—did you frequently say at yearly reviews, "When am I going to be permanent instead of under this Sword of Damocles?"

Mr. SWINDELL. Yes, I certainly felt that it was unusual.

Mr. GREENWOOD. Did anybody ever give you an explanation as to why you were held in limbo land all that time?

Mr. SWINDELL. No, they never did. And, of course, if I brought up our future, it is likely the future could have been that we just were put into another division. So I—

Mr. GREENWOOD. Did you ever feel that your acting status was a way to make you cooperate?

Mr. SWINDELL. Well, a fair criticism from somebody looking at it from that—

Mr. GREENWOOD. I am not—I am asking you if you ever felt that way.

Mr. SWINDELL. Felt?

Mr. GREENWOOD. Did you ever say to yourself, "I know why I am only Acting. That is to make me behave"?

Mr. SWINDELL. Well, I don't think I felt that directly, no. I mean, I think I tried to do the best I could.

Mr. GREENWOOD. Did you ever think, "If I don't give my superiors what they want, I won't get to be made—a permanent position"?

Mr. SWINDELL. Did I ever feel if I don't give what they want—I just tried to be a professional, to follow the instructions that were given me.

Mr. GREENWOOD. Okay. All right. Thank you, lady and gentlemen of the panel. Appreciate your contribution today, and you are excused.

The Chair would call our second panel consisting of Dr. Lance A. Liotta, M.D. and Ph.D., Chief of the Laboratory of Pathology at the National Cancer Institute, Dr. J. Carl Barrett, Ph.D., Director, Center for Cancer Research at the National Cancer Institute; Dr. Anna D. Barker, Ph.D., Deputy Director, Advanced Technologies and Strategic Partnerships at the National Cancer Institute; and Dr. Emanuel Petricoin, Lead Microbiologist, Center for Biologics Evaluation and Research, at the Food and Drug Administration.

Welcome. You may have—I don't know whether you were here at the beginning of this hearing, but as I told the first panel of witnesses, that pursuant to the custom of this committee we take our testimony under oath. And so I would request if any of the four of you object to giving your testimony under oath. Okay. I see no objection.

I also should advise you that, pursuant to the rules of the House and of this committee, that you are entitled to be represented by an attorney. Do any of you choose to be represented by an attorney? Dr. Liotta, you are represented by an attorney. Would you identify your attorney, or would you have your attorney identify himself into the microphone, please?

Mr. MORTON. Mr. Chairman, Charles Morton on behalf of Dr. Liotta.

Mr. GREENWOOD. And Dr. Petricoin, your attorney—would your attorney please identify himself?

Mr. SCHATZOW. Michael Schatzow, S-C-H-A-T-Z-O-W, on behalf of Dr. Petricoin.

Mr. GREENWOOD. Thank you.

And I assume Dr. Barrett and Dr. Barker are not represented by counsel? Okay.

Well, in that case, would you rise and raise your right hand?

[Witnesses sworn.]

Mr. GREENWOOD. Okay. You are under oath, and I believe, Dr. Liotta, you have an opening statement?

Dr. LIOTTA. Yes.

Mr. GREENWOOD. And you are recognized for 5 minutes to give that opening statement. Welcome.

TESTIMONY OF LANCE A. LIOTTA, CHIEF, LABORATORY OF PATHOLOGY; ACCOMPANIED BY J. CARL BARRETT, DIRECTOR, CENTER FOR CANCER RESEARCH; ANNA D. BARKER, DEPUTY DIRECTOR, ADVANCED TECHNOLOGIES AND STRATEGIC PARTNERSHIPS, NATIONAL CANCER INSTITUTE; AND EMANUEL PETRICOIN, LEAD MICROBIOLOGIST, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION

Mr. LIOTTA. Thank you, Mr. Chairman, and members of the committee, for the opportunity to appear before you today to discuss my role as a scientist at the NIH and my various collaborative efforts. I am humbled to contribute to the NCI goal to create scientific knowledge and rapidly translate this knowledge to reduce suffering due to cancer.

I grew up loving science. My father was a science high school teacher. Both of my parents encouraged my inquisitiveness and creativity. I received my Ph.D. and M.D. from Case Western Reserve University in 1976, and then came to the Cancer Institute immediately as a resident in pathology. I then became Chief of the Laboratory of Pathology.

And over my 28-year career at NCI the research supported by the Cancer Institute in my lab has generated more than 500 scholarly publications, 300 in the last 10 years. This productivity is only a reflection of the wonderful colleagues and collaborators working in the special environment of the NIH and the NCI, as well as the vision and support of the leadership.

My research accomplishments span a wide range of scientific and clinical disciplines all aimed at fighting cancer. Cancer metastases is the major cause of suffering and death. Scientists in my laboratory discovered a series of novel genes and proteins which regulate cancer invasion and metastasis. These discoveries are now moving forward in clinical studies and clinical trials.

My NCI laboratory also invented new technology called laser capture microdissection, which has enabled investigators for the first time to pluck out molecules directly from cancer cells in a human biopsy specimen. This was developed through research cre-

ated with Arcturus and is now in use in more than 1,000 labs worldwide and has generated many thousands of publications.

We created a unique joint agency initiative with NCI and the FDA called the clinical proteomics program. The goal was to translate discoveries about proteins, the functional machinery of the cell, into direct patient benefit as fast as possible. Under the CPP, the clinical proteomics program, we developed a new way to study cancer biopsies, which could map the deranged protein circuitry of the cancer patient's tumor—individual tumor.

The promise of this approach is improved therapeutic efficacy with lower toxicity using a panel of drug treatment individualized for that patient's tumor, and this technology has already been translated to research in ongoing clinical trials.

The great hope is that improved detection of early stage cancer will produce more cancer cures. We set out to develop a new approach to discover markers for cancer. In 1998, under our clinical proteomics program, we proposed that there existed in blood thousands of previously unknown markers that might reflect what was shed into the blood from early stage cancer.

We generated data in our lab from an instrument called a mass spectrometer, and generated large amounts of data that we needed to analyze with a pattern recognition algorithm. We tried many pattern recognition algorithms, and then published early results that showed that our hypothesis might be true.

We then tried Correlogic Systems software, and it looked promising. This resulted in a publication in *Lancet* and subsequently a CRADA with Correlogic. I want to point out that that CRADA had a limited work scope to use Correlogic software, and we were free to use other software before, during, and after.

We then moved on to discover, in collaboration with our colleagues at NCI Frederick proteomics facility, thousands of new markers and identified them, never before known in the blood. And because the U.S. Government is steward of this list of new markers, it is not in the CRADA—of any CRADA we have—we believe this can have broad public health benefit, which will stimulate the large diagnostic industry.

This committee is investigating outside activities by NIH scientists. Because I have had outside activities during the course of my career, let me address this issue. I take my job as a dedicated public servant very seriously. I believe that I have upheld and maintained the highest ethical standards in all of my official capacities.

I have consulted with the appropriate personnel and endeavored to follow the regulations within NIH guidance and obtained guidance at all times when it was needed with respect to such regulations. I would never knowingly engage in a conflict of interest and would immediately cease such activity if there were a change in the circumstance that led me to believe that an approved activity had become one which had a potential conflict.

My only recent paid outside activity has been an approved consulting agreement with Biospect. And I want to assure you, Mr. Chairman, that I never consulted with Biospect about my CRADAs, never consulted with them about my Government work, and this

was explicitly excluded in my consulting agreement, along with my—the other exclusions in my ethics package.

My work on this consultation was placed on hold during the NIHEAC rereview of outside activities concurrent with the Blue Ribbon Panel. Last week I learned new information relative to this activity that Biospect requested raw data which we make publicly available to anyone. Because this new information might create even the slightest potential perception of a conflict, I immediately withdrew this activity. That is because my Government mission is sacred to me.

In conclusion, I am honored to serve as a scientist in the intramural program of the NCI. I have cherished the opportunity to participate in the creative intellectual environment that I feel is unparalleled in the world.

[The prepared statement of Lance A. Liotta follows:]

PREPARED STATEMENT OF LANCE A. LIOTTA, CHIEF OF THE LABORATORY OF PATHOLOGY AND CHIEF OF THE SECTION OF TUMOR INVASION AND METASTASES IN THE CENTER FOR CANCER RESEARCH, NATIONAL CANCER INSTITUTE, NIH

Thank you Chairman Greenwood and Members of the Committee for the opportunity to appear before you today to discuss my role as a scientist at the NIH and my various collaborative efforts.

I grew up loving science. My father was a science high school teacher. Both of my parents encouraged my inquisitiveness and creativity. I began inventing things at an early age. By college I was spending my summers working and inventing solutions for the Dupont Corporation at its Experimental Station in Wilmington, Delaware. I have always had a passion to be an inventor, and today I have over 80 patents and patents pending, which list me as an inventor.

My interest in medical diagnostics and pathology began during my undergraduate years (1965-1969). At that time I began doing research that led to patents for diagnostic test technology for infectious disease, as well as, general blood and body fluid testing methodologies. While in medical school, I was employed part time as a medical laboratory technician for the medical student health clinic. I was responsible for blood, culture and urine analysis, including the report generation. This training allowed me to gain exposure and expertise within the broad field of diagnostic testing methodology, and pathology diagnostic service labs.

I received my Ph.D. in Biomedical Engineering from Case Western Reserve University ("CWRU") in 1974. Two years later, I graduated from CWRU's M.D./Ph.D. program with my M.D. My Ph.D. work focused on mathematical modeling and experimental analysis of cancer invasion and metastasis. Cancer metastasis is the very definition of malignancy and causes this disease to be lethal. My Ph.D. allowed me to gain broad expertise in instrumentation, computer algorithms, mathematical modeling, and experimental animal models of cancer and analysis of clinical pathologic material. The results of my research convinced me that a major medical need was an improved understanding of when and why cancer becomes malignant. Because I was enrolled in the M.D./Ph.D. program, my Ph.D. research was supervised by both the Pathology Department of the Medical School and the Biomedical Engineering Department.

In parallel with my Ph.D. studies, I worked to achieve an M.D. with an eye toward a career as a research pathologist. For this reason, I took special clinical rotations in diagnostic monitoring and diagnostic pathology laboratory services. When I considered the next stage of my career, the NIH intramural program offered a superb environment that would support my creative freedom to pursue research contributions that could benefit public health.

Within 7 years of joining the NCI, as a pathology resident, I became Chief of the Laboratory of Pathology and Chief of the Section of Tumor Invasion and Metastasis, now part of the Center for Cancer Research. In these capacities I have three types of intramural duties: clinical service, training of research and clinical fellows, and cancer research. I am very proud of the outstanding clinical service provided by my laboratory staff to the NIH. We are responsible for all anatomic pathology service for the entire NIH. Our Lab hosts a world-class residency program. Here we recruit and train research-oriented pathologists who become academic leaders. My research contributions, supported by the NCI program, have generated more than 500 schol-

arly publications. This productivity is only a reflection of the wonderful colleagues and collaborators working in the special environment of the NIH, as well as the vision and support of the NCI and NIH leadership.

I am proud to have further served the NIH as the Deputy Director for Intramural Research under NIH Director, Dr. Bernadine Healy. I played a major role in setting up the Intramural Human Genome Program. This job gave me a great appreciation of the significant ways in which the NIH environment has continued to attract top-notch minds.

My research accomplishments to date span a wide range of scientific and clinical disciplines, including:

Cancer Metastasis—My work along with my collaborators is recognized as a groundbreaking effort to investigate the process of tumor invasion and metastasis at a molecular level. In the mid 1970s, we proposed and experimentally demonstrated the linkage between angiogenesis onset and tumor invasion and metastatic dissemination. We proposed the concept of metastasis suppressor genes. Consequently, scientists in my Laboratory of Pathology discovered a series of novel genes and proteins, which regulate cancer invasion and metastasis, thereby providing new strategies for cancer diagnosis and treatment. As a demonstration of the originality of these discoveries, all are covered by U.S. government-owned patents, both issued and filed.

New Technology for Micro Analysis of Tissue—My laboratory has invented technology in the fields of pathology diagnosis, microdissection and proteomics. Our group invented Laser Capture Microdissection (LCM), which was developed through a research CRADA (Cooperative Research and Development Agreement) with Arcuturus, Inc. and, thereby, rapidly commercialized. This technology is now in use in more than 1000 labs worldwide. The technology has enabled investigators for the first time to make broad discoveries in genomics, functional genetics, and is now extending into personalized medicine. This partnership is a prime example of what the NIH CRADA mechanism is designed to do: turn bench research into practical applications.

Clinical Proteomics Program—We created the first joint agency initiative between the NCI and the FDA in 1998 to develop new technology for the discovery of proteins important for cancer diagnosis and therapy, using actual human tissue and body fluids. Dr. Emanuel Petricoin of the FDA and I serve as co-directors. This initiative is now called the NCI/FDA Clinical Proteomics Program (CPP).

Individualized Cancer Therapy—Under the CPP, we proposed that LCM, combined with a new type of protein array, also developed in the CPP, constituted a new paradigm for patient-tailored medicine. The promise of this approach is improved therapeutic efficacy with lower toxicity, using a panel of drug treatments, individualized for the patient's tumor. This technology has already been translated to use in patients. It is being applied to patient tissue biopsies, conducted before, during and after experimental therapy, as part of ongoing NCI Clinical Center Trials.

Diagnostic Tools for Detection of Early-Stage Cancer—Another major initiative has been in the field of early detection of cancer. In 1997, based on our initial studies, we hypothesized that a large number of previously undiscovered and unknown protein markers were generated in the tissue and spilled into the blood, as a record of the disease state or the physiologic state. This hypothesis predicted that cancer developing in the tissue contained or shed proteins, which could be used as a test for early diagnosis. Our challenge was not knowing the identities of these molecules.

Proteomic Pattern Diagnostics—In 1998, in order to explore the potential existence of this new list of diagnostic markers, we applied mass spectrometry for fingerprinting analysis of tissue and blood. This was a well-established technology, but had not yet been applied to microdissected tissue. Even though we did not know the identity (name, sequence) of the molecules underlying the pattern fingerprints we recognized that this data supported our hypothesis that a large treasure-trove of previously unknown diagnostic markers existed. In our early studies, we analyzed our mass spectral data using visual graphing and the pattern recognition software that was commercially available. As we reported publicly at the American Association of Cancer Research in 1999, our results indicated the existence of a rich source of unknown markers in cancer tissue. We also reported on the first evidence of mass spectral fingerprinting diagnosis of cancer. Prior to this public disclosure, the U.S. government filed patents on this concept.

Our next step, during the fall of 1998 and spring of 1999, was to look in great depth at human serum samples from cancer and non-cancer patients, using a variety of analytical methods. We realized, based on our previous findings and expertise, that a large number of pattern recognition approaches existed for spectral analysis, including applications to mass spectrometry. Subsequently, under a government ma-

terial transfer agreement, Correlogic Systems software was employed to analyze our mass spectral data. The result was a publication in the LANCET, describing the potential research feasibility of using mass spectral fingerprints in serum for early stage ovarian cancer detection. Based on this reduction to practice, a patent jointly owned by the U.S. Government and Correlogic was filed. I am named as an inventor on this application. This promising research collaboration was extended to explore additional research applications under a research CRADA. This CRADA did not include the identity of the molecules themselves, nor did it constrain the U.S. government from its ongoing evaluation and use of other pattern recognition methods. Instead, the CRADA was aimed at evaluating the use of Correlogic's software for additional research topics.

The impact of this work from 1998 to 2002 is best exemplified by the fact that at the latest meeting of the American Association of Cancer Research, hundreds of scientists reported on exploring this field of proteomics pattern recognition, using a variety of methods.

An Abundance of New Diagnostic Marker Candidates

Our lab's consistent goal has been three-fold. 1) identification of the proteins predicted to exist by our original hypothesis, 2) continuous posting of our raw mass spectral data in the public domain, as a public service and with unfettered, full access (i.e., others have analyzed our raw data with their own pattern recognition methods and have published excellent results); and, 3) translation of these discoveries to patient benefit with the highest degree of scientific rigor, as rapidly as possible.

To that end, under the CPP, we have recently invented next-generation technology (patent applications solely owned by the Government and advertised in the Federal Register), which allows us to amplify and identify the new molecules we proposed to exist. Through the use of this government technology, and in collaboration with colleagues in the NCI-Fredrick proteomics facility, we have now identified thousands of specific proteins with diagnostic potential, which were previously unknown to exist in the blood. Because the U.S. government is the steward of this information, we believe that it can have broad public health benefits and will stimulate the large diagnostic industry of the U.S.

I have been the recipient of over 30 awards for achievement in cancer research and translational medicine. In addition, I have received numerous PHS Commissioned Corps awards, including the NIH Director's award, the Merit Award, the Distinguished Service Medal, the Meritorious Service Medal, the Surgeon General's Medallion, and the Surgeon General's Exemplary Service medal. Mr. Chairman, with the committee's permission, I would like to include my C.V., which provides further details concerning my publications, patents, and related career information.

According to published information, this committee is investigating outside activities by NIH scientists. Because I have had outside activities during the course of my career, let me address this issue. I take my job as a dedicated public servant very seriously. I believe that I have upheld and maintained the highest ethical standards in all of my official capacity over the years as Chief of the Laboratory of Pathology, Chief of the Section of Tumor Invasion and Metastasis, and former Deputy Director for Intramural Research. At all times, I have endeavored to follow the regulations governing outside activities. I have consulted with the appropriate personnel within the NIH when guidance was needed with respect to such regulations. I would never knowingly engage in any conflict of interest and would immediately cease such activity if there were a change in circumstance that would lead me to believe that an approved outside activity had become one which involved a conflict.

The research CRADA with Correlogic was signed in April 2002. At that time, Correlogic was a software company with an established proprietary pattern recognition software using a genetic algorithm with a lead cluster analysis. The purpose of the CRADA was to study the application of Correlogic's specific algorithm to analyze spectral data that had been generated and would be generated by the NCI/FDA Clinical Proteomics laboratory ("the Lab") from blood samples run on the commercially available SELDI-TOF mass spectrometer that the Lab had purchased in 1998. The CRADA's goal was to find unique discriminating patterns of unknown entities revealed by Correlogic's proprietary algorithm applied to raw mass spectral data the Lab had generated, and would generate. I began an NCI approved consulting with Biospect in December, 2002. My understanding was that Correlogic was a software company, in contrast with Biospect, that I understood to be a scientific instrument company. When I began consulting with Biospect, I understood Biospect was in the early stages of developing a new instrument and scientific technology which employed its proprietary chemistry to separate and identify molecules. I understood

Biospect desired to explore the use of blood and body fluids from animal and human sources with the goal of discovering molecules for biological and medical applications.

In view of new information obtained within the last week, I ended my outside activity with Biospect. This activity had been approved repeatedly by my supervisor and the NCI Deputy Ethics Counselor. During this past week I specifically learned that Biospect requested certain information from the NIH. For me, this caused concern. As a result, I terminated my relationship with Biospect effective immediately.

When I first came to the Cancer Institute at the NIH in 1976 to join the pathology residency program, I was fresh out of medical school. I so loved the climate of intellectual freedom there, that I decided to stay. Here it is 28 years later. I am very proud to be a part of the NIH and the NCI. I am humbled in my hope that any of my contributions may have added to the international renown of those institutions. I have always been thrilled to work with colleagues who are so very dedicated to save lives and reduce suffering through the advancement of scientific knowledge.

In closing, Mr. Chairman, I wish to express my gratitude to the CCR, NCI, NIH and PHS for giving me the opportunity to serve the public benefit within a special creative environment that respects its scientists as individuals. Here at the NIH a critical mass of scientists from multiple agencies can work together to further scientific knowledge and employ this knowledge for the common goal of saving lives.

Mr. GREENWOOD. Thank you, Dr. Liotta.

Dr. Petricoin, do you have an opening statement, sir? Okay. You are recognized for 5 minutes.

TESTIMONY OF EMANUEL PETRICOIN

Mr. PETRICOIN. Thank you, Mr. Chairman. Mr. Chairman, I am pleased to be here today, so that I may provide answers to the best of my ability to any questions that you may have and to share with you any relevant insights.

My name is Dr. Emanuel F. Petricoin, and I am a senior investigator in the Office of Cell, Tissue, and Gene Therapies in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration.

I have been a U.S. Government employee since 1993, and I have been honored to spend the entirety of my post-graduate career in the Public Health Service. I understand from the news coverage and your letter of invitation that you are investigating NIH ethics concerns, consulting arrangements, and outside awards.

I appreciate the seriousness with which you are taking this investigation. I hope that I can provide information that will help you. I believe that my outside activities, all of which were submitted, reviewed, and approved, according to the procedures in place, were performed to the highest ethical standards.

I believe I followed, to the best of my ability, not only instructions but also the intent of the ethics guidelines. On May 7, 2004, I was informed that Biospect, with whom I had an approved outside activity, had been recently and now considered based on a re-review to be a significantly regulated entity. As a result of this new classification, this approval had been revoked.

Upon notification of that decision, I immediately and without hesitation, ended this outside activity. I want to note that my approved outside activity with Biospect was listed on all of my filed OGE 450 forms, the executive branch confidential financial disclosure report. And even that as of the last review cycle, in the winter of this year, this activity was found not to be in question.

Mr. Chairman, I heard your opening statements, and I wanted to assure you that at no time did I directly consult with Biospect about the work and our research created with Correlogic, or pro-

vide them with any secret or non-public information. Moreover, I believe that my consulting agreement prohibited that very specific activity conducted with Correlogic under our research CRADA.

Mr. Chairman, ever since I can remember, I have wanted to be a scientist. My family always jokes with me about how they never recall me wanting to do anything else. From the time I won my first science fair ribbon in the fourth grade until today, I have never envisioned myself doing anything else.

I am also Washington, D.C. local. I remember as a child driving by the NIH and naval hospital and staring in disbelief at the size of the buildings and that everyone inside were all scientists. I stand before you today as an individual who I believe has been trying to make a difference in the public health, especially in light of my father's death from a sudden heart attack when I was 21 and my mother's current battle with breast cancer.

My time spent in high school and college working first as a patient transporter, then in a microbiology and clinical laboratory, solidified my decision to work in an area of science that could directly affect people's lives. I could not wait to go to college. I drove headlong into the microbiology major, receiving my Ph.D.—my degree in 3 years and my Ph.D. in 5 years.

My Ph.D. research focused on the analysis of genes, proteins, and surface molecules for gonorrhea vaccine development. I was immediately drawn to a project that did not seem esoteric but might allow me to contribute to work that could actually lead to a vaccine some day.

During my thesis work, I gained expertise in immunology, cell biology, biochemistry, protein chemistry, protein separation and fractionation methodologies, and was introduced into mass spectrometry analysis. During my part-time employment at the Southern Maryland Hospital, I gained valuable expertise in tissue and body fluid collection methods, and in clinical sampling, handling, and storage methods.

Moreover, I became adept and fully trained using a variety of robotic and microfluidic technologies. This combined experience and research in diagnostic practice was the basis of my choice to seek a post-graduate career in translational medicine on my continuing journey for bench to bedside applications.

From 1990 to 1993, I was a National Research Council fellow in a post-doctoral position in the Division of Cytokine Biology at FDA. I was very interested in a career with cancer-based applications, and because of my Ph.D. training realized that new classes of molecules and proteins were being developed which may really have an impact some day.

As icing on the cake, I was able to work in an FDA facility at the NIH, the Nation's premier research institute and my childhood fantasy. From my post-graduate work I gained valuable expertise in signal transduction biology, protein interaction technologies, protein phosphorylation, and cytokine biology.

As I entered the twilight of my post-doctoral training, I was intent on being a research scientist working for direct patient benefit. My time spent as a post-doctoral student at an FDA facility reviewed a different, but equally important, aspect of the translation and delivery of medical benefit to the bedside that I had not recog-

nized before. And I was impressed by the FDA scientists I interacted with.

I successfully competed for a publicly advertised, tenured track, U.S. Government position in 1993 and was tenured in the Center for Biologics Evaluation and Research in 1998. And I am proud that my entire post-graduate career has been spent as a U.S. Government scientist working at the Food and Drug Administration.

In 1997, as a result of a series of highly cited publications from the laboratory of Dr. Lance Liotta, I decided to work with him on a joint interagency agreement and entered into an agreement where we were focusing on translation of research at the bench to bedside practices.

I finally realized my dream job—working at the FDA and learning about the process of delivering safe and effective medicine to the public. Let me explore and expand my scientific talents which link back to the times of my laboratory experience at a hospital as a college freshman.

Mr. Chairman, I certainly receive many outside activity requests every year. Almost all of these are dismissed immediately, because they are invitations which directly relate to my official duties as an FDA employee and my ongoing U.S. Government scientific research.

I consider only those requests that invite me to participate not because of my U.S. Government position and FDA expertise, but because of my general scientific expertise built up over the years. In those instances where I choose to pursue the opportunity, I always submit an HHS 520 form, Request for Outside Activity.

This approval form—request form is then approved or declined after due diligence under currently established procedures. I would never knowingly pursue any activity which I felt would run counter to this process. And I certainly would never knowingly pursue or continue any outside activity which I felt was in conflict with a career spent as a scientist in the pursuit of public and patient benefit.

In closing, Mr. Chairman, I wish to express my gratitude to CBER, the FDA, and the Public Health Service, for providing me a working environment and research funding support for a body of work which I believe is highly successful and is one that I am extremely proud of.

I will answer, as best I can, any questions you and the panel have for me.

[The prepared statement of Emanuel Petricoin follows:]

PREPARED STATEMENT OF EMANUEL F. PETRICOIN, SENIOR INVESTIGATOR, OFFICE OF CELL TISSUE AND GENE THERAPIES, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

Mr. Chairman, I am pleased to be here today so that I may provide answers, to the best of my ability, to any questions that you may have and share with you any relevant insights. My name is Dr. Emanuel F. Petricoin III, and I am a Senior Investigator, in the Office of Cell, Tissue and Gene Therapies in the Center for Biologics Evaluation and Research, within the US Food and Drug Administration. I have been a US Government employee since 1993, and have been honored to spend the entirety of my post-graduate career in the Public Health Service.

I understand from the news coverage and your letter of invitation that you are investigating NIH ethics concerns, consulting arrangements and outside awards. I appreciate the seriousness with which you are taking this investigation. I hope that I can provide information that will help you. I believe that my outside activities,

all of which were submitted, reviewed and approved according to the procedures in place, were performed to the highest ethical standards. I believe I followed, to the best of my ability, not only the instructions but also the intent of the ethics guidelines. On May 7th, 2004, I was informed that Biospect, with whom I had an approved outside activity, had been recently and now considered, based on a re-review, to be a significantly regulated entity. As a result of this new classification, this approval had been revoked. Upon notification of that decision, I immediately and without hesitation ended this outside activity. I want to note that my approved activity with Biospect was listed on all of my filed OGE 450 forms (Executive Branch Confidential Financial Disclosure Report), and that even as of the last review cycle, this activity was found not to be in question.

BACKGROUND REGARDING MY CAREER

Ever since I can remember, I have wanted to be a scientist. My family always jokes with me about how they can never recall me wanting to do anything else. From the time I won my first science fair ribbon in the 4th grade until today, I have never envisioned myself doing anything else. Mr. Chairman, I am a Washington DC local. I remember as a child, driving by the NIH and the Naval Hospital and staring in disbelief at the size of the buildings where everyone inside were all scientists!! I stand before you today as an individual who I believe, has been trying to make a difference in the public health, especially in light of my father's death from a sudden heart attack when I was 21 and my mother's battle with breast cancer. My time spent in high school and college working first as a patient transporter, then in a microbiology and clinical laboratory, solidified my decision to work in an area of science that could directly affect people's lives.

I could not wait to go to college. While many of my friends and dorm mates waited until their sophomore years to declare a major, at the University of Maryland I charged headlong into the Microbiology major, received my degree in 3 years, and received my PhD in Microbiology in five years in 1990. My PhD research focused on the analysis of genes, proteins and surface molecules for gonorrhea vaccine development. I was immediately drawn to a project that didn't seem esoteric, but might allow me to contribute to work that could actually lead to a vaccine some day. During my thesis work, I gained expertise in pathogenic microbiology and infectious disease analysis, immunology and cell biology, biochemistry and protein chemistry, protein separation and fractionation methodologies, and mass spectrometry analysis of molecules within complex biological and bacterial samples. I successfully identified and characterized the first gene for a gonorrhea surface molecule that later became considered for a potential vaccine target. We employed a variety of protein analytical techniques, and were one of the first scientific groups to successfully employ mass spectrometry to analyze the sugars attached to lipids on the surface of disease-causing bacteria. Moreover, as a consequence of my PhD studies, I became facile in the handling of clinical specimens and body fluids as well as diagnostic testing methods for bacterial characterization. During my part-time employment at Southern Maryland Hospital, I gained valuable expertise in tissue and body fluid collection methods, clinical sample handling and storage methods, and clinical diagnostic technology. Moreover, I became adept and fully trained using a variety of robotic and microfluidic technologies. This combined experience in research and diagnostic practice was the basis of my choice to seek a post-graduate career in translational medicine—on my continuing journey for bench-to-bedside applications.

POST-DOCTORAL CAREER

From 1990 until 1993 I was a National Research Council Fellow in a post-doctoral position in the Division of Cytokine Biology, CBER/FDA. I was very interested in cancer-based applications, and because of my PhD training, realized that new classes of molecules and proteins were being developed which may really have an impact someday. However, the scientific community lacked knowledge about the way these proteins communicated with cells and what really caused cells to grow, die and spread uncontrollably. I was drawn to a laboratory which was focused on trying to understand how a widely known protein, interferon, actually worked and caused cancer to die or quelled viral infections. As icing on the cake—I was able to work at an FDA facility that was at the NIH—the Nation's premier research institute and my childhood fantasy. During my post-graduate work, I gained valuable expertise in signal transduction biology, protein-protein interaction methodologies, protein phosphorylation, and cytokine biology. For the first time, our laboratory identified and characterized members of a signaling pathway that later became the well known "JAK-STAT" pathway. This pathway is now thought to regulate and be involved in viral disease, inflammation, and cancer. Additionally, during my post-doc-

toral fellowship, I was able to extend my graduate expertise using mass spectrometry and protein separation methods by employing new proteomic technologies. Using these tools, I identified and sequenced a new protein, produced by many different cancer cell lines. This protein was experimentally demonstrated to interfere with interferon activity.

JOINING FDA/CBER

As I entered the twilight of my post-doctoral training, I was intent on being a research scientist working directly for patient benefit. My postgraduate work on the NIH campus made me realize that the unique environment provided by a vibrant scientific community all striving for translational medical benefit was the place I wanted to stay. My time as a post-doctoral student in an FDA facility revealed a different but equally important aspect to the translation and delivery of medical benefit to the bedside that I had not recognized before. I was intrigued and impressed by the FDA scientists I interacted with. I was intrigued by their unique combination of bench-side research talents as well their understanding of what it took to get a biologic approved for clinical benefit. I decided that I could blossom in such a role and was ecstatic that in 1993, I successfully competed for a publicly advertised tenure-track US Government position. I was tenured in the Center for Biologics Evaluation and Research in 1998, and am proud that my entire post-graduate career has been spent as a US Government scientist working at the US Food and Drug Administration.

FDA/NCI COLLABORATION ESTABLISHED

In 1997, as a result of a series of highly cited scientific publications from the laboratory of Dr. Lance A. Liotta of the NCI, I contacted Dr. Liotta to discuss potential collaborative opportunities to use proteomic analysis of laser capture microdissected human cancers. This discussion resulted in the first joint Interagency Agreement (IAG) between the FDA and the NCI. The focus of this IAG was to work jointly together to develop and test new proteomic technology for clinical and translational applications. I had finally realized my dream job. Working at the FDA and learning about the process of delivering safe and effective medicine to the public let me explore and expand my scientific talents which linked back to my times as a college freshman working in a hospital lab.

Based on our combined research and clinical expertise, we embarked on a variety of research projects that employed a variety of emerging proteomic technologies for discovery of diagnostic biomarkers and therapeutic targets. The overarching goal was to develop and evaluate methods for personalized medicine and early detection of cancer as a means to provide translational public health impact with a high degree of scientific rigor and an eye towards rapid patient benefit. This goal has been a consistent cornerstone of our joint collaboration. During the past 6 years, our program has successfully developed a number of new exciting proteomic technologies, with over 90 publications to our credit. These publications are the direct result of a talent pool of highly creative scientists both within the program itself as well as our fantastic set of scientific collaborators outside the program. We have entered into several documented US Government Material Transfer Agreements (MTA) and US Government Cooperative Research and Development Agreements (CRADA) that have proved highly successful. Within each of these agreements and arrangements we sought a clear path to facilitating and translating our work to public benefit without constraining our ability to maintain the necessary independent and creative freedom that has served us so successfully. In addition to the need to maintain creative freedom to operate, we are driven by a transparent process of proteomic data dissemination into the public domain. We are proud that as US Government scientists, we were the first group to offer all of our mass spectral data in the public domain, and continue to provide all of our data to the entire scientific community as a public service. This public dissemination of data and transparency has been commended by the National Cancer Advisory Board. We are also proud that while we were the first group to demonstrate the use of mass spectrometry based protein fingerprinting for cancer applications in the spring of 1999, recently hundreds of scientists at the latest meeting of the American Association of Cancer Research (April 2004) are reporting independent success using a variety of different approaches. Our raw data has been downloaded over 500 times in the past two years, and scientists, from around the world, including a 2002 National Medal of Science Winner, named by President Bush as one of the nation's leading scientists, have published extremely exciting results using our raw data as the basis of their own pattern recognition methods and tools.

Our ongoing work continues to accelerate. We have recently invented new technology that is wholly owned by the Government and has been advertised in the Federal Register. This has allowed us to identify thousands of new biomarker molecules that may be useful for cancer and disease diagnosis. We believe that this new diagnostic information archive, never before known to exist in the blood, may contain important information for the detection of many diseases—not just cancer. We hope that this information can translate into broad public health benefit.

I certainly receive many outside activity requests every year. Almost all of these I dismiss immediately because they are invitations, which directly relate to my official duties as an FDA employee and my ongoing US Government scientific research. I consider only those requests that invite me to participate not because of my US Government position, but because of my general scientific expertise which encompasses my lifetime as a scientist, and whose activities are directly unrelated to my government job. In those instances where I chose to pursue the opportunity I always submit an HHS 520 form for approval. This approval form is approved or declined after due diligence under current established procedures. I would never knowingly pursue any activity which I felt would run counter to this process, and I certainly would never knowingly pursue or continue any outside activity which I felt was in conflict with a career spent as a scientist in the pursuit of public and patient benefit.

In closing, Mr. Chairman, I wish to express my gratitude to CBER, the FDA and PHS for providing for me a working environment and research funding support for a body of work which I believe is highly successful and is one that I am extremely proud of. I will answer, as best I can, any questions you may have for me.

Mr. GREENWOOD. Thank you. Am I pronouncing—is it Petricoin?

Mr. PETRICOIN. Yes, sir.

Mr. GREENWOOD. Okay. I am advised that neither Dr. Barrett nor Dr. Barker have opening statements. Is that correct? You do not have opening statements. Okay. But you are prepared to answer our questions. Very good. Thank you.

All right. And before I begin, because one could not miss the passion in both of your statements, Dr. Liotta and Dr. Petricoin. There is no one who is questioning that you are a splendid scientist. There is no one questioning that you have chosen careers that are highly valuable to mankind.

It is an unusual phenomena for Federal employees to work—at the same time they are Federal employees to work in the private sector as well. And it obviously raises a host of ethical issues. And what this hearing is about, and what this committee is about, is trying to sort our way through these ethical issues.

We know things have gone wrong at the NIH ethically. We know that there are well-documented instances of that. We are trying to understand the underlying rules, policies, culture, that has—that leads to this, and that is why you find yourselves in front of us today. I am sure you would rather be almost anywhere else, but I am going to proceed with questions and hope you will understand the spirit in which they are given.

Let me start with you, Mr. Petricoin. Some of these questions are elementary, but I am—just follow with me here. Dr. Petricoin, do you accept a Government check?

Mr. PETRICOIN. I accept a Government check, sir, is that what you—

Mr. GREENWOOD. Yes.

Mr. PETRICOIN. Yes.

Mr. GREENWOOD. When do you get paid? You need to pull the microphone, make sure it is on and close to your mouth. Okay. When do you get paid? Every 2 weeks?

Mr. PETRICOIN. Yes, sir.

Mr. GREENWOOD. Okay. And you put that check in a bank account and you spend the money.

Mr. PETRICOIN. Yes, sir.

Mr. GREENWOOD. Okay. And when you joined the FDA, you were briefed on ethics, is that correct?

Mr. PETRICOIN. Yes. There was ethics training that I attended.

Mr. GREENWOOD. Very good. You have received annual training?

Mr. PETRICOIN. Yes.

Mr. GREENWOOD. Okay. You have received ethics counseling?

Mr. PETRICOIN. Ethics counseling, sir? The annual ethics training.

Mr. GREENWOOD. Have you ever spoken to Vincent Tolino in the Ethics Office?

Mr. PETRICOIN. Yes, sir.

Mr. GREENWOOD. Okay. Was that for counseling from Mr. Tolino?

Mr. PETRICOIN. Yes, sir. There was times when Mr. Tolino would advise me.

Mr. GREENWOOD. Right. So I am just trying to distinguish that between routine—that and routine training. Are you with me? Okay, sir.

You knew the restrictions included—and you knew that there were restrictions on certain outside activities, correct?

Mr. PETRICOIN. Yes, sir.

Mr. GREENWOOD. Okay. And you knew that restrictions include no outside consulting with significantly regulated entities like Biotechnology companies, is that correct?

Mr. PETRICOIN. Yes, sir. I realized there were restrictions on these significantly regulated entities.

Mr. GREENWOOD. Is Biospect a biotechnology company?

Mr. PETRICOIN. When Biospect approached me in 2002, it was my understanding that they were an instrument company that was developing technology for protein separation, fractionation, and identification. I looked at the FDA yellow book, which lists the significantly regulated entities. They were not listed.

And according to what was on the Ethics homepage, the next step was to see if greater than a certain percentage—I think—I believe to the best of my recollection it is 10 percent—of their gross revenues were regulated by the FDA. Since this was apparently a new company, a startup company, the focus of their efforts was, in fact, to find out applications for this tool.

Mr. GREENWOOD. Did you decide it was not a biotechnology company?

Mr. PETRICOIN. Yes, sir, based on the fact that the next determination was on my looking at the FDA website.

Mr. GREENWOOD. Was there any question in your mind that it was a technology company?

Mr. PETRICOIN. Yes. I think it was a technology company.

Mr. GREENWOOD. Why do you think it called itself biotechnology—Biospect?

Mr. PETRICOIN. Well, the determination of a significantly regulated entity, when there isn't a revenue stream, is that to the best of my understanding that all of its activities are solely regulated by the FDA. And in terms of what my understanding of Biospect

was, that did not appear to be the case. There is many areas that are—of science and technology that the FDA does not regulate.

Mr. GREENWOOD. So you thought it could—I just want to—did you think it was a biotechnology company?

Mr. PETRICOIN. Not necessarily. I think that—

Mr. GREENWOOD. I mean, not—I am not asking you based on the yellow book. I am saying, you look at this company, you see what it does, what its mission is, and you know it is a technology company. You know it uses mass spectroscopy. And it is working with biological materials, is it not?

Mr. PETRICOIN. Yes.

Mr. GREENWOOD. So, I mean, wouldn't it seem on the surface to be a biotechnology company, if ever there was one?

Mr. PETRICOIN. Well, not necessarily, because as I looked at those companies that were also on the list of approved entities, there were many entities which did technology that directly related to biotechnology, for example.

Mr. GREENWOOD. Okay. All right.

Mr. PETRICOIN. And so I submitted the approval to those that could make the decision better than I. I am a scientist, not a lawyer, so I—

Mr. GREENWOOD. That is fine. Okay. So if you would turn to Tab 27 in that notebook in front of you. That is what you just referenced. That is your request for approval of an outside activity, which you submitted to the FDA. And you provided information on the form about Biospect and the agreement you were engaging in with them.

Okay. Where did you get the information that you needed about the company to fill that form out?

Mr. PETRICOIN. This was based on an invitation letter and discussions with one of the principals that contacted me to see if I would be interested in consulting.

Mr. GREENWOOD. Okay. And what was your understanding of what you were being hired to do?

Mr. PETRICOIN. Basically, the understanding that I was operating under, and I operated under during the entire time, would be to survey the public domain for applications of their technology, including selling the machine itself all the way to, you know, environmental monitoring to discovering new molecules associated with disease.

Mr. GREENWOOD. Okay. And did you use the same contract as Dr. Liotta with Biospect?

Mr. PETRICOIN. Yes. Of course changing the name, things—

Mr. GREENWOOD. Changing the name, of course. Would you please look at Exhibit A from Dr. Liotta's contract, which is at Tab 32 of the binder on the table. The second paragraph reads, "Consulting services will relate to general professional knowledge in medical diagnostic technology, clinical sample acquisition, preparation, fractionation, separation, storage, and stability, regulatory filings, and regulatory inspections related to clinical pathology laboratories, e.g. CAP, CLIA, GMP inspections, and 510(k) or PMA filings for new diagnostic tests."

Dr. Petricoin, are any of these things things that are regulated by the FDA?

Mr. PETRICOIN. Yes, sir. But I would like to point out that my consulting agreement, which I can provide to the committee, dramatically differs from those statements.

Mr. GREENWOOD. But that is what the company does. The company does those things. I mean, this isn't—I am not asking you whether you were doing things for the company that are themselves regulated. Obviously, the FDA doesn't regulate the looking up—reviewing material in the public domain, but the FDA regulates many of the things that the company does.

Mr. PETRICOIN. The appearance of what Dr. Liotta would provide them as a consult does not necessarily to me reflect that they had solely wanted to do FDA regulatory mission-related work.

Mr. GREENWOOD. Okay.

Mr. PETRICOIN. I think at the time they were exploring every option.

Mr. GREENWOOD. But isn't it quite abundantly clear that they were interested in getting a medical device approved by the FDA?

Mr. PETRICOIN. I think they were exploring every option, sir.

Mr. GREENWOOD. They couldn't use the device, the device couldn't be used if it were not approved by the FDA, could it?

Mr. PETRICOIN. Actually, that's not to my knowledge true, sir. I think that there are things like home brew testing, which the FDA does not have regulatory authority.

Mr. GREENWOOD. Home what?

Mr. PETRICOIN. A home brew type testing.

Mr. GREENWOOD. Beer?

Mr. PETRICOIN. Oh, excuse me. It's a, the home brew is the reference to a diagnostic testing that certain laboratories can perform if it's housed in one location. At this definition, I am not an expert.

Mr. GREENWOOD. Okay, but you don't need a 510(k) for that, correct?

Mr. PETRICOIN. Yes, a 510(k) is an FDA. But CLIA

Mr. GREENWOOD. Was there any, I'm trying to get at, was it not abundantly clear that this company was interested in getting FDA approval for its equipment?

Mr. PETRICOIN. It was not abundantly clear to me. My understanding was they were looking at every aspect of science and technology. And science and technology being such a huge field, and the regulations that I saw in place on the FDA website, where

Mr. GREENWOOD. Wasn't the wonderful promise, or isn't the wonderful promise of this technique, this device, that it is going to be able to allow for us to have very advanced diagnoses of potential cancer victims? Isn't that what it's all about?

I mean isn't that what they're, isn't that the grandeur of their idea?

Mr. PETRICOIN. Not to my understanding.

Mr. GREENWOOD. Okay.

Mr. PETRICOIN. That they had really no specific application that they were looking at. They had developed the technology and platform and they were looking at avenues to use them. That's what my consultation was, was to look into the public domain at where any application, where technology such as this could possible be used.

Mr. GREENWOOD. Why do you think they wanted you?

Mr. PETRICOIN. I assume because of my expertise and my reputation.

Mr. GREENWOOD. In general, but not, not because of your expertise in the way FDA works?

Mr. PETRICOIN. Absolutely not.

Mr. GREENWOOD. Okay.

Mr. PETRICOIN. At no time did they ever ask me, nor did I give any advice on FDA.

Mr. GREENWOOD. I understand that. Did your consulting agreement with Biospect include this language? I think you said it is different. Your consulting agreement with Biospect did not include the language that I just had you look at in Title 32, Tab 32, rather?

Mr. PETRICOIN. That's right. And I would be happy to provide the committee with my consulting

Mr. GREENWOOD. Okay, we would appreciate that. Is Correlogic working on pattern-recognition based technology?

Mr. PETRICOIN. Yes, sir.

Mr. GREENWOOD. Okay. And we—oh, I'm sorry. Is Biospect working on pattern-recognition technology? Pattern-recognition based technology, is Biospect working on that?

Mr. PETRICOIN. The first time that I heard that Biospect was working with pattern analysis, was when my Center Director, Jesse Goodman, brought me into his office.

Mr. GREENWOOD. Who did?

Mr. PETRICOIN. Dr. Jesse Goodman, the Center Director for Center for Biologics Evaluation and Research.

Mr. GREENWOOD. Right.

Mr. PETRICOIN. He brought me into his office and informed me that, upon a recent re-review, the FDA had determined that Biospect had become a significantly regulated entity, and he used the terms pattern analysis that they had found. And that was the first that I had heard reference to that.

Mr. GREENWOOD. Do you know who Peter Levine is?

Mr. PETRICOIN. Yes, sir.

Mr. GREENWOOD. Who is he?

Mr. PETRICOIN. I believe his title is the CEO of Correlogic Systems.

Mr. GREENWOOD. Do you ever recall having a conversation with him about his unhappiness with regard to your arrangement with Biospect?

Mr. PETRICOIN. The recollection that I have of that conversation was that Mr. Levine was unhappy with the fact that there seemed to be a lot of former NCI employees in the company.

Mr. GREENWOOD. But he didn't—was he aware that you were—had this arrangement with Biospect?

Mr. PETRICOIN. I believe so, sir.

Mr. GREENWOOD. How would he have known that? Did you tell him?

Mr. PETRICOIN. I

Mr. GREENWOOD. Did you ever tell

Mr. PETRICOIN. No. Mr. Levine had that information because on one of the instances in which Dr. Liotta and I went up to an office facility, a temporary facility where we share joint secretarial services, they were both actually shared by Biospect and Correlogic.

Maybe even in some ways highlighting how little we—there was no concern on our part. And so we went up there and Mr. Levine saw us and asked what we were doing up there, we weren't having a CRADA meeting? And we told him that we were up here at a

Mr. GREENWOOD. Why wouldn't you have volunteered that information to him prior to that time?

Mr. PETRICOIN. I didn't see any need to. There was no overlap in my mind. Correlogic, in my mind, sir, was a software company that was using algorithms to look for hidden patterns in mass spec data. And those would be fingerprints that could be used for diagnosis. Biospect, my understanding was, it was an instrument company.

It was building a platform of protein separation. It was entirely different. And thus, in my mind, there was really no reason to talk to Mr. Levine.

Mr. GREENWOOD. When you were first made aware of these concerns that Mr. Levine had, did you consider terminating your consulting agreement with Biospect?

Mr. PETRICOIN. I know because I thought his concerns really relayed to the number of former NCI employees that were

Mr. GREENWOOD. So he never expressed to you that he was unhappy that you were working with Biospect?

Mr. PETRICOIN. I think he was unhappy that we, that, you know, Dr. Liotta and I had an outside activity that were perhaps taking away our time. I, my recollection of the conversation was that he expressed some question about why there were so many former NCI employees in the company.

Mr. GREENWOOD. Why do you think he had that concern?

Mr. PETRICOIN. I guess he felt that this, you know, was nepotism going on here? I don't know. He just said that didn't smell right to him. And I said I didn't know that that was illegal.

Mr. GREENWOOD. Dr. Barker, Correlogic made a complaint to NCI, did it not? Could you characterize that?

Ms. BARKER. Yes, in July 2003, actually Dr. Von Eschenbach informed me that Dr. Ren Archer, who was a consultant of Correlogic's, actually I think represents them in their, some of their marketing activities.

He's with Hill and Knowlton had complained to him that he felt as though there might be some issues surrounding Dr. Liotta's consultancy with a competing company, with which the NCI had a CRADA. And he represented that company, which was Correlogic. So I spoke with Dr. Archer and he shared that concern with me, and I assured him that we would examine Dr. Liotta's consultancy agreement and I would actually get back to him on that.

And that's the only time it's ever been raised. It hasn't been raised in meetings, but it was raised in that conversation.

Mr. GREENWOOD. Dr. Barrett, what was the issue that you were looking at, at the time?

Mr. BARRETT. Which time are you referring to, Mr. Chairman?

Mr. GREENWOOD. The reference that Dr. Barker just made.

Mr. BARRETT. Oh, okay. So, I had, we had originally approved the outside activity in 2002. And when Dr. Barker was contacted by the representative from Correlogic, I then re-reviewed the material that was available, and called Dr. Liotta in.

At that point I, the question on the table, as I understood it, was whether or not there was any conflict between the outside activity and the ongoing CRADA that we had with Correlogic.

And so I called Petricoin in, as well, to discuss how this might impact, if at all, the CRADA.

Mr. GREENWOOD. There wasn't a question of were they or were they not NCI officials and how many NCI officials, you were interested in the question of whether there is a conflict of interest?

Mr. BARRETT. Right. I was unaware of the NCI former employees being members of

Mr. GREENWOOD. My time has expired. Now, the gentlelady from Colorado.

Ms. DEGETTE. Thank you, Mr. Chairman. And Dr. Liotta and Dr. Petricoin, I want to add to the Chairman's sentiments. I think both of you are dedicated public servants and researchers and we do have to go into this.

But I do not question your dedication to research or ethics. Although I think these case studies are good examples of some of the concerns we have, Dr. Liotta, starting with you, and also I want to ask you some of these same questions, Dr. Petricoin.

In your written statement, and you alluded to this in your oral presentation. You said that when you first came to the Cancer Institute at the NIH, you were fresh out of medical school and you really loved the climate and intellectual freedom. Is that a correct paraphrase?

Mr. LIOTTA. Yes.

Ms. DEGETTE. Do you still love that climate of intellectual freedom there?

Mr. LIOTTA. Absolutely.

Ms. DEGETTE. I would assume that's one of the best things about being at the NIH is being able

Mr. LIOTTA. I love

Ms. DEGETTE. Is your microphone on, sir?

Mr. LIOTTA. Yes, that's why I stay at the NIH, because of that intellectual and creative freedom.

Ms. DEGETTE. Right. Would it be fair to say that you don't stay at the NIH because of your ability to do outside consulting or get speaking fees?

Mr. LIOTTA. I stay at the NIH because I'm dedicated to the mission, particularly of the Cancer Institute.

Ms. DEGETTE. And, Dr. Petricoin, I was also struck both by your oral testimony and your written testimony. And I actually have a 14 year old daughter who is like this.

Who is so excited by the concept of researching and being a scientist. And you said in your written statement you remember as a child, driving by the NIH and Naval Hospital, and staring in disbelief at the size of the buildings where everyone inside were all scientists, right?

And so I'm going to ask you the same question. What you really love to do is the science, right? Now, I'm sorry, you need to say words for the record.

Mr. PETRICOIN. Yes.

Ms. DEGETTE. Now, so I have the same question, is you do this because of the science, is that what makes you stay at the FDA or

is it because of the outside contracts and speaking fees you're able to attain?

Mr. PETRICOIN. No, ma'am, I stay at the NIH and the FDA because of the intellectual freedom and the creative science and the ability to hopefully make a public health difference.

Ms. DEGETTE. And that's why you went there a little over 10 years ago, right?

Mr. PETRICOIN. Yes, ma'am.

Ms. DEGETTE. Now, Dr. Liotta, you testified that you ended your outside activity with Biospect last week, when you learned that Biospect had requested certain information from the NIH. What was that information?

Mr. LIOTTA. That was information that was publicly available to everyone who asked for it, as part of our effort to disseminate the raw data from our studies to anyone who requests it.

Our goal is to develop new diagnostic technology to fight cancer, so we want as many people to be working on that as possible.

Ms. DEGETTE. Right.

Mr. LIOTTA. So we provide that data freely.

Ms. DEGETTE. But somehow you thought, because they were requesting that data, that then created a conflict of interest for you?

Mr. LIOTTA. Because I found out, unbeknownst to me, that they had requested that data, then I could not be completely, absolutely sure that they weren't going to studying something that might overlap in my, with my government work.

Even though my consulting agreement, specifically by name, excluded

Ms. DEGETTE. But because there was then a

Mr. LIOTTA. Because of that potential. And I discussed it with my, with Dr. Barrett and Dr. Wilson, and I voluntarily withdrew that outside activity because I didn't want to have even the slightest possibility.

Ms. DEGETTE. Thank you. How did you find out about that request?

Mr. LIOTTA. Mr. Pugash, from the NCI, told me.

Ms. DEGETTE. And, and just last week?

Mr. LIOTTA. That's correct.

Ms. DEGETTE. And how, did he say how he learned about it?

Mr. LIOTTA. He said that in preparation for this hearing, the Technology Transfer Branch had been trying to study everything that they could, that was relevant. And this, a document came up that reflected a request by Biospect that came in.

This was part of a turnkey system that I had no decisionmaking role in, and it just went from one office to the next.

Ms. DEGETTE. Did he tell you if they found anything else that affected ongoing agreements between NIH Scientists and outside companies, as a result of the request for this hearing?

Mr. LIOTTA. No, not that I recall.

Ms. DEGETTE. Okay. Well, at least we're doing some good, Mr. Chairman, I guess. I, now have you ever learned information in the midst of a consulting agreement that caused you to withdraw from the agreement, or was this the first time?

Mr. LIOTTA. This was the first time.

Ms. DEGETTE. Okay. And this agreement, the original agreement was approved by ethics officials?

Mr. LIOTTA. That's right. The original agreement was approved, and in fact developed in concert with ethics.

Ms. DEGETTE. Okay, so they actually helped you develop the agreement?

Mr. LIOTTA. That's right. They added language to it, they reviewed it and worked together with me to develop this agreement.

Ms. DEGETTE. Okay, now, Dr. Petricoin, you work at the FDA. So your ethics requirements are a little different. I think that's important to put out at this hearing. Is that correct?

Mr. PETRICOIN. Yes, ma'am. It is a significantly regulated entity.

Ms. DEGETTE. Significantly tighter restrictions, right? And that's because your agency is actually approving these drugs, right?

Mr. PETRICOIN. Yes, ma'am.

Ms. DEGETTE. Now you have received honoraria and/or expenses to speak to a number of groups, including Pfizer, 3M, other private companies who clients include pharmaceutical and biotech firms, correct?

Mr. PETRICOIN. Yes, ma'am.

Ms. DEGETTE. About how many over the last ten or so years?

Mr. PETRICOIN. I believe I have about 20 outside activity requests in my file.

Ms. DEGETTE. About 20 outside activity—are these, now how many for honoraria for speaking?

Mr. PETRICOIN. I believe I have only a few for, that have given me honoraria for speaking.

Ms. DEGETTE. Okay.

Mr. PETRICOIN. I have many that, or I have a number for travel reimbursement.

Ms. DEGETTE. Oh, so you actually went and spoke at some places but didn't receive honoraria, right?

Mr. PETRICOIN. Yes, ma'am.

Ms. DEGETTE. Now when you get invited to speak at something, do you go because of the honor and prestige of speaking, or because you might receive an honorarium?

Mr. PETRICOIN. It depends on the nature of the invitation. For me it's always the ability to learn when I go and give a talk.

Ms. DEGETTE. Okay.

Mr. PETRICOIN. I hope to learn something. And so if they invite me because of my general scientific expertise, it's not related to my FDA expertise or my FDA job, I can, under ethics, submit a request for approval for both an honoraria and a travel expense.

And I put that request forward and the FDA Ethics Office, and whatever process

Ms. DEGETTE. Right, but the reason you go is to learn, as you've just said, not because you're going to get paid, right?

Mr. PETRICOIN. That's right. My first level decision isn't how I can get more money?

Ms. DEGETTE. Right. Well, I'm asking you, I'm not asking you this to be insulting in any way, because that would be exactly the way I'd be if I were you. Some people are saying that there won't be these collaborations between NIH or FDA Scientists without money involvement.

I don't buy that premise. I don't know if you do. Do you buy that premise?

Mr. PETRICOIN. I do not think that anyone should be making a decision about how they advance their professional career, especially as a Scientist, where the first determinate is am I going to be making more money.

I believe personally that it should be about learning.

Ms. DEGETTE. And you're sort of early in your career at the FDA. Dr. Liotta, you're sort of mid-career, I'd say. What's your view on that?

Mr. LIOTTA. I'm at the NIH, and I stay there because of the medical mission and goal of taking science to the public benefit.

Ms. DEGETTE. And not because of the ability to get outside consulting fees or honoraria, correct? Would that be fair?

Mr. LIOTTA. That is not my primary reason, no.

Ms. DEGETTE. Okay. Now, Dr. Petricoin, every time you spoke at one of these—now you wouldn't be allowed to speak, and maybe I'm wrong. You wouldn't be allowed to speak at these outside conferences if it did, if it did have a conflict with your FDA job, right?

Mr. PETRICOIN. I was

Ms. DEGETTE. I mean that wouldn't be, you wouldn't even put it in, right? What you're saying is you're invited to speak at these because of your scientific experience outside the FDA, right?

Mr. PETRICOIN. Yes, ma'am.

Ms. DEGETTE. And every time one of these speaking engagements does get approved by—or every time you have one, it's approved by your superiors, right?

Mr. PETRICOIN. Every outside activity that I've ever put in, has gone into the process of approval.

Ms. DEGETTE. And that would be Amy Rosenburg or Phil Naguchi, correct?

Mr. PETRICOIN. Yes, those are the two first-line approving officers, because the triage that is supposed to take place, is that you first discuss your outside activity with your immediate supervisor.

They were my immediate supervisors at that time. Hopefully, they would best know what I was doing in the government.

Ms. DEGETTE. And they did approve these outside engagements?

Mr. PETRICOIN. Yes, ma'am.

Ms. DEGETTE. Now I want to talk to you about an activity that was approved in February of this year. I realize you didn't actually end up going, but I think it's a good case study.

This is an EGFR Seminar sponsored by Imclone Systems, one of our very favorite groups in this subcommittee, and Bristol Meyer Squibb, both who have received a good deal of publicity because of, of course, their submissions to your agency for approval of the drug Herbatax.

Now, were you aware that Herbatax has come before CBER for approval?

Mr. PETRICOIN. Yes, ma'am.

Ms. DEGETTE. And it's likely to come there again. It's been there several times for approval of other indications, because it's only been approved for one indication, right?

Mr. PETRICOIN. Yes, ma'am.

Ms. DEGETTE. Now were you aware of that when you accepted the invitation to pay for you to participate in the seminar at the Trump International Beach Resort in Florida?

Mr. PETRICON. I was unaware, when I first accepted, that this was a pharmaceutical sponsored and paid for event. When I learned that I just simply said I'm not going.

Ms. DEGETTE. Well, with all due respect, I've got the program here, and it says on the top, Imclone Systems, Incorporated and Bristol Meyer Squibb Company, 2004 EGFR Summit. So, did you not have that?

Mr. PETRICON. To the best of my recollection, I had an e-mail from Dr. Jose Baselga, who was a Scientist at Vanderbilt University, asking me if I would like to come and talk.

And I said that, you know, it depends on the nature of the talk, I could give the talk. And he said to me I'll forward you and agenda describing the nature of the talk that I was to give to him. I understood that I could do this as an outside activity from Dr. Baselga.

Ms. DEGETTE. Oh, okay.

Mr. PETRICON. And when he forwarded me the agenda, I attached on this

Ms. DEGETTE. Right. But see, here's why we're all a little confused up here. Because you submitted, and she just handed you a copy of the Request for Approval of Outside Activity. Did you fill that out?

Mr. PETRICON. I did, based on the

Ms. DEGETTE. Based on the stuff from the guy from Vanderbilt, right? And it was approved here by your supervisors, right?

Mr. PETRICON. Yes, ma'am.

Ms. DEGETTE. But if you take a look at Number 16, it says additional information attached, yes, and then it says agenda, and here's the agenda, right?

Mr. PETRICON. I understand your concern, ma'am. I didn't go because when I looked at it, when I looked at the agenda, the detail of the agenda, I said whoa, wait a minute.

Ms. DEGETTE. Well, well, well, wait a minute. You put in for the approval and attached the agenda.

Mr. PETRICON. Yes, ma'am.

Ms. DEGETTE. So did you later decide that it would be a problem to go?

Mr. PETRICON. Yes, ma'am.

Ms. DEGETTE. After it was approved?

Mr. PETRICON. Yes, ma'am.

Ms. DEGETTE. Oh, okay. Now, but the other thing I find interesting is you say you later saw an ethical problem because it was pharmaceutically sponsored, right?

Mr. PETRICON. Yes, when I

Ms. DEGETTE. But your supervisors had that information right in front of them when they approved it, didn't they? Because they had the agenda attached.

Mr. PETRICON. It appears so, ma'am.

Ms. DEGETTE. Now, right, he just said he did. So now, okay, here's the other thing. Another FDA official actually did attend in your place, right?

Mr. PETRICOIN. No, ma'am. A Scientist from our laboratory attended on the U.S. Government

Ms. DEGETTE. Right, and they were not paid an honorarium or expenses, right?

Mr. PETRICOIN. No, ma'am.

Ms. DEGETTE. So that's a different, that's even another interesting point from this whole, this whole transaction is, someone else went to speak and they obviously didn't do it because there was payment involved, they did it to present the scientific issues, right?

Mr. PETRICOIN. Yes, ma'am.

Ms. DEGETTE. And aside from the ethical issues that it was sponsored by pharmaceutical companies, let's say it hadn't. Let's say it had been sponsored by Vanderbilt University and you had been asked to speak. Would you have also been willing to go and speak if there were no honorarium involved in this?

Mr. PETRICOIN. Would I have been willing to go and speak if there were no honorariums?

Ms. DEGETTE. If the ethical objections weren't there?

Mr. PETRICOIN. Yes, I would have gone to learn.

Ms. DEGETTE. Okay. I have no further questions. Thank you, Mr. Chairman.

Mr. GREENWOOD. I don't want to belabor that, but just tell me if I have this wrong. You said, Dr. Petricoin, that when you saw, it was when you saw the agenda, that's when you realized I can't do this?

Mr. PETRICOIN. That's right. I said I can't do this because this has all

Mr. GREENWOOD. Did you see the agenda before or after you attached it to your application for approval?

Mr. PETRICOIN. Well, I obviously had the agenda, I attached it to my approval. I don't think I looked at the agenda, to be honest with you, sir, because I

Mr. GREENWOOD. You understand why that would make us wince?

Mr. PETRICOIN. Yes. So I believe, to the best of my recollection, that I filled out the outside activity, stapled the agenda on it

Mr. GREENWOOD. Maybe you were focused on the sunny isle beach Florida part of the thing and not what it says up here. Where it says, at the very top line, Imclone Systems Incorporated and Bristol Meyer Squibb Company.

Mr. PETRICOIN. To me, sir, that would indicate, in my mind, that I didn't look at it at all when I attached it, because that would have been the first thing I would have seen.

To the best of my recollection, no excuse about being busy, we're all busy. I probably just stapled it on and

Mr. GREENWOOD. I'm going to buy that, because it's hard to believe

Mr. PETRICOIN. That it would be there in black and white. And when I saw that, I basically said, you know, there's no doubt it says Imclone Systems Incorporated, so it makes it pretty obvious.

Mr. GREENWOOD. All right. Let me address some questions to Dr. Barrett and Dr. Barker. There's an LA Times story out today, I don't know if you've seen it.

It says FDA Chief launches internal inquiry of payments. And there's a paragraph that says the Director of the NIH, Dr. Elias A. Zerhouni, said to a spokesman late Monday that he would not stand behind one of the arrangements involving Chief of the National Cancer Institutes Pathology Laboratory.

The matter demonstrates the need for systemic review. So this is referring—pardon me? I'm sorry, systemic reform. And by that I am relating to Bio—consulting agreement between the Laboratory Chief, Dr. Lance A. Liotta, and Biospect, Inc., of South San Francisco ended Friday.

So, if this story is to be believed, Dr. Zerhouni, after being briefed on this subject, said he wouldn't have approved, or he disapproves of the relationship between Dr. Liotta and Biospect, Inc.

Were either of you present at the briefing with Dr. Zerhouni that led to this statement?

Ms. BARKER. I was not. Dr. Kington, I assume is still here, he might want to comment. But I was not, nor was Dr. Barrett, I don't believe.

Mr. BARRETT. No, I was not. Dr. Kington came to a meeting we had at the NCI on Friday, I suppose, and he called me yesterday to say that this was, they were asked for a quote, basically.

Mr. GREENWOOD. And was it explained to you, was it made clear to you why Dr. Zerhouni said that he wouldn't stand behind this arrangement?

Ms. BARRETT. It was not abundantly clear. I think he certainly had some concerns and I think there were some caveats, in my recollection, from my conversation with Dr. Kington about, you know, if all the circumstances were as portrayed, that Dr. Zerhouni would make that decision and I think that would be

Mr. GREENWOOD. Do you concur in that decision? Do you both concur in Dr. Zerhouni's conclusion, retrospectively?

Ms. BARKER. I concur.

Mr. GREENWOOD. Okay.

Mr. BARRETT. Yes.

Mr. GREENWOOD. Now do you think that this was, these arrangements were approved, and now are disapproved because simply because of new information that had surfaced? Or is it because of new policy that's come into play?

Ms. BARKER. Let me just reflect a minute on the way we came to re-approve this. In responding to your first question, after this issue was raised, and Dr. Barrett and Dr. Wilson re-reviewed this at my request. And I think you probably have that re-review.

And based on the information available and what you've heard in terms of the lack of any evidence of overlap, they re-approved and reported back to me that they were re-approving this.

And I think that, in answer to your question, I think new information in view of what I've heard in the last, as little as a week, actually, that the Biospect scope is certainly expanded, I think, relative to what Dr. Liotta was led to believe the scope of that company was.

Mr. GREENWOOD. In what way?

Ms. BARKER. I think the issue of pattern recognition that you brought up was never part of what Dr. Barrett actually reviewed when he re-approved this.

Mr. GREENWOOD. You did not know that at the time of the re-approval, Dr. Barrett?

Mr. BARRETT. At the time of the original approval, and the time of the re-review of that, there were basically three areas that I was focusing on.

One was whether or not there was overlap with the official duties of Dr. Liotta, with this outside activity. And

Mr. GREENWOOD. And were there?

Mr. BARRETT. There were not. In fact, the consulting agreement had very explicit, exclusionary language to assure that to be the case. And when originally it was approved, that was added to the language to assure that.

And when I re-met with Dr. Liotta, he re-affirmed that that was true. The second issue was whether it, there was any non-public information being revealed, and there was not.

And there was not for two reasons, I'm sure. One is because I trust Dr. Liotta's judgment, but also we've made a very conscious effort to put this information out to the public domain as part of our mission to really speed this research up.

So, in fact, there was very little non-public information that could have been released. And the third issue was whether or not this influenced his performance or official duties.

And in particular, this related to the CRADA. And it was my discussions with Dr. Petricoin and Dr. Liotta that reassured me that, in fact, we were doing everything we possibly could to facilitate the development of the clinical trial to confirm and extend the original findings of Dr. Liotta and Petricoin.

The issue of the competition, the direct competition between the two companies, was one that was less clear in the past than it is currently. So it is really that appearance of potential conflict based upon that information that I think has led us to be more cautious.

So it's a combination of Dr. Zerhouni's memorandum that, in fact, we should do everything in our power to assure there's no appearance of conflict of interest, as well as our standard procedures where we

Mr. GREENWOOD. Let me ask Dr. Liotta and Petricoin, did either of you ever tell the folks at Correllogic about your outside activity with Biospect?

Mr. PETRICOIN. I could answer.

Mr. GREENWOOD. And I think you said no, that we, and the way they found out was they found you using a common secretary pool, right?

Mr. PETRICOIN. That's correct, sir.

Mr. GREENWOOD. And Dr. Liotta, you never told the folks at Correllogic about your work with Biospect?

Mr. LIOTTA. No, I did not.

Mr. GREENWOOD. Okay. Now it would seem to me, that since you're working with these two companies, and they're doing similar things, that it would be a natural for you to say, oh, by the way, yesterday I was up talking to these guys I'm working for at Biospect, and an interesting point came up.

I mean it would seem to me that, in the course of these activities, that it would be hard to avoid mentioning to the folks at Correlogic, your work with Biospect, wouldn't it?

Mr. LIOTTA. No, I didn't

Mr. GREENWOOD. Help me understand that.

Mr. LIOTTA. I didn't see any need to, because

Mr. GREENWOOD. No, no, no, no, no, I'm not asking you if there was a need to. I'm saying it would hard to avoid if you weren't under restraint. If you had no reason to not mention to the folks at Correlogic that you were working for Biospect. It would seem a natural thing to come up in conversations.

You're doing—no?

Mr. LIOTTA. No, I felt that they were completely different from what I know about, what I knew at the time that Biospect was doing. And even today, I have no information that directly shows me that Biospect is working in the same area covered by the scope of the Correlogic CRADA.

At the time my understanding of Biospect, was that it was an instrument company.

Mr. GREENWOOD. Let me ask you this. Did the folks at Biospect know you were doing the CRADA with Correlogic?

Mr. LIOTTA. I don't know, I did not discuss that with them?

Mr. GREENWOOD. Same with you, Dr. Petricoin?

Mr. PETRICOIN. Yes, my recollection is I had no discussion with either of them about each other at all.

Mr. GREENWOOD. And you, and that wasn't because you were refraining from talking to the two companies about one another, that was just because it never came up? There was never any

Mr. PETRICOIN. Exactly. I mean, from my side, sir, there was never, there was never any overlap and the need to even discuss the science. Correlogic, the software company, had developed a specific algorithm.

Many algorithms were out there. In fact, we were using other algorithms in our U.S. public job. The CRADA with Correlogic gave us the freedom to use any algorithm.

In fact, President Bush's National Science Winner, used an algorithm that he developed and published a great paper using our public data.

So Correlogic's algorithm was specific to them. I saw no overlap whatsoever between an instrument company that was basically building a platform to identify molecules. It just didn't occur to me, sir.

Mr. GREENWOOD. And how many papers did you publish with Correlogic?

Mr. PETRICOIN. We have six, I believe sir. And one that's coming out next month. A very high impact journal on our continuing work for ovarian cancer.

Mr. GREENWOOD. And those are cooperative pieces between the two of you? When you six, those are all co-authored by Dr. Liotta and Petricoin?

Mr. PETRICOIN. I believe so, sir. I could get you that exact number, if you would like it.

Mr. GREENWOOD. And did you write papers with the other company, with Biospect?

Mr. LIOTTA. No.

Mr. PETRICOIN. No.

Mr. LIOTTA. Never say any written material at all from Biospect concerning the, you know, experiments or their data.

Mr. GREENWOOD. It's true that your reputations in this area were a result of your work with Correlogic, is that fair to say?

Mr. LIOTTA. I don't believe so.

Mr. GREENWOOD. No?

Mr. LIOTTA. Our reputations in this work, with regard to, if you're referring to mass spectrometry analyzed by pattern recognition evidence, we began studying that in '97 and '98, and presented it at the American Association of Cancer Research.

We used many commercial, several commercial methods of analyzing this data. And then after we had already presented it publicly, we, for the first time, we then entered into a material transfer agreement with Correlogic.

And then ultimately a CRADA. And that scope of that CRADA was limited to the use only of their type of software. We remained free to use any other type of software as we had done in the past during the CRADA, and continued to do.

Mr. GREENWOOD. Okay.

Mr. LIOTTA. That CRADA was specifically about their software. And all the data, before, during and after, has been generated by our Lab.

Mr. GREENWOOD. When the Biospect folks contacted you, did they tell you why they had selected the two of you? What brought the two of you to their attention?

Mr. PETRICOIN. I believe they contacted us separately, and I would hope that it was because of my scientific reputation and expertise.

Mr. GREENWOOD. And how would the folks at Biospect have known about that?

Mr. PETRICOIN. I would assume looking in the public domain or talking to people. You know, talking to, you know, due diligence was probably talking to other scientists. I don't know, sir, they didn't tell me.

Mr. GREENWOOD. Do you have an opinion as to why Biospect would have hired Dr. Strum from NCI?

Mr. PETRICOIN. I don't.

Mr. GREENWOOD. She was a technical transfer officer, right?

Mr. PETRICOIN. I, being at the FDA I don't want to—I'm under oath

Mr. GREENWOOD. Dr. Liotta, do you know?

Mr. LIOTTA. Yes, that's right. And ethics, when I reviewed this with my ethics officer and discussed the outside activity, it was clearly known and factored into the review that, particularly the re-review that former Cancer Institute employees were members of that company.

And, in fact, the person who invited me was a former NCI employee. And that was, that letter and that request and the name of the individuals on the original request for the outside activity and it was reviewed and ended up in the approval packet.

Mr. GREENWOOD. Okay. Do you think it was a coincidence that they hired these three people?

Mr. LIOTTA. I can't speak for their motivations

Mr. GREENWOOD. You're a smart guy. I mean, you're a smart man. What do you think motivated them to choose these three employees for their company? To choose you?

Mr. LIOTTA. I really can't speculate on why they would

Mr. GREENWOOD. They chose you, they chose Petricoin, they chose Strum. All involved in Correlogic. They chose the three of you when you were all involved in Correlogic. Did you question why that would be?

Mr. LIOTTA. I never questioned why that would be, because in my mind Correlogic and Biospect were completely different companies with completely different missions. And it didn't even seem like it would even be relative.

Mr. GREENWOOD. Okay, well let me just wrap up this way, before I yield to the gentlelady from Colorado. Oh, Mr. Walden, I'll yield to him in a moment.

We're trying to set public policy here. And I'd just like to know, from all four you, and I just ask you to each go down and briefly answer this question before I go to Mr. Walden.

And that is, what do you think the policy should be with regard to the situation in which you have employees working on a CRADA, as part of their regular function, their regular activities, and at the same time working for, doing outside activity with a private company, and the CRADA company not knowing about the work with the potential competitor, with this other company?

Do you think, as a matter of public policy, that they should have the right to know, while you're in their shop working with them, on company time, on taxpayer time, that you're out moonlighting, if you will, with another company?

Don't you think, do you think that they should have the right to know that? Is it good public policy for them to know it? Or is it good public policy for them to be kept in the dark?

Mr. LIOTTA. Are you addressing the question to me?

Mr. GREENWOOD. Yes, I'm addressing it to each of you down the line.

Mr. LIOTTA. I don't think I can comment on public policy that's a higher level than myself. I think that each case should be considered on an individual basis and the ethics office, when they review

Mr. GREENWOOD. Didn't you testify before the Blue Ribbon Panel on this subject? Did you not testify

Mr. LIOTTA. I testified before the Blue Ribbon Panel.

Mr. GREENWOOD. On policy? I mean did you suggest any policy to the Blue Ribbon Panel?

Mr. LIOTTA. I don't recollect exactly what I said to the Blue Ribbon Panel. I don't know whether it could be interpreted as policy or not.

Mr. GREENWOOD. Or recommendations for practice?

Mr. LIOTTA. I gave them my opinion, but I don't know.

Mr. GREENWOOD. Okay, well that's all I'm asking for, is your opinion now. I'm not asking you to set policy, I'm just asking for your opinion. Tell us what you think about this whole matter that we've been investigating all afternoon?

Do you have any regrets about it? Do you think everything went perfectly well and we're making a big stink out of nothing?

Mr. LIOTTA. In some way I think it shows that the way the ethics system works, it produces a very good result. Because even when I did, presented the application for the outside activity to begin with, normal course of action is for the ethics office to review whether I have an CRADAs that might relate to the outside activity.

So there's a checkpoint there, and a series of checkpoints. And then the way even this was handled recently, I think is the way the process should work, if new information comes up.

And then another checkpoint that was put in right in the beginning was the extra special delimiters in the consulting agreement, because we could not predict where a company would go in the future.

And so what I'd be concerned about, is that a CRADA partner who also can't predict where some other company would go into, would just turn down everything because, and that would potentially, you know, cause a lot of new complications in how outside activities are reviewed.

So I, my opinion is that the way the system works in terms of factoring that into the individual situation, is one good way to do it.

Mr. GREENWOOD. Dr. Petricoin, your thoughts?

Mr. PETRICOIN. Well I certainly think we need more advice that sheds more light than heat. And I think that's what we're trying to do. I do think I'm concerned about the idea of a CRADA partner knowing what perhaps their NIH comrades are doing on the outside, only to the extent that they would claim that the field of science and technology is their domain, and therefore, in essence, if you drew it to the most absurd, there would only be one CRADA, the very first one.

Because, by nature, there might not even be other CRADAs that you could do, if you drew it. I just think that we have to be careful, and I think we were trying to be. You know, trying

Mr. GREENWOOD. Let me—you think that it would be harmful if the CRADA participants knew about the outside activity of their NIH CRADA partners?

Mr. PETRICOIN. No, sir, I don't think it would be harmful. I think that we should try to instill ideas that basically will allow more illumination, more transparency.

Mr. GREENWOOD. Okay, all right, I misunderstood you. Dr. Barrett.

Mr. BARRETT. The purpose of the NIH and the National Cancer Institute is obviously to do everything in our possible power to move forth the science and to reduce the burden of cancer.

The groundbreaking work of Dr. Petricoin and Dr. Liotta which, and I think it is clearly their work that has been the driver for these new discoveries, represents a very important work.

And we want to do everything in our power to assure full, expedient development of that work. I think the answer to your question directly is, is should there be a policy? I think absolutely there needs to be a policy.

There needs to be some definition of conflicts of interest. It's very difficult in these relationships to really understand how two entities might be competitive, competitors of each other or not.

I think we try to do due diligence in this particular circumstance and try to define very clearly the scope of the consulting activities, yet we seem to have this appearance of conflict, and I think that's unfortunate and takes away from really the mission of what we're trying to do.

So I would be very supportive of some clear guidelines any policy.

Mr. GREENWOOD. Dr. Barker, do you have anything to add?

Ms. BARKER. I can't add much. I would, just a couple of things. The Cancer Institute is particularly interested in CRADAs. The biotechnology industry is really sort of a deliver vehicle for the cancer world right now. And so to improve on the CRADA process should be our goal.

And I was struck with the amount of review that went into this ethics review. So it's, I think there is no fault here relative to our intent to really look at this very, very carefully.

I think that review worked pretty well. The issue, though, that you've raised is a really complex one.

Mr. GREENWOOD. Didn't the review occur because there was a complaint, though?

Ms. BARKER. Yes.

Mr. GREENWOOD. I mean it wasn't normal activity?

Ms. BARKER. It was no normal activity, that's correct. But the issue you raised, which is going to bare, I think, some real consideration in terms of how we might change policy, is going to be critically important.

Because as, I think Dr. Liotta said, you can't really determine, I mean having been in the biotechnology industry at some phase in my life, you never quite know where a company might go from where they start.

So I think transparency, having our investigators completely reveal who they are working for, who they might be consulting with or what relationships they might have, and let the companies make their decisions then on that basis.

But I think we've got to be a little careful. This is a very complex question and

Mr. GREENWOOD. What's the downside of sharing the information?

Ms. BARKER. I think there is no downside to sharing the information, if in fact we have, we can actually continue the same success rate with our CRADAs. I think the thing we want to be careful of is that we don't actually make it more bureaucratic or more difficult to do a CRADA.

And right now our investigators do disclose actually. You know, if they have a, they can't have a consulting arrangement if they have a CRADA with the same company. They can't do that.

So we're saying now, is not only that, but you can't also be consulting for a company that might be a competitor of a company you're going to do a CRADA with.

So making that value judgment is going to be an interesting challenge for us as we make policy around this. But I think you're right, absolutely disclose it, and then basically let the policy drive the way the CRADAs are going to be developed.

Mr. GREENWOOD. I thank you all. I apologize to my colleagues for my flagrant abuse of the clock.

Mr. WALDEN. But it is your clock.

Mr. GREENWOOD. Mr. Walden.

Mr. WALDEN. Thank you, Mr. Chairman. Dr. Barker, I want to follow up with you on that point. When did you make the decision regarding this issue involving competitor agreements not being allowed?

Ms. BARKER. To my knowledge, that decision has not been made. I think this is the first issue that's come forward of this nature. There may be others that I'm not aware of, but this is the first one, at least, that we've seen in the Cancer Institute.

And we examined it very carefully. Dr. Von Eschenbach asked me to do due diligence on it, we did that. Dr. Barrett re-reviewed it, Dr. Wilson re-reviewed it. And based on the evidence that was there, this still basically qualified in terms of our ethical requirements. So, it's the first one like this that's come forward.

Mr. WALDEN. Let me make sure I understand what you said. So you said this still qualifies under your ethics requirements. Does that mean they could still be working for both companies? Or doing the CRADA and working for Biospect?

Ms. BARKER. I think that's what it says, under the current rules, yes.

Mr. WALDEN. Are you comfortable with that?

Ms. BARKER. I'm not comfortable with that. But, you know, we've said that, I think both Dr. Barrett and myself have said that, given what we know now, and going back and doing this over again, you probably would have disapproved this consultancy.

Mr. WALDEN. Do you have, or the people who should have, do you have the information you need to evaluate other such agreements and conflicts? I mean is the mechanism there to acquire that information?

Is that information publicly disclosed adequately so that whoever needs to do the review can get access and make that decision?

Ms. BARKER. I honestly don't know the answer to that question.

Mr. WALDEN. Does anyone on the panel know the answer to that? Dr. Barrett?

Mr. BARRETT. I think it's, we've made a very strong attempt at the NCI, and I would gather that we actually probably do better than the average Institute does in that context. But, yet, I think the answer is, it's still not adequate. And we've been actually talking about how to approve access to data bases and, for example, the disclosure of the confidentiality disclosure agreement that Dr. Liotta mentioned, you know, was not available to us until just recently.

So I think there are very specific things that can be done to improve the process and we're trying to do that.

Mr. WALDEN. Thank you. Dr. Liotta, first of all I want to commend both of you for the research that you're doing. My own mother died of ovarian cancer. I know it's a very, very, it's a very terrible form of cancer, and so I commend you for that.

And I don't want you to go away from here thinking that we don't appreciate the research that you're doing. We're trying to, public policy people trying to make sure that research, wherever it's done, is done in a way where we don't have, even by accident, conflicts.

Because I think the integrity of the process is really important. If you turn to Tab 28, and I think we'll put this up on the screen, I believe.

You'll find your request for approval, the Biospect Consulting Agreement. And the thing that strikes me is on the form, which I understand is an HHS Form 520, there's a question that says do your official duties relate in anyway to the proposed activity? You responded no.

Related to professional confidence, but not an official responsibility for the use of government funds. That was your response. And however, on Dr. Petricoin's HHS Form 520 for Biospect, when asked whether his official duties relate in anyway to the proposed activity, he marked yes, and elaborated, and I quote. Invited because of my scientific expertise. I'm just curious if you can account for the differences in responses to the same question, and I'd ask that of each of you.

Mr. PETRICOIN. Well, I can certainly respond from my end, in that I probably shouldn't have marked yes. In some ways I was doing it to even the fullest disclosure because in my mind I am, the accumulation of my scientific expertise.

Mr. WALDEN. Sure.

Mr. PETRICOIN. And so I simply yes out of the instinct that I can't separate my brains. I'm a Scientist that just continues to learn.

Mr. WALDEN. Only Steve Martin can do that.

Mr. PETRICOIN. Right. So I think in retrospect, I should have marked no, and put I was invited for my general

Mr. WALDEN. But I think you hit upon an issue. And that is you have this collection of knowledge and scientific ability. You can't park part of it somewhere out of reach, right?

I mean that's why you checked yes. And doesn't that kind of, do you see how we get to where we're at in terms of is there a conflict between the CRADA and Biospect.

I mean how could you, when you're doing whatever you're doing with Biospect, sort of park everything you know that may be associated with the CRADA, from playing over here. Now, maybe you can. I don't know how.

Mr. PETRICOIN. Well, I think the challenge is when companies change their business focus without you being involved in that.

Mr. WALDEN. Sure.

Mr. PETRICOIN. My background isn't a business developer, I'm just a Scientist. And so I wasn't asked to participate in Biospect to determine, you know, their business development.

And so that can change without me even knowing it, and in fact, it obviously did. And I think that

Mr. WALDEN. So you could get dragged into a conflict outside of your control and outside of the original decisionmaking process in the 520.

Mr. PETRICOIN. Certainly a company has every right to do what it wants to do, and my consultancy was so different from what I was doing with Correlologic, that there was never, there was the ability to partition that.

And in fact I never was at a point in any time where I thought that that was at issue.

Mr. WALDEN. Dr. Liotta, do you want to comment briefly on this point?

Mr. LIOTTA. I don't know about the, you know, the check boxes relating to Dr. Petricoin, but I would say that his explanation sounds reasonable to me concerning the fact that he might view a request for consulting having some, his total body knowledge about

Mr. WALDEN. But you checked no on the same box. I guess that's the point. And so you felt nothing you're doing related.

Mr. LIOTTA. Yes, I had general medical expertise in, and in field of Pathology and I have a PhD in Biomedical Engineering. And I have even patents in medical testing.

Personal patents way back before I came to NIH. And so I do have professional knowledge about some of the topics that might be relevant.

Mr. WALDEN. I guess that's what I'm having trouble understanding. Why do you think they even have Question 9 on the form then? Because it looks to me like, and again you guys are doing this research, but the two companies had a lot in common.

Let's go to Tabs 30 and 31, if you want to look in the book, where you'll see information from the two companies websites. And I know, didn't one of you have something to do with website information or something, working with the company?

Mr. LIOTTA. We were not involved in Biospect's website but at the time of the original request for the outside activity, the information about Biospect was surveyed and studied by the Ethics Office, as well as any information that I had.

Mr. WALDEN. Right, but

Mr. LIOTTA. They did an independent review of the two companies if they were looking at the issue about the CRADA, I don't know whether they were. But they

Mr. WALDEN. So the Ethics Office looked at both companies and said given

Mr. LIOTTA. I don't know whether they looked at both companies. I know they must have looked at Biospect to see what Biospect did, because they do their own review and re-review.

Mr. WALDEN. Well, okay. Do you see where maybe we get some questions coming here. Let me read you Correlogic's mission statement. It says, and I quote.

Correlogic's mission is to advance the early identification of various cancers and other disease and to accelerate the new drug discovery process by applying its proprietary software to the development of proteomic and other biomarkers.

Then you turn to Biospect's website, and it states, and I quote. Biospect is an emerging life sciences company founded in 2002, that is developing technology for identifying and assaying protein biomarker patterns. What's the difference between the two?

Mr. LIOTTA. I think there still could be, with knowing even that, that there still could be very big differences. Because from what I know about Correlogic, Correlogic is a software company.

And they're applying their specific type of pattern recognition algorithm, at least within the CRADA, to data that we generate.

Mr. WALDEN. And then what's Biospect do?

Mr. LIOTTA. And Biospect, to the best of my knowledge, then and now, is they were an instrument company and they were developing a new, proprietary platform for chemistry separation.

So an instrument company, software company. They seem completely different to me.

Mr. WALDEN. So you don't see any, they're in completely different, other than the fact they are both working on this sort of detection, one from an instrument side, one from a logarithm side, there's no conflict?

Mr. LIOTTA. One is a software that you use to analyze data that's already produced, in this case, by commercially available instruments. The other is a new instrument under development and measuring proteins is something 30 different kinds of instruments in a clinical lab do. When you do measurements in any clinical lab, it's proteins that you're measuring.

Mr. WALDEN. All right.

Mr. LIOTTA. So, you know, whatever the instrument was that Biospect was working on, which they did not reveal to me. I did not see any schematics, no data, experimental results from any of their instruments.

So the instrument itself is what they apparently were working on, and they asked my opinion about what they could use it to test for, in a generic sense.

And that was my role with Biospect. So I couldn't see how that had anything to do with software to analyze patterns.

Mr. WALDEN. I see.

Mr. LIOTTA. And particularly certain specific kinds of software, which is really what the Correlogic system is.

Mr. WALDEN. All right, Dr. Petricoin, how about your role, Biospect versus Correlogic?

Mr. PETRICOIN. Sure, my role with Biospect was basically to survey the field of science and biology in a way, looking for potential applications of their machine, their tool, their discovery tool.

And try to point them in directions where I thought, you know, they could apply that.

Mr. WALDEN. Why then, Dr. Barker, maybe I can go to you. Why then, if that's the case, do you, did you say earlier that you thought there is a conflict here between the two? What am I missing?

Ms. BARKER. I don't, I said in light of what we see now, that Biospect has put up on their website, then I think it's very, very difficult considering that this work is focuses around using Correlogic software for pattern recognition and they are actually using that word on their website.

Biospect was using those two words on their website. I think it would make it extremely difficult to prove this, which now looks like overlapping scopes.

Mr. WALDEN. And, in deed, you backed off the Bio—you with drew the Biospect agreement?

Mr. LIOTTA. That's correct, that's true.

Mr. WALDEN. And that involved both of you?

Mr. PETRICOIN. Yes, sir.

Mr. WALDEN. All right. And when did that occur?

Mr. LIOTTA. I withdrew it, it was on hold based on the NIHEAC re-review, and then I learned this new information, discussed it with my boss and withdrew voluntarily this outside activity.

Mr. WALDEN. When was that?

Mr. LIOTTA. Last week.

Mr. WALDEN. The end of last week, or beginning?

Mr. LIOTTA. Around the 12th?

Mr. WALDEN. May 12? Have you done any consulting with Biospect since February? Either of you?

Mr. PETRICOIN. Since February, I believe so.

Mr. WALDEN. How recently do you, and on what terms?

Mr. PETRICOIN. The best of my recollection in March, sir.

Mr. WALDEN. Dr. Liotta?

Mr. LIOTTA. I believe that I had no new assignments in the past 2 months that I dealt with, because I was on hold. But I do recall that I sent one e-mail to Biospect in that timeframe.

Mr. WALDEN. Okay. When did you start consulting with Biospect?

Mr. LIOTTA. I think it was December, it was approved December, 2003, I think. Or 2002, I started a couple of months later, I actually got the first assignment.

Mr. WALDEN. Dr. Petricoin?

Mr. PETRICOIN. Excuse me, sir?

Mr. WALDEN. When did you start consulting with Biospect?

Mr. PETRICOIN. Approximately the same time. I think my agreement began December 1, 2002, and I believe my first assignment was in the beginning of 2003.

Mr. WALDEN. Beginning of 2003, first assignment?

Mr. PETRICOIN. Yes.

Mr. WALDEN. Dr. Liotta, there's some information here under Tab 33, that lists money earned to date as \$49,375 in consulting fees. Proposed annual rate \$39,000 or \$3,250 a month. Are those accurate numbers?

Mr. LIOTTA. Yes, those are accurate numbers.

Mr. WALDEN. Okay. And this is, what period of time does this cover?

Mr. LIOTTA. I think that was just a summation of what it would be per year at the rate of whatever the current

Mr. WALDEN. I see. But that's the annual, \$39,000?

Mr. LIOTTA. It's \$3,120 a month.

Mr. WALDEN. Well, we had \$3,250.

Mr. LIOTTA. I mean \$3,100.

Mr. WALDEN. The document shows \$3,250 a month.

Mr. LIOTTA. \$3,250, okay.

Mr. WALDEN. But what about this \$49,375 consulting fees, when was that earned? Do you see where I'm looking on this sheet?

Mr. LIOTTA. Yes. I don't know how that was calculated, but it might reflect the fact that in the beginning of the consulting, I was receiving \$5,000, and then it switched—

Mr. WALDEN. A month?

Mr. LIOTTA. A month, \$5,000 a month. And then it switched and it was reduced, and that was reported in my renewal application of this outside activity.

Mr. WALDEN. Okay. I think that ends the questions I have, thank you, gentlemen.

Mr. GREENWOOD. Just a final question for Dr. Liotta and Petricoin. Your agreement with the company was 1 day a month, is that correct for both of you?

Mr. PETRICOIN. Yes, sir, initially. I'll answer for myself. It was 2 days per month, and that was reduced to 1 day per month.

Mr. GREENWOOD. And Dr. Liotta?

Mr. LIOTTA. Yes.

Mr. GREENWOOD. Same thing?

Mr. LIOTTA. Similar.

Mr. GREENWOOD. And how do you do that? Just, how do you do that? Literally 1 day of the month you, instead of going to NIH or the FDA, you drive to Biospect and sit in their building all day? How does that work?

Mr. LIOTTA. In my case, I did all the work for Biospect at home, on my computer, and surveyed publicly available information to analyze questions that they had.

And then I synthesized those, that publicly available information, into short reports, which then was presented to Biospect, maybe once every 2 or 3 months.

Mr. GREENWOOD. Okay, and Dr. Petricoin, how did you manage it?

Mr. PETRICOIN. Pretty much the same way. My job, as I stated, was to kind of survey the public domain for opportunity. And I would do that at home on my computer. And I would synthesize the information and most often

Mr. GREENWOOD. So what do you do, you call the office and you say to somebody at FDA or NIH, I'm not going to be in today I'm working for Biospect? How does that work?

Mr. PETRICOIN. No, most of my work was done on the weekends or when I got home from work. So it wasn't like I would take a whole day off or compartmentalize time.

Mr. GREENWOOD. So you didn't take any, neither one of you took time off of your regular work week for this?

Mr. PETRICOIN. Not, so to give you the full story, there was about three or four times, to my recollection, that we actually went up to Biospect's office.

Mr. GREENWOOD. Where was that?

Mr. PETRICOIN. On Democracy Boulevard. This was the shared office space.

Mr. GREENWOOD. Right. Is that like an incubator or something?

Mr. PETRICOIN. Yeah, it's where they have like shared secretarial, I guess support for these companies that are either offsite or—and we met with them and that was usually during the day or during the end of the day, and I would take annual leave.

Mr. GREENWOOD. You would take annual leave to do it?

Mr. PETRICOIN. Yes, yes, sir.

Mr. GREENWOOD. Dr. Liotta?

Mr. LIOTTA. To the best of my recollection

Mr. GREENWOOD. Pretty much the same thing? And when you're at your regular jobs, do you have issues of them calling you at work or, I mean does that happen?

Mr. PETRICOIN. The amount of time spent consulting from my end, was really to look into the public domain. It was really a relationship of me spending a lot of time kind of synthesizing information at home, looking around, nesting that down and then giving it to them, and them doing with it what they want.

There was, most of the time when we talked with them, it was by, they set up a tele-conference. We'd call in from our cell phones, and that could be even on the drive home. And it might just be sharing what we found.

Mr. GREENWOOD. So you didn't find, neither one of you found a so-called conflict of commitment that occurred in conflict with your job?

Mr. LIOTTA. If there was even a hint of that I, because in addition to my research duties I have a lot of administrative duties. If there was a hint of that I wouldn't have done the activity at all.

Mr. GREENWOOD. Thank you. We thank all four—did you want to say something Dr. Barker?

Ms. BARKER. I want to add a comment actually on the Biospect mission statement that was up there, it's not there now. But Dr. Barrett when he re-reviewed and approved Dr. Liotta's consultancy had a different mission statement for Biospect which we have here, which is really almost unrelated to the one you have up there.

I mean this one, that one up there speaks to diagnostic

Mr. GREENWOOD. Why don't you tell us what it says?

Ms. BARKER. I'm sorry?

Mr. GREENWOOD. You can read that to us.

Ms. BARKER. It says basically that Biospect will become the world leader in identifying and assaying highly informative patterns that reflect in different shape biological states with minimally invasive procedures, to improve clinical management of patient health and the drug development process.

There's no mention in here of diagnostics. And if you read this, everything we're doing in genomics and proteomics today is moving toward patterns of one sort of the other.

So this was really portrayed at that point as very much a therapeutics support kind of activity. So the mission statement for that company really, I think, changed significantly between when Dr. Barrett review and re-approved this consultancy and what we saw here today.

Mr. GREENWOOD. And did the folks at Correlogic buy that argument?

Ms. BARKER. I haven't asked them that question.

Mr. GREENWOOD. All right. Thank all of you. I hope you didn't feel that the thumbscrews were tightened too much. I appreciate your assistance in our difficult task, and this committee is adjourned.

[Whereupon, the foregoing matter was concluded at 3:16 p.m.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF
HEALTH AND HUMAN SERVICES

INTRODUCTION

Mr. Chairman and members of the Committee, like its sister agencies in the United States Department of Health and Human Services (HHS or the Depart-

ment), the Food and Drug Administration (FDA or Agency) is a public health agency. But FDA is unique in the Department because it is primarily a regulatory agency.

As a result, for more than three decades FDA has had an aggressive disclosure and review process designed to ensure that its employees do not have any conflict of interest involving companies and entities that FDA “significantly regulates.” To maintain the public trust in its public health work, FDA has placed reasonable restrictions on the financial and employment ties between FDA employees and the entities it regulates.

At this time, the Agency is confident that the specific matter described in this statement is isolated. FDA fully anticipates that, when completed, the review of outside activity requests that we have commenced will determine that the Agency’s professional scientists and administrators uniformly comply with the Agency’s stringent ethics requirements and that they conduct their regulatory work in fair, unbiased and impartial manner.

FDA’S HIGH ETHICAL STANDARDS

As a regulatory agency, FDA has a compelling need to monitor and impose reasonable restrictions on the financial and employment ties of our employees. FDA meets this standard through strict regulations governing financial interests and outside activities for all employees of the Agency. Applicable laws and regulations include the Standards of Ethical Conduct for employees of the Executive Branch (Title 5, *Code of Federal Regulations* (CFR), section 2635), Title 18, *United States Code* (USC) section 202-209, and the Department’s supplemental standards of conduct (5 CFR § 5501).

HHS’s Supplemental Regulations contain FDA-specific provisions that establish prohibited financial interest rules for employees required to file a public disclosure report (using form SF 278) or a confidential financial disclosure report (using form OGE 450), and rules for seeking approval of outside activities. The prohibited interest regulations have been in effect since the early 1970’s and supersede the Office of Government Ethics’ (OGE) general rules on financial holdings. Under these FDA-specific regulations, employees who are required to file a public or a confidential financial disclosure form are prohibited from holding a financial interest in any organization that is significantly regulated by FDA. This prohibition extends to the employee’s spouse and minor child(ren), since their financial interests are imputed to the employee under 18 USC 208. These employees also are generally prohibited from employment with a “significantly regulated” organization.

FDA has established an Ethics Program to help ensure that the decisions employees make in their official capacity are not tainted by a conflict of interest or an appearance of a conflict of interest. FDA’s Ethics Program is an integral part of the Agency’s overall operations. The program is fully staffed and dedicated to providing advice and assistance to FDA employees on ethics related laws and regulations. The Ethics and Integrity Staff are subject matter experts on the laws and regulations that form the framework of the FDA Ethics Program.

OUTSIDE ACTIVITIES

As a consequence of our strict Supplemental Regulations, employees who are required to file a public or confidential financial disclosure report are prohibited from having employment with “FDA significantly regulated organizations.” In addition, public and confidential filers may not participate in consulting activities with any significantly regulated firm. There is a very narrow exception to this broad prohibition, which is limited to the practice of medicine, pharmacy, dentistry, etc. The purpose of this exception is to allow employees to maintain their professional skills and licenses.

FDA employees are required to seek advanced approval for all outside employment and certain outside activities with the following exceptions: participation in activities of a political, religious, social, fraternal, or recreational organization (unless the position held requires the provision of professional services or is performed for compensation other than the reimbursement of expenses). Outside activities that require approval include, but are not limited to, self-employment activities, office holding in professional societies, teaching, writing and speaking activities, consultant or contracting work.

BIOSPECT, INC.

Dr. Emanuel F. Petricoin is a confidential filer in FDA’s Center for Biologics Evaluation and Research (CBER or the Center). His duties at FDA do not include reviewing pending applications for approval of new medical products.

In September 2002, Dr. Petricoin requested approval of an outside activity to provide consulting services to Biospect, Inc. The request was reviewed and approved in October 2002 by the Director, Division of Management Services, CBER. At that time CBER reviewed available information on the company to determine whether FDA regulated Biospect's activities, and we concluded that they were not FDA-regulated.

During a recent review of outside activity requests, CBER questioned the approval of this outside activity. The Center inquired about the current status of the company's business and whether an outside activity with this company is appropriate and approvable. Further review of Biospect, Inc. identifies the company as an emerging life science company that develops and identifies protein biomarker patterns. FDA consulted with HHS and subsequently determined that Biospect, Inc. participates in activities that are significantly regulated by FDA, and therefore outside activities with this company are prohibited for public and confidential filers.

On Friday, May 7, 2004, Dr. Jesse Goodman, Director of CBER met with Dr. Petricoin and advised that because Biospect, Inc. is now considered significantly regulated by FDA,

Dr. Petricoin must immediately cease all activity with respect to Biospect, Inc. Upon being informed of this, Dr. Petricoin immediately and voluntarily agreed to end all activity with Biospect, Inc. Accordingly, approval for this specific outside activity has been withdrawn and this outside activity has ended.

FDA ETHICS REVIEW

Since 1970, review of FDA employees' requests to participate in outside activities has occurred within the FDA centers, at levels below that of the Center Director. This was based on the premise that individual FDA organizations are more knowledgeable about the official duty activities of their employees and therefore are better able to identify outside activities that may present conflict of interest concerns. Within CBER, the approving authority was delegated to the Director, Division of Management Services.

FDA now believes that this delegation should be at a higher level. Consequently, on May 6, 2004, the Acting Commissioner issued an interim policy regarding the approval of outside activities. Under this policy, FDA Center Directors must review and, if an activity is allowed, approve all outside activity requests for employees within their centers. The Commissioner of Food and Drugs will be the approving official for employees in the Office of the Commissioner, and the Associate Commissioner for Regulatory Affairs will approve all requests for the employees of the Office of Regulatory Affairs.

In addition, in light of recent questions about possible conflicts of interest involving HHS agencies, the Acting Commissioner of Food and Drugs has directed a comprehensive review of all current outside activity requests for all FDA employees. Each request is being reviewed for compliance with applicable laws and regulations by Jeffrey M. Weber, Associate Commissioner for Management, Dr. Norris Alderson, Associate Commissioner for Science, and the FDA's Office of Management Programs, Ethic and Integrity Staff. Once that review has been completed, FDA will issue a final policy on the review and approval of outside activities.

CONCLUSION

FDA's commitment to the highest ethical standards in its dealings with regulated entities remains constant. FDA is confident that the current review of FDA employees' outside activities will show that the nation is well served by the dedication of FDA's expert scientists and physicians and their demonstrated ability to conduct the public business fairly and impartially. At FDA, we are committed to the maintaining the highest ethical standards to assure that the decisions employees make in their official capacity are not tainted by a conflict of interest or an appearance of a conflict of interest.

Tab	Document Description	Date
1	Zerhouni Letter - Re: Awards, Travel, and Official Duty and Outside Activity Approvals - ACTION	11/20/2003
2	Swindell Letter to Marilyn Glynn requesting that some Employees file Public Financial Disclosure Reports.	1/12/2004
3	Swindell memo to DEC's, re: Agency Procedures Reviewing Outside Activity Requests.	1/27/2004
4	Supreme Court Ruling: US, Petitioner v. Sun-Diamond Growers of California	4/27/1999
5	CRS Memo: From American Law Division re: Cash Awards/Prizes to Agency Heads	12/4/2003
6	CRS Lecture Award Opinion	5/20/2003
7	NIH Analysis of Ethics Concerning the Receipt of Lecture Awards by NIH Employees	7/17/2003
8	University of Pittsburgh Letter to Dr. George Michalopoulos re: Dickson and Mellon Awards	9/18/1997
9	University of Pittsburgh Letter to Dr. Richard Klausner re: selection of Dickson Award	9/30/1996
10	Jake Wilson memo re: Recommendation to the Dickson Award	10/1/1996
11	Criteria - University of Pittsburgh School of Medicine Dickson Prize and Mellon Lecture	10/4/1996
12	Email - from Michele Russell-Einhorn regarding Dickson Award for Dr. Klausner	10/7/1996
13	Email - from Karen Santoro regarding discussion with Phil Amarusso and Susan Sherman and Dr. Klausners acceptance of Dickson Award.	9/2/1997
14	Hand written note regarding OGE and breast cancer lawsuit settlement announcement	9/2/1997
15	Note to Harriet Rabb from Swindell - Re: Dr. Klausner and determination for the Dickson Prize	9/2/1997
16	Hand written note regarding Phil Amarusso, NCI, John Hartinger and \$300,000. Document number 40	No Date
17	Hand written note regarding case against St. Luke Montreal. Document Number 41	No Date
18	Email to Edgar Swindell, re: Dr. Klausner update. Document Number 45	9/4/1997
19	Email to Harriet Rabb, re: Dr. Klausner update. Document Number 46	9/4/1997
20	Email - Karen Santoro, re: "Dixon Prize." Document Number 55	9/11/1997
21	Email - Karen Santoro, re: Dickson Prize, Document Number 63	10/1/1997
22	Jake Wilson re: the Dickson Prize	10/1/1997
23	Swindell Memo to Richard Klausner re: Dickson Prize in Medicine	10/7/1997
24	Hand written note regarding Dr. Klausner and accepting the award while declining the prize.	10/10/1997
25	Dickie, McCamey & Chilcote Letter to Alan Garfinkel re: Bernard Fisher v. Univ. of Pittsburgh	2/18/2004
26	Internal Emails re: BRP drafts	5/14/2004
27	Request for Approval of Outside Activity for Emanuel F. Petricoin	9/30/2002
28	Request for Approval of Outside Activity for Lance A. Liotta	10/11/2002
29	BIOPECT Letter to extend a consulting agreement to Dr. Lance Liotta	10/22/2002
30	Biospect Inc. Website Information.	No Date
31	Correlogic Systems Inc. Website Information.	No Date
32	Exhibit A to Dr. Liotta's Agreement with Biospect	No Date
33	NCI Ethics Database re: Dr. Liotta's consulting agreement.	5/4/2004
34	Zerhouni Letter re: Financial Disclosure	5/14/2004
35	NHI Memo re: Resubmission of Outside Activity Approvals	No Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

TAB 1

 National Institutes of Health
 Bethesda, Maryland 20892
www.nih.gov

NOV 20 2003

 TO: IC Directors
 OD Senior Staff

FROM: Director, NIH

SUBJECT: Awards, Travel, and Official Duty and Outside Activity Approvals--ACTION

Congress has completed the doubling of the NIH budget, which is an expression of the priority given to biomedical research by the American people. It is also emblematic of the trust and confidence the Nation's lawmakers have in NIH and its employees. This trust is a precious commodity that must be maintained through outstanding performance and strict adherence to ethical principles. Should the public lose faith in the ability of NIH to support excellent research and practice high standards of ethical behavior, the biomedical research enterprise in the United States will lose its momentum.

Recently Congress and the media have been scrutinizing the implementation of ethics rules at the NIH. They are reviewing a wide range of activities that are allowed under Federal regulations, including lecture awards, outside activities, consultant arrangements, and financial holdings. Care must be taken to ensure that we continue to adhere to strict ethical practices and that we avoid the perception of conflicts of interest, even in situations where remuneration or awards are considered permissible.

As you know, NIH employees cannot accept compensation from outside entities for the performance of activities that are part of our official responsibilities. Even in cases where we are permitted to accept compensation for teaching, speaking, and writing on subjects within our field of expertise, or to accept awards recognizing our achievements, I urge you to exercise cautious judgment in accepting such honors. Although the applicable rules permit us to accept these rewards, they also encourage us to exercise sound judgment, noting "it is never inappropriate and frequently prudent for an employee to decline a gift." Each of us must ultimately assess whether the risk of adverse perception counsels against accepting the financial benefits associated with various honors. Please consider the greater good of the NIH when deciding whether to accept financial benefits offered in recognition of your work or public service. As the Director of NIH, I will not accept any financial or travel benefit offered as part of any award from an entity that does business with the NIH.

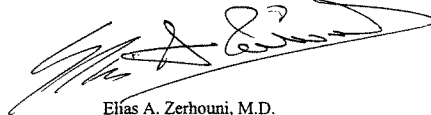
Although I am confident that our system of managing conflicts of interest at NIH has been successful in preventing breaches of Federal ethics rules, I believe we can improve our

Page 2 - IC Directors and OD Senior Staff

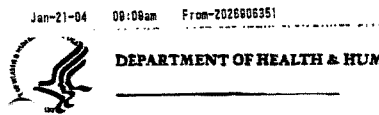
performance by subjecting ethics deliberations to a more transparent process of peer review. Therefore, I will establish a committee to provide advice to the NIH Deputy Ethics Counselors on specific activities such as the acceptance of lecture awards and consulting arrangements. This committee will provide NIH Deputy Ethics Counselors with valuable deliberative information to ensure final ethics decisions are consistent with Federal rules and avoid the perception of conflicts. The committee will also help NIH officials determine the appropriateness of engaging in activities that are not part of their official duties.

Finally, in order to coordinate better the efforts of the ethics program staff and the Office of Management (OM), effective immediately, copies of approved official duty clearances (required by our manual issuance for all IC Directors and staff) must be attached to travel paperwork when it is submitted to OM for approval. Please remind your employees that timely prior approval is required for official duty and most outside activities prior to the start of such activities.

Thank you for your cooperation.

A handwritten signature in black ink, appearing to read 'E. Zerhouni', with a stylized flourish at the end.

Elias A. Zerhouni, M.D.



DEPARTMENT OF HEALTH & HUMAN SERVICES

TAB 2

T-462 P. 002/003 F-286

Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

January 12, 2004

Ms. Marilyn L. Glynn
Acting Director
Office of Government Ethics
1201 New York Avenue, N.W.; Suite 500
Washington, DC 20005-3917

Dear Ms. Glynn:

I am writing to request your determination pursuant to § 101(f) of the Ethics in Government Act of 1978, as amended (Title 1, 5 U.S.C. App., Pub. L. No. 95-521) (hereafter "the Act"), that certain employees of the National Institutes of Health (NIH), by virtue of their level of authority, should be required to file Public Financial Disclosure Reports (SF 278s). Specifically, I request that you determine that Institute/Center (IC) Directors, IC Deputy Directors, IC Scientific Directors, and IC Clinical Directors are of "equal classification" to the filing positions that are specifically designated in the statute by category or salary level.

Although these determinations are appropriately evaluated on a "case-by-case," rather than a "class or category" basis, the four identified titles are replicated in each of the institutes and centers with substantially identical functions; only the subject matter of each component's medical research would be different. The National Institutes of Health will endeavor to provide any additional information that you require to make this determination. Inasmuch as these functional responsibilities were staffed under special authorities within Title 42 of the Public Health Service Act, I am informed that they do not have "position descriptions" as would normally be expected within the civil service. Accordingly, in support of this request, and in order to fully demonstrate that these roles carry particularly high levels of responsibility, similar to that of Senior Executive Service (SES) positions, please consider the following information provided by NIH:

The NIH is presently comprised of 27 Institutes and Centers (ICs). In fiscal year 2003, the NIH budget was \$27.9 billion. The senior leadership of each of the ICs manages their respective budget allocations, collectively identifies major areas of biomedical research within the expertise of their IC staff, establishes the research objectives and plans for their ICs, approves the individual intramural research programs within the labs of the IC and the extramural research supported by NIH funding, and serve as liaisons to the media, special interest groups, high ranking scientific and executive officials throughout the Department of Health and Human Services and other federal agencies, and to Congress. They are, at various times, involved in international relations related to healthcare issues, and policy development discussions at the highest levels of the Executive Branch.

IC Directors are appointed by the Director, NIH, report directly to the Director, and are charged with fulfilling the statutory mandates established under the Public Health Act, Title 42 of the U.S. Code. IC Directors provide overall leadership and vision to the national programs of the

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Page 2 - Marilyn L. Glynn

NIH. They are responsible for integrating key national and agency goals, priorities, and values into the intramural and extramural programs of their ICs. Along with the NIH Deputy Directors, they serve as key policy advisors to the Director, NIH, on issues such as research priorities, strategic planning, and management. IC Directors regularly speak on behalf of their organizations before special interest groups, the media, and national and international scientific experts. In the interest of ensuring that scientific discoveries are translated as broadly as possible into the tools, diagnostics and pharmaceuticals of the future, they are tasked with fostering and maintaining working relationships with other NIH ICs through inter-IC initiatives, and with developing and enhancing alliances with an ever-widening range of stakeholders.

The Deputy Directors of each of the ICs are responsible for the overall management of their respective large and diverse extramural research programs. They develop new approaches to funding research on innovative high priority studies, often involving the most vulnerable populations. Working with the Directors of their ICs, they are integral to the creation of strategic plans for their ICs.

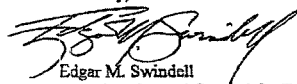
IC Scientific Directors manage and coordinate the intramural programs of each of the ICs. They set research goals and priorities, oversee the scientific and technical peer review of all intramural laboratories within their respective ICs, and advise the NIH in relation to agency-wide policies.

IC Clinical Directors provide scientific leadership and management for the intramural clinical research performed within the ICs and the NIH Clinical Center. They provide the infrastructure needed to promote high quality studies of the safety and efficacy of new and novel approaches to the vast array of human illnesses through protocol review, clinical informatics, and data and safety management. They are responsible for creating and maintaining research environments in which clinical findings influence the direction of lab studies, and coordinate inter-IC research programs.

Based upon the high level of responsibility associated with each of these functional titles, I request that you determine that their roles are of equal classification to those specifically designated in § 101 of the Ethics in Government Act and, therefore, that employees holding these appointments are required to file public financial disclosure reports.

Should you need any additional information or wish to discuss this request, please contact me, at (202) 690-7258, or Gretchen Weaver of my staff, at (301) 594-8166.

Sincerely,



Edgar M. Swindell
Associate General Counsel for Ethics
Designated Agency Ethics Official

cc: Raynard S. Kington, M.D., Ph.D., M.B.A.
Deputy Director, NIH; Deputy Ethics Counselor, NIH/OD



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T-481 P.002/003 F-370

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

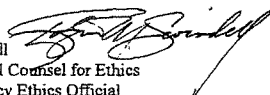
TAB 3

Office of the General Counsel
Washington, D.C. 20201

January 27, 2004

MEMORANDUM

TO: Deputy Ethics Counselors
Ethics Contacts

FROM: Edgar M. Swindell 
Associate General Counsel for Ethics
Designated Agency Ethics Official

SUBJECT: Internal Agency Procedures or Processes for Reviewing
HHS 520 Outside Activity Request Forms

Following consultation with the Office of Government Ethics (OGE), and pursuant to my authority as the Designated Agency Ethics Official (DAEO) under the Ethics in Government Act of 1978 and 5 C.F.R. Part 2638, I am directing that Deputy Ethics Counselors, supervisors and others who review and approve outside activity requests must inquire of the applicant the *amount* and *type* (e.g., cash, stock, or stock options) of income, compensation, fees, remuneration, expenses, or reimbursement that is to be received in connection with the proposed activity. When evaluating any previously approved, ongoing outside activity for continued compliance with existing law, the reviewer must also inquire retrospectively as to the cumulative amount of any income or other monetary receipts (including the type or method of payment) that was received from the outside source in connection with the approved activity. Employees will be required to provide this information if they desire to have their request considered or continued, and a failure to do so will result in denial of the request.

The information that is collected from this review process shall be annotated in "Item Number 17" on the reverse of the HHS Form 520. In this manner, the data is maintained within the existing government-wide system of ethics records, OGE/GOVT 1 (for public filers and others) and OGE/GOVT 2 (for confidential filers), and is available for the routine uses therein described.

As you know, the purpose of the prior approval process is to ensure that the proposed activity does not violate any statute or regulation, including the OGE Standards, 5 C.F.R. Part 2635, and the HHS supplemental ethics regulation, 5 C.F.R. Part 5501. To that end, eliciting the dollar amount is relevant for determining whether the compensation is so excessive or disproportionate to the time expended as to suggest, for example, that public office is being used for private gain, 5 C.F.R. § 2635.801(c); that the bribery or illegal gratuities statute is implicated, 18 U.S.C. § 201; or that a salary supplementation for performing official duties has been proffered, 18 U.S.C. § 209. Moreover, non-career Senior Executive Service employees who pursue outside activities are subject to an annual compensation limitation, currently \$23,550, under 5 C.F.R. § 2636.304.

Feb-04-04 04:40pm From:202606351

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Page 2 - Deputy Ethics Counselors

This change is effective immediately, and all internal agency procedure or process statements, policies, or manuals used within the respective operating and staff divisions for handling HHS 520s shall be amended to comply with this directive. Copies of these amendments shall be filed with the DAEO on or before February 17, 2004.

Thank you for your cooperation in implementing this requirement. If you have any questions, please call the Ethics Division at (202) 690-7258.

cc: Deputy General Counsels
Associate General Counsels
Chief Counsels, Regions I-X

TAB 4

Cite as: ____ U. S. ____ (1999)

1

Opinion of the Court

NOTICE: This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D. C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

SUPREME COURT OF THE UNITED STATES

No. 98-131

UNITED STATES, PETITIONER v. SUN-DIAMOND
GROWERS OF CALIFORNIA

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF
APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

[April 27, 1999]

JUSTICE SCALIA delivered the opinion of the Court.

Talmudic sages believed that judges who accepted bribes would be punished by eventually losing all knowledge of the divine law. The Federal Government, dealing with many public officials who are not judges, and with at least some judges for whom this sanction holds no terror, has constructed a framework of human laws and regulations defining various sorts of impermissible gifts, and punishing those who give or receive them with administrative sanctions, fines, and incarceration. One element of that framework is 18 U. S. C. §201(c)(1)(A), the "illegal gratuity statute," which prohibits giving "anything of value" to a present, past, or future public official "for or because of any official act performed or to be performed by such public official." In this case, we consider whether conviction under the illegal gratuity statute requires any showing beyond the fact that a gratuity was given because of the recipient's official position.

Opinion of the Court

I

Respondent is a trade association that engaged in marketing and lobbying activities on behalf of its member cooperatives, which were owned by approximately 5,000 individual growers of raisins, figs, walnuts, prunes, and hazelnuts. Petitioner United States is represented by Independent Counsel Donald Smaltz, who, as a consequence of his investigation of former Secretary of Agriculture Michael Espy, charged respondent with, *inter alia*, making illegal gifts to Espy in violation of §201(c)(1)(A). That statute provides, in relevant part, that anyone who

"otherwise than as provided by law for the proper discharge of official duty . . . directly or indirectly gives, offers, or promises anything of value to any public official, former public official, or person selected to be a public official, for or because of any official act performed or to be performed by such public official, former public official, or person selected to be a public official . . . shall be fined under this title or imprisoned for not more than two years, or both."

Count One of the indictment charged Sun-Diamond with giving Espy approximately \$5,900 in illegal gratuities: tickets to the 1993 U. S. Open Tennis Tournament (worth \$2,295), luggage (\$2,427), meals (\$665), and a framed print and crystal bowl (\$524). The indictment alluded to two matters in which respondent had an interest in favorable treatment from the Secretary at the time it bestowed the gratuities. First, respondent's member cooperatives participated in the Market Promotion Plan (MPP), a grant program administered by the Department of Agriculture to promote the sale of U. S. farm commodities in foreign countries. The cooperatives belonged to trade organizations, such as the California Prune Board and the Raisin Administrative Committee, which submitted overseas marketing plans for their respective commodities. If their

Opinion of the Court

plans were approved by the Secretary of Agriculture, the trade organizations received funds to be used in defraying the foreign marketing expenses of their constituents. Each of respondent's member cooperatives was the largest member of its respective trade organization, and each received significant MPP funding. Respondent was understandably concerned, then, when Congress in 1993 instructed the Secretary to promulgate regulations giving small-sized entities preference in obtaining MPP funds. Omnibus Budget Reconciliation Act of 1993, Pub. L. 103-66, §1302(b)(2)(A), 107 Stat. 330-331. If the Secretary did not deem respondent's member cooperatives to be small-sized entities, there was a good chance they would no longer receive MPP grants. Thus, respondent had an interest in persuading the Secretary to adopt a regulatory definition of "small-sized entity" that would include its member cooperatives.

Second, respondent had an interest in the Federal Government's regulation of methyl bromide, a low-cost pesticide used by many individual growers in respondent's member cooperatives. In 1992, the Environmental Protection Agency announced plans to promulgate a rule to phase out the use of methyl bromide in the United States. The indictment alleged that respondent sought the Department of Agriculture's assistance in persuading EPA to abandon its proposed rule altogether, or at least to mitigate its impact. In the latter event, respondent wanted the Department to fund research efforts to develop reliable alternatives to methyl bromide.

Although describing these two matters before the Secretary in which respondent had an interest, the indictment did not allege a specific connection between either of them— or between any other action of the Secretary— and the gratuities conferred. The District Court denied respondent's motion to dismiss Count One because of this omission. 941 F. Supp. 1262 (DDC 1996). The court

Opinion of the Court

stated:

"[T]o sustain a charge under the gratuity statute, it is not necessary for the indictment to allege a direct nexus between the value conferred to Secretary Espy by Sun-Diamond and an official act performed or to be performed by Secretary Espy. It is sufficient for the indictment to allege that Sun-Diamond provided things of value to Secretary Espy because of his position." *Id.*, at 1265.

At trial, the District Court instructed the jury along these same lines. It read §201(c)(1)(A) to the jury twice (along with the definition of "official act" from §201(a)(3)), but then placed an expansive gloss on that statutory language, saying, among other things, that "[i]t is sufficient if Sun-Diamond provided Espy with unauthorized compensation simply because he held public office," and that "[t]he government need not prove that the alleged gratuity was linked to a specific or identifiable official act or any act at all." App. to Pet. for Cert. 85a, 87a. The jury convicted respondent on, *inter alia*, Count One (the only subject of this appeal), and the District Court sentenced respondent on this count to pay a fine of \$400,000.*

The Court of Appeals reversed the conviction on Count One and remanded for a new trial, stating:

"Given that the for or because of any official act language in §201(c)(1)(A) means what it says, the jury instructions invited the jury to convict on materially less evidence than the statute demands—evidence of

 * Respondent was also sentenced to serve five years' probation on this and the other counts of which it stood convicted. Insofar as that element of the sentence was concerned, the Court of Appeals remanded for resentencing because the probation included impermissible reporting requirements. 138 F.3d 961, 977 (CA9 1998). That issue is not before us.

Opinion of the Court

gifts driven simply by Espy's official position." 138 F. 3d 961, 968 (CADC 1998).

In rejecting respondent's attack on the indictment, however, the court stated that the Government need not show that a gratuity was given "for or because of" any particular act or acts: "That an official has an abundance of relevant matters on his plate should not insulate him or his benefactors from the gratuity statute— as long as the jury is required to find the requisite intent to reward past favorable acts or to make future ones more likely." *Id.*, at 969.

We granted certiorari. 525 U. S. ____ (1998).

II

Initially, it will be helpful to place §201(c)(1)(A) within the context of the statutory scheme. Subsection (a) of §201 sets forth definitions applicable to the section— including a definition of "official act," §201(a)(3). Subsections (b) and (c) then set forth, respectively, two separate crimes— or two pairs of crimes, if one counts the giving and receiving of unlawful gifts as separate crimes— with two different sets of elements and authorized punishments. The first crime, described in §201(b)(1) as to the giver, and §201(b)(2) as to the recipient, is bribery, which requires a showing that something of value was corruptly given, offered, or promised to a public official (as to the giver) or corruptly demanded, sought, received, accepted, or agreed to be received or accepted by a public official (as to the recipient) with intent, *inter alia*, "to influence any official act" (giver) or in return for "being influenced in the performance of any official act" (recipient). The second crime, defined in §201(c)(1)(A) as to the giver, and §201(c)(1)(B) as to the recipient, is illegal gratuity, which requires a showing that something of value was given, offered, or promised to a public official (as to the giver), or demanded, sought, received, accepted, or agreed to be received or

Opinion of the Court

accepted by a public official (as to the recipient), "for or because of any official act performed or to be performed by such public official."

The distinguishing feature of each crime is its intent element. Bribery requires intent "to influence" an official act or "to be influenced" in an official act, while illegal gratuity requires only that the gratuity be given or accepted "for or because of" an official act. In other words, for bribery there must be a *quid pro quo*— a specific intent to give or receive something of value *in exchange* for an official act. An illegal gratuity, on the other hand, may constitute merely a reward for some future act that the public official will take (and may already have determined to take), or for a past act that he has already taken. The punishments prescribed for the two offenses reflect their relative seriousness: Bribery may be punished by up to 15 years' imprisonment, a fine of \$250,000 (\$500,000 for organizations) or triple the value of the bribe, whichever is greater, and disqualification from holding government office. See 18 U. S. C. §§201(b) and 3571. Violation of the illegal gratuity statute, on the other hand, may be punished by up to two years' imprisonment and a fine of \$250,000 (\$500,000 for organizations). See §§201(c) and 3571.

The District Court's instructions in this case, in differentiating between a bribe and an illegal gratuity, correctly noted that only a bribe requires proof of a *quid pro quo*. The point in controversy here is that the instructions went on to suggest that §201(c)(1)(A), unlike the bribery statute, did not require any connection between respondent's intent and a specific official act. It would be satisfied, according to the instructions, merely by a showing that respondent gave Secretary Espy a gratuity because of his official position— perhaps, for example, to build a reservoir of goodwill that might ultimately affect one or more of a multitude of unspecified acts, now and in the future. The

Opinion of the Court

United States, represented by the Independent Counsel, and the Solicitor General as *amicus curiae*, contend that this instruction was correct. The Independent Counsel asserts that "section 201(c)(1)(A) reaches any effort to buy favor or generalized goodwill from an official who either has been, is, or may at some unknown, unspecified later time, be *in a position to act* favorably to the giver's interests." Brief for United States 22 (emphasis added). The Solicitor General contends that §201(c)(1)(A) requires only a showing that a "gift was motivated, at least in part, by the recipient's *capacity to exercise governmental power or influence* in the donor's favor" without necessarily showing that it was connected to a particular official act. Brief for the United States Dept. of Justice as *Amicus Curiae* 17 (emphasis added).

In our view, this interpretation does not fit comfortably with the statutory text, which prohibits only gratuities given or received "for or because of *any official act* performed or to be performed" (emphasis added). It seems to us that this means "for or because of some particular official act of whatever identity"—just as the question "Do you like any composer?" normally means "Do you like some particular composer?" It is linguistically possible, of course, for the phrase to mean "for or because of official acts in general, without specification as to which one"—just as the question "Do you like any composer?" could mean "Do you like all composers, no matter what their names or music?" But the former seems to us the more natural meaning, especially given the complex structure of the provision before us here. Why go through the trouble of requiring that the gift be made "for or because of any official act performed or to be performed by such public official," and then defining "official act" (in §201(a)(3)) to mean "any decision or action on any question, matter, cause, suit, proceeding or controversy, which may at any time be pending, or which may by law be brought before

Opinion of the Court

could easily be regarded as having been conferred, not only because of the official's position as President or Secretary, but also (and perhaps principally) "for or because of" the official acts of receiving the sports teams at the White House, visiting the high school, and speaking to the farmers about USDA policy, respectively. The answer to this objection is that those actions— while they are assuredly "official acts" in some sense— are not "official acts" within the meaning of the statute, which, as we have noted, defines "official act" to mean "any decision or action on any question, matter, cause, suit, proceeding or controversy, which may at any time be pending, or which may by law be brought before any public official, in such official's official capacity, or in such official's place of trust or profit." 18 U. S. C. §201(a)(3). Thus, when the violation is linked to a particular "official act," it is possible to eliminate the absurdities *through the definition of that term*. When, however, no particular "official act" need be identified, and the giving of gifts by reason of the recipient's mere tenure in office constitutes a violation, nothing but the Government's discretion prevents the foregoing examples from being prosecuted.

The Government insists that its interpretation is the only one that gives effect to all of the statutory language. Specifically, it claims that the "official position" construction is the only way to give effect to §201(c)(1)(A)'s forward-looking prohibition on gratuities to persons who have been selected to be public officials but have not yet taken office. Because, it contends, such individuals would not know of specific matters that would come before them, the only way to give this provision effect is to interpret "official act" to mean "official position." But we have no trouble envisioning the application of §201(c)(1)(A) to a selectee for federal office under the more narrow interpretation. If, for instance, a large computer company that has planned to merge with another large computer company

Opinion of the Court

makes a gift to a person who has been chosen to be Assistant Attorney General for the Antitrust Division of the Department of Justice and who has publicly indicated his approval of the merger, it would be quite possible for a jury to find that the gift was made "for or because of" the person's anticipated decision, once he is in office, not to challenge the merger. The uncertainty of future action seems to us, in principle, no more an impediment to prosecution of a selectee with respect to some future official act than it is to prosecution of an officeholder with respect to some future official act.

Our refusal to read §201(c)(1)(A) as a prohibition of gifts given by reason of the donee's office is supported by the fact that when Congress has wanted to adopt such a broadly prophylactic criminal prohibition upon gift giving, it has done so in a more precise and more administrable fashion. For example, another provision of Chapter 11 of Title 18, the chapter entitled "Bribery, Graft, and Conflicts of Interest," criminalizes the giving or receiving of any "supplementation" of an Executive official's salary, without regard to the purpose of the payment. See 18 U. S. C. §209(a). Other provisions of the same chapter make it a crime for a bank employee to give a bank examiner, and for a bank examiner to receive from a bank employee, "any loan or gratuity," again without regard to the purpose for which it is given. See §§212–213. A provision of the Labor Management Relations Act makes it a felony for an employer to give to a union representative, and for a union representative to receive from an employer, anything of value. 29 U. S. C. §186 (1994 ed. and Supp. III). With clearly framed and easily administrable provisions such as these on the books imposing gift-giving and gift-receiving prohibitions specifically based upon the holding of office, it seems to us most implausible that Congress intended the language of the gratuity statute— "for or because of any official act performed or to be performed"— to pertain to

Opinion of the Court

the office rather than (as the language more naturally suggests) to *particular* official acts.

Finally, a narrow, rather than a sweeping, prohibition is more compatible with the fact that §201(c)(1)(A) is merely one strand of an intricate web of regulations, both administrative and criminal, governing the acceptance of gifts and other self-enriching actions by public officials. For example, the provisions following §201 in Chapter 11 of Title 18 make it a crime to give any compensation to a federal employee, or for the employee to receive compensation, in consideration of his representational assistance to anyone involved in a proceeding in which the United States has a direct and substantial interest, §203; for a federal employee to act as "agent or attorney" for anyone prosecuting a claim against the United States, §205(a)(1); for a federal employee to act as "agent or attorney" for anyone appearing before virtually any Government tribunal in connection with a matter in which the United States has a direct and substantial interest, §205(a)(2); for various types of federal employees to engage in various activities after completion of their federal service, §207; for an Executive employee to participate in any decision or proceeding relating to a matter in which he has a financial interest, §208; for an employee of the Executive Branch or an independent agency to receive "any contribution to or supplementation of salary . . . from any source other than the Government of the United States," §209; and for a federal employee to accept a gift in connection with the "compromise, adjustment, or cancellation of any farm indebtedness," §217. A provision of the Internal Revenue Code makes it criminal for a federal employee to accept a gift for the "compromise, adjustment, or settlement of any charge or complaint" for violation of the revenue laws. 26 U. S. C. §7214(a)(9).

And the criminal statutes are merely the tip of the regulatory iceberg. In 5 U. S. C. §7353, which announces

Opinion of the Court

broadly that no "employee of the executive, legislative, or judicial branch shall solicit or accept anything of value from a person . . . whose interests may be substantially affected by the performance or nonperformance of the individual's official duties." §7353(a)(2). Congress has authorized the promulgation of ethical rules for each branch of the Federal Government, §7353(b)(1). Pursuant to that provision, each branch of Government regulates its employees' acceptance of gratuities in some fashion. See, e.g., 5 CFR §2635.202 *et seq.* (1999) (Executive employees); Rule XXXV of the Standing Rules of the Senate, Senate Manual, S. Doc. No. 104-1 (rev. July 18, 1995) (Senators and Senate Employees); Rule XXVI of the Rules of the House of Representatives, 106th Cong. (rev. Jan. 7, 1999) (Representatives and House employees); 1 Research Papers of the National Commission on Judicial Discipline & Removal, Code of Conduct for U. S. Judges, Canon 5(C)(4), pp. 925-927 (1993) (federal judges).

All of the regulations, and some of the statutes, described above contain exceptions for various kinds of gratuities given by various donors for various purposes. Many of those exceptions would be snares for the unwary, given that there are no exceptions to the broad prohibition that the Government claims is imposed by §201(c)(1). In this regard it is interesting to consider the provisions of 5 CFR §2635.202 (1999), issued by the Office of Government Ethics (OGE) and binding on all employees of the Executive Branch and independent agencies. The first subsection of that provision, entitled "General prohibitions," makes unlawful approximately (if not precisely) what the Government asserts §201(c)(1)(B) makes unlawful: acceptance of a gift "from a prohibited source" (defined to include any person who "[h]as interests that may be substantially affected by performance or nonperformance of the employee's official duties," 5 CFR §2635.203(d)(4) (1999)) or "[g]iven because of the employee's official posi-

Opinion of the Court

tion.” §2635.202(a)(2). The second subsection, entitled “Relationship to illegal gratuities statute,” then provides:

“Unless accepted in violation of paragraph (c)(1) of this section [banning acceptance of a gift in return for being influenced in the performance of an official act], a gift accepted under the standards set forth in this subpart *shall not constitute an illegal gratuity otherwise prohibited by 18 U. S. C. §201(c)(1)(B).*” §2635.202(b) (emphasis added).

We are unaware of any law empowering OGE to decriminalize acts prohibited by Title 18 of the United States Code. Yet it is clear that many gifts “accepted under the standards set forth in [the relevant] subpart” *will* violate 18 U. S. C. §201(c)(1)(B) if the interpretation that the Government urges upon us is accepted. The subpart includes, for example— as §201(c)(1)(B) does not— exceptions for gifts of \$20 or less, aggregating no more than \$50 from a single source in a calendar year, see 5 CFR §2635.204(a) (1999), and for certain public-service or achievement awards and honorary degrees, see §2635.204(d). We are frankly not sure that even our more narrow interpretation of 18 U. S. C. §201(c)(1)(B) will cause OGE’s assurance of nonviolation if the regulation is complied with to be entirely accurate; but the misdirection, if any, will be infinitely less.

More important for present purposes, however, this regulation, and the numerous other regulations and statutes littering this field, demonstrate that this is an area where precisely targeted prohibitions are commonplace, and where more general prohibitions have been qualified by numerous exceptions. Given that reality, a statute in this field that can linguistically be interpreted to be either a meat axe or a scalpel should reasonably be taken to be the latter. Absent a text that clearly requires it, we ought not expand this one piece of the regulatory puzzle so dra-

Opinion of the Court

matically as to make many other pieces misfits. As discussed earlier, not only does the text here not require that result; its more natural reading forbids it.

III

As an alternative means of preserving the jury's verdict on Count One, the Government contends that the District Court's mistaken instruction concerning the scope of §201(c)(1)(A) constituted harmless error. As described earlier, the District Court twice read the text of §§201(c)(1)(A) and 201(a)(3), but it then incorrectly explained the meaning of that statutory language by essentially substituting the term "official position" for "official act." More specifically, the court instructed the jury as follows:

"The essence of the crime is the official's position [as] the receiver of the payment not whether the official agrees to do anything in particular, that is, not whether the official agrees to do any particular official act in return. Therefore . . . to prove that a gratuity offense has been committed, it is not necessary to show that the payment is intended for a particular matter then pending before the official. It is sufficient if the motivating factor for the payment is just to keep the official happy or to create a better relationship in general with the official.

"It is sufficient if Sun-Diamond provided Espy with unauthorized compensation simply because he held public office.

"In order for you to convict Sun-Diamond of violating the gratuity statute, you must find beyond a reasonable doubt that Sun-Diamond gave the gifts to Mr.

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Espy for or because of Mr. Espy's official government position and not solely for reasons of friendship or social purpose.

"With respect to official acts, the government has to prove that Sun-Diamond Growers of California gave knowingly and willingly Secretary Espy things of value while it had issues before the United States Department of Agriculture.

"Now the government must prove that the gratuity was knowingly and willingly given for or because of an official act performed or to be performed by the Secretary of Agriculture, Michael Espy. That means that the government must prove that Sun-Diamond Growers of California . . . knowingly and willingly gave the gratuities, at least in part, because of the Secretary's position in appreciation of Sun-Diamond Growers of California's relationship with him as a public official or in anticipation of the continuation of its relationship with him as a public official. The government need not prove that the alleged gratuity was linked to a specific or identifiable official act or any act at all." App to Pet. for Cert. 84a-86a, 87a-88a.

The Government contends that the jury's verdict rendered pursuant to these instructions necessarily included a finding that respondent's gratuities were given and received "for or because of" an official act or acts. Upon closer examination, however, this argument is revealed to be nothing more than a restatement of the same flawed premise that permeated the instructions themselves and that we have just rejected: "By returning a guilty verdict, the jury necessarily rejected respondent's theory of defense and found beyond a reasonable doubt that the gifts were motivated by the fact that the Secretary of Agricul-

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ture exercised regulatory authority over respondent's business." Brief for United States 44. The Court of Appeals tersely rejected this claim of harmless error, 138 F. 3d, at 968, and we do the same.

* * *

We hold that, in order to establish a violation of 18 U. S. C. §201(c)(1)(A), the Government must prove a link between a thing of value conferred upon a public official and a specific "official act" for or because of which it was given. We affirm the judgment of the Court of Appeals, which remanded the case to the District Court for a new trial on Count One. Our decision today casts doubt upon the lower courts' resolution of respondent's challenge to the sufficiency of the indictment on Count One— an issue on which certiorari was neither sought nor granted. We leave it to the District Court to determine whether that issue should be reopened on remand.

It is so ordered.

TAB 5

**Memorandum**

December 4, 2003

TO: House Committee on Energy and Commerce
Attention: Alan Slobodin

FROM: American Law Division

SUBJECT: Cash "Awards" and "Prizes" to Agency Heads from Grantees of the Agency

This memorandum is prepared in response to the Committee's request, as discussed with counsel Alan Slobodin. The American Law Division previously provided a legal analysis to your Committee, dated May 20, 2003, discussing federal law and interpretation concerning the receipt of cash gifts, including "awards," by an agency head from a grantee of that official's agency. In response to the Committee's subsequent inquiry to that agency, the Committee received an unsigned memorandum (or "white paper") from the Department of Health and Human Services, dated July 11, 2003, which attempted to justify the receipt of cash awards by the head of an agency in the Department, the National Cancer Institute of the National Institutes of Health, based on a particular exemption to the executive branch gifts regulation. The Committee has asked for a legal analysis of the HHS response.

The Department memorandum would construe the gifts restriction, and the narrow exemption in it for *bona fide* "awards" to federal officials from disinterested sources, in such a permissive manner as to condone the personal enrichment of the Director of an agency directly from a source receiving significant grant funding from his agency. The reasoning employed by the Department obscures and overlooks the obvious and serious ethical implications in this scenario. On its face, allowing the top administrator and final decision maker of an agency to receive cash "awards" or "prizes" from those private entities concerning whom the agency must make determinations involving millions of dollars in grant funds implicates the precise conflicts of interest and ethical issues that are addressed in various criminal laws, statutes on gifts, and standards of conduct regulations. As developed below, under the common understanding of the language used in the gift regulations and exemptions, and under relevant administrative rulings and examples, as well as legal interpretations by the Supreme Court, — a private grantee of the Federal Government clearly "has interests that may be substantially affected" by the official powers and duties of the Director of the grantor federal agency, and as such, may not be the source of substantial gifts of cash, even in the form of "awards," given to that particular Government official.¹

¹ 5 U.S.C. § 7353(a)(2); 5 C.F.R. §§ 2635.202, 2635.203(d), 2635.204(d); 8 Op. O.L.C. 143, 144 (continued...)

Background. The limitations and restrictions on gifts, and the prohibitions on private salary supplementation of federal employees are, as noted by the Office of Government Ethics, “aimed at preventing the Government employee from becoming beholden to anyone in the private sector who might affect the independence or judgment of that employee.”¹ There is, of course, a grave concern that official decisions may actually be influenced, even subtly influenced, when a private recipient of federal largess “awards” the responsible federal official with cash in appreciation of his public duties.² Such conduct not only provides a potential lucrative reward for those *past* decisions favorable to the grantee, but also provides an opportunity for a potentially generous “incentive” for *future* official conduct favorable to the grantee by that official and other agency officials who are possible future recipients of such “awards.” In addition to actual influence over official decision making, however, there is an extended concern that permitting such conduct diminishes the confidence of the public in the independent, impartial and even-handed administration of federal programs.³ The Supreme Court has noted the important interest of the Government in adopting rules to avoid even “potential conflicts of interest in the performance of governmental service” to “maintain[] the public’s confidence in the integrity of the federal service.”⁴

To address the ethical issues inherent in the receipt of things of value by federal officials from private sources when there exists any “nexus” between the interests of the donor entity and the official duties and responsibilities of the recipient federal official, there has developed in the Federal Government a multi-layered structure of criminal laws, general statutes, and standards of conduct regulations which seek to regulate these situations. The criminal laws include the federal bribery statute which provides criminal penalties for any federal official who receives something of value “in return for” being influenced in the performance of an official act; the “illegal gratuities” clause of the same bribery statute which prohibits the receipt of things of value that are connected to official duties in particular

¹ (...continued)

(1984); Office of Government Ethics [OGE] Advisory Opinions Nos. 83 x 11 (July 26, 1983), and 92 x 7 (February 26, 1992); see *United States v. Sun-Diamond Growers of California*, 526 U.S. 398, 405-411 (1999).

² Office of Government Ethics, Opinion 81 X 31, October 2, 1981, in *Informal Advisory Letters and Formal Opinions, 1979 - 1988*, at 210; Paul H. Douglas, *Ethics in Government*, at 45 - 49 (Harvard University Press 1952); Roswell B. Perkins, “The New Federal Conflict of Interest Law,” 76 *Harvard Law Review* 1113, 1137 (1963), discussing 18 U.S.C. §209.

³ *Id.*; the late Senator Paul Douglas, explained in his treatise *Ethics in Government*, *supra* at 44, that often “the corruption of public officials by private interests takes a more subtle form” than outright bribes, through indirect financial support which may “put the public official under such a feeling of personal obligation that the latter gradually loses his sense of mission to the public” Douglas noted that sometimes subtle “shifting loyalties” from the community to narrow private interests may lead an official to make decisions favorable to “his private benefactors and patrons” while all the time “the official will claim – and may indeed believe – that there is no causal relationship between the favors he received and the decisions which he makes.”

⁴ “The proper operation of a democratic government requires that officials be independent and impartial; ... and that the public have confidence in the integrity of its government.” H. R. Rpt. No. 748, 87th Congress, 1st Session, 4-6, House Judiciary Committee (1961). The Office of Government Ethics has recognized the imperative to “ensure that every citizen can have complete confidence in the integrity of the Federal Government” 5 C.F.R. 2635.101(a).

⁵ *Crandon v. United States*, 494 U.S. 152, 164-165 (1990).

ways, – received “for or because of” a particular official act performed or to be performed by the officer or employee; and a criminal conflict of interest provision which prohibits federal employees in the executive branch from working on or being involved “personally and substantially” in any official particular matter in which they have a personal or imputed financial interest.⁶ In addition to these provisions of criminal law, it should be noted that a specific criminal provision of federal law also prohibits the receipt of money or things of value intended as private “compensation,” or as a salary supplementation, for one’s official duties performed for the United States Government.⁷ Under this latter provision, 18 U.S.C. § 209, there has been developed and recognized by the Department of Justice an exemption from the criminal law for *bona fide* awards to federal officials for their public service from sources “detached from” and “disinterested in” the area of responsibilities of the recipient federal official.⁸

Statute and General Regulations on Gifts. In addition to the provisions of federal criminal law noted above, there are non-criminal statutes of general applicability, as well as administrative regulations governing the acceptance of gifts and other “self-enriching” activities of federal officials.⁹ The principal statutory provision in federal law regarding gifts from private sources was adopted as part of the Ethics Reform Act of 1989,¹⁰ codifying for the most part somewhat similar ethical rules and limitations on the receipt of gifts by federal employees which had been in effect for the executive branch since 1965 by way of Executive Order and agency regulations.¹¹

The current law on gifts from outside sources, codified at 5 U.S.C. § 7353, prohibits the receipt of “anything of value” by a federal official from what have come to be known as “prohibited sources.” In the current gifts law, the “prohibited sources” are expressly set out in two separate categories of persons or entities, to include those persons:

- (1) seeking official action from, doing business with, or (in the case of executive branch officers and employees) conducting activities regulated by, the individual’s employing entity; [5 U.S.C. § 7353(a)(1)] or
- (2) whose interests may be substantially affected by the performance or nonperformance of the individual’s official duties. [5 U.S.C. § 7353(a)(2)]

Under the gifts statute, the supervisory ethics offices for particular employees and officials may issue regulations detailing the gift limitations and providing reasonable exceptions to the general prohibitions.¹² The Office of Government Ethics has issued gift regulations under this statutory provision for the executive branch of Government, setting out numerous restrictions and exemptions to the general prohibition. Under the regulations,

⁶ 18 U.S.C. § 201(c)(1)(B); 18 U.S.C. § 201(b)(2); 18 U.S.C. § 208.

⁷ 18 U.S.C. § 209.

⁸ 8 Op. O.L.C. 143, 144 (1984).

⁹ As noted by the Supreme Court there is now “an intricate web of regulations ... governing the acceptance of gifts and other self-enriching actions by public officials.” *United States v. Sun-Diamond Growers of California*, 526 U.S. 398, 409 (1999).

¹⁰ P.L. 101-194, Sec. 303, November 30, 1989, 103 Stat. 1746.

¹¹ See Executive Order No. 11222, Section 201, May 8, 1965 (now superseded by E.O. 12674, April 12, 1989), and former regulations, 30 F.R. 12529, October 1, 1965, 5 C.F.R. §735.202.

¹² 5 U.S.C. § 7353(b).

the Office of Government Ethics sets out the categories of what constitutes a “prohibited source” from whom things of value may not be received as follows at 5 C.F.R. § 2635.203:

- (d) *Prohibited source* means any person who:
- (1) Is seeking official action by the employee’s agency;
 - (2) Does business or seeks to do business with the employee’s agency;
 - (3) Conducts activities regulated by the employee’s agency;
 - (4) Has interests that may be substantially affected by performance or nonperformance of the employee’s official duties; or
 - (5) Is an organization a majority of whose members are described in paragraphs (d)(1) through (4) of this section.¹³

Regulatory Exemption for Certain Bona Fide Awards. Based on the guidance and principles developed in the Department of Justice’s exemption for *bona fide* awards under 18 U.S.C. § 209, the Office of Government Ethics promulgated an exception from the gifts prohibitions for certain “*bona fide* awards” for meritorious public service given by certain entities to federal officials when the recipient federal officials are not in positions to affect the interests of the donor of the award or prize. The current regulatory exemption provides as follows, at 5 C.F.R. § 2635.204:

- (d) *Awards and honorary degrees.* (1) An employee may accept gifts, other than cash or an investment interest, with an aggregate market value of \$200 or less if such gifts are a bona fide award that is given for meritorious public service or achievement by a person who does not have interests that may be substantially affected by the performance or nonperformance of the employee’s official duties or by an association or other organization the majority of whose members do not have such interests. Gifts with an aggregate market value in excess of \$200 and awards of cash or investment interests offered by such persons as awards or incidents of awards that are given for these purposes may be accepted upon a written determination by an agency ethics official that the award is made as part of an established program of recognition:
- (i) Under which awards have been made on a regular basis or which is funded, wholly or in part, to ensure its continuation on a regular basis; and
 - (ii) Under which selection of award recipients is made pursuant to written standards.

The examples given by the Office of Government Ethics and the rulings by that agency, as well as the Department of Justice interpretations under § 209, have demonstrated that a *bona fide* award, to fit the exemption, must (among other qualifications for a cash award) come from a person, group, or entity that is to a certain degree “independent” of the recipient public official, in the sense that the public official is not in a position to act favorably to the giver’s interests. The Department of Justice has expressly stated that the exemption from the criminal statute at 18 U.S.C. § 209 that it has recognized for *bona fide* awards to federal officials from outside sources, must come from donors who are “detached from and disinterested in the performance of the public official’s duties.”¹⁴

The example expressly provided in the published regulations of the Office of Government Ethics uses the Nobel Prize to illustrate the type of “award” from independent sources that may be received by a federal official:

¹³ 5 C.F.R. § 2635.203(d).

¹⁴ 8 Op. O.L.C. 143, 144 (1984).

Example 1: Based on a determination by an agency ethics official that the prize meets the criteria set forth in § 2635.204(d)(1), an employee of the National Institutes of Health may accept the Nobel Prize for Medicine, including the cash award which accompanies the prize, even though the prize was conferred on the basis of laboratory work performed at NIH.¹⁵

Similarly, an advisory ruling from the Office of Government Ethics provided another example of when the receipt of a *bona fide* award by a particular official would not raise ethics and conflict of interest concerns, that is, again, when the recipient/awardee is not in a position to exercise official duties or responsibilities that may substantially affect the interests of the donor:

A nonprofit organization presents its annual award consisting of \$5,000 and a medallion for "Greatest Public Service Performed by an Elected or Appointed Official" to an employee of the Bureau of Prisons. The organization applied long-standing written criteria in judging all of the candidates. *The organization has no relationship with the Bureau of Prisons.* Because it is a *bona fide* award for public service, it is not intended to compensate the employee for his services to the Bureau of Prisons and would not violate section 209.¹⁶

Where there existed apparent or potential conflicts of interest for employees of an agency with respect to the donor entity, however, because those employees worked in a subject "area" of interest to the donor, the Office of Government Ethics, in applying an earlier version of the exemption, found that the requisite independence or disinterestedness of the donor was not present, and that the awards could not be accepted.¹⁷

The Office of Government Ethics has not published an interpretation specifically addressing the issue of the head of an agency receiving cash "awards" from a grantee of that agency. There is, however, *no* ruling from the Office of Government Ethics which interprets this narrow exception from the general gifts prohibition for *bona fide* "awards" in such a manner as to allow the personal enrichment of a federal official, such as an agency Director, from any entity, such as a grantee of the Director's agency, which is so vitally concerned with and connected to the area of official responsibilities and powers of the intended recipient. Under the general principles of the administrative and regulatory exemptions, a grantee of an agency can hardly be said to be "detached from" or "disinterested in" the official duties and responsibilities of the Director of the grantor federal agency. As explained below, such conduct not only raises general ethics and conflict of interest concerns and appearances, it appears to specifically violate the express prohibition on gifts from interested parties.

Meaning of Phrase "Interests That May Be Substantially Affected" by the Officer's Duties. The regulatory exception for *bona fide* awards thus does *not* allow, for obvious ethics and conflict of interest reasons, a public official to receive an award from an entity which is in the "fourth category" of regulatory "prohibited sources," that is, from an entity that "has interests that may be substantially affected" by the performance or nonperformance of that official's public duties. The Memorandum from the Department of Health and Human Services admits its confusion and lack of understanding of the plain language of this

¹⁵ 5 C.F.R. §2635.204(d), *note*.

¹⁶ OGE, Memorandum, DO-02-016, "18 U.S.C. § 209 Guidelines," July 1, 2002, *see* OGE Advisory Letter 83 x 10. Emphasis added.

¹⁷ OGE Opinion 83 x 11, July 26, 1983.

a “prohibited source” for general “gifts” for every officer and employee of the agency (merely because of the laboratory’s status as an agency “grantee”) and, at the same time, may also be a “prohibited source” for the Director of that agency for an “award,” because the Director’s general supervisory, administrative and operating authority relative to all of his agency’s decisions may, obviously, have a substantial effect on the interests of the laboratory/facility. It is thus the “status” of the position that the intended recipient holds, and the incumbent’s ability or capacity to exercise governmental authority affecting the donor entity, that is the relevant measure of the application of the fourth “prohibited source” category.

In further clarification of the phrase used in the regulatory exemption, the Supreme Court of the United States clearly explained that for a particular public official, this “fourth category” of “prohibited sources” in the Office of Government Ethics regulations, from whom things of value may not be received because the donor has “interests that may be substantially affected” by the duties of the official, relates to those situations where the public official “is in a position to act favorably to the giver’s interests,” that is, where the public official has the “capacity to exercise governmental power or influence in the donor’s favor,” regardless of whether there is a particular, identifiable matter immediately before the official.²³ The clause in the ethics regulation thus clearly is directed at the powers and responsibilities of the office of the incumbent recipient, rather than the immediacy of any particular matter and, in the case of a grantee of a federal agency, would obviously be applicable to the Director of the agency who has final statutory, administrative and operational authority over the agency decision-making vitally affecting the interests of the donor entity.

In *United States v. Sun-Diamond*, the Supreme Court analyzed a prosecution of a federal official, the Secretary of Agriculture, under the “illegal gratuities” clause of the bribery statute for his receipt of various gifts from business entities which could be affected by the exercise of the Secretary’s official duties because they had businesses that were regulated by the Department. It should be noted that for a number of years, in several federal circuits, so-called “status gifts” were successfully prosecuted as “illegal gratuities.”²⁴ Status gifts were things of value received by an official which were given because of that employee’s official position in the Government, that is, given to an officer or employee who “was in a position to benefit” the private donor entity. The United States Government in *Sun-Diamond* argued unsuccessfully for that specific interpretation in the case of the Secretary of Agriculture:

The Independent Counsel asserts that “section 201(c)(1)(A) reaches any effort to buy favor or generalized goodwill from an official who either has been, is, or may at some unknown, specified later time, be *in a position to act* favorably to the giver’s interests.” Brief for United States 22 [Court’s emphasis]. The Solicitor General contends that § 201(c)(1)(A) requires only a showing that a “gift was motivated, at least in part, by the recipient’s *capacity to exercise governmental power or influence* in the donor’s favor”

²² (...continued)

laboratory/facility because their particular responsibilities do not affect its interests.

²³ *United States v. Sun-Diamond Growers of California*, 526 U.S. 398, 405-411 (1999).

²⁴ *United States v. Niederberger*, 580 F.2d 63, 69 (3rd Cir. 1978), *cert. denied*, 439 U.S. 980 (1978)(golfing trips for I.R.S. officer paid for by Gulf Oil Corp. when officer was merely “in a position to use his authority in a manner which could affect the gift-giver”); *United States v. Alessio*, 528 F.2d 1079, 1082 (9th Cir. 1976), *cert. denied*, 426 U.S. 94 (1976)(gift to prison administrator).

without necessarily showing that it was connected to a particular official act. Brief for United States Dept. of Justice as *Amicus Curiae* 17 [Court's emphasis].²⁵

The Supreme Court, however, found that for a violation of the "illegal gratuities" provision, there must be some particular, identifiable "official act" to which the gift is connected.²⁶ The Supreme Court noted in *Sun-Diamond* that so-called "status gifts," that is, gifts to a federal official which were prohibited "by reason of the recipient's mere tenure in office" because they were in a position to act favorably on the donor's behalf,²⁷ were not necessarily "illegal gratuities," but rather would come within, be regulated by, and would violate the OGE *regulations* on gifts. Specifically, the unanimous court found such gifts, that is, things of value given to a public official who has the capacity to act favorably on the donor's behalf at some time, to be gifts which would violate the regulations expressly prohibiting the receipt of gifts from anyone who "has interests that may be substantially affected by performance or nonperformance of the employee's official duties:"

[I]t is interesting to consider the provisions of 5 C.F.R. § 2635.202 (1999), issued by the Office of Government Ethics ... The first subsection of that provision, entitled 'General prohibitions,' makes unlawful approximately (if not precisely) what the Government asserts [the statute] makes unlawful: acceptance of a gift "[f]rom a prohibited source" (defined to include any person who "[h]as interests that may be substantially affected by performance or nonperformance of the employee's official duties ...")²⁸

The Supreme Court in *Sun-Diamond* thus explicitly explained that the prohibition in the executive branch regulation on accepting gifts from one who "has interests that may be substantially affected by the performance or nonperformance of the employee's official duties," is a prohibition on receiving things of value from private sources by a federal official who is merely "in a position to act favorably to the giver's interests," that is, that the recipient public official has the "capacity to exercise governmental power or influence in the donor's favor."²⁹ There need not be any identifiable, particular governmental matter currently before, or "on the desk of," the official to violate this provision of ethics regulation under the Supreme Court explanation. In fact, if there is a particular, identifiable matter involving the donor-entity immediately before the Government official who is at the same time receiving significant cash "awards" or other gifts from that entity, there may very well be more than merely an "ethics" violation of the gift regulation, but rather potential felony violations of federal criminal law.³⁰

²⁵ 526 U.S. at 405-406.

²⁶ 526 U.S. at 406.

²⁷ 526 U.S. at 408.

²⁸ 526 U.S. at 411, citing to the gifts regulations at 5 C.F.R. § 2635.203(d)(4).

²⁹ 526 U.S. at 405, 411.

³⁰ The timing of the offer and receipt of things of value, in relation to a particular official matter actually pending before a recipient Government official is a relevant circumstantial consideration in determining the requisite "intent" needed for an "illegal gratuity," that is, the intent to be rewarded or compensated for a particular official act. *United States v. Biaggi*, 853 F.2d 89, 99-100 (2nd Cir. 1988), *cert. denied* 489 U.S. 1052 (1989), evidence of required intent to reward may be inferred from the size of gift, and "the nature and sequences of events"; *United States v. Jennings*, 160 F.3d 1006, 1014, 1017-1018 (4th Cir. 1998), (referring to federal bribery law at 18 U.S.C. § 201 and similar language at 18 U.S.C. § 666, regarding bribery and gratuities in federally funded programs): "Direct (continued...)"

Authority of Agency Director. As a general matter, it is obvious and beyond reasoned argument that a Director of a federal agency has the official capacity and authority to exercise governmental power or influence which could have a favorable or unfavorable impact on the interests of a grantee of that agency, particularly an entity with a continuous grantee and certification relationship with that federal agency. In fact, under federal law, the Director of the agency in question, the National Cancer Institute, has *express* administrative control and statutory authority over all of the relevant functions of the Institute,³¹ and thus oversees the grant functions, administration and oversight of grantee programs.³²

One may not convincingly argue, under either general or conflict-of-interest-specific legal principles, that an agency grantee has no interests which may be substantially affected by the official authority, duties and responsibilities of that agency's Director merely because the Director has "delegated" certain functions regarding grants to subordinate officials. A delegation of authority by a federal official is *not* a divestiture of official authority or responsibility.³³ As noted by the United States Court of Appeals, the head of an agency who delegated authority to a subordinate official "did not, however, divest ... himself of the power to exercise his authority or relieve him of his responsibility for action taken pursuant to the delegation."³⁴ In fact, the Supreme Court has found that an official may *not* administratively divest himself of statutory authority.³⁵

³⁰ (...continued)

evidence of intent is not necessary," but may be inferred from circumstances including timing and sequences of gifts and acts. Note also 18 U.S.C. § 209, where donor's interest in immediate official matter, although clearly not necessary for a violation, may arguably provide further evidence of "intent to compensate" and "appearance of a conflict of interest ... sufficient to violate § 209." *United States v. Moore*, 765 F.Supp. 1251, 1254 (E.D.Va. 1991). The law at §209 has been described as a conflict of interest statute "in the strictest sense," that is, an "employee does not have to do anything improper in his office to violate the statute," but rather his special status as a government employee "makes an unexceptionable act wrongful - wrongful because of the potential dangers in serving two paymasters." Association of the Bar of the City of New York, Special Committee on the Federal Conflict of Interest Laws, *Conflict of Interest and Federal Service*, at 55-56 (Harvard University Press 1960). There may also be other considerations of felony violations when a public official actually participates "personally and substantially" in a particular agency matter in which the official has his own personal, financial interest. 18 U.S.C. § 208.

³¹ 42 U.S.C. §§ 285a-1, 285a-2.

³² According to the NCI web-site (<http://www3.cancer.gov/mab/hnc1.htm>), the Office of the Director "(1) Serves as the focal point for the National Cancer Program; (2) develops a National Cancer Plan and monitors implementation of the plan; (3) directs and coordinates the Institute's programs and activities; and (4) develops and provides policy guidance and staff direction to the Institute's programs in areas such as program coordination, program planning, clinical care and administrative management."

³³ *Skokomish Indian Tribe v. General Services Administration*, 587 F.2d 428, 432 (9th Cir. 1978).

³⁴ *Skokomish Indian Tribe*, *supra* at 432. For conflict of interest purposes it may be noted that the act, decision and discretion of delegating certain authority or not delegating authority, to whom such authority is delegated, and the nature – reviewability, timing, extent – of such delegation may involve, in themselves, the exercises of official duties that may substantially affect a grantee.

³⁵ *NLRB v. Duval Jewelry Company*, 357 U.S. 1, 7-8 (1958); *Equal Employment Opportunity Commission v. Exchange Security Bank*, 529 F.2d 1214, 1218-19 (5th Cir. 1976).

A superior thus clearly has “official responsibility” for, as well as “official authority” over, the actions of those subordinate officials in the chain of authority and command in his federal agency.³⁶ The assignment, review, oversight, and supervision of official actions of subordinate employees, as well as the express authority retained by that official to direct the overall functions and programs of the agency, are all among the official responsibilities and duties of a federal officer such as an agency Director. In explaining the conflict of interest principles in the concept of the “official responsibilities” of a federal officer, Professor Manning expressly noted that: “[T]he head of a department or agency would have ‘under his official responsibility’ all matters in the department or agency.”³⁷

It should be emphasized that there is *not* a requirement under the gifts prohibition/“award” restriction that the recipient official must actually participate “personally and substantially” in any current governmental matter affecting the donor/grantee for the prohibition on awards to apply, as there is under several *criminal* conflict of interest laws.³⁸ As noted, the restrictions on awards from interested parties is concerned, for obvious ethical and conflict of interest reasons, with the power to exercise governmental authority in the donor’s favor, that is, it is concerned with the status of the recipient official *vis-a-vis* the donor, and not with whether such authority is actually exercised in a particular, identifiable matter. Like many conflict of interest rules, this regulation does *not* require actual corruption, loss by the Government, or wrongful official acts, but rather is preventative and prophylactic in nature, and thus is, as the Supreme Court noted concerning another conflict of interest law, “directed not only at dishonor, but also at conduct that tempts dishonor.”³⁹ Under the relevant legal and administrative interpretations of, and the plain meaning of the language employed in the gifts/“award” limitations, therefore, an entity such as a cancer research and treatment facility which has a continuing grant and certification relationship with a federal agency such as the National Cancer Institute, clearly has interests that may be substantially affected by the actual, statutory operational, administrative and supervisory duties, responsibilities and authorities of the Director of that agency, and may thus not be a source of cash “awards” to that Director.

³⁶ See, for example, definition of “official responsibility” for purposes of certain criminal conflict of interest laws as including “direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and *either personally or through subordinates*, to approve, disapprove, or otherwise direct Government action.” 18 U.S.C. § 202(b). Emphasis added.

³⁷ Bayless Manning, *Federal Conflict of Interest Law*, at 207-208 (Harvard University Press 1964).

³⁸ While not requiring “personal and substantial” participation in a particular governmental matter affecting the donor to incur the prohibition on “awards,” even that much stricter criminal standard of responsibility and duties would not, as discussed by Roswell Perkins, “create a loophole for the lazy executive in the chain of command who may not have bothered to dig into the substance” of a particular matter. Roswell Perkins, “The New Federal Conflict of Interest Law,” 76 *Harvard Law Review* 1113, 1128 (1963).

³⁹ *United States v. Mississippi Valley Generating Co.*, 364 U.S. 520, 549 (1960). The language of the regulatory limitation prohibiting an “award” when the donor entity has interests that “may be” influenced by the official duties of the recipient indicates a focus on potential performance or influence. The Supreme Court noted in another ethics context, that the Government “appropriately enacts prophylactic rules that are intended to prevent even the appearance of wrongdoing ...” *Crandon v. United States*, 494 U.S. 152, 164 (1990).


Summary/Conclusion.

1. A federal official in the executive branch may not, under federal ethics regulations, receive a cash “award” or “prize,” even a “*bona fide* award,” from a donor which has interests that may be substantially affected by the performance or nonperformance of the official’s governmental duties.⁴⁰

2. An entity is not a “disinterested” nor “detached” source, and specifically *has* interests that “may be” substantially affected by the performance or nonperformance of the official duties of a federal officer when that officer is “in a position to act favorably to the giver’s interests,” that is, when he has the “capacity to exercise governmental power or influence in the donor’s favor.”⁴¹

3. The Director of a federal agency has the official authority, responsibility and duty to direct, oversee, manage and supervise the agency decisions regarding the making of grants and the continued certification of certain grantee entities, may not divest himself of such authority and responsibility by way of delegation, and thus, obviously, has significant federal authority, power, capacity and official responsibilities that may substantially affect the interests of such a grantee of that agency.⁴²

4. The federal gift restrictions, therefore, prohibit the Director of a federal agency such as the National Cancer Institute from personally enriching himself by accepting large cash “awards” or “prizes” from grantees of his own agency.


Jack Maskell
Legislative Attorney

⁴⁰ 5 U.S.C. § 7353(a)(2); 5 C.F.R. §§ 2635.202, 2635.203(d), 2635.204(d).

⁴¹ *United States v. Sun-Diamond Growers of California*, 526 U.S. 398, 405-411 (1999); 8 Op. O.L.C. 143, 144 (1984); OGE Advisory Opinions Nos. 83 x 11 (July 26, 1983), and 92 x 7 (February 26, 1992). There need not be a particular identifiable matter before or “on the desk of” the official for the regulation to apply, and if there *is* such an official matter immediately before the officer while he is receiving things of value, gifts and cash from that entity, then other, more serious *criminal* violations may be implicated.

⁴² 42 U.S.C. §§ 285a-1, 285a-2. *NLRB v. Duval Jewelry Company*, 357 U.S. 1, 7-8 (1958); *Skokomish Indian Tribe v. General Services Administration*, 587 F.2d 428 (9th Cir. 1978). An official need not have “personal and substantial” participation in a particular matter for the regulation to apply (Compare to 18 U.S.C. § 208).

TAB 6



Memorandum

May 20, 2003

TO: House Committee on Energy and Commerce
Attention: Alan Slobodin

FROM: Jack Maskell
Legislative Attorney
American Law Division

SUBJECT: Receipt of "Lecture Award" by High Level Agency Official from an Agency Grantee

This memorandum responds to the Committee's request, as discussed with Counsel Alan Slobodin, for an analysis of the legal issues concerning the receipt by a Director of the National Cancer Institute [NCI] of the National Institutes of Health, Department of Health and Human Services, of a "lecture award," that is, a cash "award" ostensibly for outstanding public service in the area of cancer research, which was given to the Director (along with travel expenses) upon his deliverance of a lecture to the organization making the award in December of 1999. In the matter under consideration the organization making the award, the Arizona Cancer Center, was at that time and continues to be the recipient of substantial grants from the Director's agency, the NCI. While this memo addresses a particular factual situation and event, the Committee has expressed general concern with an ethics program and system which allows the head of an agency making grants to private organizations to receive personally from those same organizations large sums of cash and travel expenses in the form of an "award" or "prize."

There are existing federal laws, regulations and Executive Orders which prohibit presidential appointees to full-time, noncareer positions from receiving *any* outside compensation¹; which limit the amount of earned income that other high-level federal officials may receive²; which regulate the receipt of payments for speeches and writings (generally referred to as "honoraria") when such activities involve descriptions of the official programs and activities of one's federal agency, or when payments are received from those who may be affected by one's official duties³; and provisions which severely limit the receipt of personal "gifts" from prohibited sources, that is, from those doing business with one's

¹ 5 C.F.R. §§ 2635.804, 2636.302; Executive Order 12674, April 12, 1989, Section 102.

² 5 U.S.C. app. §§ 501(a)(1), 502.

³ 5 C.F.R. § 2635.807(a).

agency or those seeking contracts or grants from one's agency.⁴ Federal criminal law further prohibits the receipt of private compensation or salary supplementation for performing what are official, governmental duties.⁵ While such restrictions are in place, there has been carved out of ethics regulation an exception for the receipt of *bona fide*, long standing "awards" or prizes, such as the Nobel Prize, given to a federal employee when the donor is not one who may be substantially affected by the performance or non-performance of the recipient's official duties, and when it is determined in writing by the ethics officer of the agency that the prize is regularly given and is awarded in conformance with established, written selection criteria.⁶

Limits on Compensation. The Director of the National Cancer Institute is an official who is appointed by the President (without confirmation by the Senate) to a full-time position which is not designated as, nor has the attributes of, a "career" position.⁷ As such, it would appear that the Director falls within the prohibition of Executive Order No. 12674 (as modified by E.O. 12731) on presidential appointees receiving *any* outside earned income during the course of their appointment.⁸ The Director could thus not accept private payment as compensation or consideration for giving a speech or a lecture.

Honoraria. While the so-called "honoraria ban" instituted by the Ethics Reform Act of 1989⁹ was ruled unconstitutional by the United States Supreme Court,¹⁰ and no longer will be enforced against any officer or employee of the Federal Government,¹¹ the activity of a federal official receiving private compensation for outside speaking or writing is not left completely unregulated. In addition to the outright ban on all earned compensation by presidential appointees discussed above, all employees of the executive branch are prohibited from receiving compensation for a lecture, speech or article when offered by a "person who has interests that may be affected substantially by performance or nonperformance of the employee's official duties," or when the subject of the speech deals in significant part with a matter to which the employee is presently assigned, or has worked on, in an official capacity, in the last year, or any "ongoing or announced policy, program or operation of the

⁴ 5 U.S.C. § 7353; 5 C.F.R. §§ 2635.201 *et seq.*

⁵ 18 U.S.C. § 209.

⁶ 5 C.F.R. § 2635.204(d); Office of Government Ethics [OGE], Advisory Opinions Nos. 83 x 10 (July 21, 1983), and 92 x 7 (February 26, 1992); 8 Op. O.L.C. 143, 144 (1984).

⁷ See S. Prt. 106-54, 106th Cong., 2d Sess., "United States Government Policy and Supporting Positions" (colloquially known as the "Plum Book"), at 117 (2000). The position is a presidential appointment, not a merit-based competitive selection approved by OPM, removable "at will" by the President, and would thus not be characterized as a "career" position. Note, *e.g.* definition of "career" and "non-career" Senior Executive Service appointments, 5 U.S.C. § 3132(a)(4),(7). In contrast, the "Plum Book" lists the *Deputy* Director of NCI, as opposed to the Director, as a "career incumbent," and the type of appointment as a "career appointment." *Id.* at 117.

⁸ See also 5 C.F.R. §§ 2635.804, 2636.302; and Executive Order 12674, Section 102.

⁹ P.L. 101-194, title VI, § 601(a), 103 Stat. 1760, November 30, 1989; 5 U.S.C. app. § 501(b).

¹⁰ *United States v. National Treasury Employees Union*, 513 U.S. 454 (1995).

¹¹ Office of Legal Counsel, U.S. Department of Justice, Memorandum to the Attorney General, "Legality of Honoraria Ban Following *U.S. v. National Treasury Employees Union*," February 26, 1996.

agency.”¹² For high-level officials in the executive branch of the Federal Government,¹³ however, such as the Director of the NCI, such officials are subject to broader prohibitions and restrictions on paid speeches and articles, and are prohibited by Office of Government Ethics regulations from receiving compensation for such speaking, lecturing or writing activity if the subject matter of the speech, article, or appearance “deals in significant part with ... the general subject matter area, industry, or economic sector primarily affected by the programs and operations of his agency.”¹⁴ The Director of the National Cancer Institute, or any high-ranking official of the NCI, would thus be prohibited from receiving an honorarium from a private source for a lecture which focused on cancer research funded by NCI.

Gifts. The current federal law, codified at 5 U.S.C. § 7353, prohibits any federal officer or employee from receiving a gift of any amount from a prohibited source, that is, from someone who is “seeking official action from, doing business with” or seeking to do business with, or is “conducting activities regulated by” one’s agency, or whose interests “may be substantially affected by the performance or nonperformance” of one’s official duties. The law allows exceptions to be made by the supervisory ethics agency, and numerous exceptions to the strict gift rules are provided in regulations of the Office of Government Ethics, including for gifts which are “motivated by a family relationship or personal friendship rather than the position of the employee,”¹⁵ and gifts of \$20 or less, as long as the total number of all gifts from any one person do not exceed \$50 in a calendar year.¹⁶

Awards. One of the exceptions to the gifts rule, and also apparently to the restrictions on outside earned income and private compensation, is an exception for the receipt by a federal official of a *bona fide* award or prize.¹⁷ Officers or employees of the Federal Government may receive in certain circumstances *bona fide* awards, including cash awards, for meritorious public service or achievement from outside, private entities, when that acceptance does not have conflict of interest implications and where there is no apparent “intent to compensate” the official by the private entity for the official’s duties and work for the United States Government, in violation of 18 U.S.C. § 209.¹⁸ One example given in the Office of Government Ethics regulations involves an official from the National Institutes of Health receiving the Nobel Prize:

¹² See regulations of the Office of Government Ethics, 5 C.F.R. § 2635.807(a)(2)(C),(E)(1) and (2).

¹³ The broader restriction applies to a non-career official who is compensated at a rate above GS-15.

¹⁴ 5 C.F.R. § 2635.807(a)(2)(i)(E)(3).

¹⁵ 5 C.F.R. § 2635.204(b).

¹⁶ 5 C.F.R. § 2635.204(a). Excluded from the definition of a “gift” in the executive branch are such things as modest items of food and drink which are not offered as part of a meal, greeting cards and items with little intrinsic value such as plaques or trophies, loans from financial institutions at prevailing rates, favorable rates or benefits available generally to a class of persons, rewards and prizes from contests and events, pension benefits, and anything accepted by the Government or the employee under statutory authority. 5 C.F.R. § 2635.203(b).

¹⁷ 5 C.F.R. 2635.204(d). Financial disclosure instructions indicate that the Office of Government Ethics does not consider *bona fide* awards to be “earned income,” and such awards should be reported as “other” income. *Public Financial Disclosure: A Reviewer’s Reference*, at 3-10.

¹⁸ Note, e.g., OGE Advisory Opinions Nos. 83 x 10 (July 21, 1983), 83 x 11 (July 26, 1983), and 92 x 7 (February 26, 1992); 8 Op. O.L.C. 143, 144 (1984).

Example 1: Based on a determination by an agency ethics official that the prize meets the criteria set forth in § 2635.204(d)(1), an employee of the National Institutes of Health may accept the Nobel Prize for Medicine, including the cash award which accompanies the prize, even though the prize was conferred on the basis of laboratory work performed at NIH.¹⁹

When a sizable cash award is to be bestowed on a public official from a donor organization having less independence and prestige than the Nobel organization, particularly organizations interested in the work of the official's agency, questions may be raised as to whether the receipt of such an award might appear in some circumstances to be contrary to the spirit if not the letter of federal conflict of interest principles and provisions which seek to ensure that a federal employee is compensated for his services to the Government only by the Government, is not placed in a position of "serving two masters," and is not, nor appears to be, beholden or grateful to any outside group or private interest which "could affect the independent judgment of the employee."²⁰ Furthermore, there is concern that the exception for *bona fide* prizes and awards not be used as a way merely to circumvent the earned income prohibition and the honoraria restrictions by simply designating a payment made to different officials for a speech or a lecture as a "lecture award." These conflict of interest issues arise particularly when those groups or organizations giving the "awards" or "prizes" are interested parties, that is, groups or organizations having a vital financial, economic or policy interests in the official duties, functions, and responsibilities of the recipients and/or the recipients' federal agencies, and would arise even where the group selects an official on a "regular" basis, such as yearly, to deliver a lecture to the group and receive the "lecture award." In discussing *bona fide* awards and possible conflicts of interest, the OGE gave the following as an example:

A nonprofit organization presents its annual award consisting of \$5,000 and a medallion for "Greatest Public Service Performed by an Elected or Appointed Official" to an employee of the Bureau of Prisons. The organization applied long-standing written criteria in judging all of the candidates. *The organization has no relationship with the Bureau of Prisons.* Because it is a *bona fide* award for public service, it is not intended to compensate the employee for his services to the Bureau of Prisons and would not violate section 209.²¹

In an attempt to prevent abuse of the "awards" exemption, the federal ethics regulations regarding gifts now specifically require that the prize be a *bona fide* award which must be given by an entity or person "who does not have interests that may be substantially affected by the performance or nonperformance of the employee's official duties."²² Furthermore, if the award given by such an independent source is to be a "cash" award, then a specific *written* determination must be made by the agency ethics officer that such "award" is part of

¹⁹ 5 C.F.R. §2635.204(d), *note*.

²⁰ Roswell B. Perkins, "The New Federal Conflict of Interest Law," 76 *Harvard Law Review* 1113, 1137 (1963), discussing 18 U.S.C. §209.

²¹ OGE, Memorandum, DO-02-016, "18 U.S.C. § 209 Guidelines," July 1, 2002, *see* OGE Advisory Letter 83 x 10. Emphasis added.

²² 5 C.F.R. §2635.204(d)(1).

“an established program of recognition,” that is, that it is made on a “regular basis” (or funded to be given on a continuing basis) and is awarded under specific written criteria.²³

The donor of the award in question, the Arizona Cancer Center, is a National Cancer Institute-Designated Comprehensive Cancer Center at the University of Arizona Health Sciences Center in Tucson, Arizona, and is a major grant recipient from the National Cancer Institute. In Fiscal Year 1999, for example, the University of Arizona received grants from the National Cancer Institute in the amount of \$22,193,000, and contracts in the amount of \$237,000; and in Fiscal Year 2000 received grants from NCI in the amount of \$25,249,000 and contracts in the amount of \$486,000.²⁴ Thus, in the case of the “lecture award” given to the Director of the National Cancer Institute from an organization such as the Arizona Cancer Center, the issue is immediately raised as to whether such an award could or should be given to an official such as the Director of the agency, regardless of the selection criteria for the award, since the organization is a grantee and contractor of the agency, and one subject to regular and continuous oversight, regulation and review by the Director’s agency regarding the performance of its grants, contracts and its status and designation. As such, the Center would arguably not be an independent source of an award, *vis-a-vis* either the Director or the agency, such as the Nobel organization or the non-profit organization described in the OGE example of the Bureau of Prisons employee, but rather would appear to fall clearly within the purview and concept of an interested party in the agency and its Director.

The regulations of the Office of Government Ethics expressly provide that the donor person or organization of an “award” or prize, under the awards exception, must be one who does *not* have “interests that may be substantially affected by the performance or nonperformance of the employee’s official duties.”²⁵ This provision appears to encompass a narrower range or universe of organizations and persons than a “prohibited source” generally for purposes of the gift regulation,²⁶ since a prohibited source generally for gifts encompasses and includes those doing business or seeking to do business with, or an entity regulated by, one’s agency, and thus would include and encompass an agency-wide “prohibited source” status for contractors and grantees of an agency for all agency employees.²⁷ The prohibited source provision in the case of the “awards” exception, however, is one of a personal rather than an agency-wide nature, as it relates only to the specific employee’s official duties and their potential impact upon a private entity, and might not necessarily cover all employees of an agency, as it might not apply to, for example, employees in a division or unit of an agency whose official duties are not concerned with grants, the making of a grant, or the oversight or administering of a grant, a grant program

²³ 5 C.F.R. § 2635.204(d)(1)(i) and (ii).

²⁴ *Fact Book*, National Cancer Institute, 1999, at E-12; *Fact Book*, National Cancer Institute, 2000, at E-11.

²⁵ 5 C.F.R. § 2635.204(d)(1).

²⁶ See 5 C.F.R. § 2635.203(d), defining “prohibited source.”

²⁷ OGE Opinion 94 x 5, February 7, 1994: “As you know, people and organizations generally are considered ‘prohibited sources’ on an agencywide basis. See 5 C.F.R. § 2635.203(d). And ‘agency,’ in this context, generally means either an executive branch agency or department. See 5 U.S.C. § 105; 5 C.F.R. §§ 2635.203(a) and 2635.102(a). In other words, as a general matter, if an organization is a prohibited source with respect to an agency or department, it is a prohibited source with respect to gifts made to any employee of that agency or department, but not with respect to gifts made to employees of other separate agencies and departments.”

or the grant performance with respect to a particular grantee organization. However, for the Director of the agency, the status of an entity as an agency-wide "prohibited source" for a gift as opposed to an employee-specific prohibited source for an award, appears to be a distinction without a difference. The Director of the agency has final administrative control and authority over all of the relevant functions of the Institute,²⁸ and thus oversees all grant functions, grant administration and oversight of grantee programs.²⁹ It would appear that in practice, given the authority, status, role, and the functions of the Director of the Institute, it would be difficult, at best, to justify a "compartmentalization" of the Director, and the Director's duties and responsibilities, away from those agency functions that may substantially affect the interests of a grantee of the agency such as the Arizona Cancer Center. As such, with respect to the Director of the agency, it may be argued that a grantee organization such as the Arizona Cancer Center should be considered to have the status as a prohibited source with respect to "awards" and cash prizes under 5 C.F.R. § 2635.204(d)(1), as the Center clearly has interests that may be affected by the performance or nonperformance of the Director's official duties.

It may be noted that from information provided by the Committee, it appears that the Director issued a very time-limited "recusal" regarding the grantee/donor Arizona Cancer Center at the time of seeking ethics approval for receipt of the cash award. Recusals are generally required for conflict of interest purposes under 18 U.S.C. § 208 and OGE regulations, where the employee may not participate personally or substantially in any official matter which has a direct and predictable effect on the financial interests of the employee or on the financial interests of certain connected outside persons or organizations which may be attributable or "imputed" to the employee.³⁰ This recusal, however, does not necessarily resolve the conflict of interest questions regarding the status of a grantee of the agency with respect to the acceptance of a sizable cash "award" by the agency's Director from that agency grantee. In the first instance, the recusal appears to be an express recognition that the Center, as a grantee of the NCI, not only has or is seeking business before or action from the agency, but also has financial interests that might be expected to be affected in a direct and substantial way in the course of the normal functions and duties of the Director of the Institute, such that a recusal is necessary under criminal law and regulatory disqualification requirements.³¹ That is, the Center at the time of the award must have had interests which "may be substantially affected by the performance or nonperformance" of the Director's duties, since the recusal would not be necessary had it not had such interests.

²⁸ 42 U.S.C. § 285a-2.

²⁹ According to the NCI web-site (<http://www3.cancer.gov/mab/hnc1.htm>), the Office of the Director "(1) Serves as the focal point for the National Cancer Program; (2) develops a National Cancer Plan and monitors implementation of the plan; (3) directs and coordinates the Institute's programs and activities; and (4) develops and provides policy guidance and staff direction to the Institute's programs in areas such as program coordination, program planning, clinical care and administrative management."

³⁰ See 18 U.S.C. § 208, and OGE regulations at 5 C.F.R. §§ 2635.401 *et seq.*, 2635.501 *et seq.*

³¹ The Director's recusal paraphrases the precise standards under federal law, at 18 U.S.C. § 208(a), requiring that one "may not participate personally or substantially as a government employee in any matters affecting this organization" "Recusal from Participation in Matters Involving the Arizona Cancer Center," from Director, NCI, to Deputy Director for Extramural Research, NIH, December 17, 1999 [hereinafter Director's recusal letter].

Secondly, the executed recusal does not resolve the conflicts problem inherent in the particular "award," either theoretically or practically, as it is only a recusal for a very limited, short period of time, less than one month, or more if the expenses of the Director are still being paid for and "vouchered out" by the grantee organization.³² Recusing the Director momentarily from functions affecting the grantee, that is, only for that instant or period in time when the Director receives the money and expenses, does not resolve the conflict of interest problems of the status of the Center since such a limited "recusal" does not prevent the Director from making decisions in the future, immediately *after* accepting the large cash award, which may affect new grant applications, the renewal of existing grants, and the regular oversight, audit and regulation of activities relating to continuing grants and the continuing relationship of the Center with the Institute. Allowing the receipt of the cash award from the agency's grantee upon a momentary, temporary recusal fails to recognize that the NCI and the Center have a continuing relationship based on the continued performance of grant activities, contracts, the administration and regulation of such grant programs and research, future funding and programs, and the status and designation of the Center.

The fact that significant authority and decision making will be made by agency officials, such as the Director of the Institute, affecting the grantee organization prior to and after the receipt of the cash award, raises precisely the ethics and conflict of interest concerns at which the regulations and statutes on gifts and compensation from interested parties are focused. Such cash awards to those agency officials, such as the Director, with authority over grants and contracts with the private organization not only provide a potential lucrative "reward" for past official actions of which the grantee organization approves and is appreciative, but also provide an opportunity as a potentially generous "incentive" for future official conduct favorable to the grantee organization by that official and other agency officials who are potential, future "awardees." A time-limited, momentary "recusal" from official activities affecting the donor organization, just during that time when the official is receiving the cash award and the expenses from the grantee organization, might technically suffice for the criminal conflict of interest provision at 18 U.S.C. § 208, but for the purposes of the "awards" exemption to the standards of conduct regulations would arguably be a wholly artificial contrivance attempting an overly technical interpretation of the underlying conflict of interest for gifts, awards and compensation as only "momentary," ignoring the continual status of the private organization *vis-a-vis* the duties of the Director and the Institute, the general prohibition on gifts and compensation from interested sources, as well as traditional ethics principles.³³

From information and documents provided by the Committee, it appears that the Director completed an agency form seeking permission to receive the particular award in

³² "This disqualification will remain in effect until January 15, 2000 or later, if all associated financial transactions have not been completed by that date." Director's recusal letter, December 17, 1999.

³³ Exceptions to general prohibitions are usually to be interpreted *narrowly*, as the operable intent of the provision is stated in the general restriction and not the exceptions. *A.H. Phillips, Inc. v. Walling*, 324 U.S. 490 (1945); Singer, *Sutherland Statutory Construction*, 6th Ed., Vol. 2A, at §47.08. Note federal court discussion of reasonable time for recusals concerning non-current connections to and payments from private organizations, of one to two years, in *Center for Auto Safety v. F.T.C.*, 586 F.Supp. 1245 (D.D.C. 1984). See also OGE regulations concerning an official's connections to former private organizations requiring one year recusals, and recusals of two years with respect to organizations making "extraordinary" severance payments. 5 C.F.R. §§ 2635.502(a),(b)(1)(iv); 2635.503(b)(1).

question from the agency's grantee. The form provides a box to check where it appears that the official himself certifies that the donor organization does not have "interests that may be substantially affected by the performance or nonperformance of the employee's official duties." Although the form is also signed by an ethics officer in the agency, there is no indication from the form or accompanying materials that an independent determination or inquiry was made by the ethics official to verify the statement made that the grantee organization is one which does not have interests that could be substantially affected by the performance or nonperformance of the Director's official duties. Rather, the form appears to be a process of self-certification, subject to the temporary, one month recusal required for, apparently, other (18 U.S.C. § 208) purposes.³⁴

Furthermore, the official apparently also certified on the agency form that the recipients of the award are "chosen pursuant to written guidelines or by a selection committee." The regulations of OGE regarding the awards exception require that the selection criteria for recipients of the award be "made pursuant to written standards."³⁵ The regulations do not *expressly* provide that a "selection committee" satisfies the requirement for written criteria. Furthermore, the OGE regulations require that there is a "written determination by an agency ethics official" that the donor organization and the award meet these exception requirements. There is no indication or evidence from the materials presented by the Committee that any independent determination or review of criteria was made by an ethics official, nor is there evidence of a copy of any such written criteria for selection of the award submitted to the agency from which such determination could have been made, other than the self-certification statement of the existence of such criteria by the official who was to be the recipient of the award.

Travel and travel expenses associated with the acceptance of the "award" must also be disclosed. If accepted by the official for outside activities, such travel expenses must be disclosed on the public financial disclosure statement of the Director. The Financial Disclosure Form, SF 278, requires for travel related gifts and reimbursements, the "travel itinerary, dates, and the nature of expenses provided."

If the travel for the meritorious service award and speech by the Director were considered "official travel" by the agency, then the agency may be reimbursed by the organization, or the agency may authorize the employee to accept payment on the agency's behalf pursuant to 31 U.S.C. § 1353.³⁶ Travel expense may be reimbursed or paid by a private source expressly for travel in connection with an employee accepting an award for meritorious public service.³⁷

³⁴ It is possible that if the Director signed and submitted this statement attesting that the donor organization did not have interests that "may be substantially affected by" his official duties, and if, at the time of submitting the statement the Director knew, or should have known of the Center's status as a major grantee of his agency with obvious, vital interests in decisions and duties of the Director, then there is raised an issue of whether this submission might arguably involve a false or fraudulent writing in a matter under the jurisdiction of a federal agency, under 18 U.S.C. § 1001.

³⁵ 5 C.F.R. § 2635.204(d)(1)(ii).

³⁶ 31 U.S.C. § 1353(a).

³⁷ 31 C.F.R. § 304-1.2(c)(3)(iii).

Even where agencies have express statutory authority to receive gifts, or under 31 U.S.C. § 1353 to receive travel expenses from private sources, there still may be raised issues of conflicts of interest where the private source is regulated or doing business with the agency. Although not a violation of federal conflict of interest or gift law, such acceptance might raise similar considerations of potential influence, the appearance of influence or of a possible subtle diminution of impartiality that underlie the gift limitations for individual federal employees.³⁸ The principles of avoiding an appearance of loss of impartiality of a Federal agency itself, and the issue of agency self-imposed limitations (even where the agency has specific gift acceptance authority) on the acceptance of private gifts and reimbursements, which may be particularly relevant when that agency has regulatory or oversight functions, was discussed in a broad context by the Office of Government Ethics in an advisory opinion issued in 1986:

To avoid adverse appearances, we think you should consider imposing limitations on the use of the [agency's] gift acceptance authority. Under gift acceptance authority, the agency, rather than the employee, accepts the payment. As a result, the adverse appearances that are present when the employee accepts such a payment are not necessarily present when the agency itself is accepting the funds. Even so, we generally suggest that agencies avoid accepting reimbursements from organizations that do business with or are regulated by the agency. ... [W]here the offeror is a profit-making enterprise that stands to benefit financially depending upon the [agency's] comments, you might perceive the appearance as sufficient to preclude acceptance of travel expenses.

Another factor you might consider in determining whether to permit acceptance is the nature of the activity associated with the travel, and whether it is a statutory responsibility of the agency. ... Some agencies have more narrowly drafted gift acceptance statutes than [your agency's], which they use for the limited purpose of sending their employees to conferences, meetings, and seminars, attendance at which is not statutorily mandated. Even in those instances, agencies tend to avoid accepting payments of expenses from entities with whom the agency does business because of the possibility of an appearance of impropriety.³⁹

There are now Government-wide regulations which direct agencies not to approve private reimbursement for travel if acceptance "would cause a reasonable person with knowledge of all the facts relevant to a particular case to question the integrity of agency programs and operations."⁴⁰ In addition to considering the identity of the source, the purpose of the meeting, and the value and character of the travel expenses provided, the agency should consider in making such conflict of interest determinations the "nature and sensitivity

³⁸ The gift limitations and the prohibition on private salary supplementation are "aimed at preventing the Government employee from becoming beholden to anyone in the private sector who might affect the independence or judgment of that employee." Office of Government Ethics, Opinion 81 X 31, October 2, 1981, in *Informal Advisory Letters and Formal Opinions, 1979 - 1988*, at 210; see also discussion of the theory underlying the gift regulation in Federal Government concerning influences and having one's "independence undermined," in Paul H. Douglas, *Ethics in Government*, at 45 - 49 (Harvard University Press 1952).

³⁹ United States Office of Government Ethics, Letter Opinion 86 X 10, August 8, 1986, in *Informal Advisory Letters and Formal Opinions, 1979 - 1988*, at 643, 644-645.

⁴⁰ 41 C.F.R. § 304-1.5.

of any matter pending at the agency affecting the interests" of the non-federal source of payments and the significance of the employee's role in such a matter.⁴¹

Because of conflict of interest potential in such payments from outside, private sources, the agency must submit reports of payments accepted and authorized over a certain amount to the Director of the Office of Government Ethics no later than May 31 of each year, and must detail the nature of the meetings and expenses, the times and places of travel and other information. These reports are to be available for public inspection and copying.⁴² Any cash payments accepted "are credited to the appropriation applicable to such expenses."⁴³

⁴¹ 41 C.F.R. § 304-1.5(a)(1)-(6).

⁴² 31 U.S.C. § 1353(d). 41 C.F.R. § 304-1.9. For travel expenses over \$250.

⁴³ 31 U.S.C. § 1353(a).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

TAB 7

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

JUL 17 2003

The Honorable W.J. "Billy" Tauzin
Chairman, Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The Office of the General Counsel at the Department of Health and Human Services prepared the enclosed legal analysis in response to the issues raised by your June 26 letter regarding the receipt of lecture awards by NIH employees.

I would like to meet with both you and Mr. Greenwood at your earliest convenience to discuss this legal analysis and work together to address your concerns about policies regarding NIH personnel accepting lecture awards.

Sincerely,

A handwritten signature in black ink, appearing to read "Elias A. Zerhouni", written over a horizontal line.

Elias A. Zerhouni, M.D.
Director

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

JUL 17 2003

The Honorable James C. Greenwood
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Greenwood:

The Office of the General Counsel at the Department of Health and Human Services prepared the enclosed legal analysis in response to the issues raised by your June 26 letter regarding the receipt of lecture awards by NIH employees.

I would like to meet with both you and Mr. Tauzin at your earliest convenience to discuss this legal analysis and work together to address your concerns about policies regarding NIH personnel accepting lecture awards.

Sincerely,

Elias A. Zerhouni, M.D.
Director

Enclosure

**NATIONAL INSTITUTES OF HEALTH
OFFICE OF LEGISLATIVE POLICY AND ANALYSIS**

Fax Transmittal
Shannon Building, Room 244
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DATE: 7/17/03
TO: Alan Slobodan
FAX PHONE: 202-225-1919
FROM: Marc Amolonsky
SUBJECT: Responses to Reps. Tauzin and Greenwood
This transmittal contains 15 pages, including the cover sheet.

COMMENTS:

NOTE: The attached information may be confidential. It is intended only for the addressee(s) identified above. If you are not the addressee(s), or an employee or agent of the addressee(s), please note that any dissemination, distribution or copying of the communication is strictly prohibited. If you have received this fax in error, please destroy the document and notify the sender of the error. Thank you.

ANALYSIS OF ETHICS AND RELATED ISSUES CONCERNING THE RECEIPT OF
LECTURE AWARDS BY NATIONAL INSTITUTES OF HEALTH EMPLOYEES

This analysis addresses the issues raised in a letter dated June 26, 2003, from the House Committee on Energy and Commerce concerning the implementation of ethics requirements relating to prizes or lecture awards given to National Institutes of Health (NIH) officials and employees in recognition of meritorious public service or achievement.

The need to protect the public interest by ensuring that government decisions are not influenced by "kick backs" or rewards for official action is addressed principally by federal criminal statutes that proscribe bribery and illegal gratuities tied to official acts. 18 U.S.C. §§ 201(b)(2) and 201(c)(1)(B). Where an employee's actions fall short of criminal conduct, the concern about avoiding an "appearance of impropriety" is governed by detailed ethics standards against which the employee's conduct can be judged on an objective basis. 5 C.F.R. Part 2635.

At present, no law expressly bars an agency or component head from receiving a *bona fide* award from an outside entity merely because the donor is regulated by, does or seeks to do business with, or seeks official action from the agency or component that the intended honoree administers. The statutory ban on salary supplementation, 18 U.S.C. § 209; the regulatory bar on the receipt of compensation for speeches related to official duties, 5 C.F.R. § 2635.807; and the executive order that prohibits Presidential appointees to full-time, non-career positions from receiving "any earned income for any outside employment or activity," E.O. 12674, § 102(a), (April 12, 1989), are not applicable because the Department of Justice and the Office of Government Ethics have determined that *bona fide* awards, including the cash incident to such awards, are to be treated as *gifts* in recognition of meritorious public service or achievement rather than as *compensation* or *earned income* for delivering the speech that is routinely expected of the honoree at the award presentation.

Award Approval Standard. Gifts to executive branch employees are governed by 5 U.S.C. § 7353, which bars the solicitation or acceptance of anything of value from persons or entities defined as prohibited sources, subject to such reasonable exceptions as the supervising ethics office for the executive branch, by regulation, deems appropriate. The Office of Government Ethics implemented this statute in the Standards of Ethical Conduct for Employees of the Executive Branch at 5 C.F.R. Part 2635, Subpart B. These rules expressly permit employees to accept *bona fide* awards and cash incident thereto from most prohibited sources, e.g., contractors, grantees, regulated entities, applicants for governmental action, etc., including organizations a majority of whose members are of the enumerated type, *provided* that the award is determined by agency ethics officials to be part of an established program of recognition, as defined in regulatory criteria. 5 C.F.R. § 2635.204(d)(1). This exception to the prohibited gifts rule is unavailable, however, if the awarding entity is a special type of prohibited source, i.e., a person or entity who "has interests that may be substantially affected by the performance or nonperformance of the [award recipient's] official duties."

Interpretation of the Standard. The Office of Government Ethics has not formally opined on the meaning of the above quoted phrase. Although frequently cited by OGE when recounting the definition of a prohibited source, the phrase has not been the subject of detailed discussion. Commentary, where available, has tended either to elide over any distinctions among the various types of prohibited sources, conflate the concepts, or assume without analysis that a given donor had interests that could be affected substantially by the employee in discharging his official duties. See OGE 83 x 10 (July 26, 1983) ("you (referring to the addressee of the opinion letter) have stated that [the company] has interests which may be affected by the performance or non-performance of the duties of [the employee]") (applying rule then effective at 5 C.F.R. § 735.203(e)(3) which permitted acceptance of awards for a "meritorious public contribution or achievement" only if offered by organizations within enumerated civic, public, or eleemosynary categories). Absent specific OGE guidance, the interpretation utilized within the Department was premised on a detailed, internal analysis of the regulatory text, the substance of which is recounted below.

History and Analysis of Regulatory Text. The language currently found in the prohibited source definition at 5 C.F.R. § 2635.203(d)(4) and the awards exception at 5 C.F.R. § 2635.204(d)(1) can be traced to § 201(a)(3) of E.O. 11222 (May 11, 1965), the predecessor to E.O. 12674. The Civil Service Commission issued implementing regulations that incorporated the phrase in a prohibited gifts rule then codified at 5 C.F.R. § 735.202. When E.O. 12674 supplanted the Johnson Administration directive in 1989, the same phrase was carried forward in § 101(d) of the order and used by Congress in drafting the provisions of the gift statute, 5 U.S.C. § 7353. The OGE Standards at 5 C.F.R. § 2635.203(d) (1992) again restated the phrase by defining a "prohibited source" to include a person or entity who "has interests that may be substantially affected by the performance or nonperformance of the employee's official duties."

When drafting the *bona fide* awards rule for the 1992 executive branch-wide standards, OGE rejected the approach taken in the earlier conduct regulations which permitted acceptance of awards only from "a charitable, religious, professional, social, fraternal, nonprofit educational, recreational, public service, or civic organization." 5 C.F.R. § 735.203(e)(3) (1991). The new OGE Standards were designed to allow acceptance of all *bona fide* awards offered under an established program of recognition for meritorious public service or achievement, *provided* that the donor does not have "interests that may be substantially affected by the performance or nonperformance of the [award recipient's] official duties."

Without realizing that this provision contextually is an exception to a ban on gifts from prohibited sources, the reader might assume, after a cursory examination, that the prohibition on receiving awards from entities that have "interests that may be substantially affected by the performance or nonperformance of the employee's official duties" means that federal employees cannot accept *bona fide* awards from contractors, grantees, and regulated entities that have matters pending before their agency. As a matter of semantic logic, however, this is not the rule that OGE promulgated. Interpreting the quoted phrase simply to equate "those persons who have interests that the award recipient can affect substantially," on the one hand, with "contractors,

grantees, and regulated entities," on the other, would yield the tautological formulation that an employee is permitted to accept an award from a "prohibited source," provided that it is not from a "prohibited source." The caveat to the exception to the prohibition perform must have a different meaning.

To ascribe meaning to the provision and avoid the tautology, an entity that "has interests that may be substantially affected by the performance or nonperformance of the employee's official duties" must be a special type of prohibited source, i.e., one that poses potentially severe appearance problems, not one that merely is seeking official action by, does business or seeks to do business with, or conducts activities regulated by the employee's agency.

In assessing whether the award donor is the special type of prohibited source, a parsing of the regulatory text suggests several inquiries. First, from the use of the present tense verb in the phrase "has interests," one may infer that the intended award recipient must ascertain whether, at the time of the acceptance of the award, the offeror then presently has any interests arising out of pending controversies or other matters, beyond the general fact that the entity receives grants or contracts or is regulated by the agency. In essence, the regulation suggests a temporal qualifier. Drawing on the parallel provision governing honorary degrees, timing would appear to be a significant factor. See 5 C.F.R. § 2635.204(d)(2) (honorary degree from a university may be accepted if the timing of the award of the degree would not cause a reasonable person to question the employee's impartiality in a matter affecting the institution). The text suggests a bright line, snap shot focus on the situation at the time of acceptance of the award. If the offeror had pending matters in the past and may have them in the future, then the offeror would simply be a "garden variety" prohibited source from which *bona fide* awards legitimately could be accepted.

Given the otherwise circular logic of a contrary interpretation, the text leads one to conclude that the rule forbids *bona fide* awards in circumstances where there is "something on the official's plate," e.g., where grant application papers are on the desk for approval, or allegations of impropriety have arisen and the official must decide to order an investigation. Awards tendered when the official knows, or has reason to believe, that such matters are pending elsewhere in the agency, but will reach his or her "in-box" in the reasonably foreseeable future, would be similarly proscribed. Conversely, mere speculation that such matters might arise in the future would appear insufficient to bar the award.

The next inquiry suggested by the regulatory text involves the nature of the employee's official duties. The phrase refers to entities that have interests that may be substantially affected by the *performance or nonperformance of the employee's official duties*. The rule is not drafted so as to refer to entities that have interests that may be substantially affected by *matters to which the employee is assigned or for which the employee has official responsibility*. Thus, to ascertain whether the award recipient can substantially affect a pending matter through action or omission (as opposed to merely possessing ultimate authority), the reviewer would inquire whether the duties of the position normally encompass handling the types of matters that are pending? For example, a key question would be whether final sign-off authority on a pending grant application

previously had been assigned to another agency official under a pre-existing delegation. If, as an organizational matter, the intended award recipient normally is uninvolved in the quotidian details of grants administration, then the pendency of a grant matter within the agency would render the donor a mere “prohibited source” as to the intended award recipient. (An employee would not be permitted, of course, to accept an award if the employee, after learning of the award, purposely delegated or reassigned work to avoid responsibility for the pending matter.)

The regulatory language also requires an assessment whether the actual exercise of the official duties assigned to the position would *substantially* affect the identified pending interests of the award donor. For example, ministerial acts carrying out decisions mandated by law or effectuating completed decisions made by others or rendered prior to tender of the award might not be deemed by themselves to have affected substantially the resolution of a pending matter. On the other hand, actually making the final decision, no matter how perfunctory the review, would be of significance to the matter. Moreover, in order to “substantially affect” the offeror’s interests, the text suggests that an employee’s exercise of assigned duties must have more than a *de minimis* impact on the interest involved. For example, a decision on a general regulation that modestly increases paperwork for all grantees might not have a substantial impact on any one grantee, depending on all the circumstances.

Status or Position. The inquiries suggested by the regulatory text apply equally to all employees. The text does not appear to warrant applying a different rule for agency or operating division heads. The Office of Government Ethics, as the author of the regulation, clearly knew how to treat certain classes of employees differently, often by employing extremely complex definitional criteria (e.g., outside earned income limitations in 5 C.F.R. § 2636.303 are expressly applicable to Presidential appointees in positions classified above GS-15 of the General Schedule or, in the case of positions not under the General Schedule, for which the rate of basic pay is equal to or greater than 120 percent of the minimum rate of basic pay for GS-15, that are either: (1) appointees paid under the Executive Schedule, 5 U.S.C. §§ 5311-5318; (2) non-career appointees to the Senior Executive Service; or (3) confidential or policy-making Schedule C equivalents; *see also* 5 C.F.R. § 2641.201 which defines “senior” and “very senior” employees for purposes of the post-employment prohibition, 18 U.S.C. § 207, on representational contacts to the employee’s former agency, known as the one-year “cooling-off” period). Given that the awards rule is not similarly crafted, the omission of any qualifying language relating to status or position has interpretive significance. *See Rusello v. United States*, 464 U.S. 16, 23 (1983), *citing United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972) (“where Congress [or other legislative or regulatory body] includes particular language in one section of a statute [or regulation] but omits it in another section of the same [law], it is generally presumed that [the drafter] acts intentionally and purposely in the disparate inclusion or exclusion”).

One example that demonstrates an application of the awards rule is that employees in a division or unit of an agency whose official duties are not concerned with grants could accept a *bona fide* award from a grantee, albeit a prohibited source as to the agency as a whole, because their assigned work will have no impact on the grantee. However, nothing in the regulatory text

suggests that this situation is the only one to which the awards exception would apply. Moreover, because the employees in this example do not have official responsibility for grants as a general proposition, there never would be a circumstance in which a grant matter would be placed before them for deliberation. Thus, the example provides no interpretive assistance in resolving the fundamental dichotomy between a view that equates the dispositive phrase with the mere possession of superintending responsibility for matters handled by others and an interpretation, based on the foregoing analysis of the regulatory text, that inquires whether the employee actually, rather than derivatively through status or position, has matters pending before him for imminent disposition.

Without recapitulating the circular nature of the former interpretation, it suffices in support of the latter to underscore that if OGE had intended to write a rule that prohibited agency or component heads from receiving awards from entities that have, or may have, matters pending under their official responsibility, either individually or before subordinates, it need have looked no further for operative language than its own regulations implementing the predecessor to 18 U.S.C. § 207(a)(2), the two-year “official responsibility” ban on post-employment representation, and the definitions in 18 U.S.C. § 202. See 5 C.F.R. § 2637.202(b) (“official responsibility” is defined as “the direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct Government actions”).

Nobel Prize Paradigm. An example in the OGE Standards following 5 C.F.R. § 2635.204(d)(1) is often cited for the basic proposition that *bona fide* awards can be accepted by federal employees:

Example 1: Based on a determination by an agency ethics official that the prize meets the criteria set forth in § 2635.204(d)(1), an employee of the National Institutes of Health may accept the Nobel Prize for Medicine, including the cash award which accompanies the prize, even though the prize was conferred on the basis of laboratory work performed at NIH.

In the context of evaluating awards tendered by prohibited sources, this example provides no interpretive assistance. Rarely, if ever, would the Nobel Foundation have matters pending before the NIH or any other agency of the United States Government. The import of the example is twofold: (1) to demonstrate that a monetary award can be accepted by the NIH employee even though medical research and science are, in a broad sense of the word, “interests” of the Nobel Selection Committee which are affected by his work; and (2) to emphasize that *bona fide* awards that are tied directly to accomplishments in the federal workplace are permissible gifts and not compensation, within the meaning of the salary supplementation ban, 18 U.S.C. § 209, for services rendered to the NIH.

Appearance of Impropriety. Recourse to the aspirational principle that employees shall endeavor to avoid even the appearance of impropriety, enunciated in E.O. 12734, § 101(n), and restated in

the OGE Standards at 5 C.F.R. § 2635.101(b)(14), is equally unavailing for interpretive purposes. The awards exception to the prohibited gifts rules, like the other exceptions contained in 5 C.F.R. § 2635.204, was drafted by OGE in such a way that "the exception itself addresses major appearance concerns." 57 Fed. Reg. 35006, 35012 (August 7, 1992). Some may consider it imprudent—as a matter of personal moral standards or simply to avoid an adverse "perception" under the often cited "front page of the *Washington Post*" test—to accept an award offered by a prohibited source. Nevertheless, according to OGE, acceptance of a *bona fide* award under the exception is "deemed not to violate" the ethical principles upon which the Standards are premised, including appearances. 5 C.F.R. § 2635.204. The impetus for drafting detailed, even admittedly legalistic, conduct rules was precisely to place reasonable and intelligible limits on the potentially boundless scope of an "appearance" standard that invites inconsistent and subjective interpretation.

Awards Form. The interpretation and evaluative factors discussed above for determining whether an awarding entity "has interests that may be substantially affected by the performance or nonperformance of the [award recipient's] official duties" were disseminated department-wide to the Deputy Ethics Counselors in the operating divisions and other agency components in 1998. An award approval form was developed which: (1) educates potential award recipients concerning the applicable law; (2) places a burden on the applicant to evaluate seriously those matters that are pending before him; (3) requires the applicant to attest to the factual circumstances at issue; (4) focuses the attention of the reviewers to each element of the regulatory requirements; and (5) provides written documentation of the disposition of the approval request.

To the extent that the approval form leads one to conclude that awards are permitted solely on self-certification, that impression is incorrect. Ethics officials evaluate the criteria within their purview on a case-by-case basis. However, it would be impractical for reviewers in effect to "look over the shoulder" and "cast an eye" on the desk of every award applicant to learn at any given moment what assignments or matters were before them. Accordingly, the form does rely to a significant degree on the applicant's truthfulness and good faith. Absent a significant increase in administrative resources for agency ethics programs, this procedure would appear to be the only alternative.

Safe Harbor. Turning specifically to Dr. Richard Klausner's situation, he was individually advised of the factors used to evaluate whether the awarding entity "has interests that may be substantially affected by the performance or nonperformance of [his] official duties." On each awards form, he attested to the fact that no such matters were pending at the time of the award or in the foreseeable future. In making his certification, he would have been permitted to rely on the interpretive factors disseminated within the Department. The fact that Dr. Klausner presided over a grant-making entity in and of itself would not have been disqualifying under the interpretation rendered at that time. Unless Dr. Klausner was untruthful or failed to disclose to the ethics officials all relevant circumstances, the award approval by the Designated Agency Ethics Official (DAEO) or the DAEO's authorized representatives provides a safe harbor under

which Dr. Klausner could not be disciplined, were he an employee, or otherwise be deemed to have violated the ethics rules. 5 C.F.R. § 2635.107(b).

Recusal. Recusals can be required if there is an actual conflict of interest under the criminal statute, 18 U.S.C. § 208, or an “appearance of a conflict” resulting from, *inter alia*, a “covered relationship,” as defined in the impartiality standard, 5 C.F.R. § 2635.502. In the award situation, an employee arguably has a financial interest in receiving the money incident to the award. However, given the donative, as opposed to contractual, context, the prospective award recipient may not have a legal right to the funds that is sufficient to create a financial interest within the meaning of section 208. Nevertheless, assuming for purposes of argument that the statute applies, a recusal obligation would arise only with respect to official participation in a particular matter that would directly and predictably affect the ability of the donor to meet its financial commitment to pay the funds. Rarely would such a matter exist; essentially, the matter would have to send the donor into bankruptcy for the recusal to apply. Accordingly, the criminal conflict of interest statute generally is not implicated in the awards context.

The employee’s interest in receiving an approved monetary award, however, does create a “covered relationship” with the awarding entity within the meaning of 5 C.F.R. §§ 2635.502(a) and (b)(1)(i) (a financial relationship that involves other than a routine commercial transaction). During the pendency of any outstanding payments or travel reimbursement that are incident to the award, employees are required to recuse from official participation in any particular matter involving specific parties in which the awarding entity is a party or represents a party, if a reasonable person with knowledge of the relevant facts likely would question the employee’s impartiality in the matter. Notably, this recusal obligation applies only to “specific party matters,” such as contracts, grants, audits, investigations, lawsuits, or similar matters that involve identified parties, and not to “particular matters of general applicability,” such as legislation, regulations, policies, or other general matters that are focused on the interests of a discrete and identifiable class of persons. Moreover, the recusal obligation exists only during the pendency of the “covered relationship” that initially engendered the disqualification. Recusals triggered by awards last only from the time the employee receives notification of the award until such time as any and all financial transactions associated with the award are completed. Receiving an award and delivering a speech at the event do not constitute employment or consultation and hence do not create a “covered relationship” within the meaning of 5 C.F.R. § 2635.502(b)(1)(iv), the provision that imposes a one year retrospective inquiry when determining the duration of a recusal as to specific party matters involving only the relationships enumerated therein. In other words, there is no legal basis to impose a one year recusal following the receipt of an award.

As noted previously, by regulation, employees do have a narrow recusal obligation as to specific party matters involving the donor as a party or party representative during the pendency of the award. Employees may choose to memorialize in writing their obligation to disqualify themselves from certain matters. Recusal documents executed by federal officers or employees do not represent “admissions” by those employees that matters involving the entity named therein are presently pending before the signatory, and they should not be interpreted as such. Recusal

memoranda represent only an employee's written memorialization of his obligation to recuse. There is no requirement that such writing be prepared. *See* 5 C.F.R. § 2635.402(c) ("disqualification is satisfied by not participating in the particular matter"). Rather, certain employees choose to prepare recusal memoranda for two basic purposes: (1) to communicate to staff that *if* matters involving or affecting the named entity arise that normally would come to the signing official, they should be diverted to an alternate; and (2) to alert the official who would instead receive the matter (but who, otherwise, would not) as to the basis for the change in processing so that government business is not delayed unnecessarily. To avoid confusion and delay, and for the protection of the employee and the integrity of agency programs and operations, an employee's obligation to recuse is addressed, to the extent possible, *before* matters arise.

Travel. Under the authority of 31 U.S.C. § 1353 and the implementing regulations of the General Services Administration (GSA), 41 C.F.R. Part 304-1 (citations are to regulations in effect prior to June 16, 2003, when the new "plain English" version codified at 41 C.F.R. Parts 304-1 through 304-9 became effective; *see* 68 Fed. Reg. 12602), agencies are permitted to accept payment from a non-federal source for the travel, subsistence, and related expenses of a government official to attend, while in travel status, "any meeting or similar function relating to the official duties of the employee." 41 C.F.R. § 304-1.2. Meetings and similar functions are defined to include "[a]n event at which the employee will receive an award or honorary degree, which is in recognition of meritorious public service that is related to the employee's official duties, and which may be accepted by the employee consistent with the standards of conduct regulation." 41 C.F.R. § 304-1.2(c)(3)(iii).

Although an award is based on individual achievement and considered a personal gift governed by the OGE Standards, any travel benefits associated with the award that are provided by non-federal sources to the agency under authority of 31 U.S.C. § 1353—whether provided in kind or through reimbursement—are deemed gifts to the agency and not to the employee personally. As such, acceptance of travel, lodging, meals, and other subsistence expenses from non-federal sources are submitted for advance approval on an HHS Form 348. The Department reports these payments on a semi-annual basis to OGE. 41 C.F.R. § 304-1.9. Employees who file financial disclosure reports are obligated only to report travel gifts and reimbursements personally received by them during the reporting period. Where, as may be the case of official travel to an award event, the agency accepts the payment, employees are not required to disclose separately the reimbursement on their own financial disclosure reports. *See* 5 C.F.R. § 2634.105(n)(3) note and § 2634.304(c).

Agencies generally are required to assess whether acceptance of a non-federal source payment for travel would cause an informed, reasonable person to question the integrity of agency programs or operations. This analysis is guided by a non-exclusive list of relevant considerations, such as (1) the monetary value and character of the tendered benefits; (2) the identity of the parties; (3) the nature and sensitivity of any pending matter affecting the interests of the payor; and (4) the significance of the traveling employee's role in the matter. 41 C.F.R. § 304-1.5. When

this regulation was initially promulgated, GSA specified in the explanatory preamble that the rule was not intended to bar agency acceptance of payment from non-federal sources merely because such entities were “prohibited sources” within the meaning of the OGE Standards applicable to gifts to employees. 57 Fed. Reg. 53283, 53286 (November 9, 1992). Rather, the rule was meant to preclude agency acceptance of travel reimbursement from a contractor, grantee, or regulated entity when a request for agency action or other matter involving that entity *as a party* is pending and the traveler is the very official before whom the matter is lodged for disposition. *Id.* Thus, the GSA travel reimbursement rule evaluates whether the traveling employee’s actual exercise of official authority with respect to an extant matter involving the payor is sufficiently proximate in time and organizational location within the agency decision-making process to warrant denial of the reimbursement. This analysis is similar to that under the awards rule, but it is more permissive in that acceptance is precluded only when those pending matters are of the “specific party” variety and involve the payor as a party.

The comments section to the GSA rulemaking document contains several examples that illustrate the various distinctions in the travel reimbursement context:

[W]e did not amend the rules to prohibit acceptance of payment from a “prohibited source,” as suggested by at least one comment. ... In the case of official travel that the agency determines to be in furtherance of its mission, we do not believe that acceptance of payment should be precluded solely on the basis that the non-Federal source seeks official action on some matter from someone at the agency. Thus, in connection with an Army Assistant Secretary’s speech on the topic of reductions in force, given at an Army contractors’ convention, we do not believe that the agency’s acceptance of payment from the contractor should be precluded solely because the non-Federal source happens to have a contract with some component of the Army. ... [P]ayment [should not be accepted] from the company if the Assistant Secretary was then serving as the source selection official for a procurement involving that contractor as a competitor. ... On the other hand, it might be appropriate for the National Institutes of Health to accept a large pharmaceutical association’s offer to fund a scientist’s trip to a conference on AIDS even if the scientist was at the time performing experiments in relation to a promising new drug developed by a company that belongs to the association. Similarly, acceptance of payment from a trucking industry association might be authorized in the case of a Department of Transportation attorney who is asked to address the association concerning the interpretation of a regulation that he/she drafted and that is applicable to the entire industry.

57 Fed. Reg. 53286-53287.

The GSA regulations also expressly provide that “nothing in ... part [304-1] prohibits an agency or employee from accepting payment ... when consistent with the applicable standards of ethical conduct regulation concerning personal acceptance of gifts.” 41 C.F.R. § 304-1.8(a).

Accordingly, if the awards rule in the OGE Standards permits the employee to accept the underlying honor and monetary reward, then the agency derivatively may accept the travel-related benefits incident thereto, without the need to evaluate separately the factors specified in section 304-1.5 (although the analysis required under the latter cited rule parallels that of the former to a significant degree).

In the case of lecture awards offered to NIH officials based upon their meritorious public service or other achievement, their receipt of the award and participation in the award event is, as noted in the travel reimbursement regulations, deemed to be related to their official duties. This nexus or "relatedness" permits agencies to authorize the honoree to attend in a government travel status and, when delivering the lecture, to speak in his or her official capacity about agency business. Although the honor and any money incident to the award are personal in nature and premised on meritorious public service or achievement already accomplished, the travel rule recognizes that the award lecture provides an opportunity for the dissemination of an official message to appropriate audiences,

Interpretative Options. The issue of whether the awards rule could be interpreted differently to apply a more rigorous standard for future application to agency or component heads ultimately is a matter for OGE deliberation. Given the concerns raised about this issue, OGE may well choose a different approach. Neither the Department nor NIH can resolve definitively the interpretive issue posed. By way of background, the relevant authorities and jurisdiction are recounted below.

Following recommendations of the President's Commission on Federal Ethics Law Reform, President George H. W. Bush issued the seminal ethics directive, E.O. 12674, that established the framework for evaluating the conduct of federal employees. The Office of Government Ethics was ordered to formulate a uniform set of ethical standards for the entire executive branch, thereby preempting the field of agency regulation of employee conduct. The Standards of Ethical Conduct for Employees of the Executive Branch, 5 C.F.R. Part 2635, promulgated on August 7, 1992, and made effective on February 3, 1993, were the result.

Federal departments and agencies were authorized to issue, jointly with OGE approval, supplemental ethics regulations to establish prior approval procedures for outside activities, to impose prohibited financial holdings requirements, and to address ethics issues unique to the programs and operations of the respective agencies. However, to ensure executive branch uniformity with respect to the core ethics requirements, OGE does not permit agencies unilaterally to impose ethics requirements that are more restrictive than the OGE Standards. For example, the OGE gift rules provide that an employee can accept a gift from a prohibited source valued at \$20 or less. The Department and NIH are bound by this exception and cannot impose an inconsistent policy that reduces the dollar threshold to zero if the Department or NIH were so inclined. In assessing the propriety of accepting awards from an outside source, both the Department and NIH are similarly required to implement the OGE rules as interpreted by duly authorized ethics officials, until such time as OGE revises the regulation or provides definitive guidance.

/17/2003 THU 16:28 FAX 3014960840

0014

Although instituting an NIH policy banning "lecture awards" *per se* might have the salutary effect of removing any perception whatsoever that the recipient has been or may be influenced by the donor, agencies are not permitted to prohibit that which the OGE Standards may permit. Moreover, even if NIH were afforded such latitude, the costs in terms of recruitment and retention of eminent scientists at the NIH may be considerable. NIH scientists assert an important governmental interest in receiving recognition for contributions to medical research or other meritorious public service or achievement and in being offered the opportunity to deliver prestigious lectures associated with these honors. Apart from employee morale, the enhanced credibility and standing of NIH scientists before their peers in academia advances considerably the interests of the Government in demonstrating leadership in scientific research, disseminating critical information to appropriate audiences, and attracting the most qualified scientists to public service. That monetary stipends attach to many lecture awards is considered a recognized and permitted practice within the research community.

Prudential Concerns. That said, as the OGE gift rules cogently state, "[e]ven though acceptance of a gift may be permitted by one of the exceptions ..., it is never inappropriate and frequently prudent for an employee to decline a gift offered by a prohibited source or because of his official position." 5 C.F.R. 2635.204. The various awards for Dr. Klausner were approved, either under the signatures of the DAEO or those of Deputy Ethics Officials acting under his authority. The approvals were based on factual information, to which the applicant attested, regarding whether matters involving the donor were presently or imminently before the applicant for disposition. Supporting documentation, as appropriate, was reviewed to verify that the awards were made "as part of an established program of recognition: (1) under which awards have been made on a regular basis or which is funded, wholly or in part, to ensure its continuation on a regular basis; and (2) under which selection of award recipients is made pursuant to written standards [or a selection committee]. 5 C.F.R. § 2635.204(d)(1) (the bracketed phrase is an interpretive gloss approved by OGE whereby the evaluation of candidates by a selection committee may provide the functional equivalent of written standards). The reviewers approved awards in technical compliance with the criteria and in accordance with the extant legal interpretation inasmuch as employees have the right to have their conduct judged against objective criteria. Dr. Klausner was counseled concerning the precise legal nature of the approval. Employees are routinely advised whether their proposed conduct is legally permissible, but each individual remains ultimately responsible for assessing whether adverse public perception or the potential for controversy would counsel against accepting that which the law may permit.

July 11, 2003

MAR-05-2004 FRI 02:31 PM OFFICE GENERAL COUNSEL

FAX NO. 412 624 1606

P. 05



UNIVERSITY of PITTSBURGH
MEDICAL CENTER

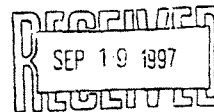
Department of Surgery

September 18, 1997

TAB 8

300 Kaumann Building
3471 Fifth Avenue
Pittsburgh, PA 15213-3221
412-692-2652
Fax: 412-692-2520

George Michalopoulos, M.D., Ph.D.
Interim Dean, School of Medicine
Chairman and Professor, Department of Pathology
200 Lothrop Street
University of Pittsburgh Medical Center
S410 B.S. Tower
Pittsburgh, PA 15261



George K. Michalopoulos, M.D., Ph.D.
Department of Pathology

Dear Dr. Michalopoulos,

We have met on three separate occasions of the late Spring and Summer to consider candidates for the upcoming Dickson and Mellon awards. I would like to summarize our deliberations and present our nominations for these two important awards below. The Dickson lectureship is a well supported series, which has engaged some of the best and brightest of American scientists. Many of these individuals have gone on to win major national awards. We considered a variety of individuals from several fields and these included James Allison, Günter Blöbel, Floyd Bloom, James Darnell, Stephen Elledge, David Ho, Richard Horwitz, James Ihle, Mario Capecchi, Richard Klausner, Richard Kolodner, James Rothman, Erkki Ruoslahti, Robert Tjian, and Don Wiley. This number of outstanding candidates made our work difficult but it was clear that a majority of the committee were in favor of Richard Klausner, a prominent physician and scientist involved in the study of protein packaging and transport, the T-Cell receptor chains, and suppress ocomogene. He is currently Director of the National Cancer Institute. I have inquired at the NCI and it is clear that he is capable of receiving this award. It was the feeling of the Committee that early December would be the best time to highlight him and have his presentation, if he is available. Furthermore, we believe that it would be worthwhile to insure a broad participation in his two lectures and to invite local press as well as members of the Dickson Foundation.

Our candidates for the Mellon award, which we believe would be best setup for the Spring of this next year in March or April, included Mina Bissell, Henry Bourne, Pierre Chambon, Mary-Claire King, Michael Phelps, Klaus Rajewsky, Randy Scheckman and Richard Tsien. After our meeting yesterday, it became clear that Mina Bissell was our number one candidate. She has studied interaction of epithelial cells with the cell matrix and gives an outstanding and energetic lecture. Again appropriate planning between your office, the committee and the office of special events should begin coordinating these lectures as soon as possible to realize their greatest benefit for the University and its' scientists and clinicians.

MAR-05-2004 FRI 02:31 PM OFFICE GENERAL COUNSEL

FAX NO. 412 624 1606

P. 06

George Michalopoulos, M.D., Ph.D.
September 18, 1997
Page 2

I would be happy to answer any questions regarding our selections, please let me know if there is anything that I might further do to develop the process for these two lectureships.

With warm personal regards.

Sincerely yours,



Michael T. Lotze, M.D.
Professor of Surgery, Molecular Genetics and Biochemistry
Chief, Section of Surgical Oncology
University of Pittsburgh Medical Center
Co-Director, Biological Therapeutics, UPCI
Co-Director, Human Gene Therapy Program
Phone: 412-383-9000
Fax: 412-624-1172
E-mail: Lotze@pittsburg.nb.upmc.edu

Enclosure

- CV of Dr. Klausner
- CV of Dr. Bissell



cid-0001
University of Pittsburgh

CC: Mike

TAB 9

School of Medicine
Department of Molecular Genetics and Biochemistry
Office of the Chairman and William S. McElroy
Professor of Biochemistry

E1246 Biomedical Science Tower
Pittsburgh, Pennsylvania 15261
412-648-8105
Fax: 412-624-6824
E-mail: joe@server1.mgen.pitt.edu

September 30, 1996

Richard D. Klausner, M.D.
Chief, Cell Biology & Metabolism Branch
National Institute of Child Health &
Human Development, NIH
Building 18, Room 101
Bethesda, MD 20892-0001

Dear Dr. Klausner:

It is indeed a great pleasure for me to inform you that you have been selected as the recipient of this year's annual Dickson Prize award. This prize is given to the country's most outstanding scientific leaders whose contributions to their fields have had a very significant impact on progress in medical research. The Dickson Prize is the University's most prestigious scientific achievement award in which the recipient also receives a very substantial honorarium and will be our guest at an awards banquet and lecture. I have enclosed a list of past recipients and you can readily see that you are in distinguished company. Congratulations on your outstanding achievements and we would be very pleased if you would accept the 1996 Dickson Prize.

Sincerely,

Joseph C. Glorioso, Ph.D.
Chair, Dickson Prize Committee

TAB 10



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FILE

*Klausner: this*National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

October 1, 1996

TO: Richard Klausner, M.D., Director, NCI

FROM: Maureen O. Wilson, Ph.D., Deputy Ethics Counselor, NCI

SUBJECT: Recommendation Regarding the Dickson Prize

I have reviewed the situation surrounding the Dickson Prize offered by the University of Pittsburgh and addressed to you as Chief, Cell Biology and Metabolism Branch, NICHD. It is my recommendation that you decline acceptance of the award based on the reasons below.

The University of Pittsburgh is a grantee, contractor and cooperative group trial participant funded by the NCI. Under these circumstances, the University is clearly a prohibited source as defined by the Office of Government Ethics Standards of Conduct at 5 CFR 2635.203 (d):

...any person who:

- (1) Is seeking official action by the agency;
- (2) Does business or seeks to do business with the agency;
- (3) Conducts activities regulated by the agency;
- (4) Has interests that may be affected by the performance or nonperformance of the employee's official duties;

This is reaffirmed in the Supplemental Standards of Conduct for Employees of the Department of Health and Human Services issued July 30, 1996 at 5 CFR 5501.102 which redefines prohibited sources to represent those persons or organizations doing business at the NIH level. The NIH Manual 2300-735-4 on "Outside Work, Financial Interest and Related Activities," also clearly states that it is NIH policy not to accept awards from organizations, the interests of which may be affected by the performance or non-performance of an employee's official duties.

Although you, as Director, NCI, do not actually sign either grants or contracts, you are the ultimate responsible party for all of the Institute's activities, unless you have disqualified yourself from matters involving a specific party. Because the Institute is currently a co-defendant with the University in a suit brought by Dr. Bernard Fisher, it

000025

JEFF: DI: AERUX TELECOPIER 7021 110- 4-96 : 8:51 : 3014021506- 22528:# 3

Page 2 - Richard Klausner, M.D.

would be inappropriate for you to be disqualified from dealing with the University of Pittsburgh. Therefore, it is difficult for you to accept the award in your official capacity and it is clearly inappropriate for you to accept the award as an outside or personal activity as the University both does business with us and is seeking action from the Institute and thus, from you as its director.


Maureen O. Wilson, Ph.D.

cc: Dr. Kirschstein, Deputy Director and DEC, OD, NIH

000026

TAB 11

File w/ Klausner
Dickson AreaUNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE
DICKSON PRIZE AND MELLON LECTUREDICKSON PRIZE IN MEDICINE

Established in 1969 by the estates of Joseph E. Dickson, MD, and Agnes Fischer Dickson to be awarded to a person (or persons) in the medical field "who has made the most progress in the United States for the year in question."

Restricted to U.S. citizens

Late autumn, early winter

MELLON LECTURE

Established in 1915 by Richard B. Mellon for one or more lectures annually in the field of biomedical sciences.

Spring

PROCEDURE FOR SELECTION

- 1) The dean of the School of Medicine appoints a selection committee
- 2) Nominations are solicited from faculty members of the School of Medicine and previous awardees (optional)
- 3) Committee makes recommendations to the dean (letter summarizes the decision process - meetings, nominations, committee members - and states the reasons for the selection)
- 4) The dean calls the awardees; formal letter of invitation is sent by the president
- 5) Health Sciences Special Events office coordinates the visits

Rank

7/88

000068

Post-it Fax Note	7571	Date	04-90	Page	3
To	Mieko	From	Mieko Gile		
Co./Dept.		Co.	Univ. of Pitt.		
Phone #		Phone #	212-448-8106		
Fax	301-407-7200				

TAB 12

file
Dr. Klausner**Russell-Einhorn, Michele**

From: Russell-Einhorn, Michele
To: Edgar M. Swindell; Jack Kress; 'Karen Santoro'; Linda Conte; Rick Thomas; Stan Olesh
Subject: FW: Dickson Award for Dr. Klausner
Date: Monday, October 07, 1996 1:51PM

Here is the message I sent to Jake Wilson. I spoke with Don Williams who conferred with Stuart Ricks. I asked Don specifically whether the issue is that at the time the award is offered the University has the conflicting interests--Don asked Stuart this and Don thought yes this is the issue. I also asked Don if a disqualification would work and he said Stuart said it would not work. He then called Stuart to get a better answer, got back on the phone with me and said Stuart confirmed that a disqualification would not work but was not so clear why. Stuart did, however, very definitely state that on the basis of the information given to him, Klausner could not accept the award from Pittsburgh.

Such is the wisdom from OGE.

From: Russell-Einhorn, Michele
To: Wilson, Maureen
Subject: Dickson Award for Dr. Klausner
Date: Monday, October 07, 1996 1:48PM

I just received a phone call from the Office of Government Ethics regarding whether Dr. Klausner may accept the Dickson Award from the University of Pittsburgh. The Office of Government Ethics said that he could not accept the award because at the time the award was offered to him the University of Pittsburgh had interests that could be substantially affected by the performance or non-performance of the employee's official duties. Given the current litigation involving NCI, the University and Dr. Fisher, the recent audit by NCI regarding costs charged to contracts by the University and the fact that the University is a grantee, OGE felt that all of these were more than sufficient to indicate that the University has interests that could be affected by the performance or non-performance of the duties of the Director of NCI.

442

TAB 13

Santoro, Karen

From: Santoro, Karen
Sent: Tuesday, September 02, 1997 12:56 PM
To: 'eswindel@os.dhhs.gov'
Subject: Dr. Klausner

I spoke to the Phil Amarusso and Susan Sherman to clarify Dr. K's role in the NCI disbursment of the settlement monies to the University. It is my understanding that DOJ will offer a letter verifying the amount and the terms that NCI agreed to and that Dr. Klausner would not be required to sign anything in this respect.

I have not heard anything further about the Dixon/University relationship. I will follow up before my afternoon meeting.

*Karen Santoro
Office of the General Counsel, Ethics Division
(301) 402-2576*

TAB 14

she called OGE ^{for MCE} for back-up

breast cancer lawsuit
settlement just announced

Fisher dismissed suit against NIH

she would not have approved it

cooling off → need one
year

have they
filed
papers
in
court?

call Pat Krochak

? actual dismissal

on heels of litigation

~~Fisher~~
Shuman

call E &
OGE back-up

at salary
engagement of Univ

Fisher still affiliated
w/ Univ

Distinguished Professor
w/ Univ → she
no compensation

case now
dismissed
not agreed
to pay \$25,000
attorney to Fisher

need for
statute confirmation
MCE
dismissal signed

not yet resolved
written to J. says in
sub 000036

TAB 15

September 2, 1997

Note to Harriet Rabb

Attached is information documenting last year's determination for Dr. Klausner regarding the Dickson Prize. Note that all the information provided to us refers to the prize as the University of Pittsburgh's award. We will have to make inquiries into the exact relationship between the Dickson Foundation and the University in this matter. Despite the foundation's presumably separate legal status, there may be co-extensive directors, merged decision-making, or other factors indicating that the foundation and the university are one and the same for the purpose of this award. As a consequence, I cannot assure you, at this point, that the award can be approved.

This is not a matter committed to ethics officials for advice only, but rather the regulations condition lawful acceptance of the award on the written determination of an agency ethics official. Within certain parameters, the regulations allow receipt of awards from prohibited sources as an exception to the gift rules, provided that the award is not from a specific type of prohibited source, i.e., one that presently has "interests that may be substantially affected by the performance or nonperformance" of the employee's official duties. 5 C.F.R. § 2635.204(d).

Assuming that an award from the Dickson Foundation is, in substance, an award from the University of Pittsburgh, acceptance would be possible provided that there are no pending matters or controversies involving the University of Pittsburgh that Dr. Klausner can affect substantially through the performance or nonperformance of his official duties. Merely regulating university research generally or having general superintendence over the NCI "grants to universities" process usually would not preclude receipt of the award, as such responsibilities typically do not entail matters likely to have a substantial effect on a university's interests. However, the pendency of litigation, as earlier, or investigations, audits, specific pending grant applications, or other similar matters (including possibly the execution and enforcement of the settlement agreement or reimbursement issues with the university, should they claim the monetary figure they paid to Dr. Fisher is an overhead cost attributable to a federal grant) would likely bar acceptance.


(The Office of Government Ethics was consulted on last year's determination, and OGE determined that a potential award recipient cannot remove the award prohibition by simply recusing from those matters involving the award donor that he could affect substantially.)

000012

If Dr. Klausner were to assure affirmatively that there were no longer any pending matters involving the university that he could affect substantially through the performance or nonperformance of his official duties, then the award potentially could be authorized as a legal matter. (Note that if an employee were to err and fail to make a full disclosure of all relevant circumstances, then the "safe harbor" protective effect of an advance authorization would be lost.)

Awards received personally must be reported on the SF 278 Public Financial Disclosure Report. As a Presidential appointee, Dr. Klausner's SF 278 is one usually sought in blanket requests by the press and political organizations.

I wanted to apprise you of the various issues that we will need to address in considering the possible receipt of the award. I will let you know when I receive further information on the Dickson Foundation.


Ed Swindell

000013

TAB 16

Phil Amarusso
NCI
John Hartinger

\$300,000

something to
present to Office
of Financial
Management that
would issue
payment OFM

→ Susan Skerman x 66043

offering letter from DOT to verify
NCI payment
not requiring Dr. Kausner
to sign anything
unless DOT says otherwise

per
Phil

some reference to NCI needed

note to OFM

NCI authorizes payment

letter from DOT ok w/his
office

000040

TAB 17

case against / St. Luke
Montreal

GC will be getting to
translating
complete the day

Still pending
NCI asking for settlement

Fisher participating in this aspect
as well

* Susan

letter
concerning the R. ...
still needed / 45 days

under agreement
Pittsburg is paying total sum of \$F

(NCI) is writing check to University
financial
person at the Institute

Tom Hunter CD
65803

Dr. Klausner orally approved that
payment

check can be issued by another person
or by wire transfer

000041

TAB 18

To : Edgar M. Swindell@OGC.IO@OS.DC
Cc :
Bcc :
Subject : harriet rabb@OGC.IO@OS.DC
Date : re: Dr. Klausner update
Date : Thursday, September 4, 1997 at 12:38:47 pm EDT
Attach :
Certify : N
Encrypt : N

As I understood an earlier conversation, even if Dickson and Pitt are associated, this may not be a bar if there's no personal participation by Dr. Klausner in the ongoing settlement implementation process rising to the level of impermissible in statutory terms. Is that correct?

000045

TAB 19

To : harriet rabb@OGC.IO@OS.DC
 Cc :
 :
 : Edgar M. Swindell@OGC.IO@OS.DC
 Subject : re: Dr. Klausner update
 Date : Thursday, September 4, 1997 at 1:18:29 pm EDT
 Attach :
 Certify : N
 Encrypt : N

FBI Kanan,
 This is the
 request?
 communication
 I have had to date
 with Harriet
 on the Klausner
 issue. Ed

 Not precisely. OGE earlier advised that if there is a pending matter or controversy in which the potential award donor has interests that may be substantially affected by the performance or nonperformance of the employee's official duties, then the award cannot be accepted and the potential prize recipient cannot escape the prohibitive effect of the rule by recusing or not participating in those matters. The focus of the gift rule is on whether there is a correlation between the matter and the responsibilities or duties of the official to whom the gift is offered, irrespective of whether that official actually exercises his or her authority over the matter. (This is in contrast to financial conflicts rules which do focus on actual participation vel non.) The only means by which the award could be received, assuming Dickson and Pittsburgh are effectively the same, is for there to be assurances that, at present and at a time in close temporal proximity to the award ceremony, there is no pending matter or controversy particularized to that university that falls within the ambit of the NCI Director to affect substantially. I, of course, do not know if there are other matters involving the University of Pittsburgh, but, at least with respect to the Fisher litigation, one could see that current settlement execution and implementation issues are ministerial and administrative tasks assigned to lower level officials in comparison with the decision in which Klausner did participate, i.e., approval of the settlement agreement. When we have more information, I would be pleased to discuss this matter with you at your convenience.

000046

TAB 20

Santoro, Karen

From: eswindel@os.dhhs.gov[SMTP:eswindel@os.dhhs.gov]
Sent: Thursday, September 11, 1997 7:46 AM
To: ks172s@NIH.GOV
Subject: re: Re: Dixon Prize

Comments by : Edgar M. Swindell@OGC.IO@OS.DC
 Date : Thursday, September 11, 1997 11:46:04
 Forwarded to : INTERNET[ks172s@NIH.GOV]
 Comments:
 I talked with Harriet, and we decided, based on Klausner's response, to cease all actions on this matter for now.

=====

Forwarded to: Edgar M. Swindell@OGC.IO@OS.DC
 cc:
 Comments by: harriet rabb@OGC.IO@OS.DC

----- [Original Message] -----

>So, what should we do at this moment? Wait to see if the award is given?
 >Settle now that the award can/can't be accepted so the effort to decide
 >whether to make the award isn't bootless? Please let me know what would be
 >best in the circumstances.

Why don't we wait.
 Rick

451

TAB 21

Santoro, Karen

From: eswindel@os.dhhs.gov[SMTP:eswindel@os.dhhs.gov]
Sent: Wednesday, October 01, 1997 10:21 AM
To: Santoro, Karen
Subject: re: Dickson Prize

Karen, do not do anything with respect to Klausner until you speak to me first.



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health

TAB 22

Maureen O. Wilson, Ph.D.
 Assistant Director
 Deputy Ethics Counselor
 National Cancer Institute
 31 Center Drive MSC 2473
 Building 31, Room 4A48
 Bethesda, Maryland 20892-2473

Phone: 301-496-1148
 FAX: 301-402-1508
 E-mail: wilsonm@31b4.nci.nih.gov

October 1, 1997

TO: Richard Klausner, M.D., Director, NCI

FROM: Maureen O. Wilson, Ph.D., Deputy Ethics Counselor, NCI

SUBJECT: Dickson Prize

I spoke with Diane Moore of the Dean's Office, University of Pittsburgh, who provided the additional information regarding the Dickson Prize.

1. Dickson is not a foundation in the traditional sense, it is a bequest bound by conditions limiting its use to the award of the Dickson Prize.
2. The bequest is held by a bank and the award is made from the interest accrued.
3. The process for selecting the awardee is attached but fundamentally it is as follows:
 - a. The Dean of the School of Medicine appoints a selection committee which is not formally limited to members for the University of Pittsburgh staff, but has not included members outside that staff.
 - b. The committee obtains nominations from faculty and from previous awardees.
 - c. The committee makes a formal recommendation (selection) to the Dean.
 - d. The Dean officially notifies the winner of the award.

Although the formal legal decision will be at Harriet Rabb's level, I would have the following concerns:

1. The bequest was made to the University of Pittsburgh and, although formally restricted by the conditions of the bequest, the money is Pittsburgh's to award.
2. As there is no foundation, but simply a bank account, we can not formally separate the business structure of the Dickson Foundation from the University of Pittsburgh and must look at the selection process and its level of independence from the University. Clearly because the selection committee appears to all be drawn from Pittsburgh staff, we can not distinguish between the University and the Foundation.

000065

October 1, 1997

3. The award is then considered to be made by a committee composed of Pittsburgh staff from funds in which the University has a financial interest.
4. The resultant conflict of interest issues to be overcome, then include:
 - a. The conflict of interest arising from the status of the University, as a grantee of the NCI, awarding to you a not insubstantial monetary prize and your ability, as the Institute Director, to continue to play an indirect, but dominant, role in all assistance/contract award efforts including those made to the University of Pittsburgh.

The conflict of interest involving the University as a grantee could be overcome by the issuing of a waiver under 18 USC 208(b)(1) to permit you to continue your official role in the assistance/contract award process, recognizing the basis of the award as your scientific achievements and not your association with the NCI. As you know, your waivers must be approved at the Secretary's level, so the legal basis to issue such a waiver would clearly be established at that level.

- b. The real or apparent conflict of interest issues to be overcome relating to the recent litigation between the University, the NCI, and Dr. Fisher, which resulted in the formal restoration of an official title with the University and Dr. Fisher's ability to participate in the application for federal funds and have access to data developed through federally funded efforts. The NCI agreement to consider Dr. Fisher for appointment to an NCI advisory committee, a Special Government Employee appointment, also must be evaluated in this context.


The issues created by the recent litigation are more nebulous, because they involve obligations incurred by the NCI to permit Dr. Fisher's continued access to data and ability to participate in the grant/contract application/award process which, of necessity, involve the University of Pittsburgh and other grantees/contractors in fulfillment of those obligations. Given that the litigation was only recently settled, the major issue to be overcome is the appearance that the NCI agreed to cooperate with Pittsburgh to settle the litigation, including the monetary payments as well as other tangibles and intangibles, and that this award is being made as a result of that agreement. It is the prerogative of the Department to authorize acceptance of the award despite this appearance and to document the basis for the decision in the context of the associated waiver.

Realizing that we are exploring your ability to accept an award not yet made, had this question occurred at least 12 months post settlement, a generally acceptable cooling off period, the implications that the decision to award derived from NCI's cooperation in the litigation would be of less concern; a waiver would still be required because the award is being made by a grantee, but the burden of justification would be less.

000066

October 1, 1997

For your information, however, I will point out that it is clearly the decision of your appointing authority, now identified as The Honorable Donna Shalala, to grant you the necessary waiver and authorizations under 18 USC 208(b)(1) to continue to execute your full responsibilities as Director, NCI, and to accept the award for your personal scientific achievements. The decision would have to be based on the premise that acceptance of such an award by a prominent federal personality is in the public health interest despite any public perception of conflict of interest, and that such an award would not be deemed to influence the integrity of your performance of official duty responsibilities. This decision can be made if it is the Department's position that public opinion and, therefore, the ability of the Department to carry out its public health responsibilities are not adversely affected. Please contact me if you have additional questions.



Maureen O. Wilson, Ph.D.

000067



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

TAB 23

Office of the General Counsel
Washington, D.C. 20201

October 7, 1997

MEMORANDUM

TO: Richard Klausner, M.D.
Director
National Cancer Institute
National Institutes of Health

FROM: Edgar M. Swindell *Edgar M. Swindell*
Acting Associate General Counsel for Ethics
Designated Agency Ethics Official

SUBJECT: Dickson Prize in Medicine

Summary

This memorandum is in response to your inquiry whether you may accept the Dickson Prize in Medicine offered by the University of Pittsburgh annually to an individual in the medical field "who has made the most progress in the United States for the year in question." As more fully discussed below, I conclude that you may accept this award and the monetary stipend associated therewith, provided that, at the time of your acceptance, the University of Pittsburgh has no current interests associated with matters pending before you that may be substantially affected by the performance or nonperformance of your official duties.

Instructions

As a Presidential appointee, you may accept the award only upon the written authorization of the Designated Agency Ethics Official (DAEO). This Office has developed the attached standard form for that purpose. The form requires that you supply information concerning the award, append appropriate documentation, check the appropriate boxes sequentially as indicated, and sign and date the form. Your signature attests to the accuracy of each statement and provides the factual basis upon which the DAEO must rely in approving the award under the gift regulations in the Office of Government Ethics (OGE) Standards of Ethical Conduct, 5 C.F.R. § 2635.204(d). In particular, your affirmative assurance that Statement 2 in Part II of the form is correct will be determinative. Because the legal standard in Statement 2 requires some explanation in order for you to answer factually, this memorandum will outline the factual background, explain in detail the legal requirements governing acceptance of awards, and analyze the options thereunder.

000075

Factual Background

The Dickson Prize in Medicine was established in 1969 by the Estates of Joseph E. Dickson, M.D., and Agnes Fischer Dickson to be awarded to the person in the medical field "who has been judged by the University of Pittsburgh ... to have made the most progress [in the United States] for the year in question." The will of each individual provided for the creation of a testamentary trust, the corpus of which was to be invested by the Mellon Bank, as successor trustee, and one-half of the annual income distributed to the prize recipient. (The prize currently carries a stipend in the range of \$30,000.) By court order in 1987, the respective trusts were combined into a single trust denominated the Dickson Foundation, which, according to the trustee, is exempt from federal income tax under Internal Revenue Code section 501(c)(3) and qualifies as a private foundation under section 509.

As structured, the trustee maintains an investment account, the profits of which are disbursed at the direction of the University of Pittsburgh. The Dean of the School of Medicine appoints a selection committee. Nominations are solicited from faculty members and, optionally, from previous awardees. The committee makes written recommendations to the Dean, detailing the procedures to which the committee adhered in the decision process and providing justification for the selection. The formal invitation is tendered by the President of the University.

Legal Authorities

Prizes that reward federal employees constitute items of value that must be subjected to scrutiny under specific statutory and regulatory rules. Subject to certain exceptions, a criminal provision, 18 U.S.C. § 209, prohibits both the offer and acceptance of salary supplementation from non-federal sources as additional compensation for the services rendered by federal employees to the Government. The Department of Justice has consistently held, however, that the statute "applies only to payments made or received with the intent to compensate for Government services and that the requisite intent cannot be inferred from the bestowal upon a Government official of a bona fide award for public service or other meritorious achievement." See OGE Informal Advisory Opinion (OGE Op.) 92 X 7; OGE Op. 83 X 11 (and Department of Justice opinion letters cited therein at footnote 2).

A civil statute, 5 U.S.C. § 7353, prohibits any federal employee from soliciting or accepting anything of value from persons or entities defined as prohibited sources of gifts, subject to such reasonable exceptions as the supervising ethics office for the executive branch deems appropriate. The Office of Government Ethics implemented this statute in the Standards of Ethical Conduct at 5 C.F.R. Part 2635, Subpart B.

Under the regulations, the basic rule is that a federal employee shall not, directly or indirectly, solicit or accept a gift: (1) from a prohibited source; or (2) given because of the

000076

Page 3 - Richard Klausner, M.D.

employee's official position. Prohibited sources are defined as any person or entity which:

- (1) Is seeking official action by the employee's agency;
- (2) Does business or seeks to do business with the employee's agency;
- (3) Conducts activities regulated by the employee's agency;
- (4) Has interests that may be substantially affected by the performance or nonperformance of the employee's official duties; or
- (5) Is an organization a majority of whose members are described [above in lines (1) through (4)].

5 C.F.R. § 2635.203(d).

Awards from most types of prohibited sources can be accepted, however, under certain conditions. The regulations provide, in pertinent part, as follows:

Gifts with an aggregate market value in excess of \$200 and awards of cash or investment interests offered by [a person who does not have interests that may be substantially affected by the performance or nonperformance of the employee's official duties] as [bona fide] awards or incidents of [bona fide] awards that are given for [meritorious public service or achievement] may be accepted upon a written determination by an agency ethics official that the award is made as part of an established program of recognition:

- (i) Under which awards have been made on a regular basis or which is funded, wholly or in part, to ensure its continuation on a regular basis; and
- (ii) Under which selection of award recipients is made pursuant to written standards.

5 C.F.R. § 2635.204(d)(1). However, as the above language indicates, awards may not be accepted from prohibited sources that have interests that may be substantially affected by the performance or nonperformance of an employee's official duties.

Analysis

Based on information provided by the University of Pittsburgh, the Dickson Prize in Medicine clearly satisfies the criteria for a bona fide award for meritorious public service or achievement made as part of an established program of recognition. However, the prize may not be accepted if the offeror is a person or entity which has interests that may be substantially affected by the performance or nonperformance of the official duties assigned to the position of National Cancer Institute (NCI) Director.

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In order for you to exclude this possibility (and, thus, be able to check the block on Part II of the Award Review Form indicating that Statement 2 is correct), we must first identify the offeror. For these purposes, I must conclude that the award is being tendered by the University of Pittsburgh. Although the trust that generates the stipend incident to the award may have a separate legal existence, this "foundation" has no independent officers, but rather a trustee whose sole function is investment of the corpus. Moreover, the selection of the award recipient and the disposition of the trust annual income, which are akin to exercising a power of appointment, are controlled by the University. Indeed, invitations to past award ceremonies refer to the Dickson Prize as being "awarded annually by the University of Pittsburgh." To conclude otherwise would elevate form over substance.

Therefore, in order to accept the award, you must assure that the University of Pittsburgh has no interests that may be substantially affected by the performance or nonperformance of your official duties. In interpreting this regulatory test, one might argue that, as a component head, you cannot accept awards from any entities that have business before the organization you administer. This is simply not the case. To interpret the regulation in this manner would mean that virtually any prohibited source would be an impermissible donor. Thus, a provision which purports to provide an exception to the ban on gifts from prohibited sources would, in effect, only restate the basic rule that an employee cannot accept a gift from a prohibited source. To give meaning to this provision in a manner that does not lead to absurd results, it is clear that an entity that "has interests that may be substantially affected by the performance or nonperformance of the employee's official duties" is a special type of prohibited source, i.e., one that poses potentially severe appearance problems, not one that merely is seeking official action by, does business or seeks to do business with, or conducts activities regulated by your agency. See 57 Fed. Reg. 35005, 35017-18 (August 7, 1992) (limitations on awards from persons affected by the employee's duties added to ethics standards to deal with appearance problem).

In assessing whether the award donor is the special type of prohibited source, the regulatory test focuses on several inquiries. First, keying on the present tense verb "has," we must ask whether, at the time of the acceptance of the award, the offeror presently has any interests arising out of pending controversies or other matters, beyond the general fact that the entity receives grants or contracts or is regulated by the agency. In essence, the test has a temporal qualifier; timing is a significant factor. Compare 5 C.F.R. § 2635.204(d)(2) (honorary degree from a university may be accepted if the timing of the award of the degree would not cause a reasonable person to question the employee's impartiality in a matter affecting the institution). Moreover, the rule suggests a bright line, snap shot focus on the situation at the time of acceptance of the award. If the offeror had pending matters in the past and may have them in the future, then the offeror is simply a "garden variety" prohibited source from which bona fide awards may be accepted. The rule forbids such awards in circumstances where there is "something on the official's plate," e.g., where grant application papers are on the desk for approval, or allegations of impropriety have arisen and the official must decide to order an investigation. Similarly prohibited would be awards tendered when the

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official knows, or has reason to believe, that such matters are pending elsewhere in the agency, but will reach his "in-box" in the reasonably foreseeable future. On the other hand, mere speculation that such matters might arise is insufficient to bar the award.

The next inquiry involves the scope of the employee's official duties. Does the position description normally encompass handling the types of matters that are pending? For example, is final sign-off on a pending grant application delegated to another agency official?

Finally, the test inquires whether the exercise of the official duties assigned to the position would substantially affect the identified pending interests of the offeror. For example, ministerial acts carrying out decisions mandated by law or effectuating completed decisions made by others or rendered prior to tender of the award might not be deemed by themselves to have substantially affected the resolution of a pending matter. On the other hand, serving as the final deciding official, no matter how perfunctory the review, would be of significance to the matter. Moreover, in order to "substantially affect" the offeror's interests, an employee's duties must have more than a de minimis impact on the interest involved. For example, a decision on a general regulation that modestly increases paperwork for all grantees might not have a substantial impact on any one grantee, depending on all the circumstances.

You will need to apply this interpretive guidance to your own situation. I have not been apprised of any pending matters involving the University of Pittsburgh that would be disqualifying in your case. The University of Pittsburgh most likely receives grants from NCI; but unless there is a specific grant application or performance controversy pending, and you would normally be involved in approving or deciding the matter, this fact would not preclude receipt of the award. I am aware of the recent settlement of the lawsuit filed by Dr. Bernard Fisher against the University of Pittsburgh and NCI, but have been advised that any outstanding obligations under that agreement flow only from NCI to Dr. Fisher and from the University to Dr. Fisher respectively. I understand that, for purposes of administrative convenience, the University cut one check to Dr. Fisher which included both the University's own financial obligation to Dr. Fisher under the settlement agreement as well as attorneys' fees which the federal defendants agreed to pay to Dr. Fisher. The University will be entitled to reimbursement for its having advanced the federal defendants these funds. I do not know if the reimbursement check has been paid; but in any event, I do not view this as a pending matter that you can affect substantially, but rather a routine, and already approved, transaction to be handled by funds disbursement officials.

If the award is approved and matters requiring your participation subsequently arise involving the University, the ethics rules would not require you to decline the honor. However, during the period between acceptance of the award and the later of the award ceremony or the final receipt of all monetary items associated with the award (including the stipend and any travel reimbursement), you must adhere to the recusal obligations specified in 5 C.F.R. § 2635.502(a)(1). Specifically, you would be deemed to have a "covered relationship" with the University of Pittsburgh for the duration of any period during which financial obligations

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to you remain outstanding. Section 502 requires that, under circumstances where a reasonable person would question your impartiality, you must disqualify yourself from participation in any particular matters involving specific parties in which the University of Pittsburgh is a party or represents a party to the matter.

Conclusion

Based on information provided to me, and assuming that you answer affirmatively Part II, Statement 2, of the Awards Review Form, the University of Pittsburgh presently would not appear to have any extant matters that would require your participation in a manner that would substantially affect its interests. In order to approve the award, I will need your assurance that my understanding is correct. Please complete the attached form and forward the original to my attention at Room 710-E Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201. If you should have any questions, please call me at (202) 690-7258.

Attachment

000080

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Prepared by: OGC/ETHICS:ems:klausner.mem:10/7/97
Subject Matter: Awards and Honorary Degrees; Gifts

000081

TAB 24

Dr. Klausner

10/10/97

for ES

accept award
decline \$

pending matters
could not get award

can treat as WAG
plague

he must pay for cost of Pitts trip
WAG does not permit travel expenses

substantive speech?
could he paid for Govt.

§1353 conflict analysis

meal

do not use form

not considered an award

→ get copy of Secretary's memo

FAX

9-6875

000085

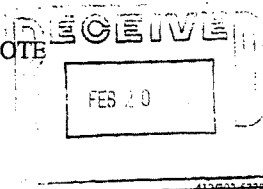
MAR-05-2004 FRI 02:32 PM OFFICE GENERAL COUNSEL

FAX NO. 412 624 1806

P. 07

LAW OFFICES OF
DICKIE, MCCAMEY & CHILCOTE

A PROFESSIONAL CORPORATION
 TWO PPG PLACE, SUITE 400
 PITTSBURGH, PENNSYLVANIA
 15222-5402
 TEL. 412/281-7272
 FAX. 412/392-5367
 WWW.DMCLAW.COM

TAB 25

Wilbur McCoy Otto
 Attorney-at-Law

412/392-5280
 otto@dmclaw.com

Direct Fax: 412/392-5566

February 18, 2004

Alan Garfinkel, Esq.
 General Counsel
 University of Pittsburgh
 1710 Cathedral of Learning
 Pittsburgh, PA 15260

VIA FAX & US Mail

RE: Bernard Fisher, M.D. v. University of Pittsburgh, et al

Dear Alan:

We have now thoroughly reviewed our case files in reference to the above matter incidental to the requests set forth in Congressman Greenwood's letter dated 2/2/04 directed to Chancellor Nordenberg.

We have summarized below our responses referencing each of the questions addressed in Congressman Greenwood's:

- 1) a) The U.S. Government did not contribute any more money towards the Fisher case settlement beyond the \$300,000;
- b) To our knowledge the \$300,000 paid by the U.S. Government did not in any way result from any reallocation of nor subtraction from any NIH or NCI grant, contract or other funds for the University of Pittsburgh;
- 2) There are no records in our files, nor do we have any recollection of any reference whatsoever to a Dickson Prize in Medicine [nor any other prize or award];
- 3) After searching all case records - including those dated between 8/1/95 and 8/27/97 - no records or documents have been covered which relate or refer to any communication between the University of Pittsburgh and NCI or NIH relative to any litigation involving Dr. Fisher.

Please do not hesitate to contact us further if you should have any additional questions.

Thanks kindly.

Sincerely,

Wilbur McCoy Otto

WMO:bg
 Enclosure

NOTE: We have also enclosed herewith a copy of the 2/2/04 letter with my responses to each of the questions hand noted.

From: Slobodin, Alan
Sent: Friday, May 14, 2004 3:49 PM
To: Washington, Ann; Hemard, Casey; Nelson, David; McNiece, Jessica
Subject: FW: draft recommendations

-----Original Message-----

From: Flamberg, Gemma (NIH/OD) [mailto:FlamberG@OD.NIH.GOV]
Sent: Friday, May 14, 2004 3:20 PM
To: Slobodin, Alan
Cc: Smolonsky, Marc (NIH/OD)
Subject: FW: draft recommendations

Per your request.

-----Original Message-----

From: Gottesman, Michael (NIH/OD)
Sent: Thursday, April 22, 2004 7:24 PM
To: Ruiz Bravo, Norka (NIH/OD); Barros, Colleen (NIH/NIA); Kington, Raynard (NIH/OD); Skirboll, Lana (NIH/OD)
Cc: Kawazoe, Robin (NIH/OD); Kutkat, Lora (NIH/OD)
Subject: RE: draft recommendations

Basically, yes. Advising can be to NIH grantees, non-NIH grantees, and to the University itself in a variety of capacities. Consulting can be contractors who work for universities in various ways. There are a variety of governance boards at many universities (overseers, trustees, alumni councils, etc.).

Michael

From: Skirboll, Lana (NIH/OD)
Sent: Thursday, April 22, 2004 1:17 PM
To: Gottesman, Michael (NIH/OD); Ruiz Bravo, Norka (NIH/OD); Barros, Colleen (NIH/NIA); Kington, Raynard (NIH/OD)
Cc: Kawazoe, Robin (NIH/OD); Kutkat, Lora (NIH/OD)
Subject: RE: draft recommendations

I have been following this discussion and I agree that we may have a definition problem. What kinds of consulting with universities might there be:

t/s/w

Advising

5/14/2004

FW: draft recommendations

Page 2 of 5

Boards of trustees?

What others?

Lana

Lana Skirboll, Ph.D.

Director, Office of Science Policy, NIH

Bldg 1, Room 103

301-496-2122

301-502-1759 (fax)

Lana_Skirboll@nih.gov

-----Original Message-----

From: Gottesman, Michael (NIH/OD)

Sent: Thursday, April 22, 2004 10:08 AM

To: Skirboll, Lana (NIH/OD); Ruiz Bravo, Norka (NIH/OD); Barros, Colleen (NIH/NIA); Kington, Raynard (NIH/OD)

Cc: Kawazoe, Robin (NIH/OD)

Subject: RE: draft recommendations

I guess we need to be clearer about what we mean by "consulting" with universities. If this means giving a public talk and then meeting privately with various scientists to discuss science, this is the essence of current scientific exchange and should not be discouraged. If it means serving on a university advisory committee to give advice about getting NIH grants, then this is obviously a problem. Once again, the answer is very specific to the activity.

Michael

From: Kington, Raynard (NIH/OD)

Sent: Thursday, April 22, 2004 9:52 AM

To: Gottesman, Michael (NIH/OD); Skirboll, Lana (NIH/OD); Ruiz Bravo, Norka (NIH/OD); Barros, Colleen (NIH/NIA)

Cc: Kawazoe, Robin (NIH/OD)

Subject: Re: draft recommendations

Nope - re IM scientists having outside activities with academia, I am not talking about t/s/w with academia but rather consulting with universities. Re the 1-year rule. It may have been an NIH practice and even an NIH rule, but it (in my mind) clearly was not consistent with OGE rules. I think that at the very least that

5/14/2004

FW: draft recommendations

Page 3 of 5

distinction should be noted by the panel.

Raynard S. Kington, M.D., Ph.D.

Deputy Director, NIH

KingtonR@od.nih.gov

301-496-7322

-----Original Message-----

From: Gottesman, Michael (NIH/OD) <MGottesman@nih.gov>

To: Skirboll, Lana (NIH/OD) <SkirbollL@od1tm1.od.nih.gov>; Ruiz Bravo, Norka (NIH/OD) <ruizbran@od.nih.gov>; Barros, Colleen (NIH/NIA) <BarrosC@nia.nih.gov>; Kington, Raynard (NIH/OD) <KingtonR@OD.NIH.GOV>

CC: Kawazoe, Robin (NIH/OD) <KawazoeR@od.nih.gov>

Sent: Thu Apr 22 09:32:35 2004

Subject: RE: draft recommendations

Raynard,

If you are saying that our intramural scientists cannot give talks and receive honoraria from any NIH-funded universities (assuming the honoraria don't come from NIH funds), then I must respectfully disagree. This is precisely the kind of activity which keeps scientists in the mainstream of current research and I believe the BRP wants to preserve this kind of activity, which always involves very modest honoraria. Many of these activities are done now as official duty, which is also fine, but this is mostly because people want to talk freely, in an academic, public environment, about their current work.

With respect to the one-year rule, there was considerable trans-NIH discussion of this when it was first promulgated by Steve Benowitz, including several discussions at SD meetings. This was a clear rule that everyone could understand and it was widely disseminated through the ICs. To say that the rule "never existed" would ignore this history. Virtually every intramural scientist uses this as a rule of thumb when they give talks as part of outside activities.

Michael

From: Kington, Raynard (NIH/OD)

Sent: Thursday, April 22, 2004 9:03 AM

To: Skirboll, Lana (NIH/OD); Gottesman, Michael (NIH/OD); Ruiz Bravo, Norka (NIH/OD); Barros, Colleen (NIH/NIA)

Cc: Kawazoe, Robin (NIH/OD)

5/14/2004

FW: draft recommendations

Page 4 of 5

Subject: Re: draft recommendations

Two comments:

1. I think the BRP does not understand that in some IC's there is not a bright line between intra and extramural (eg, epi program at NCI). Also, I simply do not buy the notion that intramural scientists do not have greater access to the inner thinking of their IC than a scientist at X university, especially schools that are not in the old boys network. I think (and I think many outside people would agree) that our IM scientists should not consult with universities and other institutions that are funded by us (which - correct me if I am wrong - appears to me would be allowable under their proposed rules).

I think that allowing IM scientists at the base of the pyramid to consult for pay with academia presents at least the appearance of allowing certain (wealthy presumably) schools an unfair advantage in applying for funds.

2. They got it wrong again on page 12. Current rules do not allow t/s/w if the work has been completed within a year. That is a myth and they need to correct that. It was the practice in some IC's but that is not the actual rule. The rule is based on whether the subject relates to the current work of the employee.

Raynard

Raynard S. Kington, M.D., Ph.D.

Deputy Director, NIH

KingtonR@od.nih.gov

301-496-7322

-----Original Message-----

From: Skirboll, Lana (NIH/OD) <Skirboll@od1tm1.od.nih.gov>

To: Gottesman, Michael (NIH/OD) <MGottesman@nih.gov>; Ruiz Bravo, Norka (NIH/OD) <ruizbran@od.nih.gov>; Kington, Raynard (NIH/OD) <KingtonR@OD.NIH.GOV>; Barros, Colleen (NIH/NIA) <BarrosC@nia.nih.gov>

CC: Kawazoe, Robin (NIH/OD) <KawazoeR@od.nih.gov>

Sent: Tue Apr 20 10:12:33 2004

Subject: draft recommendations (BRP)

ask and yee shall recieve -- here are the current recommendations. Please do not share them with others. If you feel you must, please let me know. I need to track who has what when.

Lana

Lana Skirboll, Ph.D.

Director, Office of Science Policy, NIH

5/14/2004

FW: draft recommendations

Page 5 of 5

Bldg. 1 Room 103, 9000 Rockville Pike, Bethesda, MD 20892

301-496-2122 (phone); 301-402-1759 (fax)

Lana_Skirboll@nih.gov


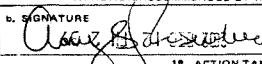
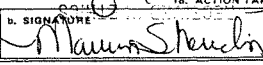
TAB 27

REQUEST FOR APPROVAL OF OUTSIDE ACTIVITY*

(Ref.: HHS Standards of Conduct Regulations)

- ☒ Initial request
☐ Revised Request
☐ Renewal

1. NAME (Last, First, Initial) PETRICON, EMANUEL F	2. ORGANIZATIONAL LOCATION (Operating Division, Bureau, Division) DTP/OTRR CBE R/BD, 4
3. TITLE OF POSITION SENIOR INVESTIGATOR	4. GRADE AND SALARY (Federal) TITLE 42
5. NAME, ADDRESS AND BUSINESS OF PERSON OR ORGANIZATION FOR WHOM OUTSIDE SERVICES WILL BE PERFORMED 810SPECT, INC. 951 GATEWAY BLD. SUITE 900 FREDERICK, MD 21701	6. LOCATION WHERE SERVICES WILL BE PERFORMED
7. NATURE OF ACTIVITY (Indicate type of activity, e.g., teaching, consultative services, and give full description of specific duties or services to be performed. Specify, when possible, the scheduled days of week and hours of day proposed activity will be performed.) Consulting services limited to scientific expertise on complex biological mixture analysis, predictive identification of target biological states by predictive analysis of biological tissues and fluids.	

8. ESTIMATED TIME INVOLVED	
a. PERIOD COVERED FROM October 1, 2002 TO October 1, 2004	b. ESTIMATED TOTAL TIME DEVOTED TO ACTIVITY (If on a continuing basis, give estimated time per year) 4 DAYS / MONTH
c. WILL WORK BE PERFORMED ENTIRELY OUTSIDE USUAL WORKING HOURS? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF "NO," INDICATE ESTIMATED NUMBER OF HOURS OR DAYS OF ABSENCE FROM WORK 1 DAY / MONTH Will take annual leave for all time absent	
9. DO YOUR OFFICIAL DUTIES RELATE IN ANY WAY TO THE PROPOSED ACTIVITY? <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES (Describe) Invited because of my scientific expertise	
*10. IF PROVIDING CONSULTATIVE OR PROFESSIONAL SERVICES, ARE YOUR WOULD-BE ASSOCIATES RECEIVING OR WILL THEY SEEK, A GRANT OR CONTRACT FROM A FEDERAL AGENCY? <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES (Describe)	
11. METHOD OR BASIS OF COMPENSATION <input checked="" type="checkbox"/> FEE <input type="checkbox"/> HONORARIUM <input type="checkbox"/> PER DIEM <input type="checkbox"/> PER ANNUM <input type="checkbox"/> ROYALTY <input type="checkbox"/> EXPENSES <input type="checkbox"/> OTHER (Specify)	12. WILL COMPENSATION BE DERIVED FROM A HHS GRANT OR CONTRACT? <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES (Describe)
13. THIS REQUEST IS MADE WITH FULL KNOWLEDGE OF DEPARTMENT AND OPERATING DIVISION POLICY AND PROCEDURES ON OUTSIDE ACTIVITIES. THE STATEMENTS I HAVE MADE ARE TRUE, COMPLETE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF.	
14. SIGNATURE OF EMPLOYEE 	15. DATE 9/22/02
16. ADDITIONAL INFORMATION ATTACHED <input type="checkbox"/> YES <input type="checkbox"/> NO	
17. ACTION RECOMMENDED BY REVIEWING OFFICIAL	
a. <input checked="" type="checkbox"/> APPROVAL <input type="checkbox"/> DISAPPROVAL	b. SIGNATURE 
c. TITLE Director, DTP	d. DATE 9/30/02
18. ACTION TAKEN	
a. <input checked="" type="checkbox"/> APPROVAL <input type="checkbox"/> DISAPPROVAL	b. SIGNATURE 
c. DIRECTOR, DIVISION OF MANAGEMENT SERVICES	d. DATE 10/7/02

*See reverse of form
HHS 520 (1/82)

(INSTRUCTION ON BACK OF FORM)

Prepared by: Tonya Staley Fax No.: 301-480-0853 Phone No.: 301-496-8906

REQUEST FOR APPROVAL OF OUTSIDE ACTIVITY*

10222002 Ref: HHS Standards of Conduct Regulations + NCI/NIH Rules

1. NAME (Last, First, Initial) <u>LIOTTA, Lance A.</u>		2. ORGANIZATIONAL LOCATION <u>DHHS, NIH, NCI, CCR LP, SP</u>	
3. TITLE OF POSITION <u>Chief, Laboratory of Pathology</u>		4. GRADE AND SALARY (Federal) <u>602 - 6 \$ 125,335</u>	
5. NAME, ADDRESS AND BUSINESS OF PERSON OR ORGANIZATION FOR WHOM OUTSIDE SERVICES WILL BE PERFORMED <u>Carol A. Dahl, Ph.D., Biospect Inc., 6701 Democracy Blvd. Bethesda, MD 20817</u>		6. LOCATION WHERE SERVICES WILL BE PERFORMED <u>6701 Democracy Blvd. Bethesda, MD 20817</u>	
7. NATURE OF ACTIVITY (Indicate type of activity, e.g., teaching, consultative services, and give full description of specific duties or services to be performed. Specify, when possible, the scheduled days of week and hours of day proposed activity will be performed.) <u>Also, answer (a), (b), (c), and (d) below:</u>			

☒ Initial Request
☐ Revised Request
☐ Renewal

RECUSAL ON FILE

B-1

Consultative services: Provide advice on public domain diagnostic testing methods applied to animal and human toxicology and correlation with tissue pathology.

TAB 28

Only published and publicly available information and data will be discussed. For consulting, DHHS rules regarding consulting will be observed.

Employee(s): (a) has (circle one) a project officer; (b) has no (circle one) extramural responsibilities; (c) has no (circle one) CRADA or MTA-CRADA responsibilities; (d) Branch/Office has no (circle one) grants or contracts with this organization.

8. ESTIMATED TIME INVOLVED		b. ESTIMATED TOTAL TIME DEVOTED TO ACTIVITY (If on a continuing basis, give estimated time per year)	
a. PERIOD COVERED FROM <u>Oct. 31, 2002</u> TO <u>Oct. 31, 2003</u>		<u>192 hrs/year</u>	
c. WILL WORK BE PERFORMED ENTIRELY OUTSIDE USUAL WORKING HOURS? IF NO, COMPLETE THE FOLLOWING: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO I currently have <u>81</u> DAYS/HOURS of unused annual leave. If this request is approved, I will use the following time for the activity: <u>81 DAYS/HOURS</u>			
9. DO YOUR OFFICIAL DUTIES RELATE IN ANY WAY TO THE PROPOSED ACTIVITY? Related to professional competence, but not an official responsibility for use of government funds <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES			
*10. IF PROVIDING CONSULTATIVE OR PROFESSIONAL SERVICES, DO YOUR WOULD-BE ASSOCIATES RECEIVE OR WILL THEY SEEK, A GRANT OR CONTRACT FROM A FEDERAL AGENCY? Services provided will not knowingly involve, directly or indirectly, preparation of material which could relate to any financial dealings between the outside organization and NIH <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES (Describe)			
11. METHOD OR BASIS OF COMPENSATION <input type="checkbox"/> HONORARIUM <input checked="" type="checkbox"/> FEE/ <input type="checkbox"/> NONE (See Attached) <input type="checkbox"/> ROYALTY <input checked="" type="checkbox"/> EXPENSES <input type="checkbox"/> OTHER (Specify)		12. WILL COMPENSATION BE DERIVED FROM A DHHS GRANT OR CONTRACT? <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES (Describe)	
13. THIS REQUEST IS MADE WITH FULL KNOWLEDGE OF DEPARTMENT AND OPERATING DIVISION POLICY AND PROCEDURES ON OUTSIDE ACTIVITIES. THE STATEMENTS I HAVE MADE ARE TRUE, COMPLETE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF.			
14. SIGNATURE OF EMPLOYEE <u>Lance A. Liotta, Ph.D.</u>		15. DATE <u>10-4-02</u>	
16. ADDITIONAL INFORMATION ATTACHED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO			
a. APPROVAL <input type="checkbox"/> DISAPPROVAL		b. SIGNATURE <u>[Signature]</u>	
c. TITLE <u>Director CCR/NCI</u>		d. DATE <u>10-11-02</u>	
18. ACTION TAKEN			
a. APPROVAL <input type="checkbox"/> DISAPPROVAL		b. SIGNATURE <u>[Signature]</u>	
c. TITLE <u>Deputy Ethics Counselor, NCI</u>		d. DATE <u>12/17/02</u>	

*See reverse of form
HHS-520 3/8/98

SEE REVIEWING OFFICIAL COMMENTS ON REVERSE

DO NOT WRITE
IN THIS BOX

Approval Contingent on Compliance
with Notices on Reverse Side

Employee has been appraised of the rules
governing outside activities and use of official
title and NIH/NCI affiliation.

TAB 29



October 22, 2002

Dr. Lance Liotta
8601 Bradley Blvd
Bethesda, MD 20817

Dear Lance,

On behalf of Biospect, Inc. I am pleased to extend to you a consulting agreement. As you know, we consider your scientific expertise in medical diagnostic technology, clinical sample acquisition and stability, regulatory filings and regulatory inspections related to clinical pathology laboratories relying upon knowledge obtained as a Board Certified Pathologist with CAP laboratory certification and expertise as a biomedical engineer to be of great value and we believe your input could be of great assistance in our research and development activities. Anticipated consulting services will include teleconference and electronic communications, on site meetings at Company facilities, and off site meetings as requested including during normal business hours, as well as the review and preparation of written materials. General consulting services that may be requested by the Company from time to time will relate to the Company's research and development. We expect those services to average approximately 4 days per month.

We are very enthusiastic about the opportunity to engage your expertise through consulting. Please indicate your acceptance of this offer with your signature. Upon completion of your signature, keep a copy for yourself and return the signed original to me at:

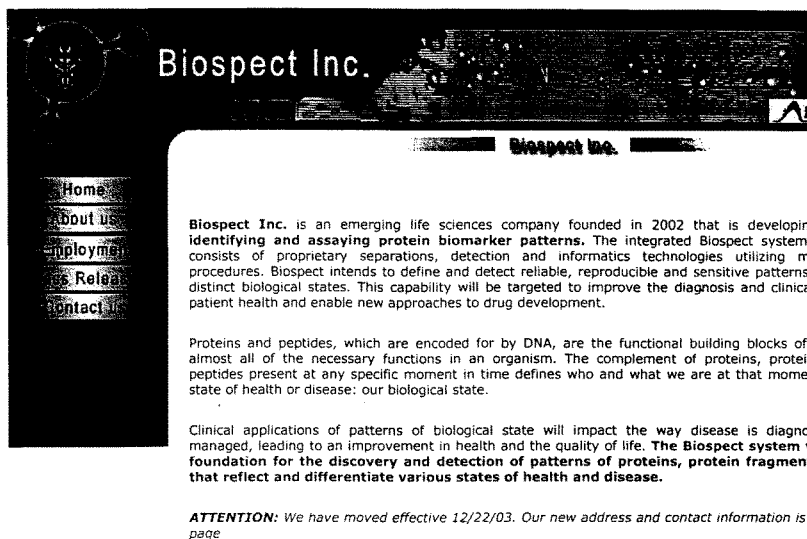
Biospect, Inc.
6701 Democracy Blvd.
Suite 300
Bethesda, MD 20817

We look forward to working with you.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Carol A. Dahl', is written over a horizontal line.

Carol A. Dahl, Ph.D.
Vice President
Strategic Partnerships



Biospect Inc.

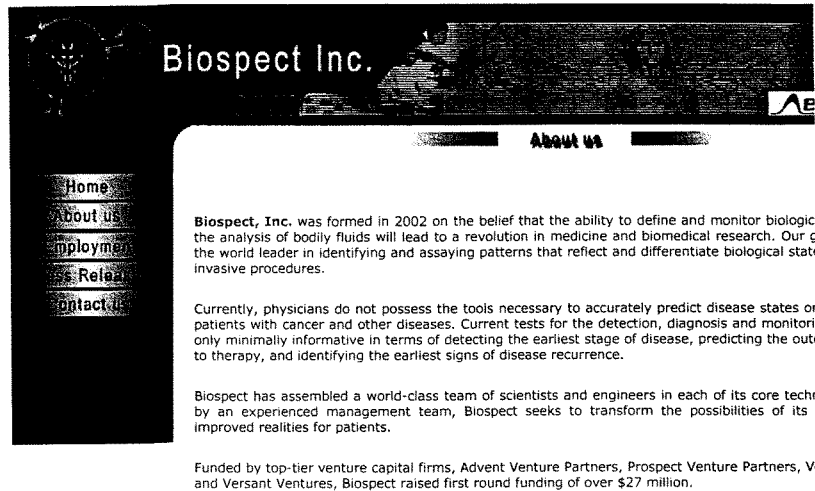
Home
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Contact

Biospect Inc. is an emerging life sciences company founded in 2002 that is developing **identifying and assaying protein biomarker patterns**. The integrated Biospect system consists of proprietary separations, detection and informatics technologies utilizing microfluidic procedures. Biospect intends to define and detect reliable, reproducible and sensitive patterns of distinct biological states. This capability will be targeted to improve the diagnosis and clinical patient health and enable new approaches to drug development.

Proteins and peptides, which are encoded for by DNA, are the functional building blocks of almost all of the necessary functions in an organism. The complement of proteins, protein peptides present at any specific moment in time defines who and what we are at that moment of health or disease: our biological state.

Clinical applications of patterns of biological state will impact the way disease is diagnosed and managed, leading to an improvement in health and the quality of life. **The Biospect system will be the foundation for the discovery and detection of patterns of proteins, protein fragments that reflect and differentiate various states of health and disease.**

ATTENTION: We have moved effective 12/22/03. Our new address and contact information is on the next page.



The image is a screenshot of the Biospect Inc. website. The header features the company name "Biospect Inc." in a large, bold, sans-serif font. To the left of the name is a circular logo with a stylized 'B' and 'S' inside. To the right is a small logo with the letters "AE". Below the header is a navigation bar with the text "About Us" in a bold, sans-serif font. On the left side of the page is a vertical navigation menu with the following links: "Home", "About Us", "Employment", "Release", and "Contact Us". The main content area contains three paragraphs of text. The first paragraph describes the company's formation in 2002 and its mission. The second paragraph discusses the current state of medical diagnostics. The third paragraph mentions the company's team and its goal to improve patient outcomes. The fourth paragraph lists the company's funding sources.

Biospect, Inc. was formed in 2002 on the belief that the ability to define and monitor biological fluids will lead to a revolution in medicine and biomedical research. Our goal is to become the world leader in identifying and assaying patterns that reflect and differentiate biological states without invasive procedures.

Currently, physicians do not possess the tools necessary to accurately predict disease states or patients with cancer and other diseases. Current tests for the detection, diagnosis and monitoring are only minimally informative in terms of detecting the earliest stage of disease, predicting the outcome of therapy, and identifying the earliest signs of disease recurrence.

Biospect has assembled a world-class team of scientists and engineers in each of its core technologies. By an experienced management team, Biospect seeks to transform the possibilities of its technologies into improved realities for patients.

Funded by top-tier venture capital firms, Advent Venture Partners, Prospect Venture Partners, Versant Ventures, Biospect raised first round funding of over \$27 million.

TAB 31**HOME****OUR MISSION****ABOUT US****ADVISORS****TOOLS & SERVICES****PUBLICATIONS****CONGRESSIONAL****NEWS****SITE GLOSSARY****CONTACT US****Our Mission**

The founders of Correlogic Systems, Inc. envision a world where the ability to detect the relationship between a few seemingly inconsequential bits of data out of trillions may change the future of mankind.

Correlogic's mission is to advance the early identification of various cancers and other diseases, and to accelerate the new drug discovery process by applying its proprietary software to the development of proteomic and other biomarkers. We have created patent-pending diagnostic software for use by both the scientific research and pharmaceutical research communities and the clinical diagnostic market. Through licensing, joint ventures and strategic alliances, we seek to work with manufacturers of protein separation and sequencing tools, diagnostic kit manufacturers, pharmaceutical companies, the academic research community and others to create turn-key diagnostic systems that will revolutionize the disease testing and screening market. Equally important, we also provide pattern discovery solutions to biotech and pharmaceutical companies for use in genomics, molecular biology, protein sequencing, and in new drug identification and toxicity evaluation.

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Introduction

Correlogic Systems, Inc. is a clinical proteomics company engaged in the development of tools and processes for proteomic and genomic-based clinical diagnostic systems and new drug discovery. Correlogic has developed a patent-pending, scientifically validated methodology for the early detection of various cancers and other diseases through the use of high throughput bioassays and pattern discovery software. Our technologies have a wide range of applications for the creation of disease diagnostic models, biomarker discovery, and new drug discovery processes.

Correlogic is also a clinical laboratory regulated under the Clinical Laboratory Improvement Amendments of 1988, designated to perform high complexity testing. Correlogic has entered into agreements to provide an ovarian cancer testing service in cooperation with the nation's two premier diagnostic laboratories, Laboratory Corporation of America and Quest Diagnostics.

Latest News...

On April 22, Peter Levine, President and CEO of Correlogic, appeared at the Biomedical Marketing Association's 26th Annual Conference in Boston, MA. He presented "The Importance of Partnerships in Technology Development and Commercialization in the Diagnostics Industry: A Case Study of Correlogic (OvaCheck™)".

On April 19, the *Philadelphia Inquirer* writes about Correlogic's work on ovarian cancer detection in the article, **Progress From Unraveling Proteins**.

On April 14, the *Miami Herald* writes about Correlogic's work on ovarian cancer detection in the article, **New Jersey Oncologist Says Ovarian Cancer Test May Catch Disease Early**.

The peer-reviewed journal *Endocrine-Related Cancer*, has accepted for publication "**High-Resolution Serum Proteomic Features for Ovarian Cancer Detection**", a paper co-authored by Correlogic's Chief Science Officer, Ben Hitt, along with researchers at NCI/FDA and others. This research, including the continued use of Correlogic's technology, was a further extension of our previously reported ovarian cancer results.

Correlogic's poster presentation "**High-Throughput Multidimensional Mass Spectrometry Analysis for the Detection of Early Stage Epithelial Ovarian Cancer: A Serum Test for Ovarian Cancer**," appeared at the Society of Gynecological Investigation conference in Houston, TX on March 25, 2004. The poster presented results that were 97 percent sensitive and 94 percent specific in validation.

February 10, 2004, Mitsui and Co., Ltd., Tokyo, Japan, makes equity investment in Correlogic. The companies will explore the creation of a joint venture in Japan. **Read press release.**

On January 12, 2004, Judith Reichman, M.D., medical contributor of the Today Show, profiled OvaCheck™, a blood test for the early detection of ovarian

cancer. **New Tests and Therapies May Help Enhance the Lives of Women. View the interview with NBC's Ann Curry.**

On December 1, 2003, Peter Levine, President and CEO of Correlogic, addressed Rep. Steve Israel's (D-NY) Cancer Task Force. He spoke about the upcoming ovarian blood test and other technology. The event was attended by 50 representatives from cancer advocacy and support organizations, local government representatives and healthcare providers.

Genome News Network covers Correlogic's proteomic pattern technology to detect ovarian cancer in its earliest stage. **Diagnosing Ovarian Cancer by Proteomics**, November 14, 2003.

The Wall Street Journal covers Correlogic's work on prostate and ovarian cancer detection. **Tiny Protein May Lead To Better Screen Test For Prostate Cancer**, November 4, 2003.

On October 28, 2003, Peter Levine presented the latest developments on the ovarian cancer blood test. He spoke at LabCorp's Analysts and Institutional Investors Meeting - *"Improving Patient Care Through Scientific and Technological Leadership."*

On September 19, 2003, Peter Levine addressed the Sixth Annual Ovarian Cancer National Alliance Advocacy Conference in San Francisco.

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TAB 32**EXHIBIT A**

SERVICES General consulting services that may be requested by Company from time to time relating to Company's research and development and other business activities, averaging one (1) full day per week. Company's research and development and other business activities are defined by the missions of the Company. The Company's mission is to become the world leader in complex mixture analysis of biological fluids/tissues to inform the detection, diagnosis, monitoring and treatment of human disease through the application of proprietary separation, detection, and informatics technologies.

Consulting services will relate to general professional knowledge in medical diagnostic technology, clinical sample acquisition, preparation, fractionation, separation, storage and stability, regulatory filings and regulatory inspections related to clinical pathology laboratories [e.g. CAP (College of American Pathologists), CLIA, GMP inspections, and 510(k) or PMA filings for new diagnostic tests] relying upon knowledge obtained as a Board Certified Pathologist with CAP laboratory certification and expertise as a biomedical engineer. Consulting services will also relate to general scientific expertise in diagnostic devices and microfluidics as applied to the analysis of protein and biological mixtures and the classification of biologic states through complex mixture analysis of biological fluids. Services will exclude protein microarrays, tissue microdissection, and serum proteomic pattern analysis using genetic algorithms and self-organizing maps. Services will include teleconference and electronic communications, on site meetings at Company facilities, and off site meetings as requested including during normal business hours, as well as the review and preparation of written materials.

If the consultant's name is used in the Company's public documents, it will be stated "The consultant is an employee of the US government and is performing this consultation as an approved outside activity." The Company will review the language with the consultant so that the description of the consultant conforms to government outside activity guidelines.

FEES Flat fee of \$5,000 per month, payable within 7 days after timely completion of service required that month, averaging 2 days per month. Consultant may be asked to provide documentation of hours of service.

EXPENSE REIMBURSEMENT Limited to (1) required, reasonable telephone expenses and long distance coach class (or equivalent) travel (transportation, lodging and meals) authorized in writing by company in advance, and (2) payable only 30 days after itemized invoice (and delivery of receipts).

INVOICES All invoices and receipts should be submitted to:
Dan Miller
Biospect, Inc.
Vice President, Finance and Administration
951 Gateway Blvd.
South San Francisco, CA 94080
650-952-4350 x 100 (phone); 650-952-0911 (fax)

05/15/2004 SAT 11:45 FAX 3014960840

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TAB 33

Print at: Tuesday, May 04, 2004 12:39:04 PM
 Host: 31-WILSON-1
 User: WilsonM

NCI Review (Check Biospect

Last Name: [REDACTED] First Name: [REDACTED] Mr. [REDACTED]
 HNC Code: [REDACTED] Status: [REDACTED]
 Mandatory Filer: [REDACTED]

Job Title: [REDACTED] Salary: [REDACTED]
 Pay Plan: [REDACTED] Grade: [REDACTED] Step: [REDACTED] Job Series: [REDACTED] Employment Responsibility: [REDACTED]

View CRADA: [REDACTED]
 BIOSPECT INC.

Fee: [REDACTED] 192

Start Date	End Date	Rate	Notes
1/01/2002	12/31/2002	11	
1/01/2003	12/31/2003	11	
1/01/2004	12/31/2004	11	

CRADA Number	Year	Start Date	End Date	Rate	Notes
521-000/2004	2004	10/22/2002	06/30/2003	11	
521-000/2004	2004	10/22/2002	02/24/2004	11	

NCI Review (Check Biospect

Hrs/days this \$20: 192 hrs/yr Other 520s Yes X No ☐ Total 520 Hrs/days: 296

Humana Press - Editor

CRADAs in immediate area? Yes X No ☐

Dr. Liotta was CRADA PI on the NCI-FDA-Correllogic Systems, Inc. CRADA 01403 expired 4/3/2004 (copy of COI analysis and CRADA documentation attached)

Money earned two Date: \$49,375 consulting fees - proposed annual rate of \$39,000 or \$3250/month

Organization Subsidiary Involvement Yes ☐ No X

Official Business Relatedness? Biospect and Correllogics do business in the same area, however, Dr. Liotta's consultation was limited per agreement with Dr. Barrett so that his consultation did not overlap with his official duties- this a very technical distinction.

Recommended

Based on legal analysis of an activities certified by the scientific director to be different from official duties of the employee this limited consultancy should be recommended, but it is a management decision as to any appearance of conflict of interest that approval will continue to raise.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

TAB 34National Institutes of Health
Bethesda, Maryland 20892

May 14, 2004

The Honorable James C. Greenwood
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Greenwood:

As you know, I share your concerns that prior to February of this year, NIH employees, other than those who file public financial disclosure reports, were not required to fully disclose the compensation amounts of outside activities with pharmaceutical and biotechnology companies. As I testified before the Subcommittee on Oversight and Investigations May 12, I believe the NIH ethics program lacks sufficient transparency and disclosure. I have been working with the Subcommittee, the Office of General Counsel at the Department of Health and Human Services (HHS) and the Office of Government Ethics (OGE) to rectify this problem.

With the assistance of HHS, OGE approved our request on February 6, 2004, to require all Institute and Center Directors, Deputy Directors, Scientific Directors, and Clinical Directors to file public financial disclosure reports. Recently, we submitted a second request to OGE to require senior scientists and managers occupying 500 additional positions to file public disclosure reports. This increase in the number of public financial disclosure filers will significantly add to the level of transparency within the NIH ethics program.

I have also worked with HHS to resolve issues related to the Subcommittee's request for the compensation amounts connected to consulting arrangements between NIH employees and industry. We have been able to strengthen our ethics program by requiring all NIH employees, regardless of their position or salary, to provide consulting compensation amounts for current and future activities. These amounts were provided to the Subcommittee on March 19, 2004. But the collection of compensation amounts for past, closed activities was considered an action that could raise Privacy Act considerations, and I was advised that this could put the Federal Government at risk of litigation. Therefore, we initially proceeded to request the amounts on a voluntary basis.

In light of the insufficient response to the voluntary requests for information, again working with the Office of General Counsel at HHS, I have determined that the need of Congress to have this information, NIH's need for the information as it works to propose new or to revise existing policies and procedures, and the public interest in general, override the litigation risks involved in the mandatory collection of consulting compensation amounts. Therefore, I will instruct all

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Page 2 - The Honorable James C. Greenwood

employees who had consulting arrangements since January 1, 1999, that are now closed to report the compensation amounts received pursuant to the consulting as a requirement and condition of their employment. These amounts will be provided upon collection to the Subcommittee, pursuant to the Subcommittee's request of December 8, 2003.

I hope this satisfies the Subcommittee's concerns regarding this matter. Please contact me if you have any additional questions or concerns.

Sincerely,



Elias A. Zerhouni, M.D.
Director

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TAB 35MEMORANDUM

TO: IC Directors

FROM: NIH Deputy Director and
NIH Deputy Ethics Counselor

SUBJECT: Changes to Outside Activity and Award Approval Process

On January 18, 2004, Dr. Zerhouni issued a memorandum regarding changes in the NIH Ethics Program which I forwarded to you in an e-mail message of the same day. The memorandum explained that I was appointed as the NIH Deputy Ethics Counselor (DEC), and as such, was given the additional DEC responsibilities for the IC Deputy Directors, Scientific Directors, Clinical Directors and Extramural Directors (those officials in the extramural program who report directly to the IC Director). I, as the NIH DEC, will continue to serve as the DEC for the IC Directors. The memorandum also discussed the newly established of the NIH Ethics Advisory Committee (NEAC). I now write to explain in more depth the process for submission and approval from the NEAC of outside activities and awards.

As you are aware, Dr. Zerhouni pledged to review all outside activities of NIH employees. To that end, all ongoing activities must be reviewed to determine if, consistent with applicable statutes and regulations, NIH employees should be allowed to continue to engage in these activities. Accordingly, all activities that fall within the NEAC's jurisdiction must be submitted to the NEAC for its review and recommendation. Based upon the NEAC's review, I, as the NIH DEC, will decide if the activity should continue. Furthermore, all other activities must be reviewed at the IC level. The employee's supervisor and the IC DEC together will determine whether or not the employee may continue to engage in the activity. Last, as explained below, the NEAC has jurisdiction over requests for approval of awards. These should be submitted to the NEAC for its consideration, where appropriate.

As outlined in Dr. Zerhouni's January 18 memorandum, the following activities and awards falls within the NEAC's jurisdiction:

- 1) NEAC will provide supervisory review and, if appropriate, approval for **all outside activity and award requests submitted by appointed or acting NIH OD Senior Staff and IC Directors**. The NIH DEC will serve as the final arbiter of these requests.
- 2) NEAC will advise the NIH DEC on **all outside activity and award requests submitted by IC Deputy Directors, Scientific Directors, Clinical Directors, and Extramural Directors**. The NIH DEC will serve as the final arbiter of these requests.
- 3) NEAC will advise the NIH DEC in relation to requests submitted by **any other NIH employee as follows**:

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- requests to accept awards from non-governmental sources that include a cash payment and/or travel reimbursement equal to or in excess of \$2,500;
- any outside activity request involving a biotechnology or pharmaceutical company;
- any outside activity request that involves total anticipated compensation in excess of \$10,000, or which is expressed as a future income stream;
- any outside activity for which payment will be, entirely or in part, in the form of stock, stock options, or other equity position.

Please submit to the NEAC for its review a new outside activity approval packet for any outside activity in which you are currently engaged and wish to continue. Also, please inform your staff that they must submit new outside activity approval packets to either the NEAC (through the IC DEC) if the activity falls within the NEAC's jurisdiction, or to their supervisors and the IC DEC in order to continue with the activity. Failure to timely obtain new approvals for the activities will result in the cancellation of the previously obtained approvals. The attached memorandum may be used by you to inform your staff of the changes to the outside activity and award approval process. It details the NEAC's jurisdiction, the deadline for submissions to the NEAC or the IC for ongoing activities, and what information must be presented when seeking approval of ongoing or new outside activities, or awards.

Please contact me if you have any questions.

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MEMORANDUM

TO: IC Employees

FROM: IC Director

SUBJECT: Procedure for Review of Ongoing and New Outside Activities and Certain Awards

As you know, outside activities in which NIH employees engage and certain awards given to NIH employees have recently received significant media and Congressional attention. To assure that these activities in no way negatively affect our mission to advance the public health, we are reviewing all ongoing outside activities, and subjecting some activities and awards to heightened review by the newly established NIH Ethics Advisory Committee (NEAC). I write to explain the NEAC's jurisdiction and the procedures for submitting requests for approval of ongoing or new outside activities, and certain awards.

The NEAC has the following responsibilities and authority:

1) NEAC will provide supervisory review and, if appropriate, approval for **all outside activity and award requests submitted by appointed or acting NIH OD Senior Staff and IC Directors**. The NIH DEC will serve as the final arbiter of these requests.

2) NEAC will advise the NIH DEC on **all outside activity and award requests submitted by IC Deputy Directors, Scientific Directors, Clinical Directors, and Extramural Directors**. The NIH DEC will serve as the final arbiter of these requests.

3) NEAC will advise the NIH DEC in relation to requests submitted by **any other NIH employee as follows**:

- requests to accept awards from non-governmental sources that include a cash payment, and/or travel reimbursement equal to or in excess of \$2,500;
- any outside activity request involving a biotechnology or pharmaceutical company;
- any outside activity request that involves total anticipated compensation in excess of \$10,000, or which is expressed as a future income stream;
- any outside activity for which payment will be, entirely or in part, in the form of stock, stock options, or other equity position.

The attached documents entitled "NIH Ethics Advisory Committee," and "Activity Requests Subject to the NIH Ethics Advisory Committee (NEAC) Jurisdiction" provide additional information.

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As explained more fully below, you are required to provide specific information with respect to compensation if you wish to continue an outside activity or have a new activity considered for approval. Therefore, please comply with the following deadlines for review of ongoing and new outside activities:

- 1) For ongoing activities, submit packets through supervisory channels to the IC DEC **no later than Tuesday, February 17, 2004**; and
- 2) For new outside activities, submit packets through supervisory channels to the IC DEC **at least six weeks in advance** of the anticipated start date of the activity.

If your activity is scheduled to occur prior to February 17, contact your IC DEC immediately for expedited review of the outside activity packet.

You should follow the already-established IC process for outside activity approval. That is, the IC Program Staff is available to help you with preparing the packet and the IC Ethics Staff is available to advise on the appropriateness of any undertaking. Your supervisor must still approve the activity and the IC DEC must review it before the packet is forwarded to the NEAC. (If the activity does not fall within the NEAC's jurisdiction, the activity will be reviewed and approved by your supervisor and IC DEC.) Once supervisory approval is obtained and the IC DEC review is completed, the IC DEC will forward those activities that fall under the NEAC's jurisdiction to the NEAC for action.

The following information must be submitted if you desire to have your request for approval considered or continued:

- **HHS Form 520.** This Form must now include information about the *amount* and *type* (e.g., cash, stock, or stock options) of income, compensation, fees, remuneration, expenses, or reimbursement that is to be received in connection with the ongoing or proposed activity. In addition, you must include, retrospectively, the cumulative amount of any income or other monetary receipts (including the type or method of payment) that was received by you from the outside source in connection with the ongoing activity for the past 5 years. We have been informed by the HHS Designated Agency Ethics Official that failure to provide the required information with respect to the amount and type of compensation will require the NIH DEC to cancel the ongoing outside activity or deny a request to begin a new one. The compensation information should be supplied in "Item Number 17" on the reverse of the HHS Form 520. Also, when reporting the period covered by the activity, the "from" date in box 8a of the Form 520 should reflect the date the activity originally started.
- **NIH Supplemental Information sheet to the HHS Form 520.** This supplemental sheet must include a thorough answer to question 3, "Explain how the proposed outside activity is different from the scientific activities performed as part of your official duties."

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- **NIH Form 2657.** This form must be completed by the employee and signed by the outside organization, where applicable.
- **Invitation Letter from Outside Organization.** Additional information that describes the activities and/or the organization may be included as well.
- **Your PD or Billet.** If you do not have a current PD or billet, please include a detailed explanation of your current job responsibilities.

Please note that any packet that is not complete will be returned, and approval will be held in abeyance until the packet is properly completed and the review can be performed.

If your request involves an already approved activity, you may reuse the previously submitted documents as long as all the required information is included, i.e., amend the previously submitted outside activity packets to include compensation information. You must, however, resign and redate the HHS Form 520.

If you have any questions, please contact [name], [IC name] DEC.

cc: [name], [IC name] DEC

NIH ETHICS CONCERNS: CONSULTING ARRANGEMENTS AND OUTSIDE AWARDS

TUESDAY, JUNE 22, 2004

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2123, Rayburn House Office Building, James C. Greenwood (chairman) presiding.

Members present: Representatives Greenwood, Bilirakis, Stearns, Walden, Rogers, Barton (ex officio), DeGette, Schakowsky, Waxman, and Dingell (ex officio).

Staff present: Alan Slobodin, majority counsel; Mark Paoletta, majority counsel; Ann Washington, majority counsel; Casey Hemard, majority counsel; William Harvard, legislative clerk; David Nelson, minority investigator and economist; and Jessica McNiece, minority staff assistant.

Mr. GREENWOOD. The subcommittee will come to order.

The Chair welcomes our first panel and recognizes himself for the purposes of making an opening statement.

Good morning. This is the third hearing the subcommittee has convened about NIH ethics concerns. Two earlier hearings were held last month, in particular the subcommittee has focused on consulting arrangements and outside awards because of the legitimate important and well recognized public interest in controlling conflicts of interests.

As the United States Supreme Court noted in its 1990 opinion in *Kramden v. United States* restrictions “designed to prohibit and to avoid potential conflicts of interest in the performance of governmental services are supported by the legitimate interests in maintaining the public’s confidence in the integrity of the Federal Service.”

Without appropriate controls on conflicts of interest, the Office of Government Ethics has stated “The public’s confidence may be seriously compromised where circumstances suggest public servants are using their positions for private gain.”

As Dr. Elias Zerhouni, Director of the NIH has said, the NIH’s “public health mission is too important to have it undermined by any real or perceived conflicts of interest.”

Our previous two hearings established widespread agreement that the NIH ethics program needs strengthening. At the first hearing on May 12 the NIH Blue Ribbon Panel on Conflict of Interest Policies presented its report and recommendations. Dr. Elias

Zerhouni testified about actions taken in response to concerns about NIH's management of conflict of interest.

At the second hearing on May 18 the subcommittee highlighted two cases illustrating conflicts of interest concern arising from consulting agreement and lecture awards. The example of a consulting agreement we examined to highlight the issue is the case of Dr. Lance Liotta of the National Cancer Institute, Dr. Manuel Petricoin of the FDA and their arrangement with Biospect, a south San Francisco life sciences company.

The subcommittee was concerned that Dr. Liotta and Dr. Petricoin, the leaders for the U.S. Government in a cooperative research and development agreement known as CRADA with Correlogic Systems, Inc. of Bethesda, Maryland were allowed to work as paid consultants for Biospect, a company in the same filed as Correlogic.

The example we used of an outside award focused on the circumstances surrounding the decision to allow Dr. Richard Lausner, then the Director of the National Cancer Institute, to receive the 1997 Dixon Prize in Medicine from the University of Pittsburgh. We learned that the hearing that the concerns of the NCI ethics officer were disregarded and HHS ethics attorneys were pressured to allow Dr. Klausner to accept the prize and a check for \$40,000.

The award was also of concern because it was offered at a time when the University of Pittsburgh was both a recipient of NCI funding as well as a party to a recently settled lawsuit in which both the NCI and the university were codefendants where Dr. Klausner had approved the use of \$300,000 funding NCI as a portion of the payment in that settlement.

At today's hearing, the subcommittee will hear testimony and present information that will provide more insight and greater detail about the NIH ethics concerns on consulting arrangements and outside awards.

In addition, the subcommittee will hear testimony and examine new actions and restrictions proposed by Dr. Zerhouni aimed at strengthening the NIH ethics program.

With respect to consulting arrangements, the subcommittee has been compiling information provided both by the NIH and a number of drug companies about the financial details of deals that occurred over the last 5 years. The task has proven to be enormous. It took several months for the NIH and HHS to find a way to provide these financial details in the first place. Without a preexisting data base, NIH in responding to the committee's request has had to rely on each of its 27 institutes and centers to provide information on the agreements. This has also led to problems of accuracy and reliability.

More significantly, information received from the drug companies has revealed a significant number of troubling discrepancies. So far the committee staff has identified about 100 situations in which the drug company reported a consulting agreement, but the NIH did not include the agreement in the data given to the committee. This is essentially disturbing given that the committee sent request letters to only 20 of the companies that had the most agreements out of hundreds of companies on the NIH lists. One hundred is a significant number from such a subsample of 274.

Consider this example. Pfizer provided information showing that Dr. Trey Sunderland of the National Institute of Mental Health had been paid over \$517,000 in fees honoraria and expense reimbursement in connections with consulting activities for the period 1999 to the present. So far, however, NIH has reported to the committee that there are no outside activity request forms covering Dr. Sunderland's activities, nor are these financial details accounted for in his financial disclosure reports.

Pfizer has also reported that Dr. Sunderland's associate, Karen Putman of the NIMH was paid \$64,000 in consulting fees and reimbursement from 2001 to 2004. Some of these fees were for assisting Pfizer in its program to study biomarkers of neurological disease. Once again, NIH has no outside activity request documents accounting for this activity. In fact, NIH has confirmed that Dr. Sunderland instructed Dr. Putnam not to clear these activities.

These so called outside activities appear related to their government work. Dr. Sunderland and Dr. Putnam in their capacities at NIMH published a major study in 2003 on the value of potential markers for identifying people with Alzheimer's Disease.

These discrepancies between information provided by the drug companies and the NIH and this example raise the specter of a substantial number of outside drug company and biotechnology consulting agreements involving NIH scientists, which were not even reported or submitted for clearance at NIH. Because of the grave concerns this presents, the subcommittee will further investigate these agreements that were not reported to the NIH. As a result, the subcommittee is not yet in a position to release the listing of the NIH consulting agreements today.

The concern that there is a substantial number of outside deals that are conducted in total secrecy even from the NIH is not implausible. For example, the committee has recently learned that Dr. Alan Moshell, Skin Diseases Branch Chief and Program Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, was retained as an expert witness reportedly at a rate of \$600 per hour in a number of private product liability lawsuits involving the drug, Accutane, which is used to treat severe acne. HHS and NIH have reported to the committee that Dr. Moshell did not file outside activity request forms for these activities, even though HHS and NIH acknowledge that Dr. Moshell should have disclosed these activities to NIH and should have filed an outside activity request separately for each expert-witness activity to obtain approval. In 1985, Dr. Moshell filed an outside activity request and obtained approval to conduct clinical practice as a dermatologist. This request form did not specifically cover service as an expert witness, but Dr. Moshell has indicated that he did not believe that a specific request form was needed for that purpose.

In addition to these new concerns on outside activities, the subcommittee has also learned of additional information about the case study involving Dr. Liotta, Dr. Petricoin, and their outside agreement with Biospect while working on the Correlogic CRADA. We will hear about this new information later. But let me provide one example of our concerns.

At the May 18 hearing, Dr. Liotta testified under oath that his work at Biospect had been "placed on hold" since February 2004

pursuant to Dr. Zerhouni's directive that all existing consulting relationships with pharmaceutical or biotechnology firms be stopped and resubmitted to the newly created NIH Ethics Advisory Committee known as (NEAC) for review and input, before such activities could be reapproved, if appropriate.

Further, Dr. Liotta confirmed his activities with Biospect were on hold in response to the following e-mail from the NIH Ethics Director, Holli Beckerman Jaffe, dated May 5, 2004: "Please also confirm with him that while he has not received any payments since February (in other words, he was last paid in February), he has not consulted with Biospect since February; the arrangement has been put on hold until he receives approval from Dr. Kington. I know I'm beating a dead horse, but I want to be very clear on the facts. It's in the best interest that we have all the facts and no uncertainty."

The subcommittee has now recently received records from Predicant Biosciences, the new name for Biospect. These records show that Dr. Liotta received and cashed checks from Biospect dated March 1, April 1, and May 1, 2004. These transactions all occurred during the period that Dr. Liotta claimed that the Biospect agreement was "on hold."

Although the subcommittee will not be releasing the consulting agreements listings at this time, we will be releasing information pertinent to consulting arrangements and outside awards. That information includes statistical information about: The activities of the NEAC, use of Title 42 authority, and the list of the 77 scientists who appeared on the NIH consulting agreement list who are also principal investigators on CRADAs.

I ask unanimous consent to put the binder of hearing documents, including this information, into the record. Without objection, it will be included in the record.

On the issue of lecture awards, the subcommittee is releasing the list of awards that NIH provided to the committee and identified as responsive to our request for information on "lecture awards." In addition to the lecture awards list, the subcommittee has identified additional issues in connection with award approvals for Dr. Klausner. For example, Dr. Klausner as the Director of the National Cancer Institute is a Presidential appointee and must have his award requests approved by the HHS Designated Agency Ethics Official. His award requests cannot be approved by an official at the NIH. The committee has identified two instances in 1997 in which the Deputy Director of NIH, not the HHS Ethics Official, approved Dr. Klausner's awards.

In another case, an award to Dr. Klausner from the University of Arizona was approved by an HHS ethics attorney who did not have a written delegation of approving authority for awards of Presidential appointees. In that same case, the first-class travel for Dr. Klausner was improperly approved as part of the award-approval process because a first-class travel approval request must go through a separate approval procedure. This mistaken approval reportedly occurred because the HHS travel manual did not track all of the applicable requirements contained within the GSA regulations with regard to acceptance of first-class travel from a non-Federal source.

These additional issues deepen our concerns about what has happened in the NIH ethics program. However, Dr. Zerhouni appears before this subcommittee to present a comprehensive set of proposed additional restrictions, in addition to other recent actions, to improve the NIH ethics program. I note that some of the problems, such as deliberate misconduct, cannot be easily addressed by any kind of ethics proposals, no matter how strong the restrictions. That said, this set of proposals has some positive features to commend it. In the area of outside awards, based on my understanding of the proposals, the combination of the pre-screened list of awards, the additional guidance from the Office of Government Ethics, the NEAC review, and the prohibition of any cash to an official responsible for a funding decision with the entity offering the award, should address the concerns.

In the area of management process changes, I understand NIH will create an electronic data base for tracking ethics matters and HHS will have increased resources to conduct random audits.

These are constructive and substantial changes. In the area of drug-company consulting, Dr. Zerhouni is not proposing a total ban. However, Dr. Zerhouni is offering a number of substantial restrictions that will curb some of the kinds of cases that are of the greatest concern. Those restrictions include a prohibition on outside consulting for senior leadership positions, expanding public disclosure requirements to cover an additional 600 NIH employees, NEAC review, and limits on income and time. I am withholding judgment on this part of the package; my position will be based in part on what I learn at today's hearing. However, I have already reached the conclusion that whatever final action is taken on outside consulting, it should take place in the context of legislative changes regarding the use of Title 42 authority.

The widespread use of so-called "special" compensation authorities intended for consultants in Title 42 to boost the pay of continuing, full-time NIH employees looks highly questionable on policy, if not legal, grounds. The data provided by HHS shows nearly \$5 million in retention bonuses were paid to 444 Title 42 employees for the period of July 1, 1999 to May 1, 2004. The use of retention bonuses along with the questionable use of Title 42 is part of the gaming that has occurred with the salaries of NIH scientists. Recent data shows almost one-third of new NIH employees were hired under Title 42 authority in 2003. The gaming must end. I am prepared to support a straightforward approach to providing good salaries to NIH scientists, worthy of the crown jewel of the U.S. Government.

Dr. Zerhouni, I know you are ready to work with me. Your proposals and your testimony will receive a respectful hearing from me. You have shown yourself as a serious and constructive partner with the subcommittee in addressing these ethics issues.

I welcome Dr. Zerhouni and the other witnesses to today's hearing. I note on the second panel we will hear from Peter Levine, the President of Correlogic Systems, and Dr. Jonathan Heller, the Vice President for Information and Project Planning at Predicant Biosciences, the new name for Biospect.

I note that Mr. Levine, although he is cooperating with the committee, is appearing pursuant to a subpoena.

Finally, I welcome the witnesses from the National Cancer Institute who will appear on the third panel.

I look forward to the testimony and to making a stronger and better NIH.

The Chair yields to the gentlelady from Colorado for her opening statement.

Ms. DEGETTE. Thank you, Mr. Chairman.

This is the Oversight and Investigation Committee's third hearing on conflicts of interest and the National Institutes of Health. The significance of this issue cannot be understated, and I expect that today's hearing will provide us with a fuller understanding of the problems.

The first hearing gave this committee the opportunity to hear from members of the Blue Ribbon Panel and Dr. Zerhouni. At that time, I expressed concerns with the scope of the Blue Ribbon Panel's recommendations. I am pleased that Dr. Zerhouni is back again with us today to talk about the subcommittee and to talk about some expansions of some of those issues we talked about at that first hearing.

After reviewing some of the proposed expansions to the NIH ethics rules which are being contemplated, I am pleased that NIH leadership takes these issues seriously and is endeavoring to restore ethical integrity, but I remain concerned about the challenges that the absence of what I think is a bright line task for receipt of outside industry compensation provides. At the same time we must maintain the integrity of the NIH as our Nation's premier research institution and to that end, we need to continue to have the ability to attract the very best and brightest at all levels of the NIH.

Today we're going to have the opportunity to look at these additional steps which are being proposed by the NIH regarding conflicts of interest and to learn about one or more of the cases that we talked about in our last hearing. As I said at the previous hearings, these conflicts of interest deserve scrutiny and they must be resolved. The ethos of the organization much change, and I know Dr. Zerhouni and his senior management team agree. These new recommendations are a necessary step, but there must be a comprehensive effort toward implementation and elimination of inconsistent standards which now exist across the 23 institutes.

I am confident that the scientists at NIH can adequately address the committee's concern and put a better system into place. But the question remains how do we accomplish this? NIH may still need to strengthen some of the recommendations even further to achieve this, and I look forward to hearing from our witnesses about that.

I would also add that this subcommittee has a long history of examining these issues and does not take its investigative role lightly. The subcommittee's ability to interview witnesses and uncover issues is part of its very core mission. I am glad that Mr. Azar is here today to talk about some of these interviews of government witnesses and HHS and what transpired.

We have been that conflicts of interest at the NIH are relatively rare, but even rare cases must be prevented especially when they are as spectacular as we have heard in our previous two hearings. The public's trust in this remarkable institution is at stake. These

scientists who are entrusted with taxpayer dollars must answer to their institution and the public and protect its integrity. The scientists also should remember their work is the hope for many Americans who are ill or who are taking care of a family member with an illness. Their scientific work for some Americans is the difference between life and death. A conflict of interest or even the appearance of a conflict of interest could have devastating effects.

NIH's mission is to uncover new knowledge that will lead to better health for everyone. But when there are conflicts of interest, how can we make sure this mission is being carried out?

I am still concerned about NIH's ability to acquire information and data on hours spent on outside activities and also compensation received from outside activities. This is a very delicate issue and disclosure is the key. Centralization of ethics review and creation of an electronic data base are going to be very important. However, as they say the devil is in the details and we need to find out how exactly outside activities will be monitored. That is why I go back to the fact that in the absence of a bright line test it will be very difficult to eliminate some of the abuses we have seen in the past.

As the committee has discovered and as we will discuss today, there is an astounding amount of activity that has not been under scrutiny or even disclosed. This is an unacceptable situation. I know that Dr. Zerhouni and his team agree with me, and I look forward to working with them on this issue.

And thank the Chair for continuing this series of hearings. And yield back.

Mr. GREENWOOD. The Chair thanks the gentlelady and recognizes the chairman of the full committee, the gentlemen Mr. Barton for his opening statement.

Chairman BARTON. Thank you, Mr. Greenwood. And we appreciate your leadership on this important hearing.

I stated at the last oversight hearing on these NIH issues that the hallmark of my chairmanship will be to hold agencies responsibilities and to produce results in better government and better services and policies for the American people. I am proud to report that because of your work and Ms. DeGette's work this is happening with regard to our investigation at NIH.

The committee continues to uncover more and more troubling information about what has happened in the NIH ethics program. For example, it appears that there may be a substantial number of NIH scientists who engaged in outside activities such as drug company consulting in stealth, that is without any notice at all or any approval by the NIH. If these suspicions are confirmed, these unapproved compensated activities would represent a very serious breach of NIH policy, Federal ethic regulation and possibly in some cases even criminal laws.

In addition, we are continuing to examine cases. One of the cases which we reviewed at our last hearing dealing with conflicts of interest arising out of consulting agreements your subcommittee has heard and will testimony today about a remarkable case in which the NIH and FDA scientists who were collaborating with a private company on a joint invention under a public/private partnership called a CRADA at the same time were secretly consulting with

their own private partner's competitor. As a result of those secret deals progress may have been slowed on the public/private partnership that could have led to prompt commercialization of a life-saving ovarian cancer diagnostic test.

I also understand that the subcommittee may be presented with information today that raises serious questions about the accuracy of some testimony that has been received at the last hearing.

Having said all of that, this subcommittee is getting the facts. Through oversight we are identifying the issues that provide a roadmap for solutions. The problems that we are continuing to uncover at the NIH are further justification for why this committee needs to reauthorize the NIH for the first time in over a decade. The committee needs to lead the way in restoring NIH's luster as the crown jewel for research of the Federal Government. As Chairman Greenwood has noted, during this investigation we have uncovered issues of concern and are continuing to uncover still more. It is unpleasant to face the harsh truth about the results of the apparently lax ethic culture at the NIH and the poor judgment and perhaps even misconduct of some individuals at that illustrious institution. Having said that, it is a process that we must go through to ensure that NIH will continue to be the world's premier medical research medical institution. NIH's work is too important to allow it to be hindered by questions about the integrity of its scientists, and therefore the scientific process.

Our oversight is not just about identifying problems. We want to stimulate solutions. In this regard I am very pleased to read that both HHS and NIH seem to be getting the message about our concerns over the NIH's ethics program. And Dr. Zerhouni's testimony, which I have read, indicates that he is serious about improving the ethics at the agency in which he is director of. He is making his agency responsible to the Congress and to the American people. He has a plan, and I think it is a good plan, and I think this committee should give it serious consideration. Because of the enormity of the taxpayer investment in NIH and the enormity of the responsibility entrusted to NIH, it is critical that we, when I say "we" I mean the Congress and the NIH administration, work together to make sure that NIH remains the standard for medical research in the world. I am pleased to say that it looks like we are making progress in this regard.

While we need to work with Dr. Zerhouni to establish solutions, we must do all that we can do to stop things like from ever happening again. And just as NIH has enormous responsibility to the American people, this committee has the responsibility to conduct the kind of oversight that brings these problems to light and then helps find solutions to prevent them from happening again.

I want to commend Ranking Member DeGette for her excellent work and her staff's work, and Mr. Dingell for the full committee staff work on this effort. We are doing oversight in the proud tradition of the Energy and Commerce Committee, and I think the end result is going to be good for the American people.

I also want to compliment Dr. Zerhouni. Your testimony about proposed solutions is excellent. To the extent that we need to back you up with legislative language in that statute, we are very willing to do that once we finalize what needs to be done.

With that, Mr. Chairman, I would yield back.

Mr. GREENWOOD. The Chair thanks the gentleman.

And he recognizes the ranking member of the full committee, the gentleman from Michigan, Mr. Dingell.

Mr. DINGELL. Mr. Chairman, good morning.

Thank you for recognition, and let me commend you for opening this inquiry, for holding this hearing and for insisting that Mr. Azar testify despite the opposition of the Department of Health and Human Services.

The ethics concerns at the NIH, National Institutes of Health and the Food and Drug Administration, FDA, merit the full attention of this subcommittee, as do efforts to hinder, obstruct, delay or otherwise impede the work of this subcommittee.

We are still learning how far and wide the problem of outside payments goes. When NIH initially refused to compel its employees to disclose the extent of consulting dollars received from drugs and biotech companies, you and Chairman Barton surveyed 20 drug companies for their payments to NIH employees. The companies responded regarding some 264 contracts with scientists employed at NIH. When comparing these contracts with the information ultimately submitted to us by the NIH, the staff discovered that some 100 of the 264 consulting contracts were not reported to NIH. What else is out there?

We, as well as NIH and FDA, have a duty to ensure that this probe does not harm research or regulatory approvals. But ignoring the problems at FDA and NIH is not an option. The research community, the health care industry and the American people simply cannot tolerate a system where the state of our technology is sold to the highest bidder. We cannot tolerate a system where the development of lifesaving drugs and biologics may be delayed while the auction is being conducted. Nor can we tolerate hinderance and obstruction by the Department of Health and Human Services. Officials in charge of legislative affairs and some misguided government lawyers have tried to stifle the investigation in which we are now engaged. They have sought to stonewall our requests for documents and interviews and otherwise have sought to prevent the Congress and the American people from discovering very serious problems.

This subcommittee over the years has seen to it that the truth is produced with the cooperation of those who were being investigated or without their cooperation. And there are many who have had reason to repent in a very real way the failure to cooperate with this committee. I hope that those who will appear this morning and others who will be inquired of by the subcommittee will keep this thought in mind.

Moreover, I would note that we find that the curious reluctance of the Inspector General here to do more than desk audits is unacceptable. The American people have the right to know what is going over at the Department. I support all efforts to enforce that right, and I will do everything I can to see to it that there is no obstruction of the business of this committee.

I thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the Oregon, Mr. Walden for his opening statement.

Mr WALDEN. Thank you, Mr. Chairman. I am going to waive my opening statement.

Mr. GREENWOOD. The gentlelady from Chicago, Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Chairman Greenwood and Ranking Member DeGette for convening today's hearing, the third in a series of oversight opportunities to review concerns about ethics at the National Institutes of Health and the consulting arrangements and outside awards of NIH personnel.

This issue is so critical because it goes to the integrity of science and the safety and efficacy of medical technology upon which the American public and medical community rely. Consumers and their caretakers in the medical field, rely on sound science for guidance on the most appropriate types of care. Consumers need to know that the science upon which their doctors rely is based on legitimate evaluations and not tainted by side deals. I think most American consumers would assume that cash, stock, stock options and other types of pay for outside consulting arrangements that NIH personnel have with drug companies and others in industry, would be against the rules. I know I was surprised to hear that some senior officials at NIH received cash gifts as part of the awards given to them by some of the same companies that receive funding from NIH. In some cases, it appears that these deals could amount to more than the regular salaries of some NIH personnel. It is hard for me to accept any argument that NIH's medical scientists or senior personnel need to enter into such agreements. These agreements are not just a question of a little moonlighting, they are day-lighting too, with the very prescription drug and medical device companies whose science NIH is supposed to objectively evaluate.

Why can't NIH commit to finding scientists who will do their jobs for the salary they agree to receive without doing lucrative side deals outside of the office?

Even the appearance of such behavior is damaging and NIH and other agencies must take action to ensure the proper safeguards are in place to prevent such activities. So, today, I am looking forward to hearing the response to concerns raised by this subcommittee. I hope the response will include immediate and concrete steps to remove even the appearance of questionable ethics at NIH. Anything short will be unacceptable. Thank you.

Mr. GREENWOOD. The Chair thanks the gentlelady.

And recognizes the chairman of the Health Subcommittee, the gentleman from Florida, Mr. Bilirakis for an opening statement.

Mr. BILIRAKIS. Thank you very much, Mr. Chairman.

The past two hearings you have held on this issue have been extremely informative, to say the least. And I am sure we all appreciate the opportunity to have another chance to discuss these concerns with officials from the NIH.

Dr. Zerhouni, thank you so much for coming here today. You have always been extremely generous with your time and unbelievably helpful in all of your efforts, and ours I might add. I commend your efforts to improve conflicts of interest management at NIH by creating the Blue Ribbon Panel that created guidelines for revamping the review of consulting arrangements and outside awards, and expanding the number of NIH employees who file internal and pub-

lic financial disclosure reports. Once again you have taken the initiative to ensure that NIH is operating to the best of its ability.

I have gotten to know Dr. Zerhouni fairly well recently because just in this Congress alone, my Subcommittee on Health has held five hearings to highlight research activities at the NIH and to educate members and others about the work that the NIH is doing so that we can better assess how to help them to better met their stated mission.

Now that our hearings have concluded, Chairman Barton and I are committed to passing bipartisan legislation to reauthorize the NIH. It is something we have high hopes of being able to do.

One thing that we would like to accomplish with this reauthorization package is to strengthen the role of the Director of the NIH. And I look forward to hearing from Dr. Zerhouni about how we could be helpful to him in implementing the recommendation to the Blue Ribbon Panel.

And, Dr. Zerhouni, if I do not get around to asking you that specific question, I would ask now that you might submit in writing to us what we can do in the law to strengthen your role.

As I said before, if there are more transparency with respect to these consulting fees and awards, such as making the information more public, then maybe there would not be the need for a high level of concern.

I along with you, Mr. Chairman, would like to thank and welcome the other witnesses here today, and look forward to hearing particularly this panel's testimony.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman.

And recognizes the gentleman, Mr. Rogers for an statement, who passes.

That being said, we welcome Dr. Zerhouni and Mr. Azar. Thank you for being here.

As you know from previous experience, it's the custom of this committee to take testimony under oath. And do either of you object to taking testimony under oath? Do either of you wish to be represented by counsel?

[Witnesses sworn.]

Mr. GREENWOOD. Before I recognize you for your opening statement, Dr. Zerhouni, let me say what I have said in public as many times as I can. I know that this is not a lot of fun for you and the NIH to go through this very public process of oversight, but I consider you to be as ethical a person as I know. I consider you to be a partner with me and with this committee in our efforts to tighten up the ethics, and I am not proud of our relationship, and look forward to your testimony, and you are recognized to give it.

TESTIMONY OF HON. ELIAS ZERHOUNI, DIRECTOR, NATIONAL INSTITUTE OF HEALTH; AND ALEX AZAR, II, GENERAL COUNSEL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. ZERHOUNI. Thank you, Mr. Chairman, for your kind words, and you have my commitment to continue to be partners in this issue. I want to thank the members of the subcommittee.

I am here to testify about my proposal to overhaul the ethics system and its process, its management and its controls. We have

worked very closely with my colleague, Mr. Azar in the Office of General Counsel to come up with what we believe could be a proposal that will not only strengthen, but completely overhaul, completely transform the way we manage ethics at our Federal agency.

The events and arrangements that have been the subject of the subcommittee's oversight was, as you know, rooted in the significant loosening of NIH ethics rules and policies that occurred in 1995. These changes were the results of converging interests at the time. NIH's desire to strengthen the research enterprise to the use of "innovative" recruitment and retention policies. And the second was a governmentwide change in ethics policies.

In retrospect I believe that the new rules were not sufficient to guard against the perception of conflict of interest or reality of conflict of interest.

Further, I have reached the regrettable conclusion that some NIH employees have violated these lenient rules in that the agency's ethics system did not adequately guard against these violations, both in the content of the rules, in the process to manage the rules and in the controls that should have been independent and formal.

So I am completely committed, and you have my pledge, that any employees who violated the rules will be subject to appropriate panels. I am looking forward to work as diligently as we can with the committee. I know Mr. Azar is also committed to do the same. We intend to cooperate. We want to cooperate. If there is any perception that we did not, we want to correct that. And you have my word and my colleagues at the Department who do believe in the same thing.

It is clear that our public health mission is too important, really, to have any shadow of a doubt that what NIH does is in the public's interest first and foremost. And it is really regrettable to me and painful to me that the actions of a few may have tainted the good work of thousands of scientists who have not participated in any of these actions and who work daily at NIH to solve the mysteries of disease and advanced treatments and cures for these diseases. So I think it is important that we move diligently, I believe, to completely change the system of ethics at NIH.

I will summarize, and you have my testimony in writing, but I would like to summarize the salient points, not to take too much of your time, of what is it that we are proposing and the core principles that we are trying to follow.

No. 1, in terms of industry consulting. I think it is absolutely important to build a firewall between the employees at NIH who have any authority whatsoever in grant making or contract making from any consulting with industry. That means that the entire senior leadership, including directors, reports to directors, deputy directors, scientific directors, clinical directors and all staff involved in making decisions for contract and grants in the extramural components of NIH be prohibited, period. And this is a total damp.

We also want to protect the agency from any further perception of conflict of interest, and we are going to do this by restricting very strongly the activities of scientists who have no authority over the extramural activities or granting activities within NIH.

I would like to point out that NIH is both a Federal agency that distributes grants, but also a very advanced research laboratory with scientists who we recruit to do things for the government of public health interests. It is important to look at that in a different light, and I know that it would be so much easier to just ban outright the activities. And, as you know, I have made the point that perhaps we should look at that, and I would like you to keep an open mind about why we believe it should be done that way.

However, that being said, I think strict restrictions should be put in place. No. 1, I do not believe that stock or stock options should be used as payments for any outside activity for anyone at NIH. And I intend to prohibit any of such relationships.

Stock and stock payments create an inextinguishable conflict, and I do not wish to have that.

Second, I will prohibit the holding of stock in individual biotechnology and pharmaceutical companies for all employees that file a public or confidential public disclosure report of any kind and establish and establish for all employees a \$5,000 de minimis in terms of individual stock ownership of theirs with their direct family for nonfilers. And we will insist that divestiture occur.

I think this will create a scrubbed environment, I believe, for ethics at NIH so that we will no longer have any of these issues.

In addition, because I am concerned about conflict of commitment, who is the employee working for the Government or some other entity, I will go further than what the Blue Ribbon Panel proposed. I will limit annual compensation from all outside activities with industry to 25 percent of the employee's base salary, and no more than half of such income to come from any one source. And limit the time spent engaged in all activities with industry to 400 hours annually.

This is a set of rules which will not create a incentive because the compensation for outside activity will then be equal to the rate of compensation for official activities.

We will also publicly disclose all outside activity with industry. We will have a data base, we will find ways to make sure that the following principle is followed: If you cannot disclose it publicly, it will not be allowed. Period, end.

We will prohibit membership, and this is a recommendation that I am making, a proposal I am making which was not part of the Blue Ribbon Panel. Mr. colleague Mr. Azar helped me tremendously in defining those relationships. Any membership on corporate boards will be prohibited for all employees. I believe that membership in boards is a conflict of commitment and fiduciary responsibility. I want my employees to be responsible to NIH, period. However, we will allow limited service on scientific advisory boards for ad hoc participation, and again, not for any of the senior employees. Only the ones that are in the laboratories. Because there is value there and we need to make sure that it is reviewed centrally, but it be allowed.

In addition, in terms of rewards I think this is an issue that you have raised, and I have to say that I reviewed all the cases that came to my attention, worked with you. And I believe that there are awards that are very legitimate. There are awards that relate to the meritorious accomplishments of a scientist, sometimes before

they came to NIH. I think it would be unwise for us to prevent the recruitment of a director who may be a potential recipient of a Nobel Prize or a Laska Award, or many other prizes that have a long established life, that have a process that is independent on any granting institution in the sense of having a foundation and a clear process, an open process of nomination, an open process of awarding the award. But to do so, we are proposing something pretty novel. We're going to scrub, essentially, every award out there. We're going to create a list, we're going to submit that list and the criteria of that list to our independent advisory committee to the Director of NIH, which is law, in statute. And we're going to ask them is the Nobel Prize okay. Is the Laska Award okay? Is this prize okay? Does it fit the characteristics. And then we'll create a public registered list, if you will, of acceptable awards for NIH scientists.

Now, further, if the award is received by an NIH employee, it will still be reviewed by a central committee, central advisory ethics committee for the following issues.

If the official offered the award is responsible for a funding decision with the entity offering the award, either directly the person, the employee, or through a subordinate—this is really an extension of rules that I think is very drastic and very important to understand. And I think we owe it to Mr. Azar who made the recommendation, that the receipt of the award may be prohibited and indefinitely the receipt of the cash component of the award will be prohibited.

In determining whether an award creates a real or apparent conflict of interest, the new act will consider how the employee can effect the interests of the entity so that we do not end up with just formal analysis, but a wider analysis not just directly related to the entity that offers the award, either directly or through the actions of a subordinate.

Pre-screened award lists will be maintained by the NIH ethic office publicly posted, updated regularly and the name of any NIH employee who is a recipient of an award would also be posted publicly.

I think it is important also to impose restrictions not just on relationships with industry, because as I have looked at potential for both real and perceived conflict of interest, I find also that consulting with nonprofits, grantee institutions can be a concern. So I am going to propose that we prohibit this for all employees.

You may ask, as Congresswoman DeGette asked me, why are you more strict for nonprofit grantee universities than you are for industry? Well, the difference is that grantee institutions come and ask for public money. Industry pays for the outside activities of the scientist. And in every case where we need to have science advice given to our grantees, we will do so after determination by supervisory review under an official duty scheme rather than an outside activity scheme which will prevent personal rewards of any kind in that kind of a relationship.

Consulting with nonprofits, nongrant institutions is another issue. There we do not have the potential of conflict of interest in terms of disbursement of funds. In this case we will prohibit it, nonetheless, for senior leadership, people who have grant making

or contract making authority, and we will determine by supervisory review whether there's any overlap between official duty and that activity.

So even though you may be director of institute X, if you are to serve on a nonprofit disease related group, we will prohibit that for senior leadership but we will allow it for nonsenior, nonauthority type leaders.

Clinical practice, we do need to maintain the clinical skills of our doctors at NIH, and the clinical center is hyperspecialized and there is not enough for them to maintain the general scales, and we would like to continue to allow that within limits of commitment. Because it doesn't present a conflict of interest, but also limits of the marketbasket that we will see around the metropolitan area. If you are a radiologist, you will be allowed to make more than a radiologist in academic practice in this marketplace.

The reason I want to do this is to avoid what I call the perverse incentive. If an outside activity is rewarded at a higher rate, you have the perverse incentive to favor that outside activity. I want to eliminate that.

Seven, academic pursuits. Pure academic pursuit. Working a general textbook, editing a journal, writing an article, a peer review article, doing continuing medical education, teaching a course at the university level; those are the core of the activities of our scientists. I really do not wish to restrict those activities. I think it would be unwise to do so.

Public financial disclosure reports, we have already extended our request to OGE from 93 positions to 508 position that will be publicly filed. We are asking also the recommendation of counsel for NIH authority to determine 278 filing status for its employees so that we can adapt quickly to the changes.

In addition, step nine, we will also review all of our employees with or without authority involved in human subject research. I believe personally that this is a different set of consideration even more important than conflict of interest with companies because it involves human lives, it involves advice that we will give to the American public. So all of those employees will file reports if involved in clinical research. And we will determine who that is and we will propose that list.

Finally, I think that no set of rules will be successful unless you build around them a process, a management process with strong controls. Here is what I propose to do.

I have already established a centralized committee, the NEAC committee, and it is doing an outstanding job. But in addition to that, we will centralize the oversight of every NIH ethics activity in the Office of the Director. There will be ethics officers in the institutes, obviously, to help everybody, but the oversight will be centralized so that there is no conflict of reporting relationship between the person who is making the decision for the director or for somebody in that institute.

We will ethics functions in the supervisory performance plan. We will add a central director of ethics who will be—all of the director of ethics will have performance plans and he deputy director will be in charge of that.

We will initiate random audits, and we are working with our general counsel to implement that.

In addition to this, I think something that I think is needed as a tool to in fact provide the response to the concerns that you have, Congresswoman DeGette, and that is a full electronic data base that will be cross related between every step of the activities and every step of the ethics process in one place. So I can respond to your inquiries in 2 weeks rather than 4 months, Mr. Chairman.

And we will extend formal training programs. And you have my commitment that one of the components of a good control ethics program is also disciplinary actions. I believe that we have been lax in making sure that if there is clear violations of existing rules, that we should really send a message. I intend to send that message and I will be very forceful in that regard.

In closing, I hope that you will take my commitment to you as a very sincere honest commitment that I will do everything in my power to make sure that NIH resumes its brilliant destiny as one of the most trusted agency in the Federal Government. And you have my commitment that I will work very closely with my colleagues here to collaborate with you.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Elias Zerhouni follows:]

PREPARED STATEMENT OF ELIAS A. ZERHOUNI, DIRECTOR, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman and Members of the Subcommittee, I am Elias A. Zerhouni, Director of the National Institutes of Health (NIH) at the U.S. Department of Health and Human Services (HHS). I am here to testify about my proposal to strengthen the ethics system at NIH by changing our rules, practices, and procedures.

I have reached the conclusion that drastic changes are needed as the result of an intensive review by NIH of our ethics program, which included internal fact-finding as well as the external review of a Blue Ribbon panel. This review was prompted in part in response to the inquiry of this Subcommittee and the bipartisan concerns of Chairman Greenwood, Ranking Member Deutsch, Congresswoman DeGette, and the full Committee Chairman, Mr. Barton, as well as the Committee's Ranking Member, Mr. Dingell, and other members of the panel.

The events and arrangements that have been the subject of the Subcommittee's oversight and NIH's reviews were rooted in a significant alteration of NIH's ethics rules and policies that occurred in 1995. These changes were the result of converging interests. The first was NIH's desire to strengthen the research enterprise through the use of innovative recruitment and retention policies. The second was a government-wide standardization of ethics policies, which resulted in a decision by NIH to change its ethics rules to conform to the new policies.

As we move forward, I regret that the reputation of NIH has been challenged over ethics concerns and that the conduct of individual scientists who have devoted their lives to battling disease and easing the suffering of millions of patients has been questioned. I believe the NIH and its employees were operating within rules that allowed or did not specifically address many of the arrangements that the Subcommittee has questioned, including lecture awards and consulting with industry. In retrospect, there was not a sufficient safeguard against the perception of conflict of interest.

As I have testified previously, our public health mission is too important to have it undermined by any real or perceived conflicts of interest. It is imperative that Congress and the American people trust that the decisions made by our scientists are motivated solely by public health priorities and scientific opportunities, not personal financial concerns.

The first step in maintaining such trust was the creation of the NIH Ethics Advisory Committee (NEAC). The NEAC, an internal NIH committee, is providing a centralized, consistent, and rigorous review of all consulting arrangements with pharmaceutical and biotechnology companies, awards valued in excess of \$2500, and all requests from senior NIH officials. Composed of Institute and Center Directors and scientific leaders, and with the participation of ethics officials, the Committee pro-

vides unprecedented review by peer scientists of applications for outside activities and awards. NEAC looks carefully at each request under its jurisdiction so that, for instance, NIH employees are not consulting on matters that are related to their official duties or pose other potential concerns. Only those requests for approval that have passed muster at the Institute level, by both the employee's supervisor and the Institute's Deputy Ethics Counselor (DEC), are forwarded to the NEAC for review. Upon NEAC review, it is only those arrangements that do not pose conflict of interest concerns that are recommended for approval and forwarded to the NIH Deputy Ethics Counselor. As a result of the unprecedented review by peer scientists now applied to the ethics program, the culture at NIH is already changing.

On May 12, I testified before this subcommittee about four principles for change in the NIH ethics program:

- 1) Enhance public trust in NIH by preventing conflicts of interest through the restriction of financial relationships that employees may have with outside organizations;
- 2) Increase levels of transparency in the NIH ethics program by requiring much more internal as well as public disclosure of the details of financial relationships that employees have with outside organizations, including consulting arrangements and awards;
- 3) Balance NIH's ability to recruit and retain the best scientific expertise while expediting the translation of research advances;
- 4) Establish effective monitoring and oversight of employee activities.

Today I am announcing that NIH, working with the HHS Office of the Secretary, will seek a major reform of the Agency's ethics program by requesting restrictive rules and by seeking to increase the public availability of information related to outside activities with industry. As you know, this process cannot happen overnight. We are aggressively working with the Office of the Secretary and OGE to make sure that we have in place a set of rules that ensures the appropriate ethical oversight while continuing to encourage scientific creativity. The following framework lays out our attempts to implement the principles described above.

Principle One: Enhance Public Trust

- *Prohibited Holdings:* We are working to prohibit the holding of stock in individual biotechnology and pharmaceutical companies as is done at the Food and Drug Administration. There, all employees that file either a public or confidential financial disclosure report are prohibited from holding stocks in significantly regulated entities. Non-filers are permitted to hold only up to \$5000 of such stock, which is \$10,000 below the current federal rules for *de minimis* financial interests.
- *Awards:* We are actively pursuing a two-step process. First, any NIH employee should be prohibited from accepting any award unless the award has been pre-screened. Such a process would include an independent advisory committee that includes non-government individuals and the NIH DEC, and a determination by the DEC that the award meets the regulatory definition of *bona fide*. Second, even if the award has been determined to be *bona fide*, specific awards to employees still should be reviewed on a case by case basis by the NEAC, and approved by the NIH DEC to ensure that the acceptance of the award does not create a real or apparent conflict of interest for the employee in relation to official duties. As an additional restriction, NIH will seek to prohibit any official—including Institute and Center Directors—who are responsible, either directly or indirectly through subordinates, for a funding decision affecting the entity offering the award, from receiving the cash component of an award. It is my intention that this restriction will not preclude the acceptance of cash in the case of certain exceptional *bona fide* awards, such as the Nobel Prize. The list of pre-screened *bona fide* awards would be posted publicly, as will the NIH recipients of such awards.
- *Outside Activities with Industry:* While we continue to encourage consultation with industry as part of official duties, I intend to prohibit senior NIH employees, as well as all employees involved in extramural funding decisions or Cooperative Research and Development Agreements, from consulting with industry for compensation or any other form of remuneration. Other employees would be permitted to consult only if the arrangement has been reviewed by the NEAC and approved by the NIH DEC, and certain restrictions are in place. These are: 1) payment may not include stock or stock options; 2) annual compensation from all outside activities with industry must be limited, and no more than half of that limit may come from any one source; and 3) a cap on the number of hours annually that an employee can spend on all outside activities with industry.

- *Participation on Industry Boards:* I seek to prohibit all NIH employees from membership on corporate boards of the pharmaceutical and biotechnology industries. In addition, employees should be allowed to participate in industry scientific advisory boards as ad-hoc participants only if such participation has been reviewed by NEAC, and approved by the NIH DEC.
- *Consulting (includes speaking) with Grantee Institutions:* While we continue to encourage consultation with grantee institutions as part of official duties, I will seek to prohibit all NIH employees from consulting with NIH grantee institutions for compensation or any other form of personal remuneration.
- *Consulting (includes speaking) with Non-profits that are not Grantee Institutions:* I seek to prohibit NIH senior leadership from consulting with these entities.
- *Clinical Practice:* NIH seeks to limit employee annual compensation for clinical practice.

Principle Two: Increase Transparency

- NIH, working with HHS and OGE, has already increased the number of senior managers who must publicly disclose their compensated activities with outside organizations and the amounts received. This has been increased by 93 positions. We are hopeful that OGE will grant HHS' recent request to extend public financial disclosure to an additional 508 positions.
- I will seek authority from OGE for NIH to determine which of its employees must submit public financial disclosures.
- We are working towards requiring that outside activities with industry be publicly disclosed. This will include disclosure to CRADA partners.
- NIH employees will continue to be required to disclose the amount of compensation earned from outside activities.
- I will review the duties and responsibilities of employees who currently do not file any financial disclosure reports, specifically those involved in human subjects work, to increase the number of employees who file such reports to avoid any involvement in a real or apparent conflict of interest.

Principle Three: Recruit and Retain Best Scientific Expertise While Expediting Translation of Research Advances

- I will encourage NIH scientists to continue teaching, speaking or writing about their research as part of their official duties.
- In order to encourage scientific interactions involving the exchange of knowledge and the exercise of intellectual leadership by NIH scientists, NIH will continue to allow certain types of outside activities—including teaching and lecturing opportunities and collaborations with the private sector—but only under clear, rigorous rules meant to eliminate conflicts of interest.

Principle Four: Establish Effective Monitoring and Oversight Mechanisms

- I will continue to require that supervisors fulfill their responsibilities in both reviewing proposed outside activities and, if NEAC ultimately approves the outside activity, in monitoring the effect that the activity might have on the employee's official duties. Before any proposed outside activity is forwarded to the NEAC for review, supervisors will be asked to determine whether the activity can and should be undertaken as part of the employee's official duties, and if not, whether the proposed outside activity will cause a conflict, either of interest or of commitment. In addition, supervisors will be expected to monitor employees' compliance to ensure compliance with the limitation on hours.
- NIH will improve its ability to manage and track approved activities with outside organizations by increasing the accountability of managers, creating a centralized system, centralizing review of senior managers and scientists, conducting random audits of files pertaining to activities with outside organizations, and continuing the rigorous review by peers conducted by the NEAC.
- NIH will develop and implement a new, more understandable method of training employees on ethics rules, and we will establish a web site that displays rules in plain language, updates employees on regulatory trends and changes and discusses—anonously—ongoing cases as examples of best practices or unacceptable practices.

We are severely restricting the ability of NIH employees to consult with industry. However, as I have previously testified, the easiest way to approach this matter would be to ban all consulting with industry. I do not want to discourage the kind of intellectual excitement and curiosity that leads our scientists to want to work with industry. I want to provide an environment for them in which they have the same kind of professional and intellectual opportunities as their counterparts in academia. I want the intramural program to continue to attract the best and the brightest. With these principles in mind, I am working to strike a careful balance—

whereby those individuals in key decision-making positions will be prevented completely from consulting, while stringent limits will apply to other employees.

Mr. Chairman, Members of the Subcommittee, in summation, I have described the three core elements of reforming the ethics process at NIH. Number one, we are applying review of applications for outside activities by peer scientists. Number two, we are requiring full disclosure and transparency in the program. And number three, NIH is working to reduce, restrict, or eliminate the types of activities about which this Subcommittee has raised concerns.

Thank you for this opportunity to speak before the Subcommittee on these matters once again. I would be happy to answer any questions you may have.

Mr. GREENWOOD. The Chair thanks the gentleman. And would wax poetic enough to say that if the NIH is indeed the crown jewel of research, I think those recommendations will certainly make it sparkle more than it has in the past.

Dr. Azar, you are recognized for your opening statement.

Did I call you Dr. Azar? Mr. Azar.

TESTIMONY OF ALEX AZAR, II

Mr. AZAR. Thank you, Mr. Chairman. And thank you for inviting me to speak with you today.

As General Counsel for the U.S. Department of Health and Human Services my office is responsible for providing representation and legal advice to HHS on a wide range of issues. By providing such legal services to the Secretary of HHS and the organization's various agencies and divisions, the Office of the General Counsel supports the development and implementation of the Department's programs.

OGC has over 400 attorneys and a comprehensive support staff located across the United States. Our office has a diverse and challenging portfolio, with legal issues about technical rules for agency programs on topics as disparate as health financing and welfare, as well as a broad range of general legal issues facing every Federal agency such as administrative law, personnel and employment law, information law, and, of course, ethics.

OGC's main role in the area of ethics is through the Ethics Division's provision of legal advice regarding applicable laws and regulations to the ethics officials who run the agency's ethics program. In HHS, the ethics program is overseen by a Designated Agency Ethics Official, a DAEO, appointed by the Secretary and who, in our case, also heads OGC's Ethics Division. The DAEO oversees and coordinates a decentralized Departmental ethics program. The DAEO also appoints Deputy Ethics Counselors, DEC's, who are senior management officials chosen by each operating division. Each of these DEC's, along with agency heads and management are responsible for running ethics programs tailored to the needs of extensive, geographically dispersed workforces composed of many professionally trained employees with varied responsibilities. As managers closest to day-to-day operations, these DEC's are equipped and responsible for identifying and evaluating the relevant ethics issues in their respective components. Additionally, the DEC's and their staffs possess the scientific and technical expertise necessary to identify and resolve ethics issues in situations involving science, medicine, and other complex fields.

Within their respective operating divisions, the DEC's are responsible for reviewing public and confidential financial disclosure forms, considering outside activity requests, providing ethics advice

to individual employees, initiating ethics education and training programs, and ensuring that violations of the conflicts statutes or the conduct standards are reported to investigatory authorities and where appropriate, seeing that disciplinary action is taken. Individual employees are, of course, ultimately responsible for their own actions.

As an attorney who has devoted over half of my professional career to serving the Federal Government and who attaches great importance to public service, my objective in leading OGC has been to ensure the best possible legal advice to assist in the accomplishment of HHS' critical missions. I view the role of OGC not as making policy, but rather as providing those who do set policy with the best possible legal advice. This means that the function of my office is to work to identify the Department's policy objectives and then to identify the range of permissible legal options to accomplish those policy objectives and advise on the legal and other risks associated with those options. Of course, legal advice is often accompanied by advice regarding considerations such as appearances, judgment, and other factors that may be relevant to the agency's situation. Where there is no established Government-wide interpretation of a law, it is the Department, then, which decides which interpretation of law to adopt and what course of action to take. In so doing, the Department can appropriately balance the considerations, among many others, relevant to accomplishing the agency's objectives.

I strongly believe that such advice, including advice about appearances, is particularly important in the area of Government ethics; where the law may be arcane and complex, but where other non-legal factors invariably play a large role.

Consistent with the President's statement that, "Everyone who enters into public service for the United States has a duty to the American people to maintain the highest standards of integrity in Government," I have initiated and led a successful effort to obtain and dedicate additional resources to enhance the Ethics Division in OGC. This initiative, which is already underway, will enhance the ability of the DAEO to scrutinize and oversee the Department's ethics activities. In addition, it will dramatically strengthen the ability of the DAEO to oversee these programs and their officials.

As part of this initiative, the Department will institute systematic oversight of the ethics programs within the various operating divisions of the Department through regularized compliance auditing and program review. The initiative will increase component accountability for ethics program implementation, augment financial disclosure review and training development, and enhance the capabilities of the Ethics Division and the authority of the DAEO. To my knowledge, this will make HHS OGC's Ethics Division the largest single legal office devoted exclusively to Government ethics outside of the Office of Government Ethics.

These efforts will help ensure that the DAEO is in the best position to oversee HHS' and NIH's ethics program in the future. The Department is also committed to helping the committee understand the past implementation of and compliance with the current ethics rules at NIH. In this regard, we have worked hard to solve a number of legal issues relevant to the committee's work and to support

NIH's efforts to identify and rectify areas of concern. The goal of ensuring public confidence in the integrity of NIH is one that the Department shares with the committee and a goal we can best accomplish together.

The proposal outlined by Dr. Zerhouni today is an important fruit of that collaborative effort. The proposal was largely born out of the work Dr. Zerhouni has led to find ways to build on the recommendations of the Blue Ribbon Panel. The Department was pleased to see that NIH proposed to take strong steps to provide additional review of awards and prohibit outside activities with grantees of NIH by the leadership of NIH as well as employees involved in the grants process. And the Department worked with Dr. Zerhouni to strengthen the proposal even further. The result has been a collaborative effort to address the issues raised by the committee, including a proposed prohibition on holding of stock in individual biotechnology and pharmaceutical companies like that in place at the Food and Drug Administration. There are also proposed prohibitions on outside activities by senior NIH leadership with industry and extensive limitations for all other employees. As a lawyer, my predisposition is for bright line rules, such as complete prohibitions, which are easy to administer and interpret. However, the proposal balances this consideration with the needs identified by Dr. Zerhouni to ensure that NIH can recruit and retain the Nation's most talented scientists and allow them to contribute to the march of human scientific progress outside the confines of the workplace.

In conclusion, Mr. Chairman, the Department shares the committee's commitment to maintaining the highest ethical standards at NIH and thereby ensuring that the vitality and promise of NIH is not undermined by any lack of public confidence in the motivations of its employees and their conduct. OGC remains committed to helping NIH understand applicable laws, further identify legal options, and give legal advice relevant to NIH's ethics program. And the Department remains committed to cooperating with this committee in its important work.

Thank you for the opportunity to speak with you today. And I would be pleased to answer your questions.

[The prepared statement of Alex Azar follows:]

PREPARED STATEMENT OF ALEX AZAR, GENERAL COUNSEL, U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

Thank you for inviting me to speak with you today to discuss ethics issues at the National Institutes of Health (NIH) relating to consulting arrangements and outside awards.

As General Counsel for the U.S. Department of Health and Human Services (HHS) my office is responsible for providing representation and legal advice to HHS on a wide range of health and human services issues. By providing such legal services to the Secretary of HHS and the organization's various agencies and divisions, the Office of the General Counsel (OGC) supports the development and implementation of the Department's programs. OGC has over 400 attorneys and a comprehensive support staff located in many locations across the United States. Our office has a diverse and challenging portfolio, with legal issues about technical rules for agency programs on topics as disparate as health financing and welfare, as well as a broad range of general legal issues facing every federal agency such as administrative law, personnel and employment law, information law, and, of course, ethics.

OGC's main role in the area of ethics has been the Ethics Division's provision of legal advice regarding applicable laws and regulations to the ethics officials who run the agency's ethics program. In HHS, as in most large Cabinet Departments, the

ethics program is overseen by a Designated Agency Ethics Official (DAEO) appointed by the Secretary and who, in our case, also heads OGC's Ethics Division. The DAEO oversees and coordinates a decentralized Departmental ethics program. The DAEO also appoints Deputy Ethics Counselors (DECs), who are senior management officials chosen by each operating division. Each of these DECs, along with agency heads and management in each component, are responsible for running ethics programs tailored to the needs of extensive, geographically dispersed workforces composed of many professionally trained employees with varied responsibilities. As managers closest to day-to-day operations, these DECs are equipped and responsible for identifying and evaluating the relevant ethics issues in their respective components. Additionally, the DECs and their staffs possess the scientific and technical expertise necessary to identify and resolve ethics issues in situations involving science, medicine, and other complex fields. Within their respective operating divisions, the DECs are responsible for establishing a system for reviewing public and confidential financial disclosure forms, considering outside activity requests, providing ethics advice to individual employees, initiating ethics education and training programs, and ensuring that violations of the conflicts statutes or the conduct standards are reported to investigatory authorities and where appropriate, seeing that disciplinary action is taken. Individual employees are, of course, ultimately responsible for their own actions.

As an attorney who has devoted over half of my professional career to serving the federal government and who attaches great importance to public service, my objective in leading OGC has been to ensure the best possible legal advice to assist in the accomplishment of HHS' critical missions. I view the role of OGC not as making policy, but rather as providing those who do set policy with the best possible legal advice. This means that the function of my office is to work to identify the Department's policy objectives and then to identify the range of permissible legal options to accomplish those policy objectives and advise on the legal and other risks associated with those options. Of course, legal advice is often accompanied by advice regarding considerations such as appearances, judgment, and other factors that may be relevant to the agency's situation. Where there is no established Government-wide interpretation of a law, it is the Department, then, which decides which interpretation of law to adopt and what course of action to take. In so doing, the Department can appropriately balance the considerations identified by their lawyers among many others relevant to accomplishing the agency's objectives.

I strongly believe that such advice, including advice about appearances, is particularly important in the area of government ethics—where the law may be arcane and complex, but where other non-legal factors invariably play a large role. Consistent with the President's statement that, "Everyone who enters into public service for the United States has a duty to the American people to maintain the highest standards of integrity in Government," I have initiated and led a successful effort to obtain and dedicate additional resources to enhance the Ethics Division in OGC. This initiative, which is already being implemented this year, will enhance the ability of the DAEO to scrutinize and oversee the Department's ethics activities. In addition, it will dramatically strengthen the ability of the DAEO to oversee these programs and their officials.

As part of this initiative, the Department will institute systematic oversight of the ethics programs within the various operating divisions of the Department through regularized compliance auditing and program review. The initiative will increase component accountability for ethics program implementation, augment financial disclosure review and training development, and enhance the capabilities of the Ethics Division and the authority of the DAEO. To my knowledge, this will make HHS OGC's Ethics Division the largest single legal office devoted exclusively to government ethics outside of the Office of Government Ethics.

These efforts will help ensure that the DAEO is in the best position to oversee HHS' and NIH's ethics program in the future. The Department is also committed to helping the Committee understand the past implementation of and compliance with the current ethics rules at NIH. In this regard, we have worked hard to solve a number of legal issues relevant to the Committee's work, as well as to support NIH's efforts to identify and rectify areas of concern. The Committee's oversight in this area has also been helpful in identifying areas of concern. We hope these steps have aided the Committee's work and helped provide insight into the relevant processes and issues. The goal of ensuring public confidence in the integrity of NIH is one that the Department shares with the Committee and a goal we can best accomplish together. As NIH moves forward, with the help of the Department and my office, to address those concerns, the Department continues to value the Committee's informed views and welcome the Committee's suggestions regarding steps that may be taken to ensure that the tremendous trust that the Congress and the public place

in NIH is as unquestioned as the vast contributions NIH has made towards advancing the nation's health and the promise it holds to continue doing so.

The proposal outlined by Dr. Zerhouni today to strengthen the ethics rules at NIH is an important fruit of that collaborative effort. The proposal was largely born out of the work Dr. Zerhouni has led to find ways to build on the recommendations of the Blue Ribbon Panel, which were a helpful starting point. The Department was pleased to see that NIH proposed to take strong steps to provide additional review of awards and prohibit outside activities with grantees of NIH by the leadership of NIH as well as employees involved in the grants process. And the Department worked with Dr. Zerhouni to strengthen the proposal even further. The result has been a collaborative effort to address the issues raised by the Committee, including a proposed prohibition on holding of stock in individual biotechnology and pharmaceutical companies like that in place at the Food and Drug Administration (whereby such holdings are prohibited for all employees that file financial disclosure reports, and there is a \$5,000 limit on such holdings by other employees. There are also proposed prohibitions on outside activities by senior NIH leadership with industry and extensive limitations for all other employees. As a lawyer, my predisposition is for bright line rules, e.g., complete prohibitions, which are easy to administer and interpret. This Committee's oversight work has also demonstrated the difficulty in applying complicated rules to real world scenarios. However, the proposal balances this consideration with the needs identified by Dr. Zerhouni to ensure NIH can recruit and retain the nation's most talented scientists and allow them to contribute to the march of human scientific progress outside the confines of the workplace.

In conclusion, the Department shares the Committee's commitment to maintaining the highest ethical standards at NIH and thereby ensuring that the vitality and promise of NIH is not undermined by any lack of public confidence in the motivations of its employees and their conduct. OGC remains committed to help NIH understand applicable laws, further identify legal options, and give legal advice relevant to NIH's ethics program. And OGC remains committed to cooperating with this Committee in its important work.

Thank you for the opportunity to speak with you today. I would be pleased to answer your questions.

Mr. GREENWOOD. Thank you very much, sir, for your testimony.

The Chair recognizes himself for 5 minutes.

And let me just again editorially comment that it is probably the case that the NIH has the most complicated set of circumstances around which to build an ethical system because of the outside activity and because of some of the recruiting issues. But it is my sense that with what you have proposed and a couple of things that we may need to do legislative, I think the NIH will end up with the tightest ethical standards anywhere in the Federal Government.

Let me just be very clear, Dr. Zerhouni, with regard to outside activity and disclosure. Is it your proposal that all, every single approved outside activity would be disclosed or is there—

Mr. ZERHOUNI. This is my intent. Obviously, we are going to have to work with the current laws as to what can or cannot be done and how it can be done. But that is my intent.

Mr. GREENWOOD. Mr. Azar, what impediments might there be to full disclosure, public disclosure and to the extent that there, what might we need to do legislative to overcome them?

Mr. AZAR. Mr. Chairman, we believe that it is possible for us to get to work to get the—it is called the 520 form on which outside activities are required and approved, to get those made public. Put them up on the Internet if the NIH wishes to put them as part of the data base.

What the agency will have to do to do that, and we have provided them with advice this, will be to either get the Office of Government Ethics to modify their system of records under the Privacy Act in which the form 520's kept or something we could ourselves,

create our own system of records in which the ethics forms, the 520's would be kept, and have listed as one of the disclosures when you create that system of records that it would be disclosed automatically on the Internet once filed.

So these are things that we will work very collaboratively with NIH to help them achieve their goal, but it is definitely something that can be done.

Mr. GREENWOOD. My counsel advises me that the Office of Government Ethics thinks that there may be some impediments to that disclosure. And so I ask you to work with us to the extent that there are any basis for legal challenge to that disclosure, we would want to clarify that in the reauthorization statute so that we can have this full disclosure.

Dr. Zerhouni, given all of the restrictions and controls, let us be clear. Tell us what kind of outside consulting arrangement do you envision as being permissible under this system.

Mr. ZERHOUNI. Obviously, outside consulting, outside work for editorial matters, writing a textbook, getting a contract from a publishing. I am assuming that is not the point of the discussion.

In terms of relationship with industry, for an employee who is not in the senior leadership, so let us say for example you were an expert on West Nile virus or the genetics of a particular process. And that, in fact, it turns out that the same technique and the same field of science that you are in is important because there is, for example, a potential to develop an alternative treatment for another disease. You may be asked to consult for that. It is not part of your official duty; that is where we will define that. And one of the issues—

Mr. GREENWOOD. Well, clearly, if it is within the scope of your official duties, you will not be compensated for that?

Mr. ZERHOUNI. That is not allowed. No, you cannot be compensated. And the determination now is not going to be done by an ethics officer alone. It is going to be done by the NEAC, which has scientists on its board who understand and can get advice on that field of science.

A good example would be a plant genetics company that wants to get advice from a human genome researcher. There is no overlap there. Would we prevent that advice from being given? No. If some other company says well I want to know about human genomics in a field that relates to what, that would be prohibited.

Mr. GREENWOOD. And we have discussed this before, but I think it is also important to us and for the public confidence, that there be very clear rules about allocation of time so that if someone is literally moonlighting, they are working in the evening after their normal duties, they are working on the weekends, if they are using their vacation time, you know that is fine. But we do need to be clear that we are not paying people to be sitting at their desks at the NIH and doing work for which they are being paid by an outside private entity.

Mr. ZERHOUNI. I take your point. We are establishing a system that will have, again, recording centrally of the activities. Four hundred hours is about 6 hours a week; people can do this 1 hour a day. So it is not very large. It is much less than universities will do. But I think it is important to allow that and limit on dollars

will also restrict that. But we will try to put systems—and I agree with the devil is in the details comment that you made, Congresswoman DeGette. We will have to work that through, but we intend to monitor that.

Mr. GREENWOOD. Thank you, Dr. Zerhouni.

The gentlelady from Colorado.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. Azar, I wanted to ask you a couple of questions. One concern, I mean OGC has, I think you said in your testimony, over 400 attorneys but they are not all doing ethics. They are doing all the legal work of HHS, right?

Mr. AZAR. Yes, ma'am.

Ms. DEGETTE. How many of them are concentrating on ethics?

Mr. AZAR. We have eleven individuals currently in the ethics division. The number of attorneys in that, I believe it is approximately six, maybe seven attorneys.

Ms. DEGETTE. So six or seven of the 400 attorneys are doing ethics.

Mr. AZAR. Yes.

Ms. DEGETTE. Now, where are they based? Are they based throughout the agency or are they based in one office?

Mr. AZAR. The head of that office, the Designated Agency Ethics Officer and Associate General Counsel for Ethics is located in the Humphrey Building on the same floor that I am on, right above the Secretary's floor as well as several of the attorneys. But two of the slots are located physically out at NIH to assist NIH directly. And then another—

Ms. DEGETTE. And there, I would assume, they are located in Dr. Zerhouni's office in the administration office?

Mr. AZAR. They are in Building 31, which is where most of the administrative staff are. Dr. Zerhouni is in Building 1, but they are with I think most of the center directors in Building 31. And they are also with—we have a branch of lawyers that assist the NIH regularly on other substantive matters, and they are now colocated with them. So there can be some extra support.

I do not mean to say that the only lawyers who ever touch an ethics issue are the people in the ethics division.

Ms. DEGETTE. Sure.

Mr. AZAR. For instance, the regional chief counsels will assist the regional administrators on ethics issues. And all lawyers should be versed somewhat in the ethnic provision—

Ms. DEGETTE. Well, one thing I have been concerned about, and I shared this with Dr. Zerhouni, is when you have 27 institutes and you have ethics personnel dispersed through those institutes, part of the problem they have had, they have had no consistency with administering ethical rules. Is that correct, Dr. Zerhouni?

Mr. ZERHOUNI. You are correct.

Ms. DEGETTE. And one of the goals I think of these new proposed rules which is important is to get it all centralized into one office so there is one set of standards being applied and also so that the individuals approving or deciding on different requests are not immediately there with the individuals. Correct, Dr. Zerhouni?

Mr. ZERHOUNI. That is correct.

Ms. DEGETTE. Now, do you agree with that, Mr. Azar, in terms of trying to reform the rules here?

Mr. AZAR. That is why I think Dr. Zerhouni's efforts to create the NIH Ethics Advisory Committee, a centralized process is very good. It also provides a peer review background of support for the DEC for the entire NIH and helps to centralize those decisions. And so we can also provide our legal advice, which we provide them with support as they make those decisions, we can provide that centrally as well as to the DEC's at each institute. But I think the more things are handled centrally, I think that is a very important point.

Ms. DEGETTE. Okay. I want to ask you, I want to turn a little bit to a different issue. That is the issue of who exactly do these HHS lawyers who show up at our committee investigations represent? Now, if you take a look at tab 25 in the notebook you will find a letter dated April 16, 2002 from yourself to Chairman Tauzin and Greenwood. Do you recognize that letter?

Mr. AZAR. Yes, Congresswoman.

Ms. DEGETTE. Now, on page two there is a paragraph at the top. And that paragraph says in part "department attorneys who accompany an employee at FDA to an investigative interview will not inform any department officials about the substance of the interview." The first sentence of that is "It is important to stress that department attorneys represent employees in their personal capacity." Correct?

Mr. AZAR. That is what the letter agreed. Yes.

Ms. DEGETTE. Yes. And that has actually been the longstanding policy of the department, correct? When you send attorneys over to represent an individual, they are there representing the individual?

Mr. AZAR. Actually, if I could clarify that. There was an agreement in 1995 between the prior Administration regarding dealings with FDA, and it is unclear in the text of it whether they are operating under official capacity or personal, but what information would be shared. This was a unique—

Ms. DEGETTE. Okay. Yes, I understand. However, your letter to Chairman Tauzin was dated April 16, 2002. And I have got to say as a former lawyer myself, this is pretty clear what it says, right?

Mr. AZAR. Well, I was trying to clarify that this is not how the department operates generally. This was and is a special accommodation that was done with this committee at the committee's request during the Imclone investigation to do that matter.

Ms. DEGETTE. Can you tell me where in this letter it says that this policy was only in effect for the Imclone investigation?

Mr. AZAR. It refers to the fact, I believe that if I could look through this, explaining the role of attorneys from the Office of General Counsel with respect to interviews of FDA employees in the Erbitux, the Imclone matter.

Ms. DEGETTE. No. It does not say in the Imclone matter.

Mr. AZAR. I am sorry?

Ms. DEGETTE. I mean it talks about the Imclone matter.

Mr. AZAR. It says the Erbitux matter.

Ms. DEGETTE. That is what was going on then, but it does not say that this is policy was limited to the Imclone matter.

Plus, why would you have a policy that when lawyers come over with witnesses that only with respect to one investigation the pol-

icy is this way, but in every other investigation including ethics at the NIH, that the policy is different?

Mr. AZAR. The department generally when we provide counsel, provides them as official counsel to assist not only the witness, often at their request, to assist them in preparing to deal with the committees, to assist them so that they feel more comfortable in working with the committee and so that they can be better prepared in assisting the committee.

The committee in the Imclone matter, this was the first dealing that we had with the committee on this type of matter. The committee had asked that we clarify their role as personal counsel. We were happy to do that in that instance.

If I could explain, Congresswoman. We subsequently learned that I had basically gotten bad advice in terms of what the role of the attorneys could be. That only the Justice Department apparently can authorize the representation of employees in their personal capacity creating a personal attorney/client relationship.

Ms. DEGETTE. Okay. Can I just ask one question, because my time is up? Did you ever inform committee staff that you had gotten that clarification from the Justice Department?

Mr. AZAR. We believed, and I want to start by apologizing to you and to the members of the committee.

Ms. DEGETTE. That would be a good start.

Mr. AZAR. I want to apologize. We thought in the context of the FDA in June 2003, in the context of interviews the next after Imclone, the next interviews, interactions we had with the committee was regarding an FDA importation proceeding where John Taylor of his staff were being interviewed. And we had instructed the line attorneys who were coming over when the committee asked, you know when they were scheduled to interview, we had instructed them to make clear to the staff that they were serving as official counsel, not as personal counsel. Obviously—

Ms. DEGETTE. Well, why did you not write a letter like you wrote in 2002?

Mr. AZAR. Obviously, I—obviously I apologize that we—that we were not clear enough. We thought for lawyers when we say we are representing in the official capacity not personal capacity, that—that says it all for us. But—

Ms. DEGETTE. But you do not have any idea whether they said that or not?

Mr. AZAR. It is my understanding that the lawyer did say it at the interview with Mr. Taylor. But I do want—I do not want to try to explain this away. As soon as in the NIH interview context, as soon—I think it was in the context of Dr. Katz', scheduling of his interview, as soon as we learned that the committee was operating under the impression of this Imclone arrangement, we raised it and said we were not operating under that assumption, and the department sat down with the committee to work out an agreement. We now have an agreement to serve as official counsel but with a restriction on the sharing of information.

And, again, Congresswoman, I am very sorry if we were not clear enough in communicating. I had intended that that be clear. I am sorry that we did not do it clearly enough. And I just hope you will accept my apology. Certainly it was not from any bad intent. We

just—we always want to try to keep our role as counsel clear with the committee. And I hope that we will be able to work on a going forward basis in a productive way under the agreement.

But that really was our intent. And I am very sorry for any—
Mr. GREENWOOD. The time of the gentlelady has expired.

The Chair recognized the chairman of the full committee, Mr. Barton.

Chairman BARTON. Thank you, Mr. Chairman.

Dr. Zerhouni, I want to again compliment you on the recommendations that you have presented to this subcommittee. I want to ask a question about the National Institutes of Health Ethics Advisory Committee. How long has that been established?

Mr. ZERHOUNI. We established this committee November 2003.

Chairman BARTON. November 2003? So it is not yet a year old?

Mr. ZERHOUNI. No, it is not yet a year old.

Chairman BARTON. And the formal membership are your institute directors? Are you a member of that committee?

Mr. ZERHOUNI. My deputy director, who is the—I have designated as the agency ethics, the DEC for the agency is a member. My director for intramural science, Dr. Michael Gottesman is a member.

We have a selection. Not just institute directors. There are scientists also on the grounds and ethics officers of the NIH. We recruited Mrs. Holli Beckerman Jaffe who now works in ethics in my office to oversee that.

I do not sit personally on the meeting.

Chairman BARTON. Okay. What is the total membership of the formal board?

Mr. ZERHOUNI. I don't have that exact number.

Chairman BARTON. Thirty people? Forty people?

Mr. ZERHOUNI. No, it is about—no, it is small. Ten people.

Chairman BARTON. Ten people? Do they have a permanent staff?

Mr. ZERHOUNI. Do they have a permanent—well, as I said, the ethics division of my office, the Office of the Director, is basically staffing that committee, Ms. Holli Beckerman Jaffe was recruited.

Chairman BARTON. But that is at your—they have no formal staff of their own? The staff they have are staff that has been deleted from your office?

Mr. ZERHOUNI. That is correct.

Chairman BARTON. Okay. The recommendation that you presented to this subcommittee I think are excellent. What has been the response within the NIH of these recommendation? Are people resistive or are they supportive, or do they feel like they have had their hand caught in the cookie jar. I mean, what is the general reaction?

Mr. ZERHOUNI. I would say mixed. I talked to the directors yesterday. I had a special meeting of the institute directors to go over what I was recommending. I would say that in the issues that relate to clerical practice, for example, they really want that to continue and I do not think there is an issue.

They were very strongly in favor of continuing pure academic activities. I think the restrictions, they are concern about the restrictions having two impacts; one is moral in the troops. And uncertainty of how we solve this issue is also impacting them and their

ability to recruit, and my own ability to recruit. But most importantly, their concern that over time it would harm recruiting because—

Chairman BARTON. Did any of them show any concern about maintaining and restoring the public trust?

Mr. ZERHOUNI. Oh, yes. I should have started with that. Absolutely, positively. I have polled every single one of them and they told me the following: Do whatever you need to do to absolutely remove this cloud from NIH. We will give you our support.

So I have the total support of all the NIH directors. Goal No. 1 is to reestablish that public trust.

Chairman BARTON. What, if any, legislative action do you need on these recommendations?

Mr. ZERHOUNI. This is something that we are evaluating, obviously, as we speak. There are things that I think we can implement. There are things that could be handled with supplemental regulations. I am not clear at this point. This is still, obviously, a proposal that needs to be worked out. And if there are changes, we will let you know, Mr. Chairman.

Chairman BARTON. Okay. Well, we want to work with you on that.

I want to read from your prepared testimony on your bullet that is headed "Outside activities with industry." And I quote, "I intend to prohibit senior NIH employees as well as all employees involved in extramural funding decisions or cooperative research and development agreements from consulting with industry for compensation or any other form of enumeration."

What has been the response to that recommendation, which I think is one of your key recommendations?

Mr. ZERHOUNI. Full support.

Chairman BARTON. Full support. So there is no reluctance on that?

Mr. ZERHOUNI. No.

Chairman BARTON. What about the next one, participation on industry boards, "I seek to prohibit all NIH employees from membership on corporate boards of the pharmaceutical and biotechnology industries."

Mr. ZERHOUNI. Full support.

Chairman BARTON. Full support of that one, too.

Okay. My time is about to expire. I want to ask a general question about our next panel. We have a situation where CRADA was established with a company called Correlogic. And at some point in time the NIH scientists who were working on that CRADA became secretly involved or secret employees of a competitive company called Biospect. Do you have any general comments on whether that is a concept that should be supported or prohibited?

Mr. ZERHOUNI. This actually was the tipping point for me. When that happened, that came up to light, I said we need the complete scrubbing, complete reform. That is not appropriate.

Chairman BARTON. But in your opinion that should not be a general practice that somebody that is working with one company secretly goes to work for another company? You would agree with us if we wanted to prohibit that by—I do not know that we need to

do it by statute, but the fact that that should not be allowed is something that you agree with?

Mr. ZERHOUNI. I agree with that.

Chairman BARTON. Okay.

Mr. Chairman, my time has expired and I yield back.

Mr. GREENWOOD. The Chair is always prepared to be lenient with the clock with the chairman, but the Chair thanks the gentleman for yielding back and recognizes the gentlelady from Chicago.

Ms. SCHAKOWSKY. Thank you. This is the first of the three hearings that I have attended, so I hope we are not going over some of the same ground. I want to talk about the basic policy questions here. It seems to me we are trying to protect the public interest over the private interest concerns of some employees of NIH. Why would it be in the public interest to ever allow any Government employee to sign a contract that would prohibit that employee from informing the government of exactly what has been asked of him or her, and what he or she may have done in fact for a profit-seeking entity that hires them?

It is my understanding that scientific advisory boards require confidentiality as do most if not all employment contracts of any kind in the biotech or drug development private sector field. How can that in the public interest?

Mr. ZERHOUNI. Well, first of all, in terms of board membership, we are prohibiting that. I agree that there is an issue there.

In terms of the public's interest, I think it is very important that there is a public interest that is balanced by three different aspects. One, obviously, is the elimination of conflict or the appearance of conflict, which is what we are trying to do.

Second, it is translation of knowledge is encouraged by Congress. There is a mandate for us to accelerate the translation of whatever discoveries into real benefit.

Third, I think there is a public interest in having the ability to recruit and retain the best possible scientists for Government service. And this is the balancing that I have, you know, have had to do by prohibiting completely activities or interactions with industry for those who have authority, that accomplishes that goal. However, it does not recognize the dual nature of NIH.

NIH is also a scientific laboratory. And we are recruiting individuals of the highest competence who we are asking to do work for the public's interest. So those individuals, you know I have to compete in the marketplace of ideas and in positions with 200 other universities. So unlike other Government employees whose job in the Government is specific to Government, like myself for example. There is not another NIH in the private sector that I could be director of. So for me it is absolutely clear. I am making the choice to serve the Government. There is no equivalent job.

If I am a scientist with no authority in a pure laboratory who comes to NIH because we want to work on West Nile virus, for example, that scientist has knowledge which is really very precious. To prohibit that scientist from having interaction will basically go counter to the public interest—

Ms. SCHAKOWSKY. I am getting at the confidentiality issue.

Mr. ZERHOUNI. Okay. Now, in terms of the confidentiality, I agree with you, and this is what I mean by process change.

In the past what we did is basically there was a self-declared statement that said well, I am consulting with company X. What the NEAC is going to do is review the source documents and pass judgment on the source documents rather than any other document.

Now, in terms of confidentiality of scientists who have no authority and so on, sometimes it relates to intellectual property issues and protection of intellectual property is a legitimate concern of both the government and the private industry. So that is the realm where I think you can see the logic of having confidentiality. But board membership—

Ms. SCHAKOWSKY. I guess we have a lot of battles about that. But if you have someone whose mandate is to advance scientific discovery and who is also working for a company where some of that discovery may be defined as proprietary, then it seems to me that you have a conflict that is not resolved in the public interest, but rather in the private interest.

Mr. ZERHOUNI. Well, in terms of fiduciary responsibilities if you were a board member or we had an employee relationship with that company, I would agree with you. We are banning that. There is no more of these relationships. However, when you talk about the public's interest, let me give you an example.

Rare disease, no interest from major pharmaceutical companies. Some small company is trying to do that. Is it in our best interest to help that company even though the intellectual property needs to be protected for that company?

It is the same logic that we have in the CRADA relationship that was an official one, and we disagree that in that context you should allow somebody to then work for the competitor. We just had this discussion with Chairman Barton. It is the same thing in this case. There are legitimate reasons to help translate technology, and I do not want to ban them.

Ms. SCHAKOWSKY. My time is up. But let me just say that it seems to me whatever we put in place, and I think I would be inclined to even go further than your recommendations, what obvious is that oversight—our oversight capacity—has to really be improved. Because what you are telling us that even the current rules which we and you have found to be very lax have not been enforced. And, since we are in such sensitive areas, my concern would also be that, in the implementation of any changes you make, the public interest is clearly preserved.

Mr. ZERHOUNI. Appreciate it.

Mr. GREENWOOD. The time of the gentlelady has expired.

The gentleman from Oregon, Mr. Walden for 5 minutes.

Mr. WALDEN. Thank you very much, Mr. Chairman.

Dr. Zerhouni, I want to commend you for your efforts to try and clean up the mess that you inherited that dates back some 9 years. And I know the work must be difficult trying to balance, making sure we maintain the best research minds in the world, working at NIH and not lose them all out to the private sector and yet deal with these conflicts.

The Los Angeles Times, I think it was back it was back in December, featured six case studies. I am assuming you are familiar with that article. How would each of those cases fared under your proposed restrictions that you have outlined today?

Mr. ZERHOUNI. Well, clearly if I recall, three of the cases were two directors of clinical centers. That would be completely out.

There was a scientific director. That would be completely out.

There were two others that would be just scientists in the laboratories. They would be limited to 25 percent at 400 hours so it would have drastically limited the amount that would have been done.

Mr. WALDEN. Right.

Mr. ZERHOUNI. And we would have reviewed not just their statement of what the work was, but the specific scientific content through the NEAC.

So I think that that is pretty much; two of the six would have been reviewed, three or four of the six would have been prohibited.

Mr. WALDEN. All right. Prohibited.

I want to get back to this issue of the 400 hours as well. Because it seemed to me from one of the prior hearings that I sat through that those hours are outside of the sort of standard 40 hour work week, correct?

Mr. ZERHOUNI. That is correct.

Mr. WALDEN. So when we're talking about somebody can earn—

Mr. ZERHOUNI. Weekend time, vacation time, personal.

Mr. WALDEN. But it does not eat into the 40 hour work week or whatever their work week is at NIH?

Mr. ZERHOUNI. No, it does not.

Mr. WALDEN. Okay. Perfect.

And then after reviewing the data produced to the committee by the various drug companies, the staff discovered some consulting agreements between Pfizer and a Dr. Pearson Trey Sunderland to the tune of \$517,000 paid to Dr. Sunderland over a period of 5½ years in six contracts. NIH apparently did not provide the committee with any paperwork on these agreements and the agreements were not itemized on the 520 disclosure forms for Dr. Sunderland.

We have assurances from Pfizer that its reporting of the agreement is correct as far as Pfizer's internal records are concerned. When staff questioned the agency about these agreements, they were not able to provide us with a reasonable explanation. Have you been made aware of this problem and what, if any, specific knowledge do you have of the situation?

Mr. ZERHOUNI. Right. I was made aware of that problem Friday, I believe, just before—Friday past. And since then my staff has worked, you know, to look up the records and find out exactly what the essence of the issue is. But from the preliminary report that I have I think there is grave concern here that neither the public disclosure forms, because that individual is subject to disclosure requirements or the procedures that should have been in place even by that time were followed. This is our preliminary evaluation. We will continue to make sure that what I am saying here is documented.

Mr. WALDEN. Now if that indeed is the case, would your recommended changes in the ethics standards—

Mr. ZERHOUNI. Okay.

Mr. WALDEN [continuing]. Would they have caught this? Or, I mean, it sounds like this person if indeed what the preliminary investigation shows is correct, we have got laws in place.

Mr. ZERHOUNI. Right.

Mr. WALDEN. So somebody is still slipping through the net. How do we do prevent that?

Mr. ZERHOUNI. Excellent question. That is the relevant question, I think, Mr. Walden.

No. 1, the fact that we will have a centralized data base of all the activities is very important.

No. 2, the fact that we want to make public disclosure of every activity. We will allow any third party player out there to know who is doing what. So competition between—

Mr. WALDEN. But what triggers data into the data base? Is that the filing of the 520?

Mr. ZERHOUNI. That is right.

Mr. WALDEN. But if the person does not file a 520, how do we get at that?

Mr. ZERHOUNI. Right. Okay. So the random audit system that we envision is going to be the sort of try to catch back. Because, obviously, you cannot legislate morality.

Mr. WALDEN. Right.

Mr. ZERHOUNI. And that is hard. But through the random audits we can Google—that is the word now in the English language—every scientific activity out there and match it against ours. So any name of any NIH employee would appear in the Google activity that we would then look and cross-correlate with our data base. That is our intent.

Mr. WALDEN. So, okay, with the data base, but again, you see, you'd be looking for a negative then, because if the person didn't file a 520, the data wouldn't be in the data base.

Mr. ZERHOUNI. Right.

Mr. WALDEN. But your name would show up.

Mr. ZERHOUNI. Right.

Mr. WALDEN. Have you tried that just in this case, for example?

Mr. ZERHOUNI. No. It happened Friday. I haven't had the time to look at that.

Mr. WALDEN. It would be interesting, because in essence, if they didn't file a 520, they're not in a data base that doesn't exist anyway right now.

Mr. ZERHOUNI. But again, the important component of that too is through good controls and implementation of disciplinary rules. I think you will send a message to the community that there is a new era in ethics, new day.

Mr. WALDEN. Well, clearly a half a million dollars over 5½ years is a pretty big problem, so I'm glad that you're on it.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentleman from California, Mr. Waxman, for 5 minutes.

Mr. WAXMAN. Thank you very much, Mr. Chairman, Dr. Zerhouni, Mr. Azar. I'm pleased to see you.

I think it's an important function of the Congress to oversee how the Government is operating and whether the President has been a Democrat or a Republican, one of the most effective ways for Congress to learn about how the Government is operating is by talking to Government employees who are actually implementing the policies.

I'm not alone in this view. Throughout the last century, Congress has repeatedly passed laws protecting its right to receive truthful information from Federal employees and the Supreme Court has repeatedly endorsed that right. Yet, in my decades in the Congress, I don't think I've ever seen an Administration that has so consistently attempted to deter Government employees from providing truthful information to Congress.

We've already heard about the Administration's decision to send Agency attorneys to these interviews and I gather that seemed to be some kind of misunderstanding, but I would think that employees must feel somewhat reluctant to talk when they are off on their own. That's been the subject of a lot of discussion today.

I want to ask about a series of other actions by this Administration whose purpose appears to be to prevent HHS employees from speaking candidly to Congress and particularly to Democratic Members of Congress.

I've recently learned of an FDA memo informing employees that they should refuse to speak to Congressional staff if called and that if forced, should not speak unless an employee from the Administration's Legislative Office could sit in and monitor the conversation.

Mr. Azar, do you acknowledge, would you acknowledge whether the Administration has adopted a policy barring Government employees from speaking to Members of Congress or the staff unless the Administration can hear everything that is said?

Mr. AZAR. Congressman Waxman, other than having read something in the press about that, I'm not terribly familiar with that particular instance that you've mentioned, but I would tell you that as far as I understand, if an individual wishes to speak to Congress in that kind of an interview oversight setting, we would not, in working with this committee, for instance, with official counsel, force ourselves on them. We view it as a service to the employee. If the employee wishes to speak to Congress without us being present, I certainly, it would not be my view that we should inject ourselves.

And so if you would permit, I'd like to look into that situation at the FDA and get back do you on the—

Mr. WAXMAN. It's my understanding that whenever an employee of the Department of Health and Human Services wants to talk to a Member of Congress or staff, that someone has to be brought in from the Department.

Mr. AZAR. We generally, I know that the legislative individuals generally try to be available to assist and coordinate to make sure balls don't get dropped to provide assistance to the employees, but I can't imagine that if an employee wished to speak to Congress about matters like that without Departmental people present, that we would have any objection to that or want to get in the way of that, Mr. Waxman.

Mr. WAXMAN. I appreciate that and I assume the reverse is also true of a Member of Congress wants to talk any employee. That employee would feel that he or she would feel that they're able to talk to us without someone from the Department being present?

Mr. AZAR. If that was their desire, yes.

Mr. WAXMAN. Earlier this year, it was widely reported that the Bush Administration ordered the Chief Medicare Actuary not to respond to requests from Democratic members about the projected costs of the Medicare Drug Benefit and projected costs of the bill was absolutely central to the debate about whether the bill was good or bad policy. And yet, the Administration insisted and I think is still insisting that Members of Congress were not entitled to this information. Are you familiar with that situation?

Mr. AZAR. I am, yes.

Mr. WAXMAN. In addition, I want to point out that from the beginning of this Administration, I've written to HHS on a number of occasions seeking information about HHS policies. In past Administrations, whether Democratic or Republican, letters have always received a response. They may not have been the response I was looking for, but we always got a response.

In this Administration, however, it appears that a new policy of ignoring congressional inquiries has been instituted. Over 15 of the letters I've sent to HHS since the start of the Bush Administration have received no response whatsoever, complete silence. And when my staff has asked for briefings, many of the requests have never been responded to.

Over 9 months ago, my staff asked for a briefing on the use of Nonoxynol-9 in condoms. A briefing was scheduled and canceled, scheduled and canceled and then postponed indefinitely. No information has been provided. And when briefings have been provided, long time career Government employees who have met with our staff have been unwilling to speak freely with their political bosses listening in. Indeed, they're hardly willing to say anything of substance. It was obviously they were seriously intimidated by Administration's information gatekeepers.

Do you think it's appropriate for the executive branch to refuse to answer letters from Members of Congress or requests for briefings?

Mr. AZAR. I can tell you that the Secretary has made it a priority since he's been in office to try to be responsive to correspondence from Congress. I'd be happy to look into your articles of correspondence that haven't been responded to. Obviously, we get—the Department does get a very large volume of questions and correspondence from Congress and that has to be handled. But I'll be happy to check into that to see what the status is of responses to you.

Mr. WAXMAN. I appreciate that. And the other thing I want to raise with you is that I've heard that specifically an employee was told at FDA, or all the employees were told at FDA that in 2001 by senior officials that career FDA employees were not to be permitted to speak to congressional staffers and they specified which ones and if they did, they'd be fired.

Do you think that would be proper? I don't know if you're familiar with that incident. But do you think that would be proper?

Mr. AZAR. Again, I am not familiar with that and I'd want to know all of the facts and circumstances around that, but as I've said, as a general matter, I don't think the Department tries to get in the way of individuals who would like to speak with Members of Congress about issues.

Mr. WAXMAN. I'm going to send you more information about that incident.

Mr. AZAR. Thank you.

Mr. WAXMAN. In conclusion, I just want to point out that one of the letters that has remained unanswered was a letter to you, January 20, 2004, asking for information about ethics waivers issued to HHS employees related to negotiations for prospective employment, particularly with regard to Tom Scully.

Is there any reason you haven't answered that letter?

Mr. AZAR. My understand is that letter was, as all congressional correspondence, was referred over to the Department where that's handled and I had thought that that had been responded to. I will check on that. I'm sorry if you've not gotten a complete response. I thought you had gotten your response on that.

Mr. GREENWOOD. The time of the gentleman has expired. The gentleman, Mr. Bilirakis, is recognized for 5 minutes.

Mr. BILIRAKIS. Thank you, Mr. Chairman. Getting back to the subject matter of this hearing, Mr. Azar, are you the chief ethics office for the Department of Health and Human Services?

Mr. AZAR. Actually, the way the Government ethics system is operated, the Secretary directly appoints an official to serve as the designated agency ethics officer and that individual is a direct report to the Secretary. And that is a gentleman named Ed Swindell who testified at the last hearing before this committee. And he serves as the point of contact, the liaison, with the Office of Government Ethics and also works with an overseas, a very decentralized ethics process—

Mr. BILIRAKIS. You're chief counsel?

Mr. AZAR. Exactly, sir.

Mr. BILIRAKIS. So he works in a—

Mr. AZAR. Yes. In his role as Associate General Counsel, providing the legal advice. He does report to me.

Mr. BILIRAKIS. He reports to you.

Mr. AZAR. He does report to me.

Mr. BILIRAKIS. Let me ask the question. Prior to this business having been really brought out in the open by the newspapers, by this committee, etcetera, was your office aware of it and if you were aware of it, did you try—I guess what I'm getting at is is your function or at least the function of the ethics portion of your office, just to put out fires when fires arise or is the function to sort of try to keep fires from taking place? I think you understand what I mean.

Mr. AZAR. Yes, I do understand that. It certainly would be our goal to not just be putting out fires, but to be proactive, if we could. In this instance, no, I had not been aware of these issues before the important work of this committee. We've tried to be very responsive in working with Dr. Zerhouni and NIH and the rest of the Department in dealing with—

Mr. BILIRAKIS. Yes, but if we have an Ethics Department there, or office or whatever you would have called it, I mean what else

do they do other than take a look at whether there might be breaches of ethics taking place within the Department?

Mr. AZAR. A large amount of the work is reviewing the financial disclosure forms that come in and certifying those, as well as providing the day to day ethics advice. But your concern, I think, is very valid, sir. And as a result, we are implementing a program that will more than double the size of the ethics office and will for the first time in—as far as I understand it, within the executive branch, will for the first time have an oversight function internal to the Department so that the designated agency ethics officer will have the capacity to conduct his own audits and oversight of the performance of the ethics officials throughout the Department.

As I understand it, this would be unique. Currently, there are periodic edits, periodic audits that happen from the Office of Government Ethics, which is an independent Executive agency. So I think your point is well taken and we are working to try to make that more of our capacity, sir.

Mr. BILIRAKIS. Well, let me ask you. You've been a public servant for quite a few years. You didn't indicate here how many, but still quite a few.

How much of this takes place, if you know, Dr. Zerhouni, Mr. Azar, let's say in the Veterans Administration? They do a lot of research, do a lot of—many of their people do the same sort of thing where they receive stock options and monies, what not, from some of the people that they work with. We have universities out there, some public, some private that do a lot of research. How much of this takes place? If you could sort of short answer as you can.

Mr. ZERHOUNI. Right. At NIH, as we've said over the years it involved about 3 to 4 percent, 5 percent of the employees. I really can't comment on how much of it takes place in another Federal agency. Really, I don't know. One thing I can say that as a Federal agency director, the one thing that hurts you is what you don't know. So I think we need to put in place mechanisms as Mr. Azar is suggesting of proactive management.

Mr. BILIRAKIS. That's the whole point. We haven't. So are—if it is taking place to any degree to speak of in the VA and some of these other, maybe these other Departments and in some of the universities and what not, are they at least aware of what's taking place here, the hearings and hopefully—do you know, Mr. Azar?

Mr. AZAR. Certainly since Friday, I believe, that when this committee has asked for information from other Departments, I think that they're certainly aware of it and from press coverage, but like Dr. Zerhouni, I'm not familiar with whether the same types of opportunities for outside consulting activities and awards present themselves to people outside of the NIH at other agencies. I don't know. NIH tends to be rather a unique entity as the crown jewel of biomedical research and being run really like a research university. I don't know that there are any other comparable entities in the Government that would be so attractive and also where there's been a fairly long-standing congressional and administration policy of encouraging interaction with the private sector to commercialize interventions.

Mr. BILIRAKIS. Let me ask this just very quickly. Stability, continuity, all very important. I've always kind of felt that many of the

problems we have up here is that there is a lack of that because everything seems to be tied into politics and there are changes in Administrations, changes in the Congress and leadership of the Congress, etcetera, etcetera.

Dr. Zerhouni, you've given us approximately 10 steps which sound terrific. God forbid there's a change in Administrations as a result of November and there would be people here who would disagree with that, God forbid, but in any case, the fact is that that sort of thing does take place, even if we're talking about the end of the 8-year term, 8-year period of time.

Then what happens? With all your good will and your good intentions and everything of that nature, do they conceivably go down the drain because they're no longer the cause of the new person——

Mr. ZERHOUNI. That's why I work very hard to find proposals that would be embedded, structural, that will be embedded in supplemental regulations, if we need to. And we're working very——

Mr. BILIRAKIS. How about embedded in the law?

Mr. ZERHOUNI. And in addition to that, I think there is a potential for, depending on what we find, for your help to be very significant here, and for the questions that you've asked. I mean is there enough authority? Do we have enough process, do we have enough controls?

Mr. BILIRAKIS. Yes.

Mr. ZERHOUNI. I think that's what we need to do and we're committed to——

Mr. BILIRAKIS. We've committed to you and we're trying to do something with NIH, but we need to also get commitments from you that you're going to help us do it correctly to help you do your job better.

Mr. ZERHOUNI. Yes.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman. The gentleman from Florida, Mr. Stearns, is recognized for 5 minutes.

Mr. STEARNS. Good morning, and thank you, Mr. Chairman.

Dr. Zerhouni, I have some slides here in front of me and I think they're from the second hearing in which they talk about money received by various scientists at NIH. For example, I have one here on H. Brian Brewer. He's Chief of Molecular Disease Branch. Does this ring a bell at all? If not, I can just have my staff——

Mr. ZERHOUNI. Not really.

Mr. STEARNS. Not really. Can I have someone from our staff take this down to him and he and I can just go through it?

The purpose of you and I just going over this is to reiterate again, I think, the whole question does the NIH have any actual evidence that the NIH scientists have left because of consulting fees being cut. Before I did that, I just wanted to take you to slide 8 which is Brian Brewer. And this was composed, comprised by taking information that we could from pharmaceutical companies and I guess—and other agencies.

But as you can see, Mr. Brewer, I assume he's a doctor, received almost \$200,000 plus stock between his travel and his fees at Pfizer, Lipid Sciences and all, Eli Lilly and all these companies. You can see that.

Now if you don't mind, I'd like you to go over to one which is a little bit more prodigious in that slide 1, Michael Brownstein. He's Chief of the Lab of Genetics. This shows that he has stock valued at almost \$2 million, that he obtained, plus over \$27,000 in fees. And when you go through this, take slide 2, now. We have Ronald Germain. Dr. Germain received \$430,000 in reimbursable expenses or consulting fees, plus stock options.

Now it seems to me that you have Government employees that are working at NIH. They have a pretty significant title, yet they're going out into industry and they're getting not only reimbursed for consulting fees, they're getting reimbursed for travel fees and then they get all these stock options.

Now I mean you can just flip through these different slides. Don't you think this is pretty egregious and totally unnecessary? Obviously, your statement is we're going to reform it, but when you look at that, isn't that rather appalling to see all of that?

Mr. ZERHOUNI. Yes, and I think we need to really look at what you're referring to and for example, there's no doubt that in the case of slide 8, for example, Brian Brewer, with the new rules that we're implementing, there will be no service on advisory boards. None of that will be—

Mr. STEARNS. I think that's what you can help us through. When you look at these slides, tell us under your proposal how this would be prevented?

Mr. ZERHOUNI. Right, that's exactly what I'm trying to do here.

I think there would be a major difference. For example, the consulting would not reach that sum in any 1 year, that a person can only do 25 percent, if that person is eligible to do that. Under certain ranks, they wouldn't be.

Mr. STEARNS. Mr. Brewer, as Chief of Molecular Disease Branch be able to do it under your proposal?

Mr. ZERHOUNI. Yes, he would. He's not someone who does—

Mr. STEARNS. He'd still be able to get almost \$200,000 plus stock?

Mr. ZERHOUNI. No, he will not be able to do that. For example, Lipid Sciences, Astr Zeneca will be out of the new system. He cannot do that.

Mr. STEARNS. Okay.

Mr. ZERHOUNI. With the new system. He cannot receive any stock in the new system. And then, when you look at his compensation, that compensation will probably be cut in half if the work that he's doing is justified and reviewed independently as seen as being independent of what he does otherwise.

Mr. STEARNS. What about in the idea of stock? What are you proposing?

Mr. ZERHOUNI. Total ban.

Mr. STEARNS. Total ban on stock.

Mr. ZERHOUNI. Total ban, for everybody.

Mr. STEARNS. Okay.

Mr. ZERHOUNI. And limit on any—I mean, we're totally banning any compensation in stock or stock options. That's No. 1. And No. 2, we are scrubbing every employee from owning any individual pharmaceutical buying that stock that has anything to do with science or potential for consulting and limiting every other em-

ployee to \$5,000. Remember, when we put a prohibition it applies to members of the family too.

So all employees who do not do science, we want to limit that to \$5,000 for one stock. But employees who do science, no stock.

Mr. STEARNS. Do you think your proposal should have been done some time ago to prevent this?

Mr. ZERHOUNI. For the benefit of hindsight, yes.

Mr. STEARNS. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and notifies the members and their witnesses we are going to do another round of questioning here.

The Chair recognizes himself.

Dr. Zerhouni, I note that NIH was notified in February 2004 about information indicating that Dr. Moshell, the Skin Disease Branch Chief, was testifying as a compensated expert witness in Accutane cases. It's my understanding that he scheduled to be deposed in a case no later than July 15, 2004. NIH acknowledges Dr. Moshell did not notify NIH about these activities and that he should have notified NIH about them. The only action taken has been to counsel Dr. Moshell, as I understand it.

Is counseling considered a disciplinary action and is that a sufficient management response in this case?

Mr. ZERHOUNI. Yes, in the strategy of managing issues like that, counseling is part of disciplinary, proactive disciplinary counseling, if you will. Because I think in this particular case, what I understand is that the gentleman was allowed to do clinical practice years ago. And in the meantime then, as you know, many clinical practitioners will also testify on cases and decide to be an expert witness, not realizing perhaps or not knowing perhaps that we have a prohibition against being an expert witness for anything where the Government may have either an interest or an involvement. He was then counseled by our ethics people, I understand.

Mr. GREENWOOD. Is it your intention to allow Dr. Moshell to testify without prior approval in the future?

Mr. ZERHOUNI. No.

Mr. GREENWOOD. So he'll have to for each and every opportunity, request that he has to testify.

Mr. ZERHOUNI. Expert witness is an activity that requires disclosure and approval.

Mr. GREENWOOD. Okay. Let me on the same subject, let me go to you, Mr. Azar.

It's been noticed that Dr. Alan Moshell, who we've just discussed, the Skin Disease Branch Chief and Program Director, has been—you heard me talk about the fact that he's been an expert witness and it has been alleged that Dr. Moshell has testified that specifically that FDA approved labeling for Accutane is legally inadequate.

Are you concerned that Dr. Moshil's involvement conflicts with the public legal position of FDA?

Mr. AZAR. Again, I just learned about this recently and I don't know all of the facts, but if they are as you've described them, I am very concerned about that and he first off, he should have sought approval of an outside activity, but also to serve as an expert witness in a proceeding in which the Federal Government is

a party or in which it has a direct and substantial interest which I would think the legality of the FDA's approved label would be such a case the DAEO, the designated agency ethics officer for the entire department has to authorize that and would consult with both FDA and with NIH as to what the Government's interest. But as described, I'm very concerned about the situation.

Mr. GREENWOOD. And help me understand the ethical issues involved here because I'm not personally clear on this because on the one hand there are, as I understand it, rules and policies that would prohibit that kind of testimony. Someone looking at it from the outside would say that sounds like you're muzzling a Federal employee who might have some important information that would expose something going wrong in the Government.

So walk me through the ethical implications of this.

Mr. AZAR. I think the basis for the rule and the reason for concern is the concern of undivided loyalty to your employer, the Federal Government here, that the Government, United States, not FDA, but the United States has a position as to the legality of its label and to have its own agents testifying to the contrary, I think is very destructive to that position.

And also, there's always the risk that the individual's title, their position within the Government is used against the Government, the fact that they are a senior individual at NIH is used to essentially lend extra credence to their testimony.

Mr. GREENWOOD. Which makes them more valuable to a Plaintiff's attorney who would be inclined to pay them handsomely for that testimony.

Mr. AZAR. Exactly.

Mr. GREENWOOD. So obviously, in circumstances where that FDA employee might be subpoenaed by the Plaintiff's attorney, that—he's permitted, he or she would be permitted to testify under those circumstances, but just not as a voluntary paid expert witness. Is that right?

Mr. AZAR. And actually, in private litigation, if an official of the Department is subpoenaed in private litigation, the Department actually is under—they're called the 2-E regulations. The Department decides whether it's in the interest of the Government to offer the individual to testify, even if it's a subpoena in a third party private piece of litigation. So it should always be subject to what's in the Government's best interest.

Mr. GREENWOOD. Dr. Zerhouni, have you been briefed about the situation involving Pearson Trey Sunderland and Karen Putnam I mentioned in my opening statement?

Mr. ZERHOUNI. Yes, last Friday I was made aware of that situation.

Mr. GREENWOOD. And I note that Mr. Walden already inquired about that. My time has expired. The gentlelady from Colorado.

Ms. DEGETTE. Thank you, Mr. Chairman. At the conclusion of my questioning, Mr. Azar, I believe you had said that there is now an agreement as to the rule of HHS counsel when they come to oversight and investigation hearings. Was that what you had said?

Mr. AZAR. Yes ma'am. That's my understanding, that there had been a letter from the Assistant Secretary from Legislation to the chairman of the committee.

Ms. DEGETTE. Right, that's in Tab 1 of your notebook from Jennifer Young.

Now I read that letter. Is Ms. Young an attorney?

Mr. AZAR. I don't believe so.

Ms. DEGETTE. Well, first of all, would it surprise you to know that—and staff can correct me. It's my understanding we got this letter, but that certainly Democratic staff has not agreed to this procedure outlined in this letter. Did you know that?

Mr. AZAR. I did not know that.

Ms. DEGETTE. And I'm told that Republican staff has not agreed to that procedure either. He confirms that.

Mr. AZAR. I'm sorry, then I had a misunderstanding. I had a misimpression of that. I thought there was.

Ms. DEGETTE. Right, and this is sometimes the problem—this is why we're a little worried about the execution of the whole ethics procedure in general, because communication is a problem.

And one question I have, again, as someone who used to practice, you know, when the attorney—when an employee, an HHS employee is asked to come in and meet with the committee, and they say that they want a lawyer to accompany them, whose interest does the lawyer represent?

Mr. AZAR. Whenever—outside of the original Inclone proceeding, whenever our lawyers have met with the individual witnesses to assist them, they should have always and I believe they have, they should have always made clear to the individual, we are official counsel. We are representing the Department. We are not your personal attorney.

Ms. DEGETTE. And if you desire personal counsel, then it is your responsibility to go out and retain that counsel. Did they advise them of that?

Mr. AZAR. I do not know for a fact whether that has been said, but that is the case, yes.

Ms. DEGETTE. Well, as someone who has represented a lot of witnesses, I know people, especially people who are concerned, get very confused about a lawyer shows up and it's a congressional investigation and it's under oath. People get very confused about who's representing them. So I might suggest to you as part of the overall departmental reforms that you develop some written guidelines to be given to potential witnesses, explaining the duties and roles of the HHS attorneys and also explaining that the person is entitled to outside counsel of their own.

My concern is if you have a witness who has information that they want to share with the committee, Republican or Democratic staff, that maybe not in the best interest of HHS or whatever, then there's a huge conflict and it's for that lawyer. You're nodding. I'm sure you agree.

Mr. AZAR. I think that's a very helpful suggestion. I can tell you when I was in practice, that if I were ever representing a corporation and speaking with an individual witness, I always did make clear I represent the company. I'm not your lawyer. You can hire a private lawyer. I just can't say for a fact that that—

Ms. DEGETTE. I did that too and I always tried to do it in writing to the witness.

Mr. AZAR. I think that's a good point.

Ms. DEGETTE. My other request of you would be if you would please sit down personally with Republican and Democratic staff of this committee and iron out some written procedures so that we can know when witnesses come in accompanied by an attorney who they're representing.

Mr. AZAR. I would be very happy to do that.

Ms. DEGETTE. Thank you very much. I have just one more question for you, Dr. Zerhouni, now that we're trying to think of how to iron out these bugs.

I was thinking about Dr. Katz who came in and testified. You might be familiar with his case. He was the fellow. He was doing some consulting with a company and the company had a subsidiary that had business pending, a grand application pending in front of the NIH and he did not know that this—that there was any connection when he later found out, I believe, after he was subpoenaed by this committee or came in to talk to this committee, he immediately severed the relationship.

So my question is in all of the ethics oversight that you're trying to do with the centralized electronics, how are we going to be able to—because as you know, corporate America and the pharmaceutical industry, in particular, and biotech, are very—the corporate relationships are very complex. How are we going to be able to catch those kinds of very real complex?

Mr. ZERHOUNI. Well, first of all, we just prevent them. So in the rules that I'm proposing, Dr. Katz being a Director of an Institute will be completely prohibited, period.

Ms. DEGETTE. But let's say it's someone who would be eligible and who honestly himself or herself may not have known about that. Because Dr. Katz did not.

Mr. AZAR. Again, I'm prohibiting every employee that has any authority in grant funding, contract making, from any activity of that sort.

Again, this would not happen under the new rules. There's no way for an individual in the line of command and their subordinates to be able to influence—

Ms. DEGETTE. And I guess your testimony is then since you're prohibiting those individuals, it wouldn't matter for someone else not in that category if there was—

Mr. ZERHOUNI. Right. Again, it's the dual nature of NIH. It's a Federal agency role and it's sort of a scientific university type activity which has no real power over allocating grants. But we'll go further than that. We are saying that our scientists will not consult with potential grantee institutions so that anybody who would then come and say I want a grant will not be able, as a university, for example.

So we're trying to build as much fire walls as we can.

Ms. DEGETTE. I understand.

Mr. AZAR. Congresswoman, I think, and please correct me if I'm wrong, Dr. Zerhouni, I think in the instance if the individual has the grant making function under them, even if they weren't involved, if there's any connection to the grant making process, they would also be precluded.

Ms. DEGETTE. And my time has expired. I'm focusing not on the individual. I'm focusing on the corporate relationship of the—in

particular, the private company that they're trying to get a grant. But I understand what you're saying, Dr. Zerhouni.

Mr. GREENWOOD. The gentleman from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I said in one of the prior two hearings, maybe in both, I don't remember, that we've always got to be careful that we do no harm. And whereas these things that have taken place in the past and we should be thinking more in terms of today and the future and trying to keep some of those bad things or at least perceptively bad things, put it that way, straighten that out, clear it up. I think it's important that we look to the future.

NIH is so highly thought of in the world. Let's face it. It's world class. In fact, you and I were in Italy not a few months ago where they're setting up their own form of the NIH. So we don't want to do anything to hurt their effort. And maybe we are doing something to hurt their effort and I hope not.

But let me just put that question to you, Dr. Zerhouni. Are we doing something here that might be hurting NIH's effort in terms of their image, their reputation, in terms of recruitment, in terms of the research in general? Maybe you could take a full period of time to respond to that.

Mr. ZERHOUNI. That's the most difficult question I have to face because again, I have to do a balancing of the analysis and it is the appropriate question to ask because many times I get asked what is the evidence that you have that by having stronger rules we may not be able to recruit or retain.

My position is what is the evidence that we have that we will do no harm? Because I think at the end of the day we need to protect that. And I'm trying to find the balance between the two. A total ban, as I've said, would be detrimental to the scientific staff who is really unrelated—

Mr. BILIRAKIS. Detrimental? Disastrous may be even a stronger adjective?

Mr. ZERHOUNI. I can't say that because again I don't have data either way, but I can say for sure that we will have people who will leave the agency and I think it will be a factor in recruiting that wasn't as much of a factor to attract someone from the outside who may have had activities. That person may have to sever them all.

And I think it relates to what the chairman said. I think we need to balance compensation and the possibility of compensation. The field of opportunities for our scientists should not be so restricted so that it will make it much easier to just walk across the street and go to a university. We have 200 competitors out there. So I'm concerned about it. But I think these rules strike a right balance and I wouldn't definitely say that they would be harmful. They have the potential to, in some areas, to prevent us from recruiting and retaining the best, but I don't believe that at this point, I can't say for sure what the impact would be.

Mr. BILIRAKIS. I'm raising the question, but I know that the chairman, both chairmen, Mr. Greenwood and Mr. Barton, are as concerned as I am, as I think all of us are in this regard.

What is the morale picture at NIH?

Mr. ZERHOUNI. I would say the morale has been lowered.

Mr. BILIRAKIS. Lower as the result of some of the things that we're doing?

Mr. ZERHOUNI. In part. Yes. I think there are other factors, obviously. I mean there are budgetary constraints. There are changes that we're bringing to the administration of NIH. Obviously, all of those things play a role, but I think this has damaged the morale, especially of the over 95 percent of the scientists who have really given their lives to NIH.

Mr. BILIRAKIS. Yes.

Mr. ZERHOUNI. It pains them to see NIH painted in such a negative light, when in fact, they've done all their best to serve NIH and the country without any of this kind of slide material that were shown here. That affects morale because really the core value of NIH is to really serve the public and do it right and all of the people I know there are really pained by this and would like to get clarification and let's move on.

I think my point is performing autopsies on what was important, we need to do that. But more importantly here is to make sure the patient is cured and moves forward.

Mr. BILIRAKIS. Thank you, Doctor, and I know the chairman well enough to know that he is just as concerned about those things as I am and again, with your help, we are going to clear this up in the interest of continuing the best research in the world.

Thank you and thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman. Mr. Stearns for 5 minutes.

Mr. STEARNS. Thank you, Mr. Chairman. Just following up what my colleague from Florida was talking about. NIH is the premiere medical research organization in the world and it will be after it's over and I think it will be better because of this and I think bringing some transparency here and also bringing to light some of the problems will make it even better. So I applaud you for what you're doing this morning in this your proposal. I guess in looking at the activities reviewed by NEAC, they looked at 317 and recommended approval of 234 of these arrangements.

My question is how many arrangements were there last year for the whole year? In other words, prior to the Act, prior to NEAC, the NIH Ethics Commission, how many total arrangements were there?

Can you put your speaker on? I can't hear you.

Mr. ZERHOUNI. I'm just going to estimate.

Mr. STEARNS. Oh sure, I'd just like, as much as possible, just a complete accuracy of how many arrangements there were.

Mr. ZERHOUNI. Yes, I'm trying to—all right, I'm going to give you the numbers I have.

Mr. STEARNS. Okay, thank you.

Mr. ZERHOUNI. Basically, we had about 365 agreements probably involving about the same number or more, less employees. That's because over 5 years, we've had about 1500. So it's about 300, 350 a year.

Mr. STEARNS. So about 300 a year, approximately.

Mr. ZERHOUNI. A little more.

Mr. STEARNS. How over how many years did we have this arrangement?

Mr. ZERHOUNI. Since 1995.

Mr. STEARNS. Okay, so we're talking about 5, 9, almost 10 years. So we're looking at perhaps maybe 3,000 arrangements, separate arrangements or are we talking about 5,000 or 10,000?

Mr. ZERHOUNI. About 3,000.

Mr. STEARNS. About 3,000.

Mr. ZERHOUNI. Of those we know, but now we're finding there are some we don't know about.

Mr. STEARNS. And would you, could you make an estimate on the ones you don't know about, how big that is? Is it 10 percent or 20 percent?

Mr. ZERHOUNI. No, really, I can't. I mean this is the information that the chairman was referring to. I don't have that information. I don't know that, but it's a small amount, obviously, relative to the total.

Mr. STEARNS. Okay, well, let's just use your figures and say there were 3,000 arrangements since 1995.

Mr. ZERHOUNI. Right.

Mr. STEARNS. Now I don't think all of them fit this presentation, what is in the slides here, where people are making almost \$2 million in stock or they're making large sums and reimbursement. Slide 5, Gary Nable made \$314,000 in expenses and travel and things like that.

I guess my question is, Mr. Azar, do you have an Inspector General on your staff?

Mr. AZAR. No sir, the Inspector General is independent and reports directly to the Secretary.

Mr. STEARNS. Do you have anybody on staff that could be an investigator?

Mr. AZAR. We really don't have any kind of investigative capacity. With this enhanced ethics function, we'll have some auditors and the ability to do that.

Mr. STEARNS. That's my question. Once this is in place, do you have any way to investigate what's happening?

Mr. AZAR. The way the ethics program would work is we will have this enhanced ethics division function for oversight and auditing.

Mr. STEARNS. Okay.

Mr. AZAR. Each deputy ethics counselor in this decentralized ethics program should also—is also responsible for oversight of the functions and the conduct of the program within their operations.

Mr. STEARNS. So the NIH will have a set of investigators too?

Mr. AZAR. Well, the NIHAC, the NIH Advisory Committee, as well as the NIH Office—

Mr. STEARNS. So the Commission will have its members and they'll have a step group, a subgroup that they can go through for investigation. Because we can put in place all these things and the Commission can recommend, but the question will be what happens in the future if there's no one checking it?

Mr. ZERHOUNI. This is a very good question and Item 10 of the grid that I testified to, we actually mentioned the fact that we're going to initiate random audits as part and parcel of the process of control of the ethics program.

Mr. AZAR. But I think also, the Inspector General's office could also be used also to come in and do audits and evaluations of the program, once we get these changes in place.

Mr. ZERHOUNI. My experience with that, Mr. Stearns, is that our audits are a very good way of identifying vulnerabilities and then referring them, obviously, to the Department and then to the Inspector General.

Mr. STEARNS. Yes.

Mr. ZERHOUNI. That's a mechanism we need to have.

Mr. STEARNS. Mr. Chairman, we've been through these oversights on the corporate problems and we found that we need accountability was the biggest problem. And we talked about the CEOs of the corporation ultimately signing their accounting reports and somehow, Dr. Zerhouni, I would expect you to also interface and not just leave it to these folks, but you should have some fiduciary responsibility to put your name on some report that this has all been corroborated and submit accounting because you ultimately have responsibility.

Mr. ZERHOUNI. I agree with you and that's why in the management process changes list that I propose, we said that we will add the ethics function to supervisors' performance plans across the NIH, add the DEC's function to the DEC's performance plan and by extension, it goes to my performance plan.

Mr. STEARNS. Okay.

Mr. ZERHOUNI. Formally and officially as part of the human resource management system that we currently have, which does not include ethics oversight as a line responsibility of the people in authority.

Mr. STEARNS. And Mr. Chairman, if I can just have a little bit of the indulgence. Another question is the people that are appointed to the NIH Ethics Commission, the screening and these individuals I guess, you know, the non-Government appointees to this Advisory Committee, what type of individuals would be the non-Government appointees to the Advisory Committee?

Mr. ZERHOUNI. In statute, every institute in the NIH has an advisory council composed of public members, 12 scientists and 6 non-scientists. That's the general pool. Those are named by the Secretary of Health and Human Services through nominations received by the Secretary that we also can propose and that is basically the source of the appointments on these committees. There's a rotation pattern, every 4 years, there's a change over. And these members are essentially members of the public.

Mr. STEARNS. Who would make the appointments to the independent advisory committee? Who are going to make these appointments?

Mr. ZERHOUNI. These appointments are already made. This is a board in statute, already existing, that is already in place to oversee NIH from the public standpoint.

Mr. STEARNS. Okay, thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes himself for 5 minutes.

Dr. Zerhouni, if you turn to Tab 22 in the binder, you'll find some statistics on activities reviewed by the NIH Ethics Advisory Com-

mittee. And it states that of 317 activities and awards received, reviewed by NEAC, NEAC recommended approval of 234.

The question is how does this rate of approval compare to the rate of activity, approval prior to implementation of the new procedures?

Mr. ZERHOUNI. well, if you look at the totality, 300, 350 this is about, on the activities, probably about two thirds maybe.

Mr. GREENWOOD. A little more than that. And your question is—what I'm trying to get at is do you know anything about the current NEAC, your creation is approving a little more than 2 out of 3.

Mr. ZERHOUNI. Right.

Mr. GREENWOOD. Do you know how that compares to previous rates of approval of—

Mr. ZERHOUNI. I think it's definitely lower because what I'm getting as reports from the members of NEAC is that every time they're looking at a case to say wait a minute, these are activities that were there before under current rules, so remember the 317 are not new ones. They're the ones that were there. Of those 317, some have been terminated. You see what I'm saying?

Mr. GREENWOOD. Right.

Mr. ZERHOUNI. In other words, the pool was the same pool that was before NEAC, being reviewed by NEAC. And of those, we've cutoff from 317 to 235.

Mr. GREENWOOD. And apparently I'm advised that prior to that, if you're now turning down a quarter or a third, it used to be that only that 1 percent were rejected. So it's an indication to me that the NEAC is for real and is making some tough decisions.

Mr. ZERHOUNI. That's my understanding, Mr. Chairman.

Mr. GREENWOOD. I do note though that in the NEAC, the NEAC sent to the committee two instances where NEAC recommended disapproval of two outside activities, but the NIH designated ethics counselor approved them anyway.

Do you know how that happens?

Mr. ZERHOUNI. Not specifically on the cases that you're referring to. I'm not sure what they are, but I will follow up with you, sir.

Mr. GREENWOOD. We'll do that. According to the data provided by NIH to the committee, the average—this is not referring to that tab any more, Dr. Zerhouni—

Mr. ZERHOUNI. Right.

Mr. GREENWOOD. The average turnover rate among scientific staff for the 1994 to 2003 period, about 10 years, that is in Tab 26 if you want to look at that.

The average turnover rate among scientific staff for those 10 years was 9.24 percent, but the average turnover rate among Title 42 employees for 2000 to 2003 was only 2.4 percent. One could draw the inference from the turnover rate that the higher salaries of Title 42 has lowered turnover rates. Would you agree that's what we're seeing there?

Mr. ZERHOUNI. That is correct.

Mr. GREENWOOD. If that's correct, then why is it important to still permit consulting when the higher salaries are already, seem to be addressing and resolving the turnover issue?

Mr. ZERHOUNI. Caps, No. 1. There have been caps since 1999, a figure that doesn't really look at cost of living and as years go by, you will see again a decreased competitive for NIH to recruit these individuals.

Mr. GREENWOOD. Suppose we lifted that cap and gave you the authority to exceed that cap where necessary. Would you still feel that the paid outside consulting arrangements, agreements were necessary?

Mr. ZERHOUNI. I would definitely look at that with favor, if I could establish a market based compensation system where really I'm not at a disadvantage. Right now, I'm in a real disadvantage in recruiting top scientific staff at NIH. I can tell you two anecdotes, that it is not that easy. When I was Vice Dean of Research and Executive Dean of a private medical school, I had more means and more flexibility in recruiting scientists or chairs of department with much lower responsibility levels than those that I'm recruiting right now at NIH. So it is, actually, a structural problem and I think there is a balance between compensation and opportunity for compensation.

Mr. GREENWOOD. And it's a tradeoff for the taxpayer as well because on the one hand the taxpayer will be adding extra compensation which would diminish your budget, which would take money from your budget as opposed to the private sector paying for that activity.

Mr. ZERHOUNI. That is correct.

Mr. GREENWOOD. Paying for the ability, the enhanced ability to retain that—

Mr. ZERHOUNI. That is correct. And you want to sort of strike a balance. We don't want to end up in the situation where we pay people high rates and their activity on Government time is to basically advise industry for free, because then you're creating a subsidy really.

Mr. GREENWOOD. Final question for me and I promise this, sometimes when we talk about what the difference is between the 20 percent of the NIH funds that stay intramurally and the 80 percent that go out to the universities, etcetera, we talk about the reason because theoretically, you could have a construct where it all went out in grants. NIH could just be a grant making entity and not do much research. And part of it is that the NIH does intramural research that no one else is supporting.

So it sort of raises the question in my mind, if that's the case, what's the competition? In other words, if you're hiring people to do research that no one else is supporting, is there really that much competition or is it a question that if they weren't doing that they would be doing something else that someone is supporting?

Mr. ZERHOUNI. That's a good question, but it's not, the operating definition is not what no one else will do. I mean we're not doing just that. About a third of what we do is really public health, relevant, things that—safety of the blood supply, vaccine development, things that really cannot be done really by the private sector we need to do and we need to accumulate the science of that. Like HIV/AIDS is a good example where a lot of the fundamental discoveries had to be made at high speed within an institution where I

can control the program. You can't control the program of 200 universities. So that's important.

Second, you also want as a Government, scientists who would work in the same areas that other universities work in, because you want to have your own experts that are not tied to having the need for grants, telling you what the real scientific truth is. So in truth, we maintain a cadre of scientists who are independently funded at the intramural program to make sure that we have an understanding of the science that people are asking us to fund. So that's the other part of it. And that's the part that I think you need to make sure you don't destroy.

Mr. GREENWOOD. The gentlelady from Colorado, do you wish to further inquire?

Ms. DEGETTE. I just have, Mr. Chairman, I just have a question and a comment.

My question is to Dr. Zerhouni, have you thought about what you would do about post-NIH employment, transfer of knowledge and issues like that?

Mr. ZERHOUNI. You mean cooling off periods?

Ms. DEGETTE. Yes.

Mr. ZERHOUNI. Yes, we have and obviously, I couldn't go into all the details here, but we are looking certainly at these issues of cooling off.

Ms. DEGETTE. Because it would seem to me that would be an important component of any enhanced ethics program that you would adopt, would you agree?

Mr. ZERHOUNI. Right, I agree. And this is definitely part of—I thought it was a detail, but it is part of our consideration.

Ms. DEGETTE. It's a detail we care about.

Mr. ZERHOUNI. I know.

Ms. DEGETTE. That actually leads beautifully into my comment which is that I have lots more questions here about how is the stock option issue going to work and what are we going to do about this and that. I mean it seems to me going back to my opening statement the details. I know you're trying to work those out. I would hope that you and your staff would continue working with this committee and our staff as you develop those details and Mr. Chairman, I would hope you would leave the option open for yet an additional hearing once those details are worked out. Because I think we all agree you're really on the right road here. We just need to see how it's all going to be executed and make sure that the same kinds of excesses that we saw in the past aren't happening now. And I thank you again for your attendance.

Mr. ZERHOUNI. I really agree with you.

Mr. GREENWOOD. Dr. Zerhouni, I lied about no more questions. Just one last one.

You've referenced going to supplemental rulemaking. Do you have a timeframe on when you expect to be able to do that and then based on how long that takes, when these new rules would take effect?

Mr. ZERHOUNI. We're working on, I'll let Mr. Azar comment on that. We're working very diligently to sort of create all of the rules that we need. Some may not need rules. There may be some areas

where can act right away. At this time, we're really doing it within the quickest amount of time possible.

Now beyond that, there are elements that are beyond my control or even Mr. Azar's control. Perhaps Mr. Azar can comment.

Mr. AZAR. It's my understanding that in the past with supplemental ethics regulations at the Department that they have, once they have been concurred in by the Office of Government Ethics, that they can go direct to final, rather than notice and comment rulemaking.

That would be my goal and I would advocate for that. Whether the Office of Management and Budget, others who obviously play a role in the decisionmaking on regulations will permit that in this case because of impacts on private parties, I don't know, but that's been a past practice and the way I would hope to go so that we could go quickly once we could secure OGE and any other affected agencies. It would obviously go through interdepartmental clearance, the Justice Department, others might have views given the relations. But my office will certainly work fully with Dr. Zerhouni's office to provide any assistance getting the regulations drafted and working to advocate and get them through as soon as possible and also working with the committee as we work on the details there.

Mr. GREENWOOD. Thank you, both. Again, I compliment you on your stellar work. It meets my approval across the board. There are a couple of details to work out, but I'm very pleased and I want you to know that and I want everyone at the NIH to know that as well.

Thank you, again and you are excused.

Mr. AZAR. Thank you.

Mr. ZERHOUNI. Thank you, Mr. Chairman.

Mr. GREENWOOD. And we will now call forward the second panel. Mr. Peter Levine, President and Chief Executive Office of Correlogic Systems, Inc. and Dr. Jonathan Heller, Vice President, Information and Project Planning, Predicant Biosciences.

Gentlemen, we welcome you. Thank you for being here. You may have heard me say to the previous panel that it is the custom of this committee to take testimony under oath and I need to ask if either of you object to giving your testimony under oath?

Okay, seeing no objection, I also need to inform you that pursuant to the rules of this committee and of the House, you are entitled to be represented by counsel. Do either of you wish to be represented by counsel?

You need to put your microphone on and speak directly into it and identify your counsel, please.

Mr. HELLER. Counsel for Biosciences is Lenny Burr.

Mr. GREENWOOD. And the gentleman directly behind you, thank you.

All right, now you stand and raise your right hands, please?

Do you swear that the testimony you're about to give is the truth, the whole truth and nothing but the truth?

[Witnesses sworn.]

Okay, you are both under oath.

Mr. Levine, do you have an opening statement? You are recognized for 5 minutes to offer it.

TESTIMONY OF PETER J. LEVINE, PRESIDENT AND CHIEF EXECUTIVE OFFICER OF CORRELOGIC SYSTEMS, INC.; AND JONATHAN C. HELLER, VICE PRESIDENT, INFORMATION AND PROJECT PLANNING, PREDICANT BIOSCIENCES

Mr. LEVINE. I don't want to take up the subcommittee's time this morning with a lengthy reading of my written testimony. I would ask, however, that it be entered into the record.

Mr. GREENWOOD. It will be entered into the record. You may summarize it as you care to.

Mr. LEVINE. Okay. In brief, Correlogic is a clinical proteomics company. We're based in Bethesda, Maryland and we specialize in the development of technologies and tools and processes that can assist in the early detection of various cancers.

The focus of Correlogics' energies over the last several years has been the development of complete diagnostic system. I think later in our testimony that will be a very important issue, based in part, on pattern recognition technology for the early detection of cancer. Our technologies and processes have a wide range of applications and can be used in the creation of disease diagnostic models and biomarker discovery and new drug discovery processes. And we are also a clinical laboratory regulated under the Clinical Laboratory Improvements Act of 1988 and currently working with the Nation's two premiere clinical diagnostic laboratories, Quest Diagnostics and Laboratory Corporation of America.

If I had my druthers, this morning, I'd be testifying only about the accomplishments of Correlogic and the results of our most recent research. I believe we're on the brink of some fantastic breakthroughs that will translate the research progress that we've made into the ability to provide more accurate and earlier detection of cancer and other diseases.

And we would not be at this critical and exciting juncture without the considerable talent and resources of the National Institutes of Health and National Cancer Center, the Food and Drug Administration and the other components of the Public Health Service.

So I hope that my comments will not be taken as a broad criticism of the life saving mission of these agencies or any kind of justification for lessening or reducing the Nation's financial commitment to the agencies.

I also ask that my testimony not be misconstrued as a critique of the vast majority of men and women in these agencies that have dedicated their professional lives and work extremely hard to bring us the kind of medical science and kind of medical improvements that we've all seen over the last many years and because of their work thousands, hundreds of thousands of our citizens have had their lives saved and they give the hope to all of us for bright future.

But as this subcommittee has already heard, all is not well at NIH. And the experience of Correlogic, these past 2 years, has revealed what I believe are some very serious flaws in the manner in which the agency implements its licensing, its CRADA and it's conflict of interest policies and procedures.

By way of very brief background, Correlogic entered into a research CRADA and a licensing agreement with the National Cancer Institute and the Food and Drug Administration and the Public

Health Service to develop a diagnostic testing system for ovarian, prostate, breast and other cancers. These agreements which we paid and continue to pay significant royalties were designed to facilitate the development and commercialization of a diagnostic testing system for the benefit of patients.

It's important to note that we have met all of our obligations and entered into contractual relationships with other well-established industry players that have been approved by the Public Health Service to satisfy the Government's requirements under our licensing agreements. Unfortunately, since our work first became known to the public in 2002, what started as a cooperative and constructive research and business relationship has clearly deteriorated. And knowing now under the light that has been shed by this subcommittee and with the full perspective of hindsight, I can now really see what has been going on for the last 2 years.

As the balance of my written testimony describes in more detail, we've been caught in a morass of conflicting interests and unilaterally changed agreements and a failure of the Agency to abide by the letter, much less the spirit of critical research and licensing agreements.

While preparing for my testimony today, I genuinely struggle to find a starting place to address the focus on subcommittee's interest. Reflecting back on the last 2 years and all that's happened, it's the concept of good faith that keeps reoccurring to me. The agencies of the Government must act in good faith.

As the subcommittee continues its work, I would ask that each and every issue under review be evaluated from this perspective. And that is, were these actions, were these decisions made in good faith or facts and legal interpretations made to support outcomes that were inconsistent with the spirit and the clear intention of preexisting agreements and relationships? To me, that is really the heart of the issue here.

And Mr. Chairman, last, let me just comment that I appear today with great reluctance. I, of course, support wholeheartedly the efforts of the subcommittee, but I'm concerned about the impact of my testimony on my company's ability to continue to do business with the Public Health Service. We have already experienced what I believe are some indications that our cooperation may wind up being rather detrimental to Correlogic moving forward and we do intend to continue doing research with the PHS. So I only hope that when the dust has settled and the attention shifts elsewhere that Correlogic is not penalized, in essence, a second time for its cooperation with the committee.

I'd be very pleased to answer your questions.

[The prepared statement of Peter J. Levine follows:]

PREPARED STATEMENT OF PETER J. LEVINE, PRESIDENT, CORRELOGIC SYSTEMS, INC.

Mr. Chairman and Members of the Subcommittee: My name is Peter J. Levine. I am President of Correlogic Systems, Inc., a clinical proteomics company based in Bethesda, Maryland, that specializes in the development of tools and processes that can assist with the early detection of various cancers and other diseases. The focus of Correlogic's energies has been the development of a complete diagnostic system based in part on the use of pattern recognition for the early detection of cancer. Our technologies have a wide range of applications that can be used in the creation of disease diagnostic systems, biomarker discovery, and new drug discovery processes. We are also a clinical laboratory regulated under the Clinical Laboratory Improve-

ment Amendments of 1988 and are currently working with the nation's two premier diagnostic laboratories, Laboratory Corporation of America and Quest Diagnostics, to provide an ovarian cancer testing service.

I wish I were testifying today just about the accomplishments of Correllogic and the results of our most recent research, because I believe we are at the brink of translating significant research progress into the ability to provide more accurate and earlier detection of certain diseases, such as stage one ovarian cancer, when the cancer is organ confined and most curable. Quite frankly, we would not be at this critical and exciting juncture without the considerable talent and resources of the National Institutes of Health, the National Cancer Institute, the Food and Drug Administration, and the Public Health Service. I hope my comments today will not be taken as a broad criticism of the life-saving mission of these agencies or as justification for lessening our financial commitment to them. I also ask that my testimony not be misconstrued as a critique of the vast majority of men and women who work there. They have dedicated their professional lives, often at great personal sacrifice, to the advancement of medical science and the health of our nation. Because of their work, hundreds of thousands of lives have been saved, and these agencies give hope to a brighter future for millions of others.

I have been asked to testify about our company's experience collaborating with these agencies, including the benefits and dangers for private companies that enter into contractual relationships with federal health agencies and with federal employees who are permitted to be both public servants and private entrepreneurs. Simply put, our experience has reflected both the promise and pitfalls of "being in business" with the National Cancer Institute and the Food and Drug Administration. It is my hope, Mr. Chairman, that your inquiry into weaknesses in the National Institutes of Health's ethics policies in general, and what has happened to Correllogic in particular, will lead to a quick resolution of these problems, and our attention can be returned to what should be our collective objective—fighting cancer and saving lives.

Origin of Our Relationship with FDA and NCI

Correllogic's relationship with FDA and NCI began in June of 1999 when I had brunch with Dr. Emanuel F. Petricoin, a senior research investigator at the FDA. Our wives had been close personal friends for many years, and Dr. Petricoin and I had met through them. During the meal, as was our custom, we caught up on professional events in our then very different worlds. He described to me the challenges he and his colleagues were facing in their search for protein biomarkers for cancer, particularly the difficulty in finding a biomarker in the massive amounts of data that could be produced by the latest generation of protein separation technologies. They were literally searching the proverbial haystack not for a needle but a single protein that might be indicative of the presence of a disease.

I had significant experience in the use of computer-generated data analysis and suggested using pattern discovery technology to search for patterns of proteins rather than individual proteins for use as a diagnostic. I explained to Dr. Petricoin that I had been working with Dr. Ben Hitt (now the Chief Scientific Officer of Correllogic) on other applications of pattern discovery technology in non-medical fields. I suggested that if this type of technology could be developed and applied to cancer research, it might be able to detect patterns of proteins that were indicative of a disease state rather than individual protein biomarkers. Rather than looking for the needle in the haystack of data, we would look at the configuration of the haystack. Using my napkin as chalkboard, I sketched out the idea.

Following the brunch, I talked through the idea with Dr. Hitt. He refined the concept and developed a powerful algorithm to test the theory that so-called "hidden patterns" of proteins, also known as proteomic patterns, could be analyzed to detect the early stages of a disease. Through 1999 and into the spring of 2000, Dr. Petricoin, Dr. Hitt and I tested the "hidden patterns" theory and in the spring of 2000, we used the basic pattern recognition algorithm that Dr. Hitt had invented. Specifically, we applied the pattern recognition technology, and hidden patterns concept to the blood from prostate cancer patients. We were able to accurately perform a diagnostic assessment based on protein patterns in the blood. At this time we were collaborating informally with Dr. Petricoin.

Encouraged, we immediately began work on applying our approach to ovarian cancer and outlining its application to other diseases. Dr. Hitt and I, along with another associate, Marc Giattini, founded Correllogic Systems in May 2000 to further develop this technology. Dr. Petricoin filed a Public Health Service Employee Invention Report, naming himself, Dr. Hitt, and me as co-inventors. Among other things, he cited our June 1999 brunch as the date on which the invention was conceived.

Formalization of Our Relationship with NCI and FDA

Things progressed rapidly after the formation of our company. Correlogic entered into a Material Transfer Agreement with the FDA to facilitate the continuation of research. The company filed a provisional patent application on the core algorithm invented by Dr. Hitt. After a period of time, Dr. Hitt, Mr. Giattini, and I were able to supplement our personal funding of the company with additional monies from private investors. Correlogic filed several additional provisional patent applications on our hidden patterns testing process, naming Dr. Hitt, myself and Dr. Petricoin as co-inventors. We began negotiations with the Public Health Service on an exclusive license agreement for our testing process, as claimed in these latter patent applications.

By July 2001, we finalized our patent filings. Correlogic bore all the expenses of these filings, as it continues to do today. By the time the non-provisional patent was filed, Dr. Petricoin had brought in his colleague and mentor, Dr. Lance Liotta, who was the Director of the Laboratory of Pathology at the National Cancer Institute. Along with the original three of us, Dr. Liotta was added as a co-inventor on the non-provisional filing of our “hidden patterns” patent application.

In February 2002, the peer-reviewed medical journal, *The Lancet*, published the results of the study the four of us (and others) had authored, which demonstrated that our testing process could detect ovarian cancer, including stage one ovarian cancer, from a single drop of blood. The actual computational analysis for the *Lancet* study was performed by Dr. Hitt alone, based upon raw laboratory data provided by Dr. Petricoin and Dr. Liotta. Because of the significance of our findings, the report was filed on the journal’s website a week in advance of publication. The publication generated overwhelming interest in the media as well as the scientific community, due to the novel nature of our process, the compelling results and, from the patient’s perspective, the simplicity of a blood test.

Congress was interested as well. A few months later the House of Representatives passed a resolution, introduced by Rep. Steve Israel and Rep. Rosa DeLauro, and co-sponsored by 147 members of the House, encouraging the government to support proteomic pattern research for ovarian cancer.

In April 2002, we entered into a Cooperative Research and Development Agreement (CRADA) with the NCI and the FDA to “utilize Correlogic’s proprietary software technology to continue their joint research to identify patterns of protein expression indicative of specific disease states.” We also signed an exclusive, worldwide licensing agreement with the Public Health Service to move our protein pattern testing process, the intellectual property rights of which were jointly held by Correlogic and the government, from the research labs into the hands of health care providers as soon as possible. The agreement contained explicit milestones and deadlines for the commercialization of our testing process.

In October 2002, the *Journal of the National Cancer Institute* published a study we performed with our federal partners on the use of our technology in the early detection of prostate cancer. In accordance with the clear purpose of and the deadlines included in the exclusive PHS license agreement to Correlogic, we entered into agreements with Quest Diagnostics and LabCorp, the nation’s two premier clinical diagnostic labs, to make our potentially lifesaving ovarian cancer test available to women across North America. We also expanded our staff and retained experts in clinical and laboratory diagnostics.

I was thrilled. We were taking an idea that I had first sketched on a napkin and turning it into, in the words of the National Institute of Health’s Office of Technology Transfer, “a high-throughput diagnostic apparatus that will apparently be capable of detecting ovarian cancer in its earliest stages.” We had obtained funding and assembled all of the corporate resources and expertise that we needed to advance the science and technology. Once the ovarian cancer testing device had been developed, we could do the same for other cancers and other diseases.

In April 2003, NCI announced in a press release, and later in a presentation at the American Association of Cancer Researchers annual meeting, that our testing process had enabled NCI, FDA, and Correlogic scientists to improve upon the initial results published in *The Lancet* for the detection of ovarian cancer. Later that year, Correlogic entered into an agreement with Advion Biosciences to use one of their technologies as a component of our ovarian cancer detection test.

This year, we began the process of finalizing the validation of OvaCheck™, our ovarian cancer test service. We are continuing our work with the National Cancer Institutes’ Laboratory of Tumor Immunology and Biology and Walter Reed Army Hospital and the Windber Institute on the application of our diagnostic testing system to the development of a breast cancer test.

All of these developments are based significantly on our initial work with the government, and our exclusive licensing agreement. Our success has hinged in no small

part on our ability to combine our expertise with that of key government scientists. We seemed to be a good example of the promise of government-private sector cooperative programs under the Federal Technology Transfer Act of 1986. In fact, I was invited by the National Cancer Institute to participate in a panel discussion on how a small company could work with the government to address a critical public health problem.

Awareness of Potential Conflicts of Interest and Related Issues

On the outside, things could not have appeared better, but internally as we would discover, there were real problems. Only now, under the light shed by this Subcommittee, and with the full perspective of hindsight can we understand some of the obstacles that we had come to view as an inherent part of the public-private partnership.

Back in 2002, a few months after the *Lancet* study, I was told that despite our exclusive licensing agreement and ongoing negotiations to expand our CRADA to include clinical testing for ovarian cancer, the National Cancer Institute had decided to “sponsor” an independent clinical trial on the hidden patterns technology, the very technology that was the essence of the patents we had jointly filed with Dr. Petricoin and Dr. Liotta. I was told that the *Lancet* study had pushed our testing technology to the forefront and that NCI wanted to move forward as quickly as possible in order to get our test into the hands of doctors and patients. We certainly agreed with the overall objective and, for that reason, had entered into our original collaboration with NCI consistent with the goals of the Federal Technology Transfer Act of 1986. However, rather than continuing along the path with Correlogic, NCI had unilaterally decided to give a contract to Science Applications International Corporation (SAIC), with which it has a long-standing contractual relationship, to set up a new laboratory to carry out these clinical trials, and Dr. Gordon Whiteley was hired to head this project, beginning with the development of a business plan. I was told not to worry, that Correlogic’s existing contractual agreements ensured that we would be an integral part of these trials and that our brand new license agreement would protect our IP and commercialization rights.

Obviously, I was concerned at what was presented to me as a *fait accompli*. The Institute’s decision impacted not only on our ability to meet required deadlines in our exclusive government licensing agreement, but also on the terms and conditions associated with our negotiations with two national clinical labs, LabCorp and Quest Diagnostics, as contemplated by the licensing agreement. When I raised these concerns with both Dr. Liotta and Dr. Petricoin, I was told not to be “paranoid,” and that NCI’s unilateral decision was really in Correlogic’s best interests. Frankly, I also was concerned—and remain concerned to this date—about the particular components that NCI had unilaterally chosen for the detection system and also about which entity would take the lead and responsibility for seeking regulatory approval following successful completion of the clinical trial.

To resolve the myriad problems associated with NCI’s decision, on August 15, 2002, I met with representatives from the Offices of Technology Transfer (and Development) for NCI, FDA and NIH. Leading the negotiations for the government was Dr. Liotta. Also participating was Dr. Svetlana Shtrom, who had been responsible for negotiating our original CRADA. We reached an agreement on how to proceed with joint clinical trials and our ongoing research CRADA, which was memorialized in a letter dated September 12, 2003, sent to me by Karen Maurey, then Deputy Director of the NCI’s Office of Technology Transfer. In late August, NIH affirmed in writing that our work under this new agreement would be accepted as compliance with the government’s deadlines in our original licensing agreement. We began drafting documents to implement the agreement.

Relying upon these agreements by the government, we pushed forward. NIH approved our entering a contractual relationship with LabCorp and Quest Diagnostics to commercialize our testing technology and turn it into a diagnostic device. We continued our research and preparation for the clinical trials, sharing our work product and future commercialization plans with FDA, NCI, and NCI’s contractor, Science Applications International Corporation. In fact, Drs. Petricoin and Liotta began participating in our conference calls with our commercial clinical lab partners, LabCorp and Quest Diagnostics.

2002 came to an end and there was still no progress, even though supposedly we were simply turning the government’s September letter into the necessary CRADA amendments and new clinical trial CRADA. I was troubled, given NCI’s persistent pattern of not communicating or explaining its intentions with regard to my company, that despite countless drafts and revisions, we were unable to finalize the necessary amendments to our research CRADA and to a new, clinical trial CRADA. What should have taken a couple of weeks at the longest was now stretching out

over months. Every time we got close, NCI's positions would change, and the agency's requirements and expectations would be amended. Correlogic agreed to virtually everything NCI proposed but there was always something else. The goal posts kept shifting, but I couldn't find out what was really going on. And every step along the negotiation path required the approval of Drs. Liotta and Petricoin.

On April 18, 2003, my fears were realized. Kevin Brand, a straightforward and competent employee in NCI's Office of Technology Transfer, called me and said, "I've got some bad news." He proceeded to tell me that NCI had decided to "go it alone" on the clinical trial.

Not only was NCI reversing the position it had agreed to the previous year, it was placing Correlogic in an untenable position with regard to our contracts with our commercial clinical lab partners and our ability to satisfy the government's own contractual deadlines. When I contacted Dr. Petricoin, he told me I was overreacting, that the September letter made clear the rights Correlogic had to seek regulatory agency approval following the clinical trials. I wrote a detailed email to NCI's Technology Transfer Office, copying Dr. Liotta and Dr. Petricoin, explaining my shock at this new development.

A few days later, Kevin Brand sent me an email proposing that rather than entering into the clinical trial CRADA, which we had been negotiating for nearly a year, NCI would agree to only a memorandum of understanding (MOU) that would be appended to our research CRADA. The MOU expressed some general and specific provisions and would have provided Correlogic with limited ability to participate in designing the clinical trial, developing the underlying analytical systems and seeking approval for a marketable diagnostic product.

Once again, just like the summer of 2002, we had no real choice but to acquiesce to NCI's evolving position. The NCI had reversed itself, and we could either accept their latest offer or terminate our relationship with the government. I kept asking myself, what was really going on? None of this made sense. Why was this so complicated? Why were there so many delays? After all, Correlogic had complied with every requirement of the prior agreements.

Despite all of the negotiations, two key points were still unresolved. Who would make the critical decision regarding the selection of the components of the diagnostic system that would be the core of our testing service? And, how were we supposed to reconcile, on the one hand, NCI's apparent interests in developing their own testing service through the work being done by their contractor, Science Applications International Corporation, with, on the other hand, the contemplated collaborative clinical trial reflecting benchmarks associated with the patent rights granted to Correlogic under our licensing agreement?

In late June and early July of 2003, I first learned of one possible explanation for the confusion and delay. Unbeknownst to me or anyone at Correlogic, Dr. Liotta and Dr. Petricoin had been working as consultants for Biospect, a direct competitor of my company. And, as I learned only much later, through the Subcommittee's May 18 hearing, they had already been doing so for seven months. Also affiliated with Biospect was Dr. Rick Klausner, whom Dr. Liotta and Dr. Petricoin had briefed about the Correlogic-NCI-FDA relationship when he was the director of the National Cancer Institute. Joining these three at Biospect was Dr. Svetlana Shtrom, the NCI technology transfer specialist who had worked on our original CRADA.

I had also learned that prior to being hired to set up NCI's clinical lab to conduct the hidden pattern tests, Dr. Gordon Whiteley had been an employee of a business run by Dr. Lance Liotta, a company called Immunomatrix.

So, while our negotiations over finalizing our clinical trial CRADA were slowly going nowhere, Dr. Liotta and Dr. Petricoin had become consultants to our competitor, Biospect, and Dr. Shtrom had become an employee. During our endless discussions with Dr. Liotta and Dr. Petricoin about Correlogic's research and plans for clinical trials, I now realized, I would have had no way of knowing, for example, whether I had been talking to Dr. Liotta, the NCI employee, or Dr. Liotta, the Biospect consultant, or Dr. Liotta, an owner of Immunomatrix, or Dr. Liotta, the employer or former employer of Dr. Whiteley. And, these are just the relationships that I know about.

I first learned about Biospect in May of 2003 in a conversation, followed by an email, with a biotech industry executive, who described the company as "your new competition," rather than from my government research partners. Since Dr. Petricoin, Dr. Liotta and I routinely discussed our collective "competition," I forwarded that email about Biospect to both Dr. Liotta and Dr. Petricoin, but they never responded. And they certainly didn't bother telling me they had been working for the company since December 2002. Included in the email I forwarded to Drs. Liotta and Petricoin were excerpts from Biospect's website. The website language

was so close to our own, that even to a casual reader, it would suggest that this was a company engaged in very much the same activities as Correllogic.

A few weeks later, I began hearing more from industry contacts about Biospect being a competitor, but now I was hearing that Drs. Petricoin and Liotta were affiliated with Biospect. In early July of 2003, I reached Dr. Petricoin by phone and raised the issue directly. I told Dr. Petricoin that I was appalled, and that people in the industry were talking about a conflict of interest. Dr. Petricoin promised to share my concerns with his ethics officer.

By this time—having watched NCI drag out our negotiations for nearly a year for no apparent reason, unilaterally tossing aside existing contractual agreements, and tolerating what appeared on its face to be a serious conflict of interest—I felt I had no choice but to ask one of our advisors to raise the conflicts issue with Dr. Barker. We were already in the process of attempting to meet with her to discuss all of the other NIH-Correllogic issues.

I raised my concerns about what was happening to my company with Dr. Barker and other Public Health Service officials in a meeting in September 2003. While I recognized that Dr. Liotta and Dr. Petricoin would probably not appreciate what I was doing, I believed strongly that my company was entitled to an objective assessment and oversight by NCI officials who were in a better position to act in an impartial manner. The meeting was relatively short, but was courteous and offered a promise of appropriate guidance from senior NCI management. I expressed concerns about actions that appeared to be undermining our exclusive license agreement and Dr. Barker indicated she would take all my concerns under advisement. The issue of potential conflicts of interest per se was not discussed as it appeared that NCI had taken the matter under review.

In October 2003, I received a packet from the National Cancer Institute, proposing, effectively, that we simply abandon all critical rights in our research CRADA that had been negotiated over the preceding year, eliminate all of the terms contained in the September 2002 letter of agreement, and enter into a very narrowly defined clinical trial CRADA. We were expected to agree to language that directly contravened specific provisions in prior written agreements with the government, including, specifically, our exclusive license agreement. Notably, it also once again left Correllogic out of the loop with regard to determining the components of the diagnostic testing system.

The Recent Subcommittee Hearings

All of us at Correllogic were disappointed, and surprised, at the testimony given to this subcommittee by Dr. Liotta and Dr. Petricoin. Their arguments for why no conflict of interest ever existed depend on minimizing Correllogic through three themes. First, they claim that Correllogic was “just” a “software” company, attempting to draw a distinction between the scope of Correllogic’s business activities and those of Biospect. In fact, the National Cancer Institute’s own documents rebut this assertion. For example, the National Institutes of Health’s Office of Technology Transfer described what we were seeking to create as a “diagnostic apparatus.” In various correspondence between NCI, Correllogic, Dr. Petricoin, and Dr. Liotta, the term most commonly used to describe the system we were building was “a device.” There were many, many meetings devoted to detailed discussions of Correllogic’s focus on the development of a diagnostic testing system. In fact, the issue of the selection and assembly of all of the components of a diagnostic testing system was, and is, at the very heart of the two year-long clinical trial CRADA negotiations. This is also the kind of information that companies consider to be among their most closely-held proprietary matters.

Second, they seem to imply that the hidden patterns technology we helped pioneer for the early detection of cancer was something related to what they had been working on for years. While it is true that Dr. Petricoin and Dr. Liotta had been working on trying to diagnose cancer for years, our approach to cancer diagnostics was something new. In fact, their own actions undermine their argument. If their assertion were true, why did Dr. Petricoin file a Public Health Service Employee Invention Report which clearly states that something novel had been invented? Why did Drs. Petricoin and Liotta work with us on filing patents in our collective names? Why did they continue to publish with us results trumpeting our novel approach?

Third, they diminish Correllogic’s role in the development of the technology on the basis that we lack all the resources and laboratories available to the government or large companies. No one at my company is suffering under any delusions in this regard. However, we had an idea that may radically change the way physicians test for cancers and dramatically improve a patient’s chance for early detection and treatment. Using our unique abilities, our staff and advisors, as well as the specific talents of government specialists and the capabilities of well-established industry

players, such as Quest Diagnostics, LabCorp, Charles River Proteomics and Advion Biosciences, we are on the brink of bringing a new testing device to market. We are hoping to follow in the footsteps of the many innovative small companies that have made a substantial contribution to the public health. Facilitating this journey is the very purpose behind the Federal Technology Transfer Act—allowing different entities in the public and private sector to pool their abilities in order to advance medical science.

Mr. Chairman, I hope my testimony today will shed some light on the need for reform of the consulting and outside activities approval process at the Public Health Service. As the experience of Correlogic demonstrates, the government's current ethics, licensing and CRADA processes allow for an inappropriate muddle of intellectual property, licensing, and commercialization rights of government agencies, private individuals, corporations, and public employees acting as private sector entrepreneurs.

It is impossible in such a Kafkaesque morass to have any hope of impartiality or basic protection of contractual rights such as patent license agreements and CRADA. It is simply wrong for a single federal employee, whose salary is paid by taxpayers, to sit in judgment, or influence the outcome of contracts affecting legal rights and obligations when he or she may have private, pecuniary interests. It is also wrong for one component of an agency to undermine contractual rights granted by the parent agency. It isn't tolerated anywhere else in government. It should not be permitted at the National Cancer Institute.

Mr. Chairman, I believe the experience of Correlogic is the exception not the rule. I remain convinced that the vast majority of employees at FDA, NCI and NIH are upstanding and dedicated public servants who would never put themselves into the kind of ethical quagmire we have experienced. Moreover, I believe, more than ever, that every American has a vested interest in the success of the kind of cooperative relationships that led to our original contract with the Public Health Service, and I hope that whatever changes the agencies and the Subcommittee feel are warranted do not undermine this critical activity.

I hope the larger ethical issues can be addressed quickly, just as I hope the specific problems facing Correlogic can be resolved expeditiously. I hope, despite my appearance today, that Correlogic will be allowed to finish the work called for in the various agreements we have signed with the NIH and National Cancer Institute and the Food and Drug Administration. I hope that the NIH will honor its license agreements. And, I hope that Correlogic will not be victimized a second time by being shunned by the NIH when we seek future research collaborations.

All we ask for is a level playing field, where a contract signed on one day cannot be discarded the next, at the whim of public employees who may have their own private, business agendas. The small private investors who have funded Correlogic, and hundreds of other small biotech companies deserve better. The men and women in our public health service deserve better. And, most importantly, the millions of Americans whose lives could be saved by the earlier and more accurate detection of cancer deserve better.

I would be happy to answer any questions you may have.

Mr. GREENWOOD. Thank you, Mr. Levine, and let me assure you, sir, that even a hint of any kind of retribution or negative response for your cooperation with this committee will absolutely not be tolerated by this committee.

Mr. LEVINE. I appreciate that very much.

Mr. GREENWOOD. And we would expect for you to inform us of any such untoward actions occur, because we will be all over it.

Mr. LEVINE. Thank you, sir.

Mr. GREENWOOD. Dr. Heller.

TESTIMONY OF JONATHAN C. HELLER

Mr. HELLER. Good afternoon, Chairman Greenwood and members of the committee. My name is Jonathan Heller and I am Vice President for Information and Project Planning at Predicant Biosciences, formerly known as Biospect.

Thank you for the opportunity to appear before you today to discuss past consulting arrangements between my company and Dr. Lance Liotta and Chip Petricoin. With your permission, before I ad-

dress these consulting relationships, I would like to take a few moments to tell you about myself and the company where I am extremely proud to work.

In 1989, I received my Bachelor's Degree with Honors in applied mathematics from Harvard University. After college, I joined the Peace Corps as a volunteer and spent 2 years in Papua New Guinea, teaching science and math. My passion for science and math ultimately led me to graduate school at the University of California, Berkeley, where I earned a PhD in Biophysics in 1997. The focus of my graduate work was on biophysical investigations of Prion proteins, which are responsible for Mad Cow disease.

In 2002, I was offered a wonderful opportunity with a small, South San Francisco startup company called Biospect. We recently changed our name to Predicant Biosciences.

I was one of the first scientists to join Predicant, which has now grown to thirty-five employees. Our goal is and has been to revolutionize patient care by developing a platform that will reliably detect and diagnose the severity of a disease by analyzing protein patterns in blood.

We are still approximately 18 to 24 months away from having a diagnostic service ready for sale on the market. As I testify today, my colleagues in California are hard at work on the company's integrated system. In very simple terms, our system works in the following way: A drop of blood from a patient is fed into our instrument; the instrument prepares the blood sample for analysis; proteins in the blood are separated into smaller groups; the grouped proteins are then sprayed into a mass spectrometer, a detection instrument; and finally, the data is analyzed to find patterns that suggest the presence of a disease. Many of our competitors focus on one, perhaps two of these steps. We believe that our comprehensive approach sets us apart, which is why we often refer to our system as a complete, "blood to answer" solution.

I manage the informatics department at Predicant. I work with a team of eight scientists and mathematicians on the last step of our integrated system, the data analysis step. We develop statistical tools for signal processing and for finding patterns in the data. These software tools help us cull meaningful information out of very large and often "noisy" data sets.

We are hopeful that our "blood to answer" solution will become an important milestone in the field of predictive medicine. We at Predicant are very hard at work to make that happen. Earlier detection, more accurate diagnoses, and better information on the acuteness of a disease will optimize treatment selection and have a dramatic impact on patient care, on outcomes, and on health care costs.

We understand that the committee recently has held several hearings on the important topic of ethics at the National Institutes of Health. Our company applauds the committee for its attention to this issue.

At the hearing on May 18, the committee considered a "case study" involving the consulting relationships between our company and Drs. Liotta and Petricoin. While Predicant was unaware that the company would be a topic for discussion at that hearing, we are grateful for this opportunity to participate in this very important

dialog and to provide our perspective on the issues raised by the committee.

Drs. Liotta and Petricoin began consulting on a part-time basis for our company in December 2002. As this committee has previously heard, they are among the most prominent scientists in the field of clinical proteomics. Predicant engaged Drs. Liotta and Petricoin because they are thought-leaders in the field, and we believed that they could assist us in conceiving of and evaluating potential applications for our system and technology. In other words, we hoped that they could help us identify which diseases to target first.

At the time that we engaged Drs. Liotta and Petricoin, our company was aware that there are important ethical restrictions that limit the type of outside activities that can be engaged in by government scientists. As a result, we sought to ensure that we followed all the applicable NIH and FDA guidelines and processes and were open and transparent in our dealings with those agencies. The consulting agreements were reviewed and formally approved by ethics officials at both the NIH and the FDA.

Because Drs. Liotta and Petricoin are government scientists, our consulting agreements with them deliberately carved out large areas as off-limits for consultations or discussions of any kind. For instance, Drs. Liotta and Petricoin could not tell us about their official government research if their findings had not been made public. This includes any research performed under a CRADA.

One of the concerns raised by the committee was that Drs. Liotta and Petricoin were consulting for Predicant at the same time they were engaged in Government work with a software development company called Correlogic. At the time that we entered into consulting agreements, we asked them to identify all of their outside activities, and we became aware of their CRADA. In addition, the fact of the collaboration between Correlogic and the Government was well known. As a result of the Correlogic agreement, the sharing of any public/non-public CRADA-related information was specifically excluded from the scope of our consulting agreements. Consistent with the agreements, Predicant never sought from Drs. Liotta and Petricoin, and they never shared with Predicant, any non-public information regarding their CRADA with Correlogic. In fact, they never shared any non-public information of any kind with Predicant.

Another important point to be made here is that, while our company and Correlogic both employ clinical proteomics to detect disease, I think it is fair to say that our two companies are pursuing different methods—both in terms of the software and technology to achieve this goal. It is our understanding, based on public information, that Correlogic's software technology uses self-organizing maps in combination with genetic algorithms to identify and analyze proteins in the blood. Predicant, on the other hand, has focused on other methods, which we hope will prove more effective. In addition, as noted, Predicant's goal is to develop a comprehensive "blood to answer" approach to disease detection, which we believe is not directly comparable to Correlogic's technology.

In closing, I would like to emphasize on behalf of all of my colleagues at Predicant that we will continue to follow our internal

ethical standards and all applicable government requirements as we strive to create new tools to aid in the detection of cancer and other diseases. We believe that we followed the rules and acted appropriately in our relationship with Drs. Liotta and Petricoin.

Thank you for the opportunity to appear before you today and to participate in the important work of the committee. I would be pleased to answer any of your questions.

[The prepared statement of Jonathan C. Heller follows:]

PREPARED STATEMENT OF JONATHAN C. HELLER, VICE PRESIDENT, INFORMATION AND PROJECT PLANNING, PREDICANT BIOSCIENCES, INC.

Good afternoon, Chairman Greenwood, Representative Deutsch, and Members of the Committee. My name is Jonathan Heller, and I am Vice President for Information and Project Planning at Predicant Biosciences, formerly known as Biospect, Inc. Thank you for the opportunity to appear before you today to discuss past consulting arrangements between my company and Dr. Lance Liotta of the National Cancer Institute ("NCI") and Dr. Emanuel "Chip" Petricoin of the Food and Drug Administration ("FDA"). With your permission, before I address those consulting relationships, I would like to take a few moments to tell you about myself and the company where I am extremely proud to work.

In 1989, I received my Bachelor's Degree with Honors in applied mathematics from Harvard. After college, I joined the Peace Corps as a volunteer and spent two years in Papua New Guinea, teaching science and math. My passion for science and math ultimately led me to graduate school at the University of California, Berkeley, where I earned a PhD in Biophysics in 1997. The focus of my graduate work was on biophysical investigations of Prion proteins, which are related to Mad Cow disease.

In 2002, I was offered a wonderful opportunity with a small, South San Francisco startup company called Biospect. After a lengthy deliberative process, our company recently changed its name to Predicant Biosciences because of trademark issues associated with the name "Biospect," and because we believe the name "Predicant" more closely reflects our mission of identifying and predicting disease.

I was one of the first scientists to join Predicant, which has now grown to thirty-five employees. Our goal is and has been to revolutionize patient care by developing a platform that will reliably detect or diagnose the severity of a disease by analyzing protein patterns in blood. Predicant is just two-years old and still in the development phase. To date, we have been concentrating on developing our technology; refining our business strategy and operational plans; developing scientific and clinical collaborations; and, most importantly, building a team of dedicated and talented scientists.

We are still approximately 18 to 24 months away from having a diagnostic service ready for sale on the market. As I testify today, my colleagues in California are hard at work on the company's integrated system. In very simple terms, our system works in the following way: A drop of blood from a patient is fed into our instrument; the instrument prepares the blood sample for analysis; proteins in the blood are separated into smaller groups; the grouped proteins are sprayed into a mass spectrometer, a detection instrument; and finally, the protein patterns are analyzed to differentiate between patterns that suggest the presence of a disease and patterns that do not. Many of our competitors focus on one, perhaps two of these steps. We believe that our comprehensive approach sets us apart, which is why we often refer to our system as a complete, "blood to answer" solution.

I manage the informatics department at Predicant. I work with a team of eight scientists and mathematicians on the last step of our integrated system—the analysis step. We develop statistical tools for signal processing and for finding patterns in the data. These software tools help us cull meaningful information out of large and often "noisy" data sets.

We are hopeful that our "blood to answer" solution will become an important milestone in the field of predictive medicine. Many dedicated scientists at Predicant are working very hard to make that happen. Earlier detection, more accurate diagnoses, and better information on the acuteness of a disease will optimize treatment selection and have a dramatic impact on patient care, outcome, and healthcare cost.

We understand that the Committee recently has held several hearings on the important topic of ethics at the National Institutes of Health ("NIH"). Our company applauds the Committee for its attention to this issue.

At the hearing on May 18, the Committee considered a “case study” involving the consulting relationships between our company and Drs. Liotta and Petricoin. While Predicant was unaware that the company would be a topic for discussion at the May 18 hearing, we are grateful for this opportunity to participate in this very important dialogue and to provide our perspective on the issues raised by the Committee.

Drs. Liotta and Petricoin began consulting on a part-time basis for our company in December 2002. As this Committee has heard previously, Drs. Liotta and Petricoin are among the most prominent scientists in the field of clinical proteomics, our company’s area of focus. Predicant engaged Drs. Liotta and Petricoin because they are thought-leaders in the field, and we believed that they could assist us in conceiving of and evaluating potential applications for our system and technology. In other words, we hoped Drs. Liotta and Petricoin would use their knowledge and experience in the field to assist us in a variety of ways, including by helping us identify which diseases to target first.

At the time that we engaged Drs. Liotta and Petricoin, our company was aware that there are important ethical restrictions that limit the type of outside activities that can be engaged in by government scientists. As a result, we sought to ensure that we followed all the applicable NIH and FDA guidelines and processes and were open and transparent in our dealings with those agencies. The consulting agreements between Predicant and Drs. Liotta and Petricoin were reviewed and formally approved by ethics officials at both the NCI and the FDA. In addition, it is our understanding that NCI officials in fact helped draft the agreement between Dr. Liotta and Predicant.

Because Drs. Liotta and Petricoin are government scientists, our consulting agreements with them deliberately carved out large areas as off-limits for consultations or discussions of any kind. For instance, Drs. Liotta and Petricoin could not tell us about their official government research if their findings had not been made public. This included any research performed under a Cooperative Research and Development Agreement, or “CRADA.”

One of the concerns raised by Committee Members at the May 18 hearing was that Drs. Liotta and Petricoin were consulting for Predicant at the same time they were engaged in government work with a software development company called Correlogic. At the time that we entered into consulting agreements with Drs. Liotta and Petricoin, we asked them to identify all of their outside activities, and we became aware of their CRADA with Correlogic as a result. In addition, the fact of the collaboration between Correlogic and the government and its general subject matter were well known in our field. As a result of the Correlogic agreement, the sharing of any non-public CRADA-related information was specifically excluded from the scope of the consulting agreements between our company and Drs. Liotta and Petricoin. Consistent with the agreements, Predicant never sought from Drs. Liotta and Petricoin, and Drs. Liotta and Petricoin never shared with Predicant, any non-public information regarding their CRADA with Correlogic. In fact, Drs. Liotta and Petricoin never shared any non-public information of any kind with Predicant. We were always of the view that they took care to ensure that their work for us did not breach any ethical or other requirements.

Another important point to be made here is that, while our company and Correlogic both employ clinical proteomics to detect disease, I think it is fair to say that our two companies are pursuing different methods—both in terms of software and technology—to achieve this goal. It is our understanding—based on public information—that Correlogic’s software technology uses self-organizing maps in combination with genetic algorithms to identify and analyze proteins in the blood. Predicant, on the other hand, has focused on other methods, which we hope will prove more effective. In addition, as noted, Predicant’s goal is to develop a comprehensive “blood to answer” approach to disease detection, which we believe is not directly comparable to Correlogic’s technology. As a result, even if it had not been prohibited by our consulting agreement, Predicant would not have sought confidential information pertaining to Correlogic’s CRADA because such information would have been of no value to our company.

In closing, I would like to emphasize on behalf of all of my colleagues at Predicant that we will continue to follow our internal ethical standards and all applicable government requirements as we strive to create new tools to aid in the detection of cancer and other diseases. We believe that we followed the rules and acted appropriately in our relationship with Drs. Liotta and Petricoin.

Thank you for the opportunity to appear before you today to participate in the important work of the Committee. I would be pleased to answer any of your questions.

Mr. GREENWOOD. Thank you, Dr. Heller. I'm going to ask—the Chair recognizes himself and Ms. DeGette and I have agreed that I'll question for both of us, so we're going to go through a fairly tight script here.

So if the staff could please play clips two and three, we will hear Dr. Petricoin's testimony from last week about discussions he had regarding this with you, Mr. Levine.

[Tape is played.]

Mr. GREENWOOD. Mr. Levine, in your discussions with Dr. Petricoin was your frustration, as he recalls, simply over the fact that Biospect employed so many former NCI employees?

Mr. LEVINE. Not at all, Mr. Chairman. My conversation with Dr. Petricoin which, in fact, did not occur at the time that Dr. Petricoin suggested that it did, was a——

Mr. GREENWOOD. When did it occur?

Mr. LEVINE. The actual oral conversation occurred or telephone conversation, I should say, occurred on or about July 8 or July 9, 2003. And it was explicit at that time that we viewed Biospect as a competitor. And what's interesting though is when I look back because of these hearings, it's very clear that in May 2003, I had sent an e-mail to Drs. Petricoin and Liotta which included the website of Biospect. It had been sent to me by an outside industry executive who said this is your new competition, Peter. And I forwarded that e-mail to Drs. Petricoin and Liotta as sort of an FYI because we were always talking about the competition out there, in essence.

So I made it very clear——

Mr. GREENWOOD. Mr. Levine, would you turn to Tab 28 in the binder there. I think that is the e-mail to which you are referring. I'm going to ask you to read it. Go to Tab 28 and then go to the second page and I think you'll find the e-mail to which you just referred.

Would you read that?

Mr. LEVINE. The incoming e-mail is directed to me from an outside industry executive. It says, "Peter, nice talking with you today. Here's some information on your new competition. I'll be in touch. Vince." And attached to the bottom of the e-mail is the website, I assume the website at that time of Biospect which describes the company. Actually, I think Dr. Heller's description just now was extremely accurate. And that's exactly as we perceived Biospect to be which was again exactly what Correlogic is doing.

I then forwarded this same e-mail with all the background material on Biospect to Drs. Liotta and Petricoin on Thursday, May 22. And the subject line was "FYI, Info on Biospect, FYI Rick Klausner, Lance and Chip, Peter."

So I brought this to their attention. I had no idea that they were consulting for Biospect. Frankly, I had never heard of Biospect before, but again this was brought to my attention by an outside industry executive.

In the 4 or 5 weeks that followed this e-mail, I was informed by a number of other biotech industry officials that they heard that Petricoin and Liotta were consulting for Biospect or had some affiliation actually. And I became worried about that. And it was brought to my attention very specifically in late June, actually, I think it was over the July 4 weekend and I went to the website

for the first time myself and all the pieces came together. I realized that Biospect was located on the same floor in our building in Bethesda and that I had indeed seen Drs. Petricoin and Liotta there which always struck me as being rather odd from time to time. And all the pieces began to come together.

So at that point I called Dr. Petricoin who I considered to be a friend and I confronted him about it, very directly, and my concern getting back to your question, Mr. Chairman, my concern was not that there were all these former NCI folks, the concern was very specifically that Biospect was a competitor and that they were consulting with a competitor.

Mr. GREENWOOD. Did your discovery of the consulting arrangement between Biospect and Drs. Liotta and Petricoin have an impact on your working relationship within the CRADA?

Mr. LEVINE. Oh, it most certainly did. I immediately instructed all the scientists at Correlogic to be very careful about the information that we shared with them. And for example, this is at a time where we were beginning our work on electrospray technology and again, I don't know much about the details at Biospect, but it certainly seems to be very much related and this was an area that we were pursuing aggressively, again, all part of the process of putting together a turnkey system that goes basically from the patient's vein to a diagnostic determination. So we cautioned, I cautioned everybody at Correlogic to be very careful about what was said until the issue was resolved.

Mr. GREENWOOD. I'm going to ask the staff to play Clip 5 now. [Tape played.]

Mr. GREENWOOD. First, let me ask you, Dr. Heller, do you consider yourself just a medical device company?

Mr. HELLER. I don't know exactly what a medical device company is, Mr. Chairman. I would say that we're trying to provide a complete solution. It contains an instrument. It contains software. It contains an application and we plan on delivering that entire system to the market for diagnosis.

Mr. GREENWOOD. Sounds like what Mr. Levine is trying to do.

Mr. HELLER. It does sound like what he has said he is trying to do. That is not our understanding of what he was trying to do.

Mr. GREENWOOD. Let me go to you, Mr. Levine. Do you agree with Dr. Liotta's assertion that you just heard, that what Correlogic is doing "seems completely different" from what Biospect is doing?

Mr. LEVINE. No, I was actually amazed at that comment because at that time, and going back actually as early as April 2002, it's very clear from the license agreement that we have with the Public Health Service and from what has now been a 2-year negotiation, that the very central issue was the creation of a turnkey system. That was the content of probably a good two-thirds of our CRADA meetings. It was the content, in fact, it was the sticking point of our negotiations with the Public Health Service and particularly with NCI was the selection of components for a turnkey system.

Mr. GREENWOOD. And is there any question in your mind that Dr. Liotta understood that?

Mr. LEVINE. Dr. Liotta was intimately involved in all those negotiations. And indeed, one of the other issues that went on in this

same time period was that, of course, the Public Health Service approved our contract with Lab Corp. of America and Quest Diagnostics and again, these are companies that with Correlogic, were attempting to deliver a turnkey ovarian cancer testing service. So again, the idea that we were only a software company is—it's very clear as early as April 2002, that was not the case.

Mr. GREENWOOD. Do you believe that other parties at NIH understood that you were not just a software company as Dr. Liotta suggested?

Mr. LEVINE. Well, I don't know where in the hierarchy of NIH the information was going. I know certainly that Drs. Liotta and Petricoin were our principal contacts at NIH, at FDA and NCI. So I don't know what they were telling their superiors, but clearly, a large number of people that ranged frankly from Dr. Shtrom of Biospect to people in the Office of Technology Transfer of NIH to the people or to the officials in the Office of Technology Transfer at NCI, all of whom were intimately aware of this. It's in documents.

Mr. GREENWOOD. Speaking of documents, in Tab 28 again, would you point out some of the NIH e-mails that show what they understood?

Mr. LEVINE. There are a series of e-mails here and for example, this is one on July 3, 2003 between Kevin Brandt and myself, cc'd to Dr. Liotta and Dr. Petricoin.

Mr. GREENWOOD. Explain who Kevin Brandt is.

Mr. LEVINE. I'm sorry. He's with NCI's Office of Technology Transfer. And again, this e-mail is describing the development of what at this point was a Memorandum of Understanding and the focus of this e-mail and I believe several others in this same group is the—for example, choosing of components. And again, the issue of choosing of components is far beyond software. It was one of the things that we were focusing on which mass spec. you use, this protein separation or ionization system do you use? Frankly, all the components Dr. Heller just described. That's exactly what Correlogic was doing.

Our business model, however, was a little bit different, apparently, than Biospect's. We were doing this through collaborations with Lab Corp. and Quest, with Avion Biosciences, with Charles River Proteomics. We were doing this by way of license agreement and contract. But clearly, every one of these e-mails and all of these negotiations were all centered on that point of developing a turnkey system.

Mr. GREENWOOD. Do you believe that it would be clear to someone comparing Correlogic to Biospect that the two companies are competitors?

Mr. LEVINE. Clearly, and in fact, again the way in which I was alerted to, was that other industry executives, including some senior executives at a very large in vitro diagnostic company that if I mentioned the name everybody would know, they were the ones who were bringing it to my attention.

Mr. GREENWOOD. Were you aware, prior to these hearings, that in August 2002, Drs. Petricoin and Liotta were in discussions with a company called Signet Labs about becoming members of their new scientific advisory board?

Mr. LEVINE. Prior to these hearings, no.

Mr. GREENWOOD. Would you go to Tab 33 and read the June 28, 2002 e-mail from Jeff Livingstone to Dr. Petricoin and Dr. Petricoin's response.

Mr. LEVINE. It says "thank you very much for your kind reply. We are aware of Dr. Liotta's excellent work in proteomics and LCN and has worked with Ben Hitt at Correlogic. I agree he'd be an excellent person to contact in this regard. At present, Signet is a privately owned small business. The core business is profitable. However, the capital necessary for commercialization or new technology will require outside financing. Our plans are to use outside investment to double our size and research activities. And we will be starting our road show next month to raise approximately \$15 million for successful commercialization of our technology. We expect this to be done through a combination of corporate and venture investments and some of our corporate partners, Zymarc, Corning, Life Science, etcetera, have expressed interest in contributing. In order to preserve capital, we are intending to offer equity compensations to those who serve as members of the SAB. Obviously, once we close on our first round of financing, this will convert to cash or cash plus equity basis, depending upon the interest of that particular SAB member." Dr. Petricoin's response dated Friday, June 28 says "Hi Jeff, I'd be interested in learning more about this. I'd like to recommend my colleague, Dr. Lance Liotta at the NCI for consideration for the SAB. I can provide you with his contact info if you wish. I highly recommend him. We would have to receive outside activity okay from ethics. Can you tell me what kind of compensation the SAB members receive for their time. Best, Emanuel."

Mr. GREENWOOD. Now read the second paragraph in the e-mail from Jeff Livingstone to Drs. Petricoin and Liotta and then the reply e-mail from Emanuel Petricoin dated August 1, 2002. Tab 32.

Mr. LEVINE. The e-mail from Dr. Petricoin to Mr. Livingstone says "Hi Jeff, both Lance and I are interested in talking with you about this. Perhaps a conference call this afternoon would be helpful to us so that we can understand better what you envision our roles to be, a bit more about your Magellan technology and how to get ethics clearance. Note that both Lance and I work with Correlogic as a CRADA partner within our Government jobs. Best, Emanuel."

And then there's another e-mail here also from Jeff Livingstone to Dr. Liotta. "Dr. Liotta, you may be aware of any correspondence with Dr. Petricoin. I've invited him to be a member of a new Scientific Advisory Board we're putting together. He, in turn, suggested we send an invitation to you. As we're very aware of your excellent work in pathology and proteomics and of course, your background is an ideal fit for a new technology we'll be launching at the DDT meeting this coming Sunday. My only concern here is there may be a conflict of interest between the companies you're working with at present, e.g., Correlogic and any companies you may intend to start. As a professional courtesy, I do not wish to put you in such a situation. We meant no slight. I trust you understand. However, if this is not the case and you are interested, then please let me know. We'd be honored to have expertise and per-

spective available for the development of our Magellan platform. Please note, I've sent a binder to Dr. Petricoin containing an overview of our company and technology, along with his invitation to the SAB. Please feel free to review it if you wish. I note you be participation"—that's the way it's written—"in the DDT meetings. See below. I intend to be at this meeting on Sunday and all day Monday. I'd be happy to meet with you in person if you have the time. If you're interested in visiting Signet while you're here, please let me know. I'd like to extend this invitation to Dr. Petricoin as well, if he'll be here for the meeting. Thank you for consideration."

Mr. GREENWOOD. Let me ask you this question. What role did Svetlana Shtrom play in the CRADA?

Mr. LEVINE. Dr. Shtrom was the NCI technology transfer specialist that I dealt with continuously really from the summer of 2000 through the fall of 2002, both through the development of the original CRADA and then the attempted amendments that began in the summer of 2002 and she was also involved indirectly, I will add though, with the negotiations with NIH's Office of Technology Transfer about the license that we had, the exclusive license for the hidden patterns technology. The reason being is that there was an overlap, if you will, between the CRADA and the license agreement. Indeed, that's one of the issues really here that makes this so complicated. It's again that we are both co-inventors, along with Petricoin and Liotta and we are the exclusive licensee of the Government's interest in that invention and at the same time operating under a CRADA.

So there was a lot of exchange of e-mails, conversations, between the Technology Transfer Office of NIH that we negotiated with for the exclusive license and NCI's Tech. Transfer Office that was responsible for the CRADA.

Mr. GREENWOOD. And when did you learn that Svetlana Shtrom was involved with Biospect?

Mr. LEVINE. At the same time, essentially, that I learned that Dr. Petricoin and Dr. Liotta were involved. I was aware that she was on the floor of our building, but never made the association.

Mr. GREENWOOD. In your testimony, you mention that you're on the brink of bringing a new testing device that can improve chances for early detection and treatment of cancer to market. Has the process of negotiating with NIH in any way slowed the process of getting your product to the American people who need it?

Mr. LEVINE. That's difficult to answer, Mr. Chairman, but certainly the amount of time, energy and effort that a little company like Correlogic has spent—a 2-year negotiation and of course, the—as we began to describe the CRADA relationship after July as the un-CRADA, certainly we could have made much more progress had there been a genuine collaboration and cooperation with our Government partners.

Mr. GREENWOOD. Okay, Dr. Richard Klausner is listed on Biospect Predicant's website as a founder and director of the company. Do you know whether or not Dr. Klausner was aware of the work being done on Correlogic's CRADA with NCI?

Mr. LEVINE. Long before any of these issues became aware, became apparent to me, in casual conversations with both Drs. Liotta and Petricoin, they mentioned to me the great interest that Dr.

Klausner had in this and indeed, I think when you look back at all that went on, there was a tremendous amount of publicity in February 2002 concerning the Lancet publication on our ovarian cancer work with Dr. Liotta and Dr. Petricoin. So I think the Agency as—I think everyone at the highest levels of the Agency was very much aware of this work, but again, I was told specifically that both Petricoin and Liotta had been brought in to talk with Dr. Klausner.

Mr. GREENWOOD. And do you know if those discussions occurred before or after his departure from NCI?

Mr. LEVINE. No, I believe they occurred before.

Mr. GREENWOOD. When you learned that Dr. Klausner was involved with Biospect, were you alarmed that the person with whom the two principal investigators on your CRADA had discussed your work, was involved with a competitor?

Mr. LEVINE. Well, all that raised troubling questions and again, the e-mail that I sent to Drs. Liotta and Petricoin on May 22 was part of that issue. And again, because we routinely over the preceding 2 years had sent e-mails and constantly talked between ourselves about what other institutions were doing, other academics, other private sector companies, knowing that there were other folks out there who were sort of racing to fill the same space.

So yes, it was very troubling and in general, the idea that the former director of NCI and actually there were at least three people that I know from NCI, two rather high positions, plus Dr. Shtrom who had worked with us directly, were all now members or were working with Biospect. Certainly, it seemed to be stacking the deck.

Mr. GREENWOOD. Okay. I will turn to you, Dr. Heller.

When did Biospect hire Dr. Liotta and Dr. Petricoin?

Mr. HELLER. I believe their consulting agreement started in December of 2002.

Mr. GREENWOOD. And how long did the consulting relationship last?

Mr. HELLER. Up until last month as far as I know.

Mr. GREENWOOD. Last month?

Mr. HELLER. Last couple of months, yes.

Mr. GREENWOOD. And do you know when Dr. Liotta stopped receiving payments?

Mr. HELLER. I don't have an exact date, but it was some time in 2004.

Mr. GREENWOOD. And did these two doctors work pretty consistently through that time period?

Mr. HELLER. They spent initially about 2 days a month and then subsequently about 1 day a month working with us.

Mr. GREENWOOD. So Biospect was still compensating Dr. Liotta for work into May, is that correct?

Mr. HELLER. I believe his last paycheck was May 1.

Mr. GREENWOOD. Look at Tab 41, I think it might help you.

Mr. HELLER. So yes, according to this, Dr. Liotta got paid on May 1, 2004.

Mr. GREENWOOD. Okay, the staff would put up a slide and if you would turn your attention to the screen, Dr. Heller.

Is this the canceled check indicative of the last time Biospect compensated Dr. Liotta?

Mr. HELLER. That looks like it is.

Mr. GREENWOOD. Okay. So he was still doing work for the company during March, April and May. Is that correct?

Mr. HELLER. I do not recall whether we actually had conversations during that time period, but I would say most likely we did, yes.

Mr. GREENWOOD. Is it likely you would have compensated him for doing nothing?

Mr. HELLER. As the agreement stood, we compensated them on the first of every month regardless. They did not have to turn in time sheets or anything like that. We did a direct deposit essentially.

Mr. GREENWOOD. You don't know whether he was still doing work during those 3 months?

Mr. HELLER. In the last couple of months, I was no longer on the phone calls with Drs. Petricoin and Liotta. I would have to guess that they were still doing work in February.

Mr. GREENWOOD. You said that you were not on the phone calls. That presumes that you know that there were phone calls?

Mr. HELLER. I assume there were phone calls.

Mr. GREENWOOD. You assume, based on what do you make that assumption?

Mr. HELLER. One of my colleagues was responsible for working with them and setting up such phone calls and he was fairly diligent about that.

Mr. GREENWOOD. Okay. The Chair will yield 10 minutes to the gentleman from Florida, Mr. Stearns.

Mr. STEARNS. Thank you, Mr. Chairman. If the staff would please play clip one. Please listen to a statement of Dr. Petricoin made at our last hearing.

[Audio file played.]

Mr. STEARNS. I guess the question would be for Dr. Heller.

Based on Biospect's relationship with Dr. Petricoin, do you believe it is likely that this encounter with Dr. Goodman was the first time Dr. Petricoin understood that Biospect did data analysis?

Mr. HELLER. With all due respect, I cannot really say what Dr. Petricoin and Dr. Liotta remember about what we told them. I have the utmost respect for Drs. Liotta and Petricoin and therefore it's actually hard for me to understand the clip that we just heard.

I believe that we had past discussions with them, starting at the beginning of their consulting relationship with us which made them aware that the company was doing pattern recognition, pattern analysis and subsequent to that we signed a confidentiality agreement with the NCI to acquire new data that was publicly available, but not yet published from Drs. Liotta and Petricoin and I believe they were aware that we had signed that consulting agreement and downloaded their data.

Mr. STEARNS. Can I summarize by saying you don't think that is believable what you just heard?

Mr. HELLER. I can't state under oath again that what they were thinking when they answered that, but it's not my knowledge.

Mr. STEARNS. Let me ask you yes or no, what you heard, do you think that is believable?

Mr. HELLER. Not to my knowledge.

Mr. STEARNS. Okay, so basically you're saying you don't think it's believable.

Did Dr. Liotta or Dr. Petricoin offer any advice to Biospect on how to set up the labs?

Mr. HELLER. I assume by that you mean our reference labs?

Mr. STEARNS. Yes, the reference labs?

Mr. HELLER. I think we, in general, discussed different routes of bringing a product to market and that included, covered the area of setting up a clinical reference lab, yes.

Mr. STEARNS. Did they advise you on certification standards? CLIA certification standards?

Mr. HELLER. One of the main things that the two of them did is they pointed us to public information because we were a small company. We didn't have a lot of resources. We didn't know exactly where to look. I believe that one of the things they pointed us to was a list of CLIA reference lab standards, yes.

Mr. STEARNS. Which Federal agency regulates CLIA standards?

Mr. HELLER. I believe it's CMS.

Mr. STEARNS. So Dr. Liotta gave Biospect advice on how to implement a CMS standard?

Mr. HELLER. I wouldn't say that he gave us advice. I would say that he pointed us in the direction of a document that told us essentially what we would have to do to meet that standard.

Mr. STEARNS. So he advised on how to make the reference lab CLIA compliant?

Mr. HELLER. Again, he pointed us to documents that described how we would do that. I wouldn't say that he actually advised us how to do that.

Mr. STEARNS. Mr. Levine, has Correlogic attended any clinical proteomics conferences?

Mr. LEVINE. Yes, we do, sir.

Mr. STEARNS. And were they with Drs. Liotta and Petricoin, did they make presentations at these?

Mr. LEVINE. Over the last 3 years, there have been a large number of conferences. We have not attended most of those. I believe there have been at least two or three where either I have been a speaker along with Dr. Petricoin or Correlogic's Chief Scientific Officer, Dr. Hitt may have been a speaker along with Dr. Petricoin.

Mr. STEARNS. And when they discussed the work they had done for Correlogic, did they acknowledge the company's contribution to the work?

Mr. LEVINE. In a minimal way. And in fact, over the last 2½ years, there was a series of e-mails that I've not provided yet to the committee, but I'd be happy to do so where we actually complain about that, that basically our contribution is being minimized.

Mr. STEARNS. So the principal investigators, you were collaborating with on this CRADA, weren't giving the company any credit for their work?

Mr. LEVINE. I wouldn't say no credit. I'd say really de minimis credit and particularly relative to the Lancet publication in which

the actual analysis, I mean the actual—the meat of the Lancet, the real discovery is what Dr. Hitt did in the computational analysis.

Mr. STEARNS. But as you mentioned, you are named with Dr. Petricoin and Dr. Liotta in filing patents in a publication. Is that correct?

Mr. LEVINE. That's correct.

Mr. STEARNS. Thank you, Mr. Chairman.

Mr. GREENWOOD. The chairman recognizes Mr. Bilirakis for questions for 10 minutes.

Mr. BILIRAKIS. Well, Mr. Chairman, I listened to some of their testimony while I was out in the anteroom. I'm not going to be specific here as Mr. Stearns and others maybe were, but—and I know in your written statements you basically refer to your experience at NIH and what not. Mr. Levine, you quite—you're pretty strong, I would say quite frankly, would not be at this critical and exciting juncture in talking about the accomplishments of your company without the considerable talent and resources of the NIH and NCI, etcetera.

You're both health care people. You're in it, obviously, to make a profit, but you're in it also because I think you care and you want to help people.

And I know you're involved in the research area and you work with NIH and some of these other groups. I'm just going to ask you to maybe complement, if you would, supplement, complement your written testimony, anything more—you sat through the—how much time did we take with the prior panel. You sat through all that.

Let's start with Mr. Levine, is it Levine?

Mr. LEVINE. Levine.

Mr. BILIRAKIS. With what I get with my last name, you shouldn't be—

Mr. LEVINE. I respond either way, I got used to it too.

Mr. BILIRAKIS. Mr. Levine, why don't you just go ahead and supplement your statement. You heard—your written statement was written prior to coming in and sitting in during the last panel. And just tell us how do you feel, I mean, how do you feel about what has happened? How do you feel about what we are doing here in terms of research? Are we helping research or are we hurting research, etcetera? Go ahead.

And then Dr. Heller, I would ask you the same thing.

Mr. LEVINE. I think, in general, that the subcommittee's work is critical and I think it will create a very significant improvement. We constantly hear about the job generation, for example, from the small business sector, well, actually both Biospect and Correlogic are small companies and if the Government wants to really realize the great potential of these public/private partnerships, you've got to be able to assure that when small companies enter into relationships with the Government that they don't get crushed. And so I think the theme that I take away from all of this is that everyone in America has to abide by their agreements. Everyone has got to play fair, but particularly the Government, particularly the Government. My God, if a Government agency can just sort of arbitrarily decide to ignore an agreement that's signed on 1 day because other people in the agency think it's not correct or because

something looks more attractive elsewhere, the whole system falls apart. So I'm actually very encouraged by what Dr. Zerhouni said.

Mr. BILIRAKIS. Excuse me, a minute, sir. I wanted to ask the questions. Dr. Zerhouni has left. Are there any NIH people in the audience? Are there any NIH folks here? Are you all taking notes? Okay.

I would hope that some of the things that you're hearing from these two witnesses will go to Dr. Zerhouni and Mr. Azar.

Okay, go ahead, sir.

Mr. LEVINE. So I'm very encouraged by what I heard this morning. The other suggestion I would make though, I realize that the focus of these subcommittee hearings are principally on conflict of interest and the consulting arrangements, but I think that all this ties into the broader issue that when you have an agency as large as NIH, and you have this very complicated interaction of licensing agreements, intellectual property, contracts, CRADAs, essentially you have the potential and I think Correllogic is caught up in the middle of this, the potential for an incredibly complicated situation where rights are being granted and then whittled away or it's confusing as to which rights were granted. So I'm not sure that I can offer a solution this morning, but I think certainly someone has got to be able to be in a position to step back and say and what are all the conflicting or potentially conflicting and overlapping relationships between this agency, this employee of this agency, this private sector company, and this is particularly true, particularly true in the area of biotech.

I have no problem whatsoever with Biospect, what Dr. Heller has said. We are both working toward the same end point and it's a great end point for the public, in general. But if it leaves too small biotech companies kind of wondering who they're talking to and what information they should be sharing and not be sharing, that can't be good for the public. So that's the lesson that I would take away from all of this.

Mr. BILIRAKIS. Based on your experience with NIH, would you look forward to working with them or any other part of the Federal Government again regarding the good work that you're doing?

Mr. LEVINE. That is a difficult question, Congressman. We do intend to continue working with the Public Health Service. And, again, in my opening comment, that is one of the concerns I have is that there are no whistleblower statutes for companies, especially small companies. But, no, we would.

I mean, overwhelmingly, all of the scientists and the executives that I have dealt with in the Public Health Service are outstanding, so I don't think that this is a systemic problem. I think there was a profound lack of common sense applied to all of this. I mean, when you step back from all of the lawyers and figuring out where the semi-colons are placed, I mean, basically, you know, none of this would pass the smell test. It just didn't make sense. So, you know, but I don't think that is the rule.

Mr. BILIRAKIS. I know the chairman basically laid out his admonishment regarding any negative suffering that you might have as a result of testifying here before you—right at the beginning of your testimony. So hopefully—I know he was pretty strong and stern when he made those comments, and I know he means it.

Okay. Dr. Heller?

Mr. HELLER. I do. I also encourage the committee's work. I think you are doing very good work, and I was encouraged by Dr. Zerhouni's plans. I think we come from a different perspective. We feel like we followed all of the ethical rules and procedures, and really up until this morning we were under the impression that Drs. Liotta and Petricoin had as well. We do not feel like we had any surreptitious or secret dealings with them in any way.

I think it is up to the committee and to Dr. Zerhouni to find the right balance between what government scientists should be allowed to do in terms of consulting and cooperative research agreements, and what not. I don't feel like I am in the proper place. I am not an ethicist in any way.

I will say that I believe that allowing government scientists to consult encourages new developments in the field, and, in fact, I believe that Drs. Liotta and Petricoin's work has really led to the blossoming of a new industry. And I think that was—that is to be encouraged in many ways.

Mr. BILIRAKIS. Are you optimistic hearing Dr. Zerhouni's 10 steps as he explained them to us? Are you optimistic that those would work?

Mr. HELLER. I am. I think the transparency is the main issue within NIH.

Mr. BILIRAKIS. Yes. Do you agree, Mr. Levine?

Mr. LEVINE. I would like to make one more comment on Dr. Heller's comment, which I agree with generally. But the last part of your comment, Dr. Heller, that consulting is a way to somehow spread the—you know, get the technology out, I really reject that idea completely. The Congress has set up very, very clear mechanisms for the technologies that are developed by government to be transferred to the private sector, through a CRADA, through licensing agreements, and, of course, both of those are mechanisms that Correlogic has availed itself of.

And, third, through the peer review and the publications and the public speaking that government scientists do. So the idea somehow that private consulting by a government scientist, where those funds go into the pocket of the scientist, and the information goes directly to the private sector company, I think that is just not—that is not a methodology for technologic transfer. There are three very, very good methods for technology transfer, and that is not one of them.

Mr. BILIRAKIS. Well, Dr. Heller, a response to that? I mean, that is a little bit of a hornet's nest there. Go ahead.

Mr. HELLER. I mean, I guess, again, I am not an expert in this, but I guess I would disagree. I believe that consulting is a valid way to get information that government scientists have out to industry. And I guess I feel also that there are a huge number of applications for these kinds of technologies.

Although in some senses Correlogic and Predicant may be competitors, in other senses there are hundreds of applications that we might want to go after. You know, specifically, from the literature I know ovarian cancer is at the top of Correlogic's list of diseases that it is trying to address. That is not on our list. And so I see

no fundamental conflict. I feel like government employees can look at the——

Mr. BILIRAKIS. So do you think that consulting is a pretty significant part of adequate research?

Mr. HELLER. I believe it is a way for government scientists to make their expertise available to biotech.

Mr. BILIRAKIS. Well, it is kind of a fundamental point I guess. All right. Thank you very much, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman.

The Chair recognizes the chairman of the full committee, Mr. Barton.

Chairman BARTON. Thank you, and I appreciate this panel still being here. I had to go do something else, and I am glad they are still here.

Dr. Heller, let me ask you a hypothetical. Let us assume that I move to Colorado, and I move to Congresswoman DeGette's district. And I know she is a crackerjack campaigner, and I find out who her consultant is that is helping her on her campaign, and I decide to run for Congress against her.

And I go to her consultant, and I say, "Now, I am going to pay you a lot more, and I want you to continue to work with Congresswoman DeGette, but don't tell her that you are working for me. Just every now and then I am going to have a board meeting, and I want you to come give me information about the campaign." Would you consider that ethical or not?

Mr. HELLER. I would not consider that ethical, but I do not believe that that is the case in front of us today.

Chairman BARTON. All right. Now, you said you don't consider that to be ethical. Now, my understanding is that the former head of NCI, Dr. Klausner, at one time was a member of the board of your predecessor company, and maybe still is a member of the board of your—the company as it is currently configured. Is that correct?

Mr. HELLER. He is.

Chairman BARTON. Okay. Now, Mr. Levine, sitting right next to you, several years ago according to his testimony had this idea, and he sketched it out on a napkin at a restaurant, about the way to find a predictive test for ovarian cancer. And he got some folks at NIH to collaborate with him and checking it out, and, lo and behold, it appeared to have viability.

And so they created what was called a CRADA, and he had several of the NIH researchers working with him on it, I think a Dr. Liotta and a Dr. Petricoin. And things were moving along swimmingly, and then, lo and behold, unbeknownst to him, they got retained to work for your company. And my guess is that Dr. Klausner recommended them.

I don't know that, but since he was the head of NCI and he had access to this information, it would—it is speculation on my part, but it would seem to be logical that if he knew what was going on that he could have pointed these individuals out to your company. Is that how it happened, or did you all just pull names out of a hat and it happened to be these two scientists that were working on the CRADA with Mr. Levine's company?

Mr. HELLER. Let me explain a number of things. First of all, I want to address the point that the agreements between Biospect, now Predicant, and Drs. Liotta and Petricoin, were at no time secret. We never kept that from public information. We divulged that to people we were working with. It is not my—

Chairman BARTON. So Mr. Levine next to you is just an idiot and didn't know?

Mr. HELLER. We never talked to Correlogic or any employees there.

Chairman BARTON. You honestly think that it is fair game to hire people that are working for a company that, if not doing exact research, something in a similar vein. In fact, apparently they are the ones—this gentleman to your right is the gentleman who had the idea, and it is okay to go in and retain them and just assume that it is Mr. Levine's job to know that they were retained and hire a private investigator to go out and search them out?

Mr. HELLER. So let me address, again, a couple of issues here. One, although Mr. Levine and his—the people he works with did talk to Drs. Petricoin and Liotta, I would call it farfetched to—with all due respect, to say that they invented pattern recognition as it comes—you know, with respect to biological data. This is something that was going on in very closely related fields.

The second thing I would like to say—

Chairman BARTON. I assume that you read his testimony about the dinner conversation that he had and sketching the idea on the napkin. You dispute that? That didn't—

Mr. HELLER. No, I completely believe that it occurred. But there were very closely related fields where people were doing very similar pattern recognition.

Chairman BARTON. Okay.

Mr. HELLER. Not in proteomics but in gene expression analysis, a very closely related field.

Second of all, I don't think that it is fair to say that we were doing exactly the same thing, or we are doing exactly the same thing as Correlogic. Mr. Levine pointed out that we are approaching the same problem from different ways, and I think there is a fundamental difference.

Chairman BARTON. Nothing wrong with that. We are not disputing that there is—

Mr. HELLER. No, but let me explain. I think we are trying to develop a complete technology solution. We are not just trying to buy parts off the shelf and fit them together, and I think that because of that we are—we think of ourselves as a very integrated company.

Chairman BARTON. Well, but—

Mr. HELLER. We do not think of ourselves as only producing software. And to our knowledge, that was Correlogic's only—

Chairman BARTON. Well, let me—Mr. Levine, do you consider yourself the software company only?

Mr. LEVINE. No, I don't, sir. And the analogy there really I think falls flat. I mean, there is virtually no company, at least in the technology world, that manufactures or produces or designs every single component of a complicated piece of equipment. I mean, if you look at a Dell computer, you will find the hard drives are made

by one company in Taiwan, and the motherboards are made by somebody else in Texas.

Chairman BARTON. Well, we will give Dr. Heller the benefit of the doubt that his company is looking at this area in a little bit different way, and maybe a little more comprehensive way.

Mr. LEVINE. Right.

Chairman BARTON. I won't dispute that. But I want to go back to how these two scientists at NIH that were under the CRADA agreement with Mr. Levine got picked to work for your company. Did Dr. Klausner have anything to do with identifying them as prospective candidates to work for your company?

Mr. HELLER. They were invited to be consultants for our company by our Acting CEO, Jim Tannenbaum.

Chairman BARTON. And how did he find out about it?

Mr. HELLER. He did work with Dr. Klausner. Dr. Klausner—

Chairman BARTON. So Dr. Klausner indicated to your Acting CEO that these were two individuals that were doing research on a similar idea and they might be worth talking to.

Mr. HELLER. I believe that would be the case, but let me also point out that there are a very limited number of people in the world who are doing this kind of research. You know, we are talking 20.

Chairman BARTON. When these two scientists were contacted by your company, was it a legal requirement that they notify Mr. Levine's company? Or was it just their own code of honor that they should indicate that they have been contacted?

Mr. HELLER. We had very carefully worded agreements. NIH participated in editing those agreements. All of the agreements that we have in place were NIH and FDA cleared. I do not know what NIH and FDA rules are with regard to disclosure. We specifically asked the consultants what other agreements they had, and we were informed—

Chairman BARTON. While they were in the CRADA with Mr. Levine's company, they were retained by your company. Were they compensated by both companies at the same time?

Mr. HELLER. I do not know whether—

Chairman BARTON. Were they compensated by your company?

Mr. HELLER. They were compensated by my company.

Chairman BARTON. All right. Mr. Levine, were they compensated by your company?

Mr. LEVINE. No, that is absolutely prohibited. The CRADA—we made a contribution in terms of our—

Chairman BARTON. So we have a situation with the government-sponsored research, the CRADA. The taxpayer is paying for their time. But with Dr. Heller's company, the investors are paying for their time, and so they have a potential conflict there that they are actually serving two masters, one of which is the public and one of which is private.

Now, I don't know what the compensation package was with Dr. Heller's company. I will assume it was on the up and up. But if it had incentives in it, the incentives would certainly be for them to give their best shot to Dr. Heller's company, because they get more money that way.

Mr. LEVINE. There were no incentives in it. It was strictly a fee per month.

Chairman BARTON. Okay. Now, I want to read you a statement, Dr. Heller, and you tell me what you think about this. This is from Mr. Levine's testimony. This is on page 10, and I quote, "So while our negotiations over finalizing our clinical trial CRADA were slowly going nowhere, Dr. Liotta and Dr. Petricoin had become consultants to our competitor, Biospect, and Dr. Shtrom had become an employee. During our endless discussions with Dr. Liotta and Dr. Petricoin about Correlogic's research and plans for clinical trials, I now realize I would have had no way of knowing, for example, whether I had been talking to Dr. Liotta, the NCI employee, or Dr. Liotta, the Biospect consultant, or Dr. Liotta, an owner of Immunomatrix, or Dr. Liotta, the employer or former employer of Dr. Whitley. And these are just the relationships that I know about."

Do you have any sympathy for Mr. Levine's plight there that, you know, he didn't know which hat his CRADA coordinator was wearing at the time?

Mr. HELLER. Let me address the fact that Svetlana Shtrom did and continues to work for Predicant. The first time I was aware that she actually was involved in establishing this CRADA was about 2 weeks ago. So we have internally had very high ethical standards. We have not discussed Correlogic or the CRADA internally at all, and I think that that is an important issue.

Chairman BARTON. Well, my time is about out, so I want to conclude with just an observation. In the political arena, if I am campaigning against Mr. Greenwood or Ms. DeGette, you know, I kind of know what the rules are. You know, everything is going to be in the public, and any funds that are raised have to be reported, and groups that support us have to report the contributions, and, you know, we fire salvos back and forth. But we kind of know what the rules are.

But what you are having us believe, that in this research situation funded by NIH, that it was okay for you to go in and retain or somehow develop some sort of a contractual relationship with the people that were helping your competitor, and you didn't have to tell anybody about it. And it was okay as long as you got some scientific agreement that got approved and got filed where nobody could read about it, and I think that is just flat wrong.

I think if the taxpayers are going to enter into a cooperative agreement, a CRADA, with any company, that anybody who represents the government, if they want to have a relationship with somebody else in the same line, that has to be transparently reported upfront, proactively, not, you know, if you smoke them out and he hires a private investigator, or just happens to find out through the grapevine, and, you know, I respect your academic background, and I respect the research that your company is doing, but I absolutely have no respect for the way you have gone in and retained the services of some of the individuals that at least ostensibly on paper were supposed to be working with Mr. Levine's company.

I just think that is irresponsible. And if we need to pass legislation to prevent it, or if we can reinforce what Dr. Zerhouni has said

in doing it administratively, I am going to encourage this committee to do that.

Mr. HELLER. May I comment on that?

Chairman BARTON. Certainly.

Mr. HELLER. I agree with your conclusion that better transparency is a good thing, and I believe that Dr. Zerhouni's recommendations will address that. I completely agree with you.

I just want to point out, we did follow all of the NIH and all of the FDA guidelines. The FDA knew, the NIH knew, exactly what we were doing. We at no time tried to keep their relationship secret in any way, and, in fact, that is probably how Peter Levine found out about this. We weren't trying to hide this in any way. I feel like that is a false accusation.

And so I agree that better transparency would be a very good thing. We feel like we followed the law, and if the laws need to change, which I believe that you are suggesting they do—and Dr. Zerhouni is suggesting they do—I believe that is a good thing as well.

Chairman BARTON. Mr. Chairman, I would ask unanimous consent for 2 minutes, just to—

Mr. GREENWOOD. Without objection.

Chairman BARTON. Mr. Levine, I don't want to comment on what Dr. Heller just said, I want to give you a chance to comment on what he just said. Do you think that there was full disclosure of the relationship between Drs. Petricoin and Liotta and Biospect/Predicant and your company that you could have known without—

Mr. LEVINE. There certainly was not, although I will say I am sympathetic, actually, to Dr. Heller's comment. The responsibility is not on Biospect to be, you know, contacting Correlogic. The responsibility was on the part of Drs. Liotta and Petricoin and NCI and FDA to make sure the situation couldn't arise. So we were not informed at all.

In fact, there were numerous occasions where the opportunity to inform us was very apparent—for example, when I sent them an e-mail with the Biospect information in May 2003. So, again, I think the issue here really is it is the role of the Public Health Service scientists, it is the role of the ethics officers within those agencies—and, again, just to stress a point, it is not just the CRADA relationship. It is the interrelationship between research that we did with NCI and FDA under the CRADA and the overarching license agreement that we have with the Public Health Service.

And just one other comment. Dr. Heller mentioned in answer to your description of my brunch discussion with Dr. Petricoin many years ago, whether or not the issue of pattern recognition has been used in other fields, of course it has been.

But the central issue here, though, is that the FDA and the NCI and the Public Health Service and Correlogic have all filed patents on these various inventions. And, of course, the central part of the licensing agreement with Correlogic was to develop a turnkey system, and that is exactly the same business goal that Biospect has.

And, again, I have no problem with what Biospect is doing. I mean, they—you know, if you can get some expertise, go ahead and do it. The problem lies with the agencies.

Chairman BARTON. So you think that if it is not Biospect's obligation, then the scientists in question should either recuse themselves, ask to be released from their obligation to your company, or, at a minimum, report it in an open and transparent fashion.

Mr. LEVINE. That is absolutely correct. In fact, I think the issue of transparency, which several individuals today have already commented on, I think that is really, really key. And, again, because I think it is not—it doesn't take a group of lawyers to figure this out.

It is really just—it is sort of a—you know, it is sort of a common sense look at the website of both Biospect at the time, and at the time from my perspective that is May 2003, perhaps earlier. And what Correlogic was doing, it didn't take an ethics officer or a scientist or a lawyer to figure out that these two companies had exactly the same goals and were working on very, very similar technologies.

Chairman BARTON. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair asks unanimous consent to—the Chair yields himself 5 minutes, and then will just be brief and then yield to Mr. Bilirakis.

Let me just understand something about your testimony, Dr. Heller. There are a couple ways to look at this issue. One is that not to worry because what you are doing is so different than from what Mr. Levine's company is doing that even if Liotta and Petricoin told you everything there was to know about what they were doing, it wouldn't have helped you anyway, because you are doing different things.

The other way to do it is to say, actually, that they didn't you anything anyway, and so there was—confidentiality was kept. I mean, which is it here? I mean, do you want us to believe that if you knew everything that Dr. Levine was doing it wouldn't help you to develop your product?

Mr. HELLER. I actually think that it is sort of both of what you are saying. We knew nothing from—other than what was in the public literature about what Correlogic was doing. It was never shared by Drs. Liotta or Petricoin or anyone else with us.

At the same time, we know specifically from the literature that they are working on these very specific software algorithms that are not the focus of what we are working on. We are working on completely different pattern recognitions and—

Mr. GREENWOOD. So if Dr. Levine wrote everything that he was doing with his product in a notebook, and you happened to stumble upon it, you wouldn't even be interested in looking through it? You wouldn't learn anything from reading what Dr. Levine is up to?

Mr. HELLER. I think we would gain some information about what he was doing. I don't know that it would be incredibly helpful to our company in any way.

Mr. GREENWOOD. Okay. Do you concur with that, Dr. Levine?

Mr. LEVINE. No, I don't. And thank you for the doctor, but it is only—

Mr. GREENWOOD. Right, Mr. Levine.

Mr. LEVINE. Unless a J.D., you know, confers doctor status on me.

The problem I have, Dr. Heller, with what you just said is that—and, you know, in general with this issue—is that when someone learns something, whether it is a scientist or just, you know, a citizen, when you learn something, you know, a month or 2 after you learn it, are you going to remember where you learned it? So whether or not—I mean, you are not in a position, and Biospect wasn't in the position, to know whether or not—

Mr. GREENWOOD. You need to address your questions to the committee.

Mr. LEVINE. I am sorry—

Mr. GREENWOOD. That is okay.

Mr. LEVINE. —Mr. Chairman. The problem is that when we would say something to a scientist at NIH, if a month later they are digesting that and then it comes back out in a conversation with somebody else, are they going to remember that they learned that or that particular piece of information, maybe not an earth-shattering, you know, not a patent pending kind of information, but the direction that the company was going in or some particular manipulation of data.

So the issue really is: how do you filter out, and how do you know that what is in your own mind, and you then provide that advice to somebody else, is really coming from your own understanding, or is it coming from something that you learned a week earlier? So that is one concern.

The second issue is that Dr. Heller mentioned, well, they are using different algorithms. But, again, what we have published, you know, publicly is one thing. But, of course, the fact that the work is ongoing with other bioinformatics—and, again, the central issue, as I mentioned earlier, is that we were developing and working on processes that began with the collection of blood and how it was handled, stored, prepared, through what kind of robotic machines would handle it, to mass spectrometry, all the way through to the end result. So it wasn't just the software issue.

Mr. GREENWOOD. Which is why the standard in ethics is not conflict of interest. It is the appearance of conflict of interest. And by casting that kind of a net, we avoid all of this—all of these nuances.

The Chair yields to the gentleman from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. All of this hitchhiking on all of these conversations, Mr. Chairman—well, Dr. Heller, I raised the question about the significance of consulting to the field of research. And you and Mr. Levine completely disagreed in terms of the significance of it and the need for it. I guess maybe that is the best way to put it is the need for it.

Now, you said there is a need for it. Can you take a couple of minutes and tell me how? I mean, do you want to pick an illustration and tell us how that illustration supports your point of view? I think it is really, as the chairman just said, a fundamental policy question. And as long as—you know, maybe bad things have not taken place. But God knows it certainly contributes to the perception of an awful lot of bad things having taken place.

So can you do that for us in a couple of minutes?

Mr. HELLER. Sure. Again——

Mr. BILIRAKIS. And I thank the chairman for the time.

Go ahead, sir.

Mr. HELLER. Again, this is not an area of my experience, but let me follow on a theme that Dr. Zerhouni mentioned in his testimony. He said, “Well, what happens if there is an NIH scientist who is studying West Nile Virus with technology that is obviously applicable to some other disease?” And I think that is a great example of what can happen.

You know, in this case, the technology is not just limited to diagnosis of ovarian cancer and the diseases that Drs. Petricoin and Liotta and Correlogic are working on. There are a huge number of diseases out there, and to gain the expertise from people who have developed it for one particular application in other applications would be of great value to the scientific industry.

Mr. BILIRAKIS. But isn't there, Mr.—am I pronouncing your name correctly when I say Levine?

Mr. LEVINE. No, Laveen is the name.

Mr. BILIRAKIS. Laveen. Dr. Heller has been using Laveen all along.

But anyhow, Mr. Levine, aren't there other ways that this important significant information, these breakthroughs and what not, are available out there for the general public and for these other industries and what not?

Mr. LEVINE. Yes.

Mr. BILIRAKIS. Other than through the consulting method?

Mr. LEVINE. Yes, absolutely. There are three methods. There is the CRADA method, which Correlogic is involved in, which, again, that is very public and it goes through a review process within the government. There is a licensing procedure where if Public Health Service scientists invent a technology which has the potential to be commercialized, it is posted in the Federal Register, and private sector companies can compete for that technology.

And third, of course, is that most government scientists are obsessed with putting out peer reviewed publications, which are then available to anyone who buys the magazine or attends a conference. So I think there are very clear methodologies which are transparent, which are fair to the public at large. And if there is any, you know, income that comes back from those activities, and particularly the licensing—whether it is direct licensing or licensing under the CRADA—those funds come back into the Federal treasury, back to the taxpayer, not into the pockets of the individual scientist.

Mr. HELLER. May I comment on that?

Mr. BILIRAKIS. Yes, Dr. Heller.

Mr. HELLER. I agree. I think that the three methods that Mr. Levine——

Mr. BILIRAKIS. But you don't think they are adequate?

Mr. HELLER. I think it doesn't account for one thing. The scientists at the NIH and the FDA are very busy people. I couldn't guess how many e-mails that they get per day. How does a company like us, like Predicant, attract the attention? How do we get their time, and how do we get their information?

The public meetings are one forum for doing that, but, you know, in general people come to these meetings for a very short period of time. They fly out. It is hard to attract people's attention. I think by being able to get focused—the focused attention through a consulting agreement, I think that is the best way. But I agree that it should be transparent.

Mr. BILIRAKIS. Yes. So you feel the only way you can get the attention is by paying them, giving them stock options.

Mr. HELLER. I mean, I think there are multiple ways but different people respond in different ways. And we—I don't think that stock options are necessarily the right thing, and we specifically did not give any stock in this case.

Mr. BILIRAKIS. Well, sir, I don't know what took place here. I don't think this committee is saying that you all did anything wrong or anything of that nature, because we don't know. I mean, that is not our job here. But I do think that the perception—and I am sure you don't blame Mr. Levin—Laveen, Levine, Levin—

I am sure you don't blame Mr. Levine for thinking that, because, boy, what a perception there is there.

Mr. HELLER. No, I do not. Absolutely not.

Mr. BILIRAKIS. So that is why we—

Mr. HELLER. But I believe the transparency would solve the issue. I think if he was made aware initially that the consulting agreement was being put in place, I think that would take care of this issue.

Mr. BILIRAKIS. Well, thanks, Mr. Chairman.

Mr. GREENWOOD. The gentlelady Ms. DeGette wants to comment.

Ms. DEGETTE. Thank you, Mr. Chairman.

I just wanted to comment. I joined in the chairman's questioning, so I didn't ask this round. But listening to the two of you gentlemen speak today, first of all I really want to thank you for coming, both of you. I know it was an imposition, and it was incredibly illuminating, some of the most illuminating testimony we have had during these series of three hearings.

What it showed to me is, first of all, the concerns that private industry has in trying to get folks' attention over at HHS, and also to try to get some of the research, which is what leads, in our view, to some of these conflicts of interest that we are seeing and which really need to be ended.

And the second thing—and really related—is the completely different motives in needing this information and research that private industry has from HHS and from the government agencies themselves. So, therefore, it is really clear to me we cannot and should not expect private industry to conduct the kind of policing operations that ethics counsel and others should be conducting.

And the final lesson that your testimony taught me is it is—and I have been saying this all along like—I have just been harping on it, which is it is very difficult, and it is a huge challenge for the HHS ethics team and for Dr. Zerhouni to put together some ethics guidelines that will actually prevent these kinds of conflicts from happening. So all I would say is I think this has been very illuminating. I thank you for your help and hope you will continue to work with us as we do this.

And to the HHS folks, good luck. I think it is really going to be hard to put ethics guidelines in place that are going to prevent these kinds of conflicts.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentlelady and thanks our witnesses.

Dr. Heller, you are excused. Mr. Levine, we are going to ask you to take a seat but remain with the speakers. We may want to come back to you as we question the third and final panel.

And I now call them forward. Dr. Anna D. Barker, Ph.D., Deputy Director, Advanced Technologies and Strategic Partnerships at the National Cancer Institute; Dr. Maureen O. Wilson, Ph.D., Assistant Director of the National Cancer Institute; and Dr. J. Carl Barrett, Ph.D., Director, Center for Cancer Research at the National Cancer Institute.

Good afternoon. We welcome all of you here. As you probably know, it is the custom of this committee to take questions under oath. The first question I have for you is: do any of you object to giving your testimony under oath? Seeing no such objections, I would then advise you that you are entitled to be represented by counsel. Do any of you wish to be represented by counsel?

Ms. BARKER. No.

Mr. GREENWOOD. Okay. In that case, I would ask you to stand and raise your right hands, please.

[Witnesses sworn.]

Okay. You are all under oath.

TESTIMONY OF ANNA D. BARKER, DEPUTY DIRECTOR, ADVANCED TECHNOLOGIES AND STRATEGIC PARTNERSHIPS; MAUREEN O. WILSON, ASSISTANT DIRECTOR; AND J. CARL BARRETT, DIRECTOR, CENTER FOR CANCER RESEARCH, NATIONAL CANCER INSTITUTE

Mr. GREENWOOD. And, Dr. Barker, do you have any opening statement or any comments you wish to make preliminary to questioning?

Ms. BARKER. We do not have an opening statement. We are here to answer your questions.

Mr. GREENWOOD. That is true of you, Dr. Wilson, and you, Dr. Barrett?

Mr. BARRETT. That's correct.

Okay. In that case, we will—okay. Let me address you first, Dr. Wilson, and ask you this. And I am going to ask the staff to pull up the slide for Dr. Wilson's questioning.

While they are doing that, I will describe it. It is an e-mail dialog between you—there it is. You may have to turn around in order to see that. It is an e-mail dialog between you, Dr. Wilson, and Dr. Liotta and Holli Beckerman Jaffe. Ms. Beckerman Jaffe writes, "Please also confirm with him that while he has not received any payment since February"—in other words, he was last paid in February—"he has not consulted with Biospect since February. The arrangement has been put on hold until he receives approval on from Dr. Kington. I know I am beating a dead horse, but I want to be very clear on the facts."

Dr. Liotta then responds, "I confirm this on hold."

Do you understand his response to mean that Ms. Beckerman Jaffe asked that he had not received any payment since February and had not consulted with Biospect since February? Was that your understanding?

Ms. WILSON. That was my understanding.

Mr. GREENWOOD. Okay. And why would it have been a problem if he had been consulting for the company beyond February?

Ms. WILSON. At the time of the new NEAC rules, all activities with Biotech, as well as others that were covered by the NEAC responsibilities were to be resubmitted for approval, and all new activities that were covered under their jurisdiction also were supposed to be submitted for approval. And our regs say you cannot proceed with an activity without obtaining prior approval.

Mr. GREENWOOD. And let me ask you this. Do you believe it was consistent with that policy to be able to receive compensation, either if there was no further activity?

Ms. WILSON. It would probably depend on the subject of the agreement. Payment for prior services would be, in my mind, acceptable. But, again, that would be subject to the agreement.

Mr. GREENWOOD. But if there was a monthly payment to be made, would you—is it your understanding of the policy that the employees should not receive payments for ongoing services?

Ms. WILSON. The intent was to cease accepting payment until review had gone forward.

Mr. GREENWOOD. Okay. I am going to ask the staff to play clip 6, in which we will hear Dr.—go ahead.

[Tape played.]

Those voices were Dr. Petricoin first and then Dr. Liotta. Was that clear to you—

Ms. WILSON. Yes.

Mr. GREENWOOD. [continuing] which was speaking when? Okay.

Based on his testimony, do you understand Dr. Liotta to be confirming what he stated in this e-mail, that he stopped working for Biospect in February?

Ms. WILSON. He indicated that it was on hold. He said he had one e-mail conversation with them. I do not know what the subject of the e-mail is, so I wouldn't know whether to call it employment or not.

Mr. GREENWOOD. What do you interpret "on hold" to mean?

Ms. WILSON. "On hold" would be—

Mr. GREENWOOD. I am going to ask you to speak a little bit more directly into your microphone. Thank you.

Ms. WILSON. "On hold" would be performance of no services.

Mr. GREENWOOD. Performance of no services. And, again, receipt of no payments for—

Ms. WILSON. Yes.

Mr. GREENWOOD. [continuing] services. Okay.

I am going to ask the staff to show the slides. This is a series of canceled checks indicating that Dr. Liotta was continuing to be compensated for his work through May. Dr. Wilson, doesn't that conflict with what he told you and Ms. Beckerman Jaffe in the e-mail?

Ms. WILSON. Yes, it does.

Mr. GREENWOOD. Okay. Doesn't this suggest that he did not terminate his agreement with the company as he was required to do by new NIH policies at the time?

Ms. WILSON. The requirement was that the activities be put on hold until they could be rereviewed, not necessarily that they be terminated. The NEAC was to determine whether they would be terminated or not.

Mr. GREENWOOD. Okay. Didn't terminate his agreement. Certainly did not—it certainly indicates that he did not terminate his agreement. But what you're saying was the termination of an agreement per se was not the policy, it was to suspend services and payment—

Ms. WILSON. Yes.

Mr. GREENWOOD. [continuing] during that time. And why did you ask him in that e-mail—or why did the Ethics Directors, excuse me, ask that—he inquired as to whether he had received any payments and wanted to confirm that he had not received any payments since February?

Ms. WILSON. To assure that, in fact, he was abiding by what NIH had put in place.

Mr. GREENWOOD. Okay. The former director of NCI, Richard Klausner, is a member of Biospect's Board of Directors. Dr. Carol Dahl, former Chief of the Office of Technology and Industrial Relations at NCI, was Vice President of Strategic Partnerships. Svetlana Shtrom, who was the Technology Transfer Officer from NCI with whom Correlogic had to negotiate its CRADA was hired by Biospect. And the two co-principal investigators on the CRADA—Drs. Liotta and Petricoin—were hired by Biospect.

And if you will look at Tabs 27 and 37 in the binder before you there, you will see information from the websites of Correlogic and Biospect. Do you see them? Tab 27, and then 37. I want you to compare them.

To me, they look remarkably similar. For example, Correlogic's site states, "Correlogic's mission is to advance the early identification of various cancers and other diseases and to accelerate the new drug discovery process by applying its proprietary software to the development of proteomic and other biomarkers."

Turning, then, to Biospect's website, it states, "Biospect is an emerging life science company founded in 2002 that is developing technology for identifying and assaying protein biomarker patterns."

Given the fact that all of these parties have a relationship with a company that bears a near-same statement of aims to its own, and is clearly a competitor, isn't it reasonable for Correlogic to be concerned that something is amiss?

Ms. WILSON. It is reasonable, yes.

Mr. GREENWOOD. Okay. Let me turn to Dr. Barrett. As you know, Dr. Richard Klausner, the former Director of the NCI, is on the Board of Directors of Biospect. Do you know Dr. Klausner? You need to turn your microphone on and make sure it is up close.

Mr. BARRETT. I do know him, yes.

Mr. GREENWOOD. Okay. And did you advocate having Dr. Klausner designated as special volunteer in your lab at NCI?

Mr. BARRETT. Yes.

Mr. GREENWOOD. Okay. If you would turn to Tab 16, you will see documentation that you submitted in September 2001 to get Dr. Klausner the special volunteer designation. Do you see that?

Mr. BARRETT. Excuse me. That was 16?

Mr. GREENWOOD. Tab 16, yes.

Mr. BARRETT. Yes, I see that.

Mr. GREENWOOD. Okay. Can I assume that you have had a professional relationship with Dr. Klausner that prompted you to do this?

Mr. BARRETT. Yes. Dr. Klausner had resigned as the Director of the National Cancer Institute to take a position, and as other outside people was allowed to be a special volunteer at the NIH. And so he was doing—continuing to do research at the NIH. He had one post-doctoral fellow who was continuing to do this research, and this agreement allowed him to continue to be a special volunteer, not paid, but actually continue that research.

Mr. GREENWOOD. And did he get that designation?

Mr. BARRETT. Yes, he did.

Mr. GREENWOOD. And does he still have the designation?

Mr. BARRETT. No, he does not.

Mr. GREENWOOD. Okay. When did it end?

Mr. BARRETT. I do not know. It was not renewed, so it certainly expired after 1 year. But I don't know if—

Mr. GREENWOOD. Are you still in communication with Dr. Klausner?

Mr. BARRETT. I have not been in communication with him since probably June 2002 would be my recollection.

Mr. GREENWOOD. Were you doing Dr. Klausner a favor when you supported him in his request to be a volunteer?

Mr. BARRETT. I think Dr. Klausner is a noted scientist, a member of the National Academy of Sciences, and was doing research that had begun when he was at the NIH. And this appointment allowed him to complete that research, which I think was in the benefit of the NCI and the NIH.

Mr. GREENWOOD. Okay. My time has expired. It appears that there is a series of votes. I am going to recognize the gentlelady from Colorado for 10 minutes, and at the end of her questioning we will recess for probably—

Ms. DEGETTE. Ten minutes or 5 minutes?

Mr. GREENWOOD. Five minutes. I am sorry.

Ms. DEGETTE. Okay.

Mr. GREENWOOD. And then we will recess for—

Ms. DEGETTE. Thank you very much, Mr. Chairman.

Mr. GREENWOOD. [continuing] 45 minutes.

Ms. DEGETTE. Dr. Barrett, I wanted to talk a little bit about some confusion from the May 18 hearing. Our written transcripts reflect that what you said is, when you were reviewing Dr. Liotta's request to consult for Biospect, you were unaware of the plethora of former NCI employees working at Biospect. Is that correct?

Mr. BARRETT. That is correct.

Ms. DEGETTE. But during the hearing, Dr. Liotta said, "When I reviewed this with my ethics officer and discussed the outside activity, it was clearly known and factored into the review that par-

ticularly the review, that former Cancer Institute employees were members of that company.”

Were you, as you testified, unaware of all of the former NCI employees or officials working at Biospect?

Mr. BARRETT. I was told that there was some relationship with Dr. Klausner. It is still not clear to me exactly what that relationship was, if he was a member—

Ms. DEGETTE. When were you told that?

Mr. BARRETT. I was told that—I guess I was told that when it was—back in August when we were rereviewing this. But that was—

Ms. DEGETTE. Okay. So when you say on May 18 that you were unaware of former NCI employees, that was incorrect?

Mr. BARRETT. No, I said I didn’t—there was a long list of individuals, and the only ones I knew about were Dr. Klausner and Dr. Dahl.

Ms. DEGETTE. Okay. But your testimony on the 18th—I am sorry I am not tracking. Your testimony on the 18th was, “I was unaware of the NCI former employees being members.” So where is the—what is the discrepancy there?

Mr. BARRETT. Maybe I didn’t appreciate the question. My understanding was there was some relationship with Dr. Klausner, but that was not clear to me. And I also knew that Dr. Dahl was a member of that company, but I was unaware of the other individual.

Ms. DEGETTE. Okay. But that is not what our record reflects that you said on the 18th. You didn’t specify that you knew about several, Dr. Klausner in particular, but not of others. So is what you are saying now correct?

Mr. BARRETT. What I am saying now is correct, yes.

Ms. DEGETTE. All right. Now, Dr. Barker, and also you, Dr. Barrett, after hearing Peter Levine testify earlier today about how Correlogic and Biospect are, in fact, competing companies, do you now question your decision to allow Dr. Liotta to be involved in a consulting relationship with Biospect at the same time he was involved in the CRADA with Correlogic?

Ms. BARKER. I said yes to that last time, and I would actually reaffirm that. I think if the information that one has today was available when this rereview was done, that it would not have been approved.

Ms. DEGETTE. Let me ask you what additional tools—and, Dr. Barrett, do you agree with that?

Mr. BARRETT. Yes, I do.

Ms. DEGETTE. What additional tools would you need to have to be able to make an informed decision? Because it is pretty clear to me you didn’t have all of the evidence at the time you were approving both of these relationships. Dr. Barker?

Ms. BARKER. Yes. When I was asked—actually, a colleague of Peter Levine’s asked that this be reviewed, raising just this issue in August 2003. And so when I did ask that question, I obviously asked the question of Dr. Wilson, the Ethics Officer, and she in turn asked Dr. Barrett to rereview those. And the system that was in place basically up until I believe the announcements today is

very, very much dependent on investigators actually giving you information about their consulting arrangements.

And I was new to NCI. I came in actually to look at some of these issues for Dr. von Eschenbach in the technology area, especially the development area. And having been in the biotechnology industry myself, I did understand some of the questions that were being asked, and so I think that—I think Dr. Wilson and Dr. Barrett reviewed it with all of the information that was available to them then.

Ms. DEGETTE. Well, I am not—yes, I am not disagreeing with that. What I am asking you is—and what you are saying is the previous system was dependent on the researchers themselves giving you information.

Ms. BARKER. Right.

Ms. DEGETTE. And probably if Mr. Levine had not contacted you all, you may have never known about this terrible conflict, right?

Ms. BARKER. Correct.

Ms. DEGETTE. So what is it about the reforms being announced today that you think will stop these kinds of conflicts in the future?

Ms. BARKER. Well, one of the things that we are doing at the NCI is to create a data base much like the one for—that Dr. Zerhouni announced today. We have been working on that.

And I think the issue here with CRADAs is complex, and we can—you know, you may have more questions about that. But I think we need to understand clearly the consulting arrangements of individuals that are going to enter into CRADAs, and they have to be—I think it has to—the understanding has to be pretty complete, and we really have not had the tools to do that in my opinion.

Ms. DEGETTE. Now, how would that—let me ask this question and then I will yield to the chairman. How would that system prevent this kind of conflict from happening?

Ms. BARKER. I should probably let Dr. Wilson answer that question, since she would review that request and act on it. But I am assuming that she would have a great deal more specific information that—

Ms. DEGETTE. Yes. Let us let Dr. Wilson answer.

Ms. WILSON. The one piece that is probably lacking in our system right now has been a complete recognition of all of the CRADA technology-type transfer arrangements.

Ms. DEGETTE. If you can speak more closely to the mike.

Ms. WILSON. Sorry. What is missing in our system has been a direct connection with the technology—all of the technology transfer agreements and with a full knowledge of these pieces. We do, in our office, look actually at CRADAs, one form of technology transfer. So in approving the outside activity, we would have looked at the Correllogic CRADA. We would have known about that. But we would not have known of any additional—

Ms. DEGETTE. And would you know about that now?

Ms. WILSON. We are putting in place a system that will actually let us in real time get that information.

Ms. DEGETTE. I will yield to the chairman.

Chairman BARTON. Well, I am going to have my own time when we come back. But it just—I want to ask Dr. Barker what informa-

tion you have today that you didn't have back on August 20 when you ruled that Dr. Liotta's duties were appropriate? What do you know today you didn't know then?

Ms. BARKER. Well, I think the—as this process has unwound, actually, we have learned a great deal more about the Correlogic's competitor, Biospect, that was actually capsuled here today. And I think just the simplicity of looking at the change in the website, which has changed over time—when Dr. Wilson reviewed this request, even back in August of last year, or the fall of last year, the website was still quite different from the website that we are viewing now. And so—

Chairman BARTON. Well, how was it different?

Ms. BARKER. It basically did speak to the fact that the focus of the company at that time was really around instrumentation, and some of the issues that Dr. Liotta has reflected in his request. I think only in the—in very recent months has the website reflected this issue of pattern recognition being a major focus of the company. It was news to—I think it was news to Dr. Wilson and the—

Chairman BARTON. Is Congresswoman DeGette coming back? Because I don't want to take all of her time if she is—I mean, I want to—

Mr. GREENWOOD. Help yourself, Mr. Chairman.

Chairman BARTON. Okay. Well, Mr. Levine is out there in the audience vigorously shaking his head that his website has changed. I don't know what the protocol is to—

Mr. GREENWOOD. Mr. Levine is still under oath and is—

Ms. BARKER. Not his website, the Biospect website.

Mr. GREENWOOD. Mr. Levine, would you like to come to the table, pull up a chair, and—

Chairman BARTON. And as soon as Congresswoman DeGette gets back, I will—

Mr. GREENWOOD. No, she has gone for the votes. She is not coming back—

Chairman BARTON. Okay.

Mr. GREENWOOD. [continuing] until after the votes.

Chairman BARTON. Have you heard—

Mr. GREENWOOD. And I would advise the chairman that we have 5 minutes and 39 seconds left on this vote.

Chairman BARTON. Mr. Levine, Dr. Barker had said that she didn't know now—she knows more now than she knew then when she approved this, and that one thing that has changed is Biospect's website. What is your response to that?

Mr. LEVINE. Well, I can't comment on what any of the NIH officials knew when. But certainly on May 22, 2003, the website was very clear, and we have all looked at that earlier. So nothing changed. In May 2003, the comparison and the similarity between what we were doing and what Biospect was doing was very clear at that time. So I am not sure what change the witnesses are referring to.

Chairman BARTON. Well, my—and, again, when I get back I will have my own time. But my comment to Dr. Barker and to Dr. Wilson and to Dr. Barrett, reading the August 20, 2003, memorandum from Dr. Wilson to Dr. Barker that Dr. Liotta's activities were ap—

propriate or acceptable or approved is based on the fact, it appears to me, that he didn't have a proprietary interest in the CRADA. And while he was being paid by Biospect, he didn't have an ownership interest, so as long as he was being paid in a consulting fashion it was okay.

Now, am I misreading that? But it doesn't really relate to the subject. I mean, it is just—it was kind of a technical ruling that, you know, Biospect was hiring him as a consultant, and so he could pretty well consult on whatever he wanted, and it was okay.

Ms. WILSON. It would not be true even before that he could consult on whatever he wanted. There were restrictions on what a Federal employee—

Chairman BARTON. That is not what the memo says.

Ms. WILSON. It is a technical analysis. Is the activity legal? Did it meet with regulations? And technically it did.

Chairman BARTON. Well, I am—we have to go vote, but we are—I assume we are going to retain these—this panel, so we can come back and get into this in more detail.

Mr. GREENWOOD. That is correct.

The committee will now recess until 3.

[Brief recess.]

Mr. GREENWOOD. The committee will come to order, and the Chair recognizes the chairman of the full committee for 10 minutes for inquiry.

Chairman BARTON. Thank you, Mr. Chairman, and I appreciate the panel staying.

I am trying to get a handle on what constitutes a conflict of interest at the time the individuals who were working on the CRADA were also asked to go to work on the Biospect company payroll as consultants. And I am looking at this August 20, 2003, memorandum, which is from Dr. Wilson to Dr. Barker, and the subject is Conflict of Interest Review, Lance Liotta, M.D.

It is Tab 7, if you all have that information.

On page 1 of the memo, it starts—it says—it has the sentence that, "Ethical conduct for employees of the executive branch requires that approval be granted," so it is a positive directive that approval be granted in response to a request for outside employment under the following conditions: that the request is submitted prior to the beginning, and unless it is determined that the outside employment involves conduct that is prohibited by statute or Federal regulation.

So if an individual wants to go to work outside the government, they have to submit it, require it to the beginning of the activity, and then if you—unless it is determined that the employment would involve conduct that is prohibited by statute, then you have to say yes.

On the next page it says that, "The nature of the consultative services requested"—this is Dr. Liotta's request to be a consultant for Biospect—"are limited in requests deemed to be advisory and unrelated to any HHS matters. These consultative services do not violate the regulation."

Now, my first question is: how was it determined that what Dr. Liotta was doing for Correlogic was unrelated to any HHS matter? Because he was doing the same thing, or at least similar work. So

who determined that it was unrelated? Did you just take Dr. Liotta's word at that?

Ms. BARKER. We did actually go through the established process. Maybe Dr. Wilson should let you sort of hear that review quickly, and then we can talk about the specifics of this case.

Ms. WILSON. In conducting the review, we look at the scope of Dr. Liotta's duties. We look at his personal financial interest, we look at his CRADAs, we look at the grant and contract activity insofar as we are able to determine it, all of the technology transfer activities insofar as we are able to identify them. And we also look at the science.

We look for the purposes of the science—as you know, science is changing on a daily basis. It is very complex now, and so our office does rely on experts who know the field much better than anyone in my office does to give us a review of whether what is proposed by the scientist is within the scope of the employee's duties or outside.

Chairman BARTON. But you know when he is asking this—I mean, he says, “I am part of a CRADA with Correlogic, and this is what Correlogic is trying to do. They are trying to find a predictive test for ovarian cancer based on some sort of an analysis of blood.” I mean, you know that, right?

Ms. WILSON. Yes.

Chairman BARTON. Now he wants to go to work for Biospect, and according to their web page they are doing the same thing. And yet in this memo it says it is—what he is requesting to do for Biospect is unrelated to any HHS matter. That just begs credulity that that would be a statement.

Ms. WILSON. This memo relates to the rereview. The original approval we did not have access to the website. Biospect's website in 2002 was not available to us. So we relied on the description of the company, on the description that was provided and the documents provided from the company as to what he was going to do.

We asked Dr. Barrett to assist us with the science of the matter. And given that it was limited by the provisions that were put into the contract, it was determined that those things were matters of general applicability.

Chairman BARTON. Well, now, so what you are telling me, if I interpret this colloquially, Babe Ruth was a great pitcher for the Boston Red Sox. He turned out to be a great hitter for the New York Yankees. And according to this ruling, he could continue to do both. He could play right field for the Yankees and hit home runs. And when he wasn't playing for the Yankees, he could go up to Boston and pitch for the Red Sox.

Ms. WILSON. By the same instance, would we have stopped him from coaching his children's little league—

Chairman BARTON. Well, I think if you would have told the owner of the Yankees that he still wanted to go pitch for the Red Sox, you know, both ownerships would have had a problem with that.

Ms. WILSON. I do not disagree with that.

Chairman BARTON. All right. Mr. Barrett, what is your take on this? Dr. Barrett?

Mr. BARRETT. Thank you. We reviewed this carefully, but I must—as we admitted last time I think, knowing what we know today, we would not have made the same decisions.

Chairman BARTON. But what do you know today that you didn't know then?

Mr. BARRETT. Let me explain that to you, Congressman. So at the time, what we knew was that the Biospect company was a new company that had a very general description of their activities. It was not clear that they were involved in the pattern recognition business. What was also known was that the CRADA with Correlogic, the Correlogic's contribution, was in terms of doing the computational analysis, the algorithm, to actually do the analysis of the patterns and the proteins.

So what we did to make sure, so it did not appear that there was any overlap, but we put very clear exclusionary language within the consulting agreement to try to make it very clear that if there was any overlap that that would be excluded, and that Biospect in fact knew that.

Clearly, it should have been the case that Correlogic—Mr. Levine—should have also been aware of this. We admitted that last time, and I think that certainly is one of the changes that needs to be—

Chairman BARTON. Well, Dr. Heller, when he was before us in the previous panel, basically said that you can't blame his company because they complied with all of the rules. And you are the people that are applying the rules, and you are saying you didn't know.

I mean, the Biospect website shows this capability will be targeted to improve the diagnosis and clinical patient health and enable new approaches to drug development. The Biospect system will be the foundation for the discovery and detection of patterns of proteins, protein fragments, that reflect and differentiate various states of health and disease.

And the Correlogic mission statement—and I am not going to read the whole thing—they want to create turnkey diagnostic systems that will revolutionize the disease, testing, and screening market. They will also provide pattern discovery solutions to biotech and pharmaceutical companies for the use in genomics, if I am saying that correctly, molecular biology, protein sequencing, and in new drug identification and toxicity evaluation.

Now, that is not word for word. But I am not a biological scientist, but it sure looks to me like they are doing the same thing.

Mr. BARRETT. Yes, sir. Based upon those two descriptors, I would agree fully with you. The—

Chairman BARTON. Well, they didn't look at that. I mean—

Mr. BARRETT. I don't know when that was available. If it was available and we did not look at it, that was certainly—

Chairman BARTON. I mean, isn't the truth is that—and this is speculation on my part—but it appears to me that prior to this subcommittee getting involved in this, after 1995 the environment at NIH was to either encourage these sort of arrangements or to give it only the most perfunctory and technical analysis. And this particular arrangement just took it a little bit too far.

But, I mean, I don't see that any effort was really made to check what was going on. You all basically took Dr. Liotta at his word,

or whatever he put into writing, and gave a very technical analysis of it, and based on that said it is okay. Now, how far off the mark am I on that?

Mr. BARRETT. I think you have a lot of merit in what you say. I think what we did do was to look, obviously, at the scope of the CRADA. And the scope of the CRADA is much more narrow than the scope of the overall mission of the company. And so within the scope of the CRADA there was very clear language in the consulting agreement that that was excluded.

Chairman BARTON. Now, as a layman, do you feel that it would be appropriate at any time for somebody in your—the three of your positions, the government positions that are reviewing this, to let the first company know that Dr. Liotta had acquired this ability to be a consultant for what appears to be a competitor? Should the law require or internal regulations require that before that approval is granted, even if it looks okay on paper, the original company ought to be notified?

Mr. BARRETT. We fully agree with Dr. Zerhouni's conclusion that these things should be transparent and should be——

Chairman BARTON. Well, you agree with it today, but you didn't at the time. Did anybody bring that up? Did anybody sit around the table or by e-mail say, "You know, we ought to let those saps at Correlogic know that the two principal people they are working with at NIH are about to have a consulting arrangement with what appears to be a competitive company"? Did anybody even think about that?

Ms. BARKER. In the concept of the Privacy Act, which we believe this outside activity to be covered by, we would not have made that personal income relationship known to the public. And from this perspective——

Chairman BARTON. Well, I am not saying make it known to the public, but, for gosh sake, why can't you make it known to the company that started the process first? I am not saying put an ad in The Wall Street Journal. But why couldn't you have notified confidentially Mr. Levine's company? That is not protected by the Privacy Act.

Ms. BARKER. We would have—we would have checked with legal counsel to determine whether they were in the chain of command, and whether they were covered by the Privacy Act or not, whether we had the ability to. Absent that, we would not have made it known.

Chairman BARTON. Well, my time has expired, and I apologize for that. But at some point in the process, if you folks are the people responsible for ruling on ethics applications, you need to step back and look at the broader picture. I don't see any attempt in the documentation to really look at what we would consider to be right and wrong.

And, you know, Dr. Zerhouni, to his credit has come around to the view that we need to change the system. And apparently you folks also agree that the system needs to be changed, which is to your credit. But in the interim, Correlogic has had two of the people that it thought were assigned by the government to work with their company have behind the scenes been working with another company, at least along a similar track.

And my analogy to Babe Ruth is kind of corny, but it is very real. You know, there is no way the New York Yankees would have let Babe Ruth go back and pitch for the Red Sox. There is absolutely no way, but yet by the approval of this application that is essentially in the research sphere what was allowed to happen.

With that, Mr. Chairman, I would yield back.

Mr. GREENWOOD. The Chair thanks the chairman and recognizes the gentleman from Florida, Mr. Stearns, for 10 minutes.

Mr. STEARNS. Thank you, Mr. Chairman.

Let me just continue along what the distinguished chairman of the Energy and Commerce Committee started to talk a little bit about this—what appears to be two scientists involved with a company, and sort of—Biospect and sort of working for NIH at the same time, not—Mr. Levine not aware of that, and then he finally became aware of it.

Mr. Levine, I went through your testimony here, and I thought I would go through and ask for some further clarification of your statements. On page 7 of it you say when you raised concerns to Dr. Petricoin and Dr. Liotta, you said they told you—“I was told not to be paranoid.” And that NCI’s unilateral decision was really in Correlogic’s best interest.

And, frankly, I was also concerned, and remain concerned to this day, about the particular components that NCI had unilaterally chosen for the detection system, and also about which entity would take the lead in responsibility for seeking regulatory approval following successful completion of the clinical trial.

When they said to you not to be paranoid, what did that mean to you?

Mr. LEVINE. Well, Congressman, two issues here. The first is that the reference I was making there was not to the conflict of interest, which I didn’t know about at the time. The reference there was really to NCI’s decision to proceed with the clinical trial and to essentially take over this area that had otherwise just been granted to Correlogic in April 2002.

So the reference really was to the activities of NCI going forward toward the clinical trial and all of those issues, although throughout my conversations over the last 3 years with Drs. Petricoin and Liotta they would continuously tell me that I was paranoid. Every time I questioned an activity or a decision coming out of NCI, they thought I was rather paranoid. And I think in hindsight I wasn’t paranoid enough.

Mr. STEARNS. Well, and then you go on—“a few weeks later I began hearing more from industry contacts about Biospect being a competitor.”

Mr. LEVINE. Yes.

Mr. STEARNS. “By now I was hearing that Drs. Petricoin and Liotta were affiliated with Biospect. In early July 2003, I reached Dr. Petricoin by phone and raised the issue directly to him.” Tell us what you said to him.

Mr. LEVINE. In that call—and I was friends with Dr. Petricoin, so I was able to be pretty blunt with him, I said that it had come to my attention through industry contacts that he and Dr. Liotta were consulting with Biospect, and I was shocked. I was appalled.

Mr. STEARNS. What was his response when you said to him, "I have heard through the industry grapevine that I am now—you are advising me—you are telling me not to be paranoid, yet I am finding you are part of my main competition." What was their response? And were you talking to both of them or to—

Mr. LEVINE. The conversation was only with Dr. Petricoin.

Mr. STEARNS. Okay. And what was his response?

Mr. LEVINE. His response was first and foremost that this was to approve the outside activity. And I, again, expressed genuine shock at that. I asked him how that could be so because the two companies were so clearly competitors, and I reiterated to him at the time the way in which I found out, which was through other people in the biotech industry, so that others perceived it as a conflict of interest, others outside of government, others outside of Correlogic.

And I then made the point to him—and this is very, very clear, since I actually wrote an e-mail shortly after my conversation with him—I made the point that, as I said earlier in the testimony, that the information that he was picking up and Dr. Liotta picking up from their collaboration with Correlogic, where that information began and where their own understanding ended, it would be very hard to tell.

So that if they were then consulting with a competitor, the fact that they might think that they are not revealing confidential information I thought became a very difficult line to determine.

Mr. STEARNS. Well, then you say later on, "I raised my concerns about what was happening to my company with Dr. Barker." And let me ask Dr. Barker: were you aware of this, too?

Ms. BARKER. Let me explain a little bit about how I became involved.

Mr. STEARNS. Okay.

Ms. BARKER. I joined the NCI in January or December actually—or January 2003, and I actually came to the NCI to join Dr. von Eschenbach to sort of work on these kinds of issues. So—

Mr. STEARNS. I need you to be brief, just because—

Ms. BARKER. Okay. Not long after I arrived, I received a call that said—from a colleague of Dr. Levine's saying that he was engaged in a CRADA with us, and he felt as though there was a potential conflict of interest for the investigators. So that is when I asked that Dr. Wilson and Dr. Barrett rereview the case and readvise us on whether or not there was a conflict of interest, so we could proceed to negotiate this.

Mr. STEARNS. Was there a conflict of interest detected?

Ms. BARKER. You know, we have just heard from Dr. Wilson and Dr. Barrett that using the guidelines they had at that time—

Mr. STEARNS. Right, okay.

Ms. BARKER. [continuing] they concluded that there was not a conflict of interest.

Mr. STEARNS. Okay.

Ms. BARKER. I think we have all agreed in retrospect that there was.

Mr. STEARNS. Okay. That is all I wanted to hear.

NCI and Correlogic have been in negotiations on the clinical trials for CRADA for a long time. Is it customary to take that long, Dr. Barker?

Ms. BARKER. In a word, no.

Mr. STEARNS. Okay.

Ms. BARKER. We have 100-plus CRADAs. This is the only one actually that has taken this amount of time to negotiate. But I will honestly say in sorting this out, it is a very complex CRADA. And by that, it involves some laboratory discoveries that are quite profound, a clinical trial, a licensed—

Mr. STEARNS. Let me put it this way. How close are we to fruition on these negotiations? Are they 1 week away, a year away, a month? Where are we right now?

Ms. BARKER. They depend actually on—a confounding factor in this has been that we started out with a technology that was developed in collaboration on the CRADA. Dr. Levine's company has actually pursued another line of investigation. He would like to add that to the CRADA, and I think the only thing that is missing here is to see the data from that technology so we can proceed to make a decision about this CRADA in terms of doing—

Mr. STEARNS. Let me see if Dr. Levine understands this negotiation the same way you do. Dr. Levine?

Mr. LEVINE. I have to respectfully disagree. The negotiations—

Mr. STEARNS. I mean, have you started something else here and it is making—

Mr. LEVINE. Well, it is not something else. It was work that we were developing—

Mr. STEARNS. It was part of the initial negotiations.

Mr. LEVINE. Exactly, part of the initial CRADA. Also, let me just add, Congressman, that there has been constant reference to how narrow the original CRADA was. Well, that was one of the issues beginning as early as August 2002 that we are attempting to change, because I can show you we have a year's worth of CRADA notes here taken by the NCI's contractor that have—perhaps 25 or 30 percent of these meetings were about software. The bulk of it was about sample preparation, mass spectrometers, turnkey systems.

So what was happening was that the research—the joint research under the CRADA was in fact going exactly down the road that I described earlier, which is the development of a turnkey system. So the goal of the negotiations was to both convert the research CRADA and eventually the clinical trial CRADA to match what was actually going on.

So in terms of where we are today, no, we—

Mr. STEARNS. Okay. So we have a little disagreement, Dr. Barker, in your—you have heard him, I have heard you. Dr. Barrett or Dr. Wilson, is there anything you would like to contribute here? We have this negotiation we all agree is going on much too long. You indicate that it is going to perhaps go on, Dr. Barker, longer because of some changes that have taken place, and Dr. Levine says no. Just, Dr. Wilson or Dr. Barrett, anything you folks want to add here?

Mr. BARRETT. Let me—

Mr. STEARNS. If you can be brief, because I have got a summary—

Mr. BARRETT. Right. I know it is—actually, there are several issues that do need to be put on the table—

Mr. STEARNS. Okay.

Mr. BARRETT. [continuing] which won't be brief. But let me make one point. That is, the ability to execute a CRADA is not something that Dr. Barker or I or the NCI has.

Mr. STEARNS. No, I understand that.

Mr. BARRETT. It goes through the NIH.

Mr. STEARNS. Just your interpretation.

Mr. BARRETT. Part of the discussion has been, what would be appropriate to put into a CRADA that would be satisfactory to all parties, most importantly the NIH? And that is part of the complexity of this.

The comment that Dr. Levine made—Mr. Levine made about us taking over an area given to Correlogic I take great exception to, because I think this is, in fact—we are continuing to do the research that the NCI is supposed to do and which we are paid to do by the public, and that is to try to understand how to improve clinical trials for ovarian and other cancer patients.

We have started a clinical trial. There is no delay in that trial. That is going along. That will collect the samples that will be used by a variety of sources for doing this analysis. We have welcomed Dr. Levine to participate in that activity and offered him unlimited access to these samples, but not necessarily through the CRADA.

The CRADA requires, again, a contribution of both parties, so there are other mechanisms. He mentioned earlier that he was also collaborating with another laboratory at NCI through a material transfer agreement, which is a very legitimate way of doing this transfer.

So there is lots of ways to move this forward, but the important thing is it is moving forward, even while these negotiations are underway.

Mr. STEARNS. I guess, Dr. Barker, can you assure us that NCI will treat Correlogic fairly in the future as they seek to work with the agency on research?

Ms. BARKER. Absolutely. I have made—I have gone to great lengths to ensure that that is the case. And just to clarify the point on—I have seen all the pieces of this now, and it took some time to sort this out, actually. But I think the point I was raising before is we do have—we have reached the point of having an agreement on I think—and I think NCI and Correlogic agree on the basics of the agreement.

I think the one question NCI has raised is: could we see some data for the other proposed technology? And we are awaiting that.

Mr. STEARNS. Thank you, Mr. Chairman.

Mr. GREENWOOD. Mr. Levine, you looked like you were about to say something.

Mr. LEVINE. Yes. The problem with the observations made just now are that we reached agreement with NCI in August 2002, and that agreement was reduced to writing on September 12 by NCI's technology transfer office. And we have now spent the last 2 years watching every part of that agreement be unravelled.

So now to say, "Well, if we show them data, we can come and be part of this trial" is—I mean, frankly, it is sophistry. I mean, we had an agreement 2 years ago to move forward together, and NCI basically has negotiated us to death. It is very difficult when you are a small company to be negotiating with all of NIH at one time.

Mr. GREENWOOD. Thank you.

The gentlelady from Colorado is recognized for 10 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

Dr. Barker, when Mr. Levine was just giving his response, I saw on your face you disagreed with that. You know, what can be done here to move this along?

Ms. BARKER. First of all, I think Dr. Levine's comment is a point well taken. When I say this was difficult to sort out, there were a lot of things on the table that had been worked out over time. And I think because of the speed of the technology, the movement of the technology, issues that arose due to the tests that Correlologic was proceeding with, the desire of NCI to proceed along a different line of technology, when I started looking at this we really had to start over. I mean, it was—no one sort of within the NCI I think was where they were a year earlier, and so—and the technology had moved along.

So I think that the agreement we have on the table now is I think appropriate, and I think it would allow Correlologic to be—to really get a 510K, and be probably first to get a 510K, and they hold a license for this technology. So I think if we can agree on this one single point in terms of using two technologies versus one, I think we could close this fairly quickly.

Ms. DEGETTE. Okay. And, Mr. Levine, does that—do you think it could be closed fairly quickly, too, given Dr. Barker's statements?

Mr. LEVINE. I will certainly give it my all, and hopefully it will be less than 2 years.

Ms. DEGETTE. And, Dr. Barker, I think I know the answer to this, but I just want to get it on the record. There are some—is there any indication that Correlologic will suffer because of its complaint to this committee or the proceedings that we have going on with respect to these issues or the clinical follow-on to the agreement we have?

Ms. BARKER. I speak on behalf of myself, Dr. von Eschenbach, all the folks at this table, and the National Cancer Institute in saying that we are most interested in this relationship, and we are very interested in CRADAs. We are desperate in Cancer to get these technologies into patients, so, trust me, we are absolutely—if this is a relationship that can and should be closed and pursued, it will be done.

Ms. DEGETTE. And there will be no retaliation against—

Ms. BARKER. Absolutely not. There will be—no. I think, actually—I think this is an interesting and I think very revealing case study, and I think that Dr. Zerhouni has taken it to heart and changed some things that needed to be changed from this case study.

It is—you know, there are some unfortunate things here, but I think we have learned some things in the system that has been in

place. And I think it is actually directing us to a new system, and the NCI has—had already begun to initiate some of these changes.

Ms. DEGETTE. So you are happy for the information they have brought forward.

Ms. BARKER. I think it has been very informative, and I think it is also going to help us in the future as we negotiate our CRADAs and put them in place to be very clear on conflict of interest. And I—that has not been a simple issue before.

Ms. DEGETTE. Dr. Wilson, I just wanted to follow up on the discussion we were having in my previous line of questioning when I yielded to the chairman. I think you had testified, and several of the others had testified, that these new systems that are being put into place—in particular, the computer systems—should function to raise a red flag to help us avoid conflicts of interest like this in the future.

And I guess I would like it if you would describe for me with a little more precision how it is these types of conflicts of interest will come up, and how your office is going to identify them in the future.

Ms. WILSON. With regard to the data that we can collect on our own employees, it will allow us to link together everything that we know that they are doing. Certainly, we have much better descriptions of what their official duties are, their current projects, contracts, grants, anything that they might be involved in. With regard to CRADAs, we have the same information, or will very shortly, accessible in real time, including more documents than we have had before, including such things as confidential disclosure agreements, which were not accessible to us before.

Ms. DEGETTE. Who were they accessible to before?

Ms. WILSON. They were on record in technology transfer offices. And we received copies of CRADA listings, but not of those other documents. And so it indicates a dealing that we have with the company as part of our official duty activities. Being able to link those together will, in fact, alert us to a number of relationships that we wouldn't have been aware of before. It will give us better description.

With regard to what Dr. Zerhouni said this morning about Googling various companies, clearly, what we can obtain from the web is subject to what is available on the web, and that—

Ms. DEGETTE. Right.

Ms. WILSON. [continuing] will continue to be a limitation. For small startup companies—

Ms. DEGETTE. So let me stop you. Is it your intention, then, anytime someone comes forward with a proposal for outside contracts that you are going to Google all of the proposed—I mean, how is that going to work mechanically? I am still grappling with how this new proposed ethical system is going to work.

Ms. WILSON. With regard to outside activities, what we actually do now when an activity is proposed, as I said, we review all of the data bases about the employee and their activities, and the Institute's involvement with whatever the proposed outside partner is. Again, they are limited by the systems that we have in place, which are being improved. We do also search the web for anything that we can find related to the companies.

Ms. DEGETTE. And then, is there some—but, I mean, if you had done that in this case, the information would have—I mean, would you have known from the web that there was a conflict between these two companies?

Ms. WILSON. There is one piece of information that was available to us in August 2003 that we had not known about before. There was a confidentiality disclosure agreement executed between Biospect and the NCI for access to the data, which is now public, that has been generated as part of the CRADA.

That certainly would have immediately signaled an interest of the company in pursuing the same direction, perhaps exactly, that the Correlogic CRADA was going down.

Ms. DEGETTE. Okay. So that—you would have caught that based on the provision of getting the confidentiality agreements. You wouldn't have caught that by surfing the web.

Ms. WILSON. No. We would have caught that within our own system.

Ms. DEGETTE. Okay. All right. I don't think I have any further questions, and I yield back.

Mr. GREENWOOD. The Chair thanks the gentlelady and recognizes himself for 10 minutes for questioning.

I am going to ask you, Dr. Wilson, to go to Tab 28. And if you go to the second page, you'll see an e-mail from Peter Levine. Do you see that?

Ms. WILSON. Yes.

Mr. GREENWOOD. Now, actually, the e-mail in question here is the address below that where it says Vince Simmon, sent Wednesday, May 21, to Peter Levine, subject Info on Biospect. Do you see that?

Ms. WILSON. Yes.

Mr. GREENWOOD. Okay. And the date is May 21, 2003. I think earlier in your response to questions you said that the information that you would have needed to demonstrate that Biospect was really involved and engaged in the same kind of activities as Correlogic wasn't available in 2003, didn't you?

Ms. WILSON. As a group, we indicated that the website was not available. The website was available, and in our 2003 analysis my office did look at that website.

Mr. GREENWOOD. Oh, did not look at it.

Ms. WILSON. We did look at it.

Mr. GREENWOOD. Right.

Ms. WILSON. It was attached to our documents.

Mr. GREENWOOD. Okay.

Ms. WILSON. Which I believe were submitted to your committee. It appears to have been an oversight, and may very well have been my office's fault that it was not provided to Dr. Barrett. So he may very well have been unaware of the—

Mr. GREENWOOD. Because clearly the—what he says, "Peter, it was nice talking with you today. Here is some info on your new competition. I will be back in touch. Vince." And then it goes on from the website there—a description of the—a complete description of Biospect, which talks—describes exactly what it does, which, of course, is very much what Correlogic was doing. You don't disagree with that in retrospect?

Ms. WILSON. I don't disagree with it in retrospect. I would have asked for—being that I would have done a technical analysis, I would have asked for further information about the nature of biological fluids analysis, and so forth, and are they truly related? Are they that close?

Mr. GREENWOOD. And wouldn't you have referred that to—that question to Dr. Barrett, since it is a scientific question?

Ms. WILSON. Yes.

Mr. GREENWOOD. Okay. I think here is what is troubling us. Mr. Levine comes in and says, "Holy God, I am upset. I am working with these guys on my CRADA, and I find out that they have never told me they are working for Biospect. I view Biospect as a competitor, and this I find appalling." Okay?

So you have the information, but the guy at Correlogic, he thinks—he thinks that his company's secrets are at risk. Okay? And one would assume that if there was no risk, no potential risk because they were in very different fields of endeavor, Mr. Levine wouldn't come in so upset and asking for a rereview, right? So you have got some—I mean, you have got a pretty good red flag going in the person of Mr. Levine. Okay? So then you rereview.

And the thing that worries us, that causes us to spend so much time on this issue, is out there at Biospect you have got on the Board the old boss of the NCI, the big man, the big dude, Klausner. Right? Knows all you guys, you worked with him and for him and all of that, and you have got Dahl out there, and you have got Shtrom out there.

And the concern is we think—we worry that in the face of the obvious concern of Mr. Levine you scanned over the horizon to look at Biospect to see if this is a problem, and there is the old gang out there making money at Biospect. And that we worry that that would have clouded your judgment.

Did you have any discussions with any of those three people—Dr. Klausner, Dr. Shtrom, Dr. Dahl? Did you have conversations with any of them during the time that you were rereviewing this agreement?

Ms. WILSON. To my knowledge, no. I know I didn't—I have not talked to Dr. Dahl I believe since she left. I could be wrong. I would have to check notes to see if we had anything. I have not talked to Dr. Shtrom. I have had a few conversations with Dr. Klausner on various situations, but not on this.

Mr. GREENWOOD. Not with regard to this, okay.

Ms. WILSON. No.

Mr. GREENWOOD. And does that apply to you as well, Dr. Barrett?

Mr. BARRETT. Absolutely, yes. I mean, absolutely not.

Mr. GREENWOOD. Okay. You haven't had any conversations with—

Mr. BARRETT. No conversations.

Mr. GREENWOOD. I mean, in retrospect, do you think that your judgment may have been clouded by the fact that former friends and associates—

Mr. BARRETT. It did not enter into my decision at all. I was told that Dr. Klausner had, you know—what I was told, as I understood, was he was part of the venture capital group that had fund-

ed this, and he was not directly involved in the management of this company. I actually overlooked the fact that Carol Dahl was the signature on one of the letters that we had, so I actually did not even make the connection until much later when it was brought to the attention of this committee.

I reviewed the statement of work and the consulting agreement. I used my knowledge of the CRADA that we had with Correlogic, and those did not seem to overlap, and that was the sole basis for the decision.

Mr. GREENWOOD. If you would turn to page—to Tab 34, you will see e-mails sent from Carol Dahl to Petricoin, and then below that is—actually, I always forget these things go in reverse order—an 8:06 a.m. message from Dr. Petricoin to Carol Dahl. Do you see that, Dr. Wilson and Dr. Barrett?

Mr. BARRETT. Yes.

Ms. WILSON. Yes.

Mr. GREENWOOD. If you look at the address that Dr. Petricoin's e-mail emanated from, it is FDA—it is seiber.fda.gov, which clearly indicates he is using his government computer to be sending e-mails with regard to his outside paid consultancy. Would you come to that conclusion?

Ms. WILSON. Yes, he is using it to confirm what appears to be a scheduling arrangement.

Mr. GREENWOOD. All right. And he is also sending it—if you look, it went to Dr. Liotta at mail.nih.gov.

Ms. WILSON. Yes.

Mr. GREENWOOD. That is not necessarily grand larceny, but, I mean, it does violate the rules, does it not? My understanding from previous conversations with others at NIH and at the FDA indicates that these private consultancies are not supposed to involve the use of government computers, telephones, equipment, etcetera. Is that correct?

Ms. WILSON. The conduct of personal business should not be done using government equipment.

Mr. GREENWOOD. Right. And certainly not on government time either.

Ms. WILSON. Yes.

Mr. GREENWOOD. Okay. Turn to Tab 11 now, please. If you would look at—would you identify that document, Dr. Wilson?

Ms. WILSON. That is a cover sheet that is generated by our computer recording the Biospect activity with the comments that my office added in submission to the NEAC committee.

Mr. GREENWOOD. Okay. And money earned to date, it says \$49,375 consulting fees, proposed annual rate of \$39,000, or \$3,250 per month. Where would that information have—how would that have been inputted into the system so that that would appear on this computer-generated form?

Ms. WILSON. There is—what you cannot see is a blank field next to—you can see a field that says “fee.” Next to it would have, in fact, been the dollar amount. And our system is limited right now. It was intended to reflect an annual rate, and if we begin to put in cumulative rates we are going to have to make some changes in the system. So it is done manually at the moment.

Mr. GREENWOOD. Okay. So that \$49,375, was that—did somebody enter that, or was that—did the computer do math—do multiplication—

Ms. WILSON. We received that information from Dr. Liotta himself, because we weren't collecting the data on that at the time.

Mr. GREENWOOD. I understand. So Dr. Liotta provided that information.

Ms. WILSON. Yes.

Mr. GREENWOOD. Okay. Now, go to Tab 41, please. Okay. If you look at—can you identify that document? Well, I will identify it. This document I don't think you have seen. But this is a document provided to the committee by Predicant Biosciences, formerly Biospect, and it is a vendor quick report, January 1, 2002, through June 5, 2004.

And the numbers on that—this is for Dr.—it is what they paid—what they report that they paid to Dr. Lance Liotta. And you will notice that the rate started out at \$5,000 per month and then was reduced to \$3,125, and that adds up to, the staff tells me, \$70,000. And so does that—would that indicate a discrepancy between the \$49,000-plus figure that we just were discussing and this \$70,000 figure that the company indicated that it paid Dr. Liotta?

Ms. WILSON. There is clearly a discrepancy. I believe what—the dollar amount Dr. Liotta furnished us may have been what he had on his W-2 equivalent form. I would have to check what he—

Mr. GREENWOOD. Do they submit the W-2 form?

Ms. WILSON. No, they are not required to.

Mr. GREENWOOD. They are not required to. Okay. But you can't explain how this discrepancy would have occurred?

Ms. WILSON. The number we used is what he provided to us.

Mr. GREENWOOD. Okay. We understand that Dr. Liotta and Dr. Petricoin were involved in helping Predicant Biosciences set up a CLIA lab, which is regulated by the Department of Health and Human Services. Is there an ethical conflict there where they are being paid to provide guidance in an endeavor that would be regulated by the Department?

Ms. WILSON. The issue I would have looked at, and I may not be looking at all of the issues, would have been whether they were engaged in a matter that would become the subject of a submission of documentation or discussions with HHS. The mere establishment of a lab according to known processes or standards would not, in my mind, fall under that, but I would have verified—

Mr. GREENWOOD. So it would be the preparation of documents themselves that would then be reviewed that would cross an ethical line.

Ms. WILSON. Communications become the subject of dealings.

Mr. GREENWOOD. Okay. How about if they—where is the line between actually doing the paperwork where you are sitting and inputting the data onto the—into the computer to print out the report or actually writing a document versus advising a client to pay—a client who is paying you how to do that or advising a client how to—a strategy for getting a new device approved through the FDA? Is there a—is that a gray area, or is there a fine line there?

Ms. WILSON. I would have to say it is a gray area in my mind. I would defer it to better legal counsel. I am not a lawyer.

Mr. GREENWOOD. Okay. Finally, Dr. Barker, you heard Dr. Levine in the very beginning of his testimony express concern and worry that the NIH and/or the FDA would act in a prejudicial form because of his role in making the committee aware of his concerns about this. How can you assure Dr. Levine and this committee that that will certainly not be the case, at least as it concerns the NIH?

Ms. BARKER. Well, I think we will proceed in good faith. And I think there have been some missteps here, but I think most of the things that have been done on this negotiation have been done in good faith. Doing it over, we probably would do it differently I think, at least the first—up to the point I think Dr. Levine described to you.

I think since then we have been—you know, we have been moving along at a reasonable rate, not rapidly enough I think, but I think in the future some of these new processes that we have already started to put in place will assure anyone actually entering into these relationships that not only will you be able to proceed I think more quickly and more efficaciously, I think you are also going to proceed without the kinds of issues that Mr. Levine has raised.

I mean, I think this new system of actually looking at everything an individual is doing, especially those folks who are entering into CRADAs, is going to be critical. And as I said before, I think one thing this case has pointed up is that we do have to very carefully consider that.

In terms of, you know, fair treatment from the NIH, FDA, and I can certainly only speak for the NCI, we will certainly make very effort to ensure that Mr. Levine and anyone else who comes to deal with us, in terms of these very important relationships, will get fair and equitable treatment.

Mr. GREENWOOD. You are not critical of Dr. Levine for his testimony today, are you?

Ms. BARKER. Not at all, actually. As I say, as I sat there, I think both Dr. Barrett and Dr. Wilson and all of us, we learned a lot today. And I think it is learning that will help us in the future. And the biotechnology industry is actually very, very important to the National Cancer Institute. So many of our products are smaller markets; that is very attractive to this industry. And so we have—and, actually, cancer is the major focus of most of the biotechnology companies that are being formed today.

So we are going to endeavor to do everything we can to build the very best relationship with this industry we can. There are about 1,500 biotech companies in the country today, and we see that as being an absolutely exploding area for the future. So it behooves the NCI and the NIH to actually work, as Dr. Zerhouni said this morning, to really make these relationships effective areas of translation of technology for the American public.

Mr. GREENWOOD. I think on that very positive note the committee will thank you very much for spending the day with us and for your testimony. It has been a big help.

Mr. Levine, we thank you particularly.

And the committee is adjourned.

[Whereupon, at 3:57 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

Tab	Document Description	Date
NIH Section		
1	Young Letter to Chairman Barton - Re: an agreement between HHS and The Committee	4/17/2004
2	Zerhouni Letter - Re: Awards, Travel, and Official Duty and Outside Activity Approvals - ACTION	11/20/2003
3	Swindell Letter to Marilyn Glynn requesting that some Employees file Public Financial Disclosure Reports.	1/12/2004
4	Swindell memo to DEC's, re: Agency Procedures Reviewing Outside Activity Requests.	1/27/2004
5	NIH Analysis of Ethics Concerning the Receipt of Lecture Awards by NIH Employees	7/17/2003
6	Jake Wilson memo re: Recommendation to the Dickson Award	10/1/1996
7	Wilson Memo - Subject: Conflict of Interest Review: Lance Liotta, M.D./HHS-520 Biospect	8/20/2003
8	NCI Memo - Subject: Evaluation of Biospect Outside Activity	8/20/2003
9	Request for Approval of Outside Activity for Emanuel F. Petricoin	9/30/2002
10	Request for Approval of Outside Activity for Lance A. Liotta	10/11/2002
11	NCI Ethics Database re: Dr. Liotta's consulting agreement.	5/4/2004
12	Zerhouni Letter re: Financial Disclosure	5/14/2004
13	NIH Memo re: Resubmission of Outside Activity Approvals	No Date
14	Burton Email - RE: Moshell	6/19/2004
15	Approval Form for Awards - Klausner - 1997 Rabbi Shai Shacknai Memorial Prize	2/7/1997
16	HHS Memo - From Barrett - Subject: Special Volunteer Designation for Richard Klausner	9/28/2001
17	Letter from the Editors - <i>Clinical Proteomics</i>	No Date
18	Dahl Email - RE: Liotta/Petricoin - NIH Biosensors Meeting with Liotta	6/25/2002
19	Dahl Email - RE: Liotta/Petricoin - Ethics Limitations	6/25/2002
20	HHS - Employment by Title 42 Authority	May-04
21	List of Pfizer - NIH Consultants from 1999 to Present	No Date
22	Burton Email - Subject: Fw: NEAC Totals	6/18/2004
23	CRADA Spreadsheet	No Date
24	NIH Lecture Award Master List	No Date
25	Azar Letter to Tauzin - Re: Role of HHS Lawyers	4/16/2002
26	Turnover Rates for NIH Scientific Staff for FY1994-FY2003	6/10/2004
Correlogic Section		
27	Correlogic Systems Inc. Website Information.	No Date
28	Levine Letter - Re: Approval of co-sublicense to LabCorp and Quest Diagnostics	11/5/2002
29	Tananbaum Email - RE: Agreement to Carol Dahl and Exec Staff	10/4/2002
30	Parnell Email to Jeff Livingstone - RE: catching up	11/19/2002
31	Liotta Email to Jeff Livingstone - RE: Inquiry	12/15/2002
32	Petricoin Email to Livingstone - Re: SAB and Meeting you next week	8/1/2002
33	Livingstone Email to Petricoin - Re: SAB Query	6/28/2002
34	Dahl Email to Petricoin - RE: Follow up and could you be available to meet?	3/31/2003
35	Petricoin Email to Heller - Re: Follow up and could you be available to meet?	3/28/2003
Biospect Section		
36	BIOSPECT Letter to extend a consulting agreement to Dr. Lance Liotta	10/22/2002
37	Biospect Inc. Website Information.	No Date
38	Exhibit A to Dr. Liotta's Agreement with Biospect	No Date
39	Petricoin Email to Heller - Re: CDA with Biospect	4/21/2003
40	Flamberg Email to Burton - Subject Additional Document re: Biospect	6/16/2004
41	Predicant Biosciences, Inc. - Vendor QuickReport	6/15/2004
42	Biospect Check to Lance Liotta \$3,125 dollars	1/1/2004
43	Biospect Check to Lance Liotta \$3,125 dollars	2/1/2004
44	Biospect Check to Lance Liotta \$3,125 dollars	3/1/2004
45	Biospect Check to Lance Liotta \$3,125 dollars	4/1/2004
46	Biospect Check to Lance Liotta \$3,125 dollars	5/1/2004

Tab	Document Description	Date
47	Presentation to Biospect	7/7/2003
48	Petricoin Email to Liotta and Dahl - Subject: Glycosylated HGB material	4/22/2003
49	Liotta Email to Heller - RE: Biospect	3/12/2004
50	Stults Email to Heller - Subject FW: Stuff	3/23/2004
51	Dahl Email to Heller - Subject FW: FDA filing strategy review	1/31/2003
OGE Section		
52	OGE Memo to Designated Agency Ethics Officials	5/27/2004
53	OGE Response to Committee Questions	6/14/2004



5-18-04
ARCHIVE
DEPARTMENT OF HEALTH & HUMAN SERVICES

Chuck
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JACKIE

Office of the Assistant Secretary
for Legislation

Washington, D.C. 20201

TAB 1

MAY 17 2004

The Honorable Joe Barton
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
Room 2125 Rayburn Building
Washington, D.C. 20515

Dear Mr. Chairman:

This letter summarizes the agreement reached between the Department of Health and Human Services (Department) and the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Oversight and Investigations (Subcommittee) concerning the role of the Department's attorneys with respect to voluntary interviews of Department employees by Subcommittee staff in the remainder of the 108th Congress following this date. The agreement acknowledges the Subcommittee's right to conduct oversight investigations concerning matters that fall within its jurisdiction. In many such cases, the Department, in the interests of accommodating the Subcommittee's work, will voluntarily make its employees available for interviews conducted by Subcommittee staff. When the Department thus accommodates the Subcommittee, the Department has a strong interest in providing appropriate Departmental representation for employees being interviewed in connection with activities they performed while acting within the scope of their employment by the Department. Also, we have found that employees want to have such representation and furthermore that such representation allows the Department to be responsive and helpful to the Subcommittee in its work.

The Department and Subcommittee agree that counsel from the Office of General Counsel (O.C.) from components of O.C. that do not, on a full-time basis, provide counsel to the component of the Department from which the witness comes may accompany employees of the Department to interviews conducted by Subcommittee staff. These attorneys will attend the interviews in their capacity as official counsel for the Department. Also, the Department agrees that following the interviews, counsel will not inform any Department officials or employees about the substance of the interviews without first notifying both the majority and minority Subcommittee staffs.

I believe that this letter fairly states our understanding. If you agree, our staffs are ready to discuss scheduling of interviews.

Sincerely,

Jennifer B. Young
Assistant Secretary for Legislation

May-03-2004 03:07pm From: Assistant Secretary for Legislation 202-690-7380

T-025 P.002/004 F-768



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

APR 16 2002

The Honorable W. J. "Billy" Tauzin
Chairman
Committee on Energy and Commerce
House of Representatives
Room 2125, Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

The purpose of this letter is to clarify the role of this Department's attorneys with respect to the investigative interviews of employees of the Food and Drug Administration (FDA) being conducted by the Subcommittee on Oversight and Investigations. On March 21, 2002, you forwarded a letter to Dr. Lester Crawford, Deputy Commissioner, FDA, indicating that the subcommittee is investigating the conduct of ImClone Systems, Inc., in developing Erbitux, a colorectal cancer drug. Your letter noted that investigative interviews of FDA employees would be necessary because the subcommittee's inquiry concerns FDA policies and procedures pertinent to the Erbitux matter, as well as other issues broadly related to the FDA approval process for drugs and biologics. Further, your letter specifically stated that arrangements could be made with the Department's Office of General Counsel to provide "personal counsel" to the employees being interviewed.

Subsequently, investigative interviews with five FDA employees were scheduled and on April 9, 2002, an attorney from the Department's Office of General Counsel accompanied an FDA employee to the first of these interviews. Prior to the start of the interview, the committee staff members conducting the interviews apparently expressed some concern about the attorney from the Department being there. Specifically, there seemed to be some question as to the role of the attorney with respect to the interview process. While the majority committee staff member and the minority committee staff member opted to proceed with the interview, they requested a letter from the Department explaining the role of attorneys from the Office of General Counsel with respect to interviews of FDA employees in the Erbitux matter.

At the outset, it is important to note that the Department recognizes that the subcommittee has the right to investigate matters that fall within its jurisdiction and that these inquiries may involve interviews of Department personnel. Because this inquiry involves conduct of Department personnel acting within the scope of their duties, the Department offered to represent these individuals in their personal capacity, as provided for in your March 21, 2002, letter.

Page 2 - The Honorable W. J. "Billy" Tauzin

I would like to address any concerns the subcommittee may have about counsel from the Department attending interviews of FDA employees in this particular matter. It is important to stress that Department attorneys represent employees in their personal capacity. Thus, Department attorneys who accompany an employee of FDA to an investigative interview will not inform any Department officials about the substance of the interview. Pursuant to an existing agreement with the Committee, moreover, an attorney who accompanies an FDA employee to these investigative interviews will not advise any other FDA employee scheduled to be interviewed of the content of any prior interviews. Also, the employees who have already been interviewed were advised of their right to retain personal counsel prior to their interviews. Any other FDA employees who are scheduled to be interviewed will also be advised of their right to retain personal counsel.

Additionally, the Department agrees that with respect to the interviews of FDA employees in this matter, no one from the FDA Office of Chief Counsel will represent an FDA employee during these interviews.

I believe that the guidelines set forth above should address the subcommittee's concerns about Department attorneys being present at these investigative interviews. Moreover, it is my understanding that the terms I have outlined are very similar to past arrangements made by the Department with respect to interviews of FDA employees in other subcommittee investigations.

Sincerely,

A handwritten signature in dark ink, appearing to read "A. Azar II", followed by a circled number "107".

Alex M. Azar II

cc: The Honorable John D. Dingell
Ranking Member

The Honorable James C. Greenwood
Chairman
Subcommittee on Oversight and Investigations

The Honorable Peter Deutsch
Ranking Member
Subcommittee on Oversight and Investigations



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

TAB 2

NOV 20 2003

TO: IC Directors
OD Senior Staff

FROM: Director, NIH

SUBJECT: Awards, Travel, and Official Duty and Outside Activity Approvals—ACTION

Congress has completed the doubling of the NIH budget, which is an expression of the priority given to biomedical research by the American people. It is also emblematic of the trust and confidence the Nation's lawmakers have in NIH and its employees. This trust is a precious commodity that must be maintained through outstanding performance and strict adherence to ethical principles. Should the public lose faith in the ability of NIH to support excellent research and practice high standards of ethical behavior, the biomedical research enterprise in the United States will lose its momentum.

Recently Congress and the media have been scrutinizing the implementation of ethics rules at the NIH. They are reviewing a wide range of activities that are allowed under Federal regulations, including lecture awards, outside activities, consultant arrangements, and financial holdings. Care must be taken to ensure that we continue to adhere to strict ethical practices and that we avoid the perception of conflicts of interest, even in situations where remuneration or awards are considered permissible.

As you know, NIH employees cannot accept compensation from outside entities for the performance of activities that are part of our official responsibilities. Even in cases where we are permitted to accept compensation for teaching, speaking, and writing on subjects within our field of expertise, or to accept awards recognizing our achievements, I urge you to exercise cautious judgment in accepting such honors. Although the applicable rules permit us to accept these rewards, they also encourage us to exercise sound judgment, noting "it is never inappropriate and frequently prudent for an employee to decline a gift." Each of us must ultimately assess whether the risk of adverse perception counsels against accepting the financial benefits associated with various honors. Please consider the greater good of the NIH when deciding whether to accept financial benefits offered in recognition of your work or public service. As the Director of NIH, I will not accept any financial or travel benefit offered as part of any award from an entity that does business with the NIH.

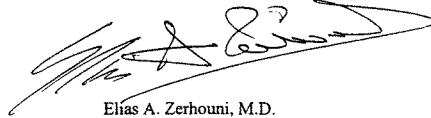
Although I am confident that our system of managing conflicts of interest at NIH has been successful in preventing breaches of Federal ethics rules, I believe we can improve our

Page 2 - IC Directors and OD Senior Staff

performance by subjecting ethics deliberations to a more transparent process of peer review. Therefore, I will establish a committee to provide advice to the NIH Deputy Ethics Counselors on specific activities such as the acceptance of lecture awards and consulting arrangements. This committee will provide NIH Deputy Ethics Counselors with valuable deliberative information to ensure final ethics decisions are consistent with Federal rules and avoid the perception of conflicts. The committee will also help NIH officials determine the appropriateness of engaging in activities that are not part of their official duties.

Finally, in order to coordinate better the efforts of the ethics program staff and the Office of Management (OM), effective immediately, copies of approved official duty clearances (required by our manual issuance for all IC Directors and staff) must be attached to travel paperwork when it is submitted to OM for approval. Please remind your employees that timely prior approval is required for official duty and most outside activities prior to the start of such activities.

Thank you for your cooperation.

A handwritten signature in black ink, appearing to read 'E. Zerhouni', is written over a horizontal line.

Elias A. Zerhouni, M.D.

Ms. Marilyn L. Glynn
 Acting Director
 Office of Government Ethics
 1201 New York Avenue, N.W.; Suite 500
 Washington, DC 20005-3917

Dear Ms. Glynn:

I am writing to request your determination pursuant to § 101(f) of the Ethics in Government Act of 1978, as amended (Title I, 5 U.S.C. App., Pub. L. No. 95-521) (hereafter "the Act"), that certain employees of the National Institutes of Health (NIH), by virtue of their level of authority, should be required to file Public Financial Disclosure Reports (SF 278s). Specifically, I request that you determine that Institute/Center (IC) Directors, IC Deputy Directors, IC Scientific Directors, and IC Clinical Directors are of "equal classification" to the filing positions that are specifically designated in the statute by category or salary level.

Although these determinations are appropriately evaluated on a "case-by-case," rather than a "class or category" basis, the four identified titles are replicated in each of the institutes and centers with substantially identical functions; only the subject matter of each component's medical research would be different. The National Institutes of Health will endeavor to provide any additional information that you require to make this determination. Inasmuch as these functional responsibilities were staffed under special authorities within Title 42 of the Public Health Service Act, I am informed that they do not have "position descriptions" as would normally be expected within the civil service. Accordingly, in support of this request, and in order to fully demonstrate that these roles carry particularly high levels of responsibility, similar to that of Senior Executive Service (SES) positions, please consider the following information provided by NIH:

The NIH is presently comprised of 27 Institutes and Centers (ICs). In fiscal year 2003, the NIH budget was \$27.9 billion. The senior leadership of each of the ICs manages their respective budget allocations, collectively identifies major areas of biomedical research within the expertise of their IC staff, establishes the research objectives and plans for their ICs, approves the individual intramural research programs within the labs of the IC and the extramural research supported by NIH funding, and serve as liaisons to the media, special interest groups, high ranking scientific and executive officials throughout the Department of Health and Human Services and other federal agencies, and to Congress. They are, at various times, involved in international relations related to healthcare issues, and policy development discussions at the highest levels of the Executive Branch.

IC Directors are appointed by the Director, NIH, report directly to the Director, and are charged with fulfilling the statutory mandates established under the Public Health Act, Title 42 of the U.S. Code. IC Directors provide overall leadership and vision to the national programs of the

Jan-21-04 09:09am From:202606351
01-20-2004 05:34pm From:OGC ADMIN OFF./ETHICS DIV.

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17331 C.003/003 C.003/003

Page 2 - Marilyn L. Glynn

NIH. They are responsible for integrating key national and agency goals, priorities, and values into the intramural and extramural programs of their ICs. Along with the NIH Deputy Directors, they serve as key policy advisors to the Director, NIH, on issues such as research priorities, strategic planning, and management. IC Directors regularly speak on behalf of their organizations before special interest groups, the media, and national and international scientific experts. In the interest of ensuring that scientific discoveries are translated as broadly as possible into the tools, diagnostics and pharmaceuticals of the future, they are tasked with fostering and maintaining working relationships with other NIH ICs through inter-IC initiatives, and with developing and enhancing alliances with an ever-widening range of stakeholders.

The Deputy Directors of each of the ICs are responsible for the overall management of their respective large and diverse extramural research programs. They develop new approaches to funding research on innovative high priority studies, often involving the most vulnerable populations. Working with the Directors of their ICs, they are integral to the creation of strategic plans for their ICs.

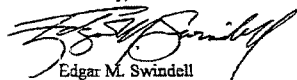
IC Scientific Directors manage and coordinate the intramural programs of each of the ICs. They set research goals and priorities, oversee the scientific and technical peer review of all intramural laboratories within their respective ICs, and advise the NIH in relation to agency-wide policies.

IC Clinical Directors provide scientific leadership and management for the intramural clinical research performed within the ICs and the NIH Clinical Center. They provide the infrastructure needed to promote high quality studies of the safety and efficacy of new and novel approaches to the vast array of human illnesses through protocol review, clinical informatics, and data and safety management. They are responsible for creating and maintaining research environments in which clinical findings influence the direction of lab studies, and coordinate inter-IC research programs.

Based upon the high level of responsibility associated with each of these functional titles, I request that you determine that their roles are of equal classification to those specifically designated in § 101 of the Ethics in Government Act and, therefore, that employees holding these appointments are required to file public financial disclosure reports.

Should you need any additional information or wish to discuss this request, please contact me, at (202) 690-7258, or Gretchen Weaver of my staff, at (301) 594-8166.

Sincerely,



Edgar M. Swindell
Associate General Counsel for Ethics
Designated Agency Ethics Official

cc: Raynard S. Kington, M.D., Ph.D., M.B.A.
Deputy Director, NIH; Deputy Ethics Counselor, NIH/OD



Feb-04-04 04:40pm From:2026806351

2026806351

T-461 P.002/003 F-370

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

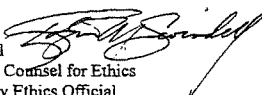
Office of the General Counsel
Washington, D.C. 20201

TAB 4

January 27, 2004

MEMORANDUM

TO: Deputy Ethics Counselors
Ethics Contacts

FROM: Edgar M. Swindell 
Associate General Counsel for Ethics
Designated Agency Ethics Official

SUBJECT: Internal Agency Procedures or Processes for Reviewing
HHS 520 Outside Activity Request Forms

Following consultation with the Office of Government Ethics (OGE), and pursuant to my authority as the Designated Agency Ethics Official (DAEO) under the Ethics in Government Act of 1978 and 5 C.F.R. Part 2638, I am directing that Deputy Ethics Counselors, supervisors and others who review and approve outside activity requests must inquire of the applicant the *amount* and *type* (e.g., cash, stock, or stock options) of income, compensation, fees, remuneration, expenses, or reimbursement that is to be received in connection with the proposed activity. When evaluating any previously approved, ongoing outside activity for continued compliance with existing law, the reviewer must also inquire retrospectively as to the cumulative amount of any income or other monetary receipts (including the type or method of payment) that was received from the outside source in connection with the approved activity. Employees will be required to provide this information if they desire to have their request considered or continued, and a failure to do so will result in denial of the request.

The information that is collected from this review process shall be annotated in "Item Number 17" on the reverse of the HHS Form 520. In this manner, the data is maintained within the existing government-wide system of ethics records, OGE/GOVT 1 (for public filers and others) and OGE/GOVT 2 (for confidential filers), and is available for the routine uses therein described.

As you know, the purpose of the prior approval process is to ensure that the proposed activity does not violate any statute or regulation, including the OGE Standards, 5 C.F.R. Part 2635, and the HHS supplemental ethics regulation, 5 C.F.R. Part 5501. To that end, eliciting the dollar amount is relevant for determining whether the compensation is so excessive or disproportionate to the time expended as to suggest, for example, that public office is being used for private gain, 5 C.F.R. § 2635.801(c); that the bribery or illegal gratuities statute is implicated, 18 U.S.C. § 201; or that a salary supplementation for performing official duties has been proffered, 18 U.S.C. § 209. Moreover, non-career Senior Executive Service employees who pursue outside activities are subject to an annual compensation limitation, currently \$23,550, under 5 C.F.R. § 2636.304.

Feb-04-04 04:40pm From:2026905351

2026905351

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Page 2 - Deputy Ethics Counselors

This change is effective immediately, and all internal agency procedure or process statements, policies, or manuals used within the respective operating and staff divisions for handling HHS 520s shall be amended to comply with this directive. Copies of these amendments shall be filed with the DAEO on or before February 17, 2004.

Thank you for your cooperation in implementing this requirement. If you have any questions, please call the Ethics Division at (202) 690-7258.

cc: Deputy General Counsels
Associate General Counsels
Chief Counsels, Regions I-X



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

JUL 17 2003

TAB 5

The Honorable W.J. "Billy" Tauzin
Chairman, Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The Office of the General Counsel at the Department of Health and Human Services prepared the enclosed legal analysis in response to the issues raised by your June 26 letter regarding the receipt of lecture awards by NIH employees.

I would like to meet with both you and Mr. Greenwood at your earliest convenience to discuss this legal analysis and work together to address your concerns about policies regarding NIH personnel accepting lecture awards.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Zerhouni", written over a horizontal line.

Elias A. Zerhouni, M.D.
Director

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

JUL 17 2003

The Honorable James C. Greenwood
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Greenwood:

The Office of the General Counsel at the Department of Health and Human Services prepared the enclosed legal analysis in response to the issues raised by your June 26 letter regarding the receipt of lecture awards by NIH employees.

I would like to meet with both you and Mr. Tauzin at your earliest convenience to discuss this legal analysis and work together to address your concerns about policies regarding NIH personnel accepting lecture awards.

Sincerely,

A handwritten signature in black ink, appearing to read "Elias A. Zerhouni".

Elias A. Zerhouni, M.D.
Director

Enclosure

605

**NATIONAL INSTITUTES OF HEALTH
OFFICE OF LEGISLATIVE POLICY AND ANALYSIS**

Fax Transmittal
Shannon Building, Room 244
(301) 496-3471
FAX: (301) 496-0840

DATE: 7/17/03

TO: Alan Slobodan

FAX PHONE: 202-225-1919

FROM: Marc Amolowsky

SUBJECT: Responses to Reps. Tauzin and Greenwood

This transmittal contains 15 pages, including the cover sheet.

COMMENTS:

NOTE: The attached information may be confidential. It is intended only for the addressee(s) identified above. If you are not the addressee(s), or an employee or agent of the addressee(s), please note that any dissemination, distribution or copying of the communication is strictly prohibited. If you have received this fax in error, please destroy the document and notify the sender of the error. Thank you.

ANALYSIS OF ETHICS AND RELATED ISSUES CONCERNING THE RECEIPT OF
LECTURE AWARDS BY NATIONAL INSTITUTES OF HEALTH EMPLOYEES

This analysis addresses the issues raised in a letter dated June 26, 2003, from the House Committee on Energy and Commerce concerning the implementation of ethics requirements relating to prizes or lecture awards given to National Institutes of Health (NIH) officials and employees in recognition of meritorious public service or achievement.

The need to protect the public interest by ensuring that government decisions are not influenced by "kick backs" or rewards for official action is addressed principally by federal criminal statutes that proscribe bribery and illegal gratuities tied to official acts. 18 U.S.C. §§ 201(b)(2) and 201(c)(1)(B). Where an employee's actions fall short of criminal conduct, the concern about avoiding an "appearance of impropriety" is governed by detailed ethics standards against which the employee's conduct can be judged on an objective basis. 5 C.F.R. Part 2635.

At present, no law expressly bars an agency or component head from receiving a *bona fide* award from an outside entity merely because the donor is regulated by, does or seeks to do business with, or seeks official action from the agency or component that the intended honoree administers. The statutory ban on salary supplementation, 18 U.S.C. § 209; the regulatory bar on the receipt of compensation for speeches related to official duties, 5 C.F.R. § 2635.807; and the executive order that prohibits Presidential appointees to full-time, non-career positions from receiving "any earned income for any outside employment or activity," E.O. 12674, § 102(a), (April 12, 1989), are not applicable because the Department of Justice and the Office of Government Ethics have determined that *bona fide* awards, including the cash incident to such awards, are to be treated as *gifts* in recognition of meritorious public service or achievement rather than as *compensation* or *earned income* for delivering the speech that is routinely expected of the honoree at the award presentation.

Award Approval Standard. Gifts to executive branch employees are governed by 5 U.S.C. § 7353, which bars the solicitation or acceptance of anything of value from persons or entities defined as prohibited sources, subject to such reasonable exceptions as the supervising ethics office for the executive branch, by regulation, deems appropriate. The Office of Government Ethics implemented this statute in the Standards of Ethical Conduct for Employees of the Executive Branch at 5 C.F.R. Part 2635, Subpart B. These rules expressly permit employees to accept *bona fide* awards and cash incident thereto from most prohibited sources, e.g., contractors, grantees, regulated entities, applicants for governmental action, etc., including organizations a majority of whose members are of the enumerated type, *provided* that the award is determined by agency ethics officials to be part of an established program of recognition, as defined in regulatory criteria. 5 C.F.R. § 2635.204(d)(1). This exception to the prohibited gifts rule is unavailable, however, if the awarding entity is a special type of prohibited source, i.e., a person or entity who "has interests that may be substantially affected by the performance or nonperformance of the [award recipient's] official duties."

Interpretation of the Standard. The Office of Government Ethics has not formally opined on the meaning of the above quoted phrase. Although frequently cited by OGE when recounting the definition of a prohibited source, the phrase has not been the subject of detailed discussion. Commentary, where available, has tended either to elide over any distinctions among the various types of prohibited sources, conflate the concepts, or assume without analysis that a given donor had interests that could be affected substantially by the employee in discharging his official duties. See OGE 83 x 10 (July 26, 1983) ("you (referring to the addressee of the opinion letter) have stated that [the company] has interests which may be affected by the performance or non-performance of the duties of [the employee]") (applying rule then effective at 5 C.F.R. § 735.203(e)(3) which permitted acceptance of awards for a "meritorious public contribution or achievement" only if offered by organizations within enumerated civic, public, or eleemosynary categories). Absent specific OGE guidance, the interpretation utilized within the Department was premised on a detailed, internal analysis of the regulatory text, the substance of which is recounted below.

History and Analysis of Regulatory Text. The language currently found in the prohibited source definition at 5 C.F.R. § 2635.203(d)(4) and the awards exception at 5 C.F.R. § 2635.204(d)(1) can be traced to § 201(a)(3) of E.O. 11222 (May 11, 1965), the predecessor to E.O. 12674. The Civil Service Commission issued implementing regulations that incorporated the phrase in a prohibited gifts rule then codified at 5 C.F.R. § 735.202. When E.O. 12674 supplanted the Johnson Administration directive in 1989, the same phrase was carried forward in § 101(d) of the order and used by Congress in drafting the provisions of the gift statute, 5 U.S.C. § 7353. The OGE Standards at 5 C.F.R. § 2635.203(d) (1992) again restated the phrase by defining a "prohibited source" to include a person or entity who "has interests that may be substantially affected by the performance or nonperformance of the employee's official duties."

When drafting the *bona fide* awards rule for the 1992 executive branch-wide standards, OGE rejected the approach taken in the earlier conduct regulations which permitted acceptance of awards only from "a charitable, religious, professional, social, fraternal, nonprofit educational, recreational, public service, or civic organization." 5 C.F.R. § 735.203(e)(3) (1991). The new OGE Standards were designed to allow acceptance of all *bona fide* awards offered under an established program of recognition for meritorious public service or achievement, *provided* that the donor does not have "interests that may be substantially affected by the performance or nonperformance of the [award recipient's] official duties."

Without realizing that this provision contextually is an exception to a ban on gifts from prohibited sources, the reader might assume, after a cursory examination, that the prohibition on receiving awards from entities that have "interests that may be substantially affected by the performance or nonperformance of the employee's official duties" means that federal employees cannot accept *bona fide* awards from contractors, grantees, and regulated entities that have matters pending before their agency. As a matter of semantic logic, however, this is not the rule that OGE promulgated. Interpreting the quoted phrase simply to equate "those persons who have interests that the award recipient can affect substantially," on the one hand, with "contractors,

grantees, and regulated entities," on the other, would yield the tautological formulation that an employee is permitted to accept an award from a "prohibited source," provided that it is not from a "prohibited source." The caveat to the exception to the prohibition perform must have a different meaning.

To ascribe meaning to the provision and avoid the tautology, an entity that "has interests that may be substantially affected by the performance or nonperformance of the employee's official duties" must be a special type of prohibited source, i.e., one that poses potentially severe appearance problems, not one that merely is seeking official action by, does business or seeks to do business with, or conducts activities regulated by the employee's agency.

In assessing whether the award donor is the special type of prohibited source, a parsing of the regulatory text suggests several inquiries. First, from the use of the present tense verb in the phrase "has interests," one may infer that the intended award recipient must ascertain whether, at the time of the acceptance of the award, the offeror then presently has any interests arising out of pending controversies or other matters, beyond the general fact that the entity receives grants or contracts or is regulated by the agency. In essence, the regulation suggests a temporal qualifier. Drawing on the parallel provision governing honorary degrees, timing would appear to be a significant factor. See 5 C.F.R. § 2635.204(d)(2) (honorary degree from a university may be accepted if the timing of the award of the degree would not cause a reasonable person to question the employee's impartiality in a matter affecting the institution). The text suggests a bright line, snap shot focus on the situation at the time of acceptance of the award. If the offeror had pending matters in the past and may have them in the future, then the offeror would simply be a "garden variety" prohibited source from which *bona fide* awards legitimately could be accepted.

Given the otherwise circular logic of a contrary interpretation, the text leads one to conclude that the rule forbids *bona fide* awards in circumstances where there is "something on the official's plate," e.g., where grant application papers are on the desk for approval, or allegations of impropriety have arisen and the official must decide to order an investigation. Awards tendered when the official knows, or has reason to believe, that such matters are pending elsewhere in the agency, but will reach his or her "in-box" in the reasonably foreseeable future, would be similarly proscribed. Conversely, mere speculation that such matters might arise in the future would appear insufficient to bar the award.

The next inquiry suggested by the regulatory text involves the nature of the employee's official duties. The phrase refers to entities that have interests that may be substantially affected by the *performance or nonperformance of the employee's official duties*. The rule is not drafted so as to refer to entities that have interests that may be substantially affected by *matters to which the employee is assigned or for which the employee has official responsibility*. Thus, to ascertain whether the award recipient can substantially affect a pending matter through action or omission (as opposed to merely possessing ultimate authority), the reviewer would inquire whether the duties of the position normally encompass handling the types of matters that are pending? For example, a key question would be whether final sign-off authority on a pending grant application

previously had been assigned to another agency official under a pre-existing delegation. If, as an organizational matter, the intended award recipient normally is uninvolved in the quotidian details of grants administration, then the pendency of a grant matter within the agency would render the donor a mere "prohibited source" as to the intended award recipient. (An employee would not be permitted, of course, to accept an award if the employee, after learning of the award, purposely delegated or reassigned work to avoid responsibility for the pending matter.)

The regulatory language also requires an assessment whether the actual exercise of the official duties assigned to the position would *substantially* affect the identified pending interests of the award donor. For example, ministerial acts carrying out decisions mandated by law or effectuating completed decisions made by others or rendered prior to tender of the award might not be deemed by themselves to have affected substantially the resolution of a pending matter. On the other hand, actually making the final decision, no matter how perfunctory the review, would be of significance to the matter. Moreover, in order to "substantially affect" the offeror's interests, the text suggests that an employee's exercise of assigned duties must have more than a *de minimis* impact on the interest involved. For example, a decision on a general regulation that modestly increases paperwork for all grantees might not have a substantial impact on any one grantee, depending on all the circumstances.

Status or Position. The inquiries suggested by the regulatory text apply equally to all employees. The text does not appear to warrant applying a different rule for agency or operating division heads. The Office of Government Ethics, as the author of the regulation, clearly knew how to treat certain classes of employees differently, often by employing extremely complex definitional criteria (e.g., outside earned income limitations in 5 C.F.R. § 2636.303 are expressly applicable to Presidential appointees in positions classified above GS-15 of the General Schedule or, in the case of positions not under the General Schedule, for which the rate of basic pay is equal to or greater than 120 percent of the minimum rate of basic pay for GS-15, that are either: (1) appointees paid under the Executive Schedule, 5 U.S.C. §§ 5311-5318; (2) non-career appointees to the Senior Executive Service; or (3) confidential or policy-making Schedule C equivalents; *see also* 5 C.F.R. § 2641.201 which defines "senior" and "very senior" employees for purposes of the post-employment prohibition, 18 U.S.C. § 207, on representational contacts to the employee's former agency, known as the one-year "cooling-off" period). Given that the awards rule is not similarly crafted, the omission of any qualifying language relating to status or position has interpretive significance. *See Rusello v. United States*, 464 U.S. 16, 23 (1983), *citing United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972) ("where Congress [or other legislative or regulatory body] includes particular language in one section of a statute [or regulation] but omits it in another section of the same [law], it is generally presumed that [the drafter] acts intentionally and purposely in the disparate inclusion or exclusion").

One example that demonstrates an application of the awards rule is that employees in a division or unit of an agency whose official duties are not concerned with grants could accept a *bona fide* award from a grantee, albeit a prohibited source as to the agency as a whole, because their assigned work will have no impact on the grantee. However, nothing in the regulatory text

suggests that this situation is the only one to which the awards exception would apply. Moreover, because the employees in this example do not have official responsibility for grants as a general proposition, there never would be a circumstance in which a grant matter would be placed before them for deliberation. Thus, the example provides no interpretive assistance in resolving the fundamental dichotomy between a view that equates the dispositive phrase with the mere possession of superintending responsibility for matters handled by others and an interpretation, based on the foregoing analysis of the regulatory text, that inquires whether the employee actually, rather than derivatively through status or position, has matters pending before him for imminent disposition.

Without recapitulating the circular nature of the former interpretation, it suffices in support of the latter to underscore that if OGE had intended to write a rule that prohibited agency or component heads from receiving awards from entities that have, or may have, matters pending under their official responsibility, either individually or before subordinates, it need have looked no further for operative language than its own regulations implementing the predecessor to 18 U.S.C. § 207(a)(2), the two-year "official responsibility" ban on post-employment representation, and the definitions in 18 U.S.C. § 202. See 5 C.F.R. § 2637.202(b) ("official responsibility" is defined as "the direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct Government actions") .

Nobel Prize Paradigm. An example in the OGE Standards following 5 C.F.R. § 2635.204(d)(1) is often cited for the basic proposition that *bona fide* awards can be accepted by federal employees:

Example 1: Based on a determination by an agency ethics official that the prize meets the criteria set forth in § 2635.204(d)(1), an employee of the National Institutes of Health may accept the Nobel Prize for Medicine, including the cash award which accompanies the prize, even though the prize was conferred on the basis of laboratory work performed at NIH.

In the context of evaluating awards tendered by prohibited sources, this example provides no interpretive assistance. Rarely, if ever, would the Nobel Foundation have matters pending before the NIH or any other agency of the United States Government. The import of the example is twofold: (1) to demonstrate that a monetary award can be accepted by the NIH employee even though medical research and science are, in a broad sense of the word, "interests" of the Nobel Selection Committee which are affected by his work; and (2) to emphasize that *bona fide* awards that are tied directly to accomplishments in the federal workplace are permissible gifts and not compensation, within the meaning of the salary supplementation ban, 18 U.S.C. § 209, for services rendered to the NIH.

Appearance of Impropriety. Recourse to the aspirational principle that employees shall endeavor to avoid even the appearance of impropriety, enunciated in E.O. 12734, § 101(n), and restated in

the OGE Standards at 5 C.F.R. § 2635.101(b)(14), is equally unavailing for interpretive purposes. The awards exception to the prohibited gifts rules, like the other exceptions contained in 5 C.F.R. § 2635.204, was drafted by OGE in such a way that "the exception itself addresses major appearance concerns." 57 Fed. Reg. 35006, 35012 (August 7, 1992). Some may consider it imprudent—as a matter of personal moral standards or simply to avoid an adverse "perception" under the often cited "front page of the *Washington Post*" test—to accept an award offered by a prohibited source. Nevertheless, according to OGE, acceptance of a *bona fide* award under the exception is "deemed not to violate" the ethical principles upon which the Standards are premised, including appearances. 5 C.F.R. § 2635.204. The impetus for drafting detailed, even admittedly legalistic, conduct rules was precisely to place reasonable and intelligible limits on the potentially boundless scope of an "appearance" standard that invites inconsistent and subjective interpretation.

Awards Form. The interpretation and evaluative factors discussed above for determining whether an awarding entity "has interests that may be substantially affected by the performance or nonperformance of the [award recipient's] official duties" were disseminated department-wide to the Deputy Ethics Counselors in the operating divisions and other agency components in 1998. An award approval form was developed which: (1) educates potential award recipients concerning the applicable law; (2) places a burden on the applicant to evaluate seriously those matters that are pending before him; (3) requires the applicant to attest to the factual circumstances at issue; (4) focuses the attention of the reviewers to each element of the regulatory requirements; and (5) provides written documentation of the disposition of the approval request.

To the extent that the approval form leads one to conclude that awards are permitted solely on self-certification, that impression is incorrect. Ethics officials evaluate the criteria within their purview on a case-by-case basis. However, it would be impractical for reviewers in effect to "look over the shoulder" and "cast an eye" on the desk of every award applicant to learn at any given moment what assignments or matters were before them. Accordingly, the form does rely to a significant degree on the applicant's truthfulness and good faith. Absent a significant increase in administrative resources for agency ethics programs, this procedure would appear to be the only alternative.

Safe Harbor. Turning specifically to Dr. Richard Klausner's situation, he was individually advised of the factors used to evaluate whether the awarding entity "has interests that may be substantially affected by the performance or nonperformance of [his] official duties." On each awards form, he attested to the fact that no such matters were pending at the time of the award or in the foreseeable future. In making his certification, he would have been permitted to rely on the interpretive factors disseminated within the Department. The fact that Dr. Klausner presided over a grant-making entity in and of itself would not have been disqualifying under the interpretation rendered at that time. Unless Dr. Klausner was untruthful or failed to disclose to the ethics officials all relevant circumstances, the award approval by the Designated Agency Ethics Official (DAEO) or the DAEO's authorized representatives provides a safe harbor under

which Dr. Klausner could not be disciplined, were he an employee, or otherwise be deemed to have violated the ethics rules. 5 C.F.R. § 2635.107(b).

Recusal. Recusals can be required if there is an actual conflict of interest under the criminal statute, 18 U.S.C. § 208, or an “appearance of a conflict” resulting from, *inter alia*, a “covered relationship,” as defined in the impartiality standard, 5 C.F.R. § 2635.502. In the award situation, an employee arguably has a financial interest in receiving the money incident to the award. However, given the donative, as opposed to contractual, context, the prospective award recipient may not have a legal right to the funds that is sufficient to create a financial interest within the meaning of section 208. Nevertheless, assuming for purposes of argument that the statute applies, a recusal obligation would arise only with respect to official participation in a particular matter that would directly and predictably affect the ability of the donor to meet its financial commitment to pay the funds. Rarely would such a matter exist; essentially, the matter would have to send the donor into bankruptcy for the recusal to apply. Accordingly, the criminal conflict of interest statute generally is not implicated in the awards context.

The employee’s interest in receiving an approved monetary award, however, does create a “covered relationship” with the awarding entity within the meaning of 5 C.F.R. §§ 2635.502(a) and (b)(1)(i) (a financial relationship that involves other than a routine commercial transaction). During the pendency of any outstanding payments or travel reimbursement that are incident to the award, employees are required to recuse from official participation in any particular matter involving specific parties in which the awarding entity is a party or represents a party, if a reasonable person with knowledge of the relevant facts likely would question the employee’s impartiality in the matter. Notably, this recusal obligation applies only to “specific party matters,” such as contracts, grants, audits, investigations, lawsuits, or similar matters that involve identified parties, and not to “particular matters of general applicability,” such as legislation, regulations, policies, or other general matters that are focused on the interests of a discrete and identifiable class of persons. Moreover, the recusal obligation exists only during the pendency of the “covered relationship” that initially engendered the disqualification. Recusals triggered by awards last only from the time the employee receives notification of the award until such time as any and all financial transactions associated with the award are completed. Receiving an award and delivering a speech at the event do not constitute employment or consultation and hence do not create a “covered relationship” within the meaning of 5 C.F.R. § 2635.502(b)(1)(iv), the provision that imposes a one year retrospective inquiry when determining the duration of a recusal as to specific party matters involving only the relationships enumerated therein. In other words, there is no legal basis to impose a one year recusal following the receipt of an award.

As noted previously, by regulation, employees do have a narrow recusal obligation as to specific party matters involving the donor as a party or party representative during the pendency of the award. Employees may choose to memorialize in writing their obligation to disqualify themselves from certain matters. Recusal documents executed by federal officers or employees do not represent “admissions” by those employees that matters involving the entity named therein are presently pending before the signatory, and they should not be interpreted as such. Recusal

memoranda represent only an employee's written memorialization of his obligation to recuse. There is no requirement that such writing be prepared. *See* 5 C.F.R. § 2635.402(c) ("disqualification is satisfied by not participating in the particular matter"). Rather, certain employees choose to prepare recusal memoranda for two basic purposes: (1) to communicate to staff that *if* matters involving or affecting the named entity arise that normally would come to the signing official, they should be diverted to an alternate; and (2) to alert the official who would instead receive the matter (but who, otherwise, would not) as to the basis for the change in processing so that government business is not delayed unnecessarily. To avoid confusion and delay, and for the protection of the employee and the integrity of agency programs and operations, an employee's obligation to recuse is addressed, to the extent possible, *before* matters arise.

Travel. Under the authority of 31 U.S.C. § 1353 and the implementing regulations of the General Services Administration (GSA), 41 C.F.R. Part 304-1 (citations are to regulations in effect prior to June 16, 2003, when the new "plain English" version codified at 41 C.F.R. Parts 304-1 through 304-9 became effective; *see* 68 Fed. Reg. 12602), agencies are permitted to accept payment from a non-federal source for the travel, subsistence, and related expenses of a government official to attend, while in travel status, "any meeting or similar function relating to the official duties of the employee." 41 C.F.R. § 304-1.2. Meetings and similar functions are defined to include "[a]n event at which the employee will receive an award or honorary degree, which is in recognition of meritorious public service that is related to the employee's official duties, and which may be accepted by the employee consistent with the standards of conduct regulation." 41 C.F.R. § 304-1.2(c)(3)(iii).

Although an award is based on individual achievement and considered a personal gift governed by the OGE Standards, any travel benefits associated with the award that are provided by non-federal sources to the agency under authority of 31 U.S.C. § 1353—whether provided in kind or through reimbursement—are deemed gifts to the agency and not to the employee personally. As such, acceptance of travel, lodging, meals, and other subsistence expenses from non-federal sources are submitted for advance approval on an HHS Form 348. The Department reports these payments on a semi-annual basis to OGE. 41 C.F.R. § 304-1.9. Employees who file financial disclosure reports are obligated only to report travel gifts and reimbursements personally received by them during the reporting period. Where, as may be the case of official travel to an award event, the agency accepts the payment, employees are not required to disclose separately the reimbursement on their own financial disclosure reports. *See* 5 C.F.R. § 2634.105(n)(3) note and § 2634.304(c).

Agencies generally are required to assess whether acceptance of a non-federal source payment for travel would cause an informed, reasonable person to question the integrity of agency programs or operations. This analysis is guided by a non-exclusive list of relevant considerations, such as (1) the monetary value and character of the tendered benefits; (2) the identity of the parties; (3) the nature and sensitivity of any pending matter affecting the interests of the payor; and (4) the significance of the traveling employee's role in the matter. 41 C.F.R. § 304-1.5. When

this regulation was initially promulgated, GSA specified in the explanatory preamble that the rule was not intended to bar agency acceptance of payment from non-federal sources merely because such entities were “prohibited sources” within the meaning of the OGE Standards applicable to gifts to employees. 57 Fed. Reg. 53283, 53286 (November 9, 1992). Rather, the rule was meant to preclude agency acceptance of travel reimbursement from a contractor, grantee, or regulated entity when a request for agency action or other matter involving that entity *as a party* is pending and the traveler is the very official before whom the matter is lodged for disposition. *Id.* Thus, the GSA travel reimbursement rule evaluates whether the traveling employee’s actual exercise of official authority with respect to an extant matter involving the payor is sufficiently proximate in time and organizational location within the agency decision-making process to warrant denial of the reimbursement. This analysis is similar to that under the awards rule, but it is more permissive in that acceptance is precluded only when those pending matters are of the “specific party” variety and involve the payor as a party.

The comments section to the GSA rulemaking document contains several examples that illustrate the various distinctions in the travel reimbursement context:

[W]e did not amend the rules to prohibit acceptance of payment from a “prohibited source,” as suggested by at least one comment. ... In the case of official travel that the agency determines to be in furtherance of its mission, we do not believe that acceptance of payment should be precluded solely on the basis that the non-Federal source seeks official action on some matter from someone at the agency. Thus, in connection with an Army Assistant Secretary’s speech on the topic of reductions in force, given at an Army contractors’ convention, we do not believe that the agency’s acceptance of payment from the contractor should be precluded solely because the non-Federal source happens to have a contract with some component of the Army. ... [P]ayment [should not be accepted] from the company if the Assistant Secretary was then serving as the source selection official for a procurement involving that contractor as a competitor. ... On the other hand, it might be appropriate for the National Institutes of Health to accept a large pharmaceutical association’s offer to fund a scientist’s trip to a conference on AIDS even if the scientist was at the time performing experiments in relation to a promising new drug developed by a company that belongs to the association. Similarly, acceptance of payment from a trucking industry association might be authorized in the case of a Department of Transportation attorney who is asked to address the association concerning the interpretation of a regulation that he/she drafted and that is applicable to the entire industry.

57 Fed. Reg. 53286-53287.

The GSA regulations also expressly provide that “nothing in ... part [304-1] prohibits an agency or employee from accepting payment ... when consistent with the applicable standards of ethical conduct regulation concerning personal acceptance of gifts.” 41 C.F.R. § 304-1.8(a).

Accordingly, if the awards rule in the OGE Standards permits the employee to accept the underlying honor and monetary reward, then the agency derivatively may accept the travel-related benefits incident thereto, without the need to evaluate separately the factors specified in section 304-1.5 (although the analysis required under the latter cited rule parallels that of the former to a significant degree).

In the case of lecture awards offered to NIH officials based upon their meritorious public service or other achievement, their receipt of the award and participation in the award event is, as noted in the travel reimbursement regulations, deemed to be related to their official duties. This nexus or "relatedness" permits agencies to authorize the honoree to attend in a government travel status and, when delivering the lecture, to speak in his or her official capacity about agency business. Although the honor and any money incident to the award are personal in nature and premised on meritorious public service or achievement already accomplished, the travel rule recognizes that the award lecture provides an opportunity for the dissemination of an official message to appropriate audiences.

Interpretative Options. The issue of whether the awards rule could be interpreted differently to apply a more rigorous standard for future application to agency or component heads ultimately is a matter for OGE deliberation. Given the concerns raised about this issue, OGE may well choose a different approach. Neither the Department nor NIH can resolve definitively the interpretive issue posed. By way of background, the relevant authorities and jurisdiction are recounted below.

Following recommendations of the President's Commission on Federal Ethics Law Reform, President George H. W. Bush issued the seminal ethics directive, E.O. 12674, that established the framework for evaluating the conduct of federal employees. The Office of Government Ethics was ordered to formulate a uniform set of ethical standards for the entire executive branch, thereby preempting the field of agency regulation of employee conduct. The Standards of Ethical Conduct for Employees of the Executive Branch, 5 C.F.R. Part 2635, promulgated on August 7, 1992, and made effective on February 3, 1993, were the result.

Federal departments and agencies were authorized to issue, jointly with OGE approval, supplemental ethics regulations to establish prior approval procedures for outside activities, to impose prohibited financial holdings requirements, and to address ethics issues unique to the programs and operations of the respective agencies. However, to ensure executive branch uniformity with respect to the core ethics requirements, OGE does not permit agencies unilaterally to impose ethics requirements that are more restrictive than the OGE Standards. For example, the OGE gift rules provide that an employee can accept a gift from a prohibited source valued at \$20 or less. The Department and NIH are bound by this exception and cannot impose an inconsistent policy that reduces the dollar threshold to zero if the Department or NIH were so inclined. In assessing the propriety of accepting awards from an outside source, both the Department and NIH are similarly required to implement the OGE rules as interpreted by duly authorized ethics officials, until such time as OGE revises the regulation or provides definitive guidance.

Although instituting an NIH policy banning "lecture awards" *per se* might have the salutary effect of removing any perception whatsoever that the recipient has been or may be influenced by the donor, agencies are not permitted to prohibit that which the OGE Standards may permit. Moreover, even if NIH were afforded such latitude, the costs in terms of recruitment and retention of eminent scientists at the NIH may be considerable. NIH scientists assert an important governmental interest in receiving recognition for contributions to medical research or other meritorious public service or achievement and in being offered the opportunity to deliver prestigious lectures associated with these honors. Apart from employee morale, the enhanced credibility and standing of NIH scientists before their peers in academia advances considerably the interests of the Government in demonstrating leadership in scientific research, disseminating critical information to appropriate audiences, and attracting the most qualified scientists to public service. That monetary stipends attach to many lecture awards is considered a recognized and permitted practice within the research community.

Prudential Concerns. That said, as the OGE gift rules cogently state, "[e]ven though acceptance of a gift may be permitted by one of the exceptions ..., it is never inappropriate and frequently prudent for an employee to decline a gift offered by a prohibited source or because of his official position." 5 C.F.R. 2635.204. The various awards for Dr. Klausner were approved, either under the signatures of the DAEO or those of Deputy Ethics Officials acting under his authority. The approvals were based on factual information, to which the applicant attested, regarding whether matters involving the donor were presently or imminently before the applicant for disposition. Supporting documentation, as appropriate, was reviewed to verify that the awards were made "as part of an established program of recognition: (1) under which awards have been made on a regular basis or which is funded, wholly or in part, to ensure its continuation on a regular basis; and (2) under which selection of award recipients is made pursuant to written standards [or a selection committee]. 5 C.F.R. § 2635.204(d)(1) (the bracketed phrase is an interpretive gloss approved by OGE whereby the evaluation of candidates by a selection committee may provide the functional equivalent of written standards). The reviewers approved awards in technical compliance with the criteria and in accordance with the extant legal interpretation inasmuch as employees have the right to have their conduct judged against objective criteria. Dr. Klausner was counseled concerning the precise legal nature of the approval. Employees are routinely advised whether their proposed conduct is legally permissible, but each individual remains ultimately responsible for assessing whether adverse public perception or the potential for controversy would counsel against accepting that which the law may permit.

July 11, 2003



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

TAB 6

FILE

*Klausner: this*National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

October 1, 1996

TO: Richard Klausner, M.D., Director, NCI

FROM: Maureen O. Wilson, Ph.D., Deputy Ethics Counselor, NCI

SUBJECT: Recommendation Regarding the Dickson Prize

I have reviewed the situation surrounding the Dickson Prize offered by the University of Pittsburgh and addressed to you as Chief, Cell Biology and Metabolism Branch, NICHD. It is my recommendation that you decline acceptance of the award based on the reasons below.

The University of Pittsburgh is a grantee, contractor and cooperative group trial participant funded by the NCI. Under these circumstances, the University is clearly a prohibited source as defined by the Office of Government Ethics Standards of Conduct at 5 CFR 2635.203 (d):

...any person who:

- (1) *Is seeking official action by the agency;*
- (2) *Does business or seeks to do business with the agency;*
- (3) *Conducts activities regulated by the agency;*
- (4) *Has interests that may be affected by the performance or nonperformance of the employee's official duties;*

This is reaffirmed in the Supplemental Standards of Conduct for Employees of the Department of Health and Human Services issued July 30, 1996 at 5 CFR 5501.102 which redefines prohibited sources to represent those persons or organizations doing business at the NIH level. The NIH Manual 2300-735-4 on "Outside Work, Financial Interest and Related Activities," also clearly states that it is NIH policy not to accept awards from organizations, the interests of which may be affected by the performance or non-performance of an employee's official duties.

Although you, as Director, NCI, do not actually sign either grants or contracts, you are the ultimate responsible party for all of the Institute's activities, unless you have disqualified yourself from matters involving a specific party. Because the Institute is currently a co-defendant with the University in a suit brought by Dr. Bernard Fisher, it

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Page 2 - Richard Klausner, M.D.

would be inappropriate for you to be disqualified from dealing with the University of Pittsburgh. Therefore, it is difficult for you to accept the award in your official capacity and it is clearly inappropriate for you to accept the award as an outside or personal activity as the University both does business with us and is seeking action from the Institute and thus, from you as its director.


Maureen O. Wilson, Ph.D.

cc: Dr. Kirschstein, Deputy Director and DEC, OD, NIH

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DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health

TAB 7

Maureen O. Wilson, Ph.D.
 Assistant Director
 Deputy Ethics Counselor
 NCI, NIH, DHHS
 31 Center Drive
 Building 31, Room 3A18
 Bethesda, Maryland 20892-2440
 Phone: 301-496-1148
 FAX: 301-403-1508
wilsonm@mail.nih.gov

August 20, 2003

MEMORANDUM

TO: Anna Barker, Ph.D.
 Deputy Director for Strategic Initiatives, NCI, NIH, DHHS

FROM: Maureen O. Wilson, Ph.D.
 Deputy Ethics Counselor, NCI, NIH, DHHS

SUBJECT: Conflict of Interest Review: Lance Liotta, M.D./HHS-520 Biospect

ISSUE

The purpose of this memorandum is advise your office regarding any real or apparent conflict of interest with Dr. Liotta's duties and responsibilities in regard to CRADA 01403 with Correlologic Systems, Inc., that may created by his personal financial interests in a approved outside consulting relationship with Biospect Inc.

DISCUSSION

The Department of Health and Human Services Supplements to the Office of Government Ethics Standards of Ethical Conduct for Employees of the Executive Branch requires that approval be granted in response to a request for outside employment activity under the following conditions:

1. The request is submitted prior to the beginning of such an activity; and
2. Unless it is determined the outside employment activity or other outside activity is expected to involve conduct prohibited by statute or Federal regulation.¹

In considering the statutory and regulatory aspects of Dr. Liotta's request to consult for Biospect, it first must be determined whether the activity constitutes a compensated professional outside

¹5 CFR § 5501.106(d)(4) Standard for Approval. Approval shall be granted unless it is determined that the outside employment or other outside activity is expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part (5 CFR Part 5501).

August 20, 2003

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employment related to the preparation of grant applications or contract proposals of other reports of documents intended for submission to HHS² or employment in HHS-funded activities.³ Since the nature of the consultative services requested are limited in the request, deemed to be purely advisory to Biospect, and unrelated any HHS matter, these consultative services do not violate regulation at 5 CFR § 5501.106.

5 CFR § 2635.802 requires that outside employment not conflict with an employee's official duties. 5 CFR 2635.807 requires that such employment not deal in significant part with "*any matter to which the employee presently is assigned or to which the employee had been assigned during the previous one year period*". Senior scientific staff, Dr. J. Carl Barrett, Director, Center for Cancer Research (CCR), NCI, NIH, has confirmed that the work contemplated by Biospect consultancy was and continues to be separate and distinct from Dr. Liotta's official duties under the Correlologic Systems CRADA. Further, Dr. Douglas Lowy determined in December of 2002 and Dr. Barrett has reconfirmed that Dr. Liotta could and can continue to be disqualified from all matters that would affect Biospect in his official duty capacity without diminishing his usefulness to the government.⁴ The Biospect consulting activity was approved on December 17, 2002, as satisfying these conditions; re-review of the activity by Dr. Barrett has reached the same conclusions (See attachment).

Further, this office, review of Dr. Liotta's personal financial relationship with Biospect for inherent conflict of interest with his official duties involving Correlologic Systems, finds the conditions required for such conflict, as defined under 18 USC 208(a), are not met. Conflict of interest exists when an employee engages, as part of his official duties, in a particular matter in which:

...he, his spouse, minor child, partner, organization in which he is serving as officer, director, trustee, partner or employee, or any person organization which whom is negotiating or has any arrangement concerning prospective employment, has a financial interest.

Under contract signed with Biospect, Dr. Liotta is explicitly named as a consultant and not considered an employee. Biospect is not a party to the Correlologic Systems CRADA nor does it have a financial interest, as defined by statute, in the CRADA. Hence, there can be no statutory

²5 CFR § 5501.106(c)(1) An employee shall not provide consultative or professional services, for compensation, to or on behalf of any other person to prepare, or assist in the preparation of, any grant application, contract proposal, program report, or other document intended for submission to HHS.

³5 CFR § 5501.106(c)(2) An employee shall not, for compensation, engage in employment, as defined in 5 CFR § 2635.602(a), with respect to a particular activity funded by an HHS grant, contract, cooperative agreement, cooperative research and development agreement, or other funding mechanism authorized by statute.

⁴5 CFR 2635.802 An employee shall not engage in outside employment or any other outside activity that conflicts with his official duties...if it would require the employee's disqualification from matters so central or critical to the performance of his official duties that the employee's ability to perform the duties of his position would be materially impaired.

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conflict of interest found between Dr. Liotta's outside employment with Biospect and his official duties involving Correlogic Systems.

Regulatory appearance of conflict of interest requires that a Federal employee be personally and substantially involved in his official capacity, in a particular matter, involving specific parties with whom he has a covered relationship. A covered relationship is defined at 5 CFR 2635.502(b) to be a personal relationship with:

1. A person, other than a prospective employer...with whom the employee has...a business, contractual or other financial relationship that involves other than a routine consumer transaction;
2. A person who is member of the employee's household, or is a relative with whom the employee has a close personal relationship;
3. A person for whom the employee's spouse parent or dependent child is, to the employee's knowledge, serving, or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant contractor or employee;
4. A person for whom the employee has, within the last year served as officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee;
5. An organization...in which the employee is an active participant.

Biospect is not a party to the Correlogic Systems CRADA; none of Dr. Liotta's relatives or members of his household are involved in the CRADA; none of the aforementioned are serving or seeking to serve as employee, etc. for Correlogic; Dr. Liotta is not an active participant, other than in his Federal capacity, to the Correlogic CRADA; and he has not served, except in his official capacity, as a consultant for Correlogic Systems. There is no apparent conflict of interest inherent in Dr. Liotta's participation in the Correlogic Systems CRADA

CONCLUSIONS:

There is neither statutory conflict of interest nor appearance of conflict of interest found between Dr. Liotta's personal financial interests embodied by his paid Biospect consultancy and his official duties relating to the Correlogic's Systems CRADA. However, because the issue of Dr. Liotta's ability to be impartial with regard to the Correlogic Systems CRADA, has been raised, Federal procedure requires that the following factors also be taken into consideration:

1. The nature of the relationship involved;
2. The effect that resolution of the matter would have upon the financial interest of the person involved in the relationship;
3. The nature and importance of the employee's role in the matter, including the extent to which he is called upon to exercise discretion in the matter;
4. The sensitivity of the matter;
5. The difficulty of reassigning the matter to another employee; and
6. Adjustments that may be made in the employees duties that would reduce or eliminate the likelihood that a reasonable person would question the employee's impartiality in the matter.

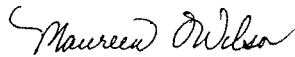
August 20, 2003

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As stated above, neither criminal nor regulatory conflict of interest has been found in Dr. Liotta's participation in the Correlogic's CRADA. Dr. Liotta's involvement in the CRADA is personal and substantial and the importance of this CRADA and associated clinical trial to the health of women everywhere can not be understated. However, Dr. Liotta, as the lead molecular pathologist from NCI, can not be reassigned from his duties with regard to the CRADA without impeding the scientific discovery process underlying the CRADA. While Dr. Liotta is called upon to exercise considerable scientific discretion in his guidance of the Correlogic Systems CRADA, he does so under the constraints of Federal law and subject to the oversight of duly constituted subcommittees to address appropriate application Federal Technology Transfer Act concerns, human subjects concerns, and conflict of interest. Any end products derived from the CRADA will be subject to such review. Any amendments to the CRADA will also be subject to equivalent review and to critical inspection by senior scientific staff, including the Office of the Deputy Director for Strategic Scientific Initiatives. Dr. Liotta's actions in regard to the CRADA may lead to further Federal patents or royalties that may accrue to the Federal government as a result of new or existing patents, but any benefit to Dr. Liotta will accrue as a result of his status as a government employee and will have no direct impact on his personal financial interests in Biospect.

Recalling the HHS standard under 5 CFR § 5501.106(d)(4) that directs the approval of outside activities unless they are in violation of statute or regulation, this office must continue to approve Dr. Liotta's his outside activity request, because no violation has been identified. Dr. Liotta also may continue his participation in the development of the technology contemplated by the Correlogic Systems CRADA requirement, because all the relevant regulatory factors have been considered and the public standard for impartiality has been met.

This office will continue to rely on Dr. Liotta to identify any change in his official duties or his personal consulting relationship that would impact this decision.



Maureen O. Wilson, Ph.D.
Deputy Ethics Counselor, NCI, NIH, DHHS

attachment

cc: Director, CCR, NCI, NIH, DHHS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

TAB 8

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

CENTER FOR CANCER RESEARCH
OFFICE OF THE DIRECTOR
Bldg. 31, Room 3A-11
31 Center Drive
Bethesda, MD 20892-2440
Phone: (301) 496-4345
Fax: (301) 496-0775

MEMORANDUM

August 20, 2003

TO: Dr. Maureen Wilson
Assistant Director, NCI

FROM: Director, Center for Cancer Research, NCI

SUBJECT: Evaluation of Biospect Outside Activity

I met with Dr. Liotta and Dr. Petricoin concerning their ongoing approved US government outside activity with Biospect. I sought to determine the potential for conflict of objectivity and interest with Correlologic Systems Inc., with whom these scientists collaborate under a cooperative research and development agreement (CRADA).

Dr. Liotta met with me together with NCI ethics staff prior to submitting this consulting activity for approval. At that time Dr. Liotta discussed his ongoing government work in proteomics and his CRADA activities including the Correlologic CRADA. This outside activity was approved on December 17, 2002.

The signed consulting agreement between Dr. Liotta and Biospect contains the following language which specifically and explicitly excludes the subject matter relating to any and all CRADA related activities with Correlologic as follows:

"The Company recognizes and understands that the consultant is a U.S. Government employee of the National Cancer Institute, National Institutes of Health (NIH) who is conducting research in the field of proteomics, as part of his official duties. The official duty research includes the following topics in proteomics: protein microarrays, tissue microdissection, serum proteomic pattern analysis using genetic algorithms and self-organizing maps (the "Government Field"). As part of his official duties, the consultant has entered into CRADA agreements with non-government companies to further develop and commercialize the Government Field, including issued and pending patents licensed to the U.S. government. The consultation provided to the company must exclude non-public information of Consultant in the Government Field. Moreover Consultant's work as an employee of NIH in the Government Field is excluded from

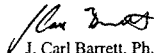
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any claims of competition by the Company. Notwithstanding any other provision of this agreement, the rights of Consultant's employer, the National Institutes of Health (NIH), shall not be abrogated by any commitment or obligation Consultant has incurred hereunder. Company recognizes that as a Federal employee, Consultant is bound by federal laws, regulations and policies, including those governing conflict of interest, standards of conduct, and intellectual property, including 45 C.F.R. Part 7. (Note: The term "Consultant" refers to the Federal employee seeking permission to act as a consultant. "Company" refers to the outside organization for which the NIH employee wishes to work/consult). Therefore, the Company recognizes and understands that the intellectual property held by the Consultant in the Government Field as part of his U.S. Government employment is outside this agreement and the Company agrees that it has no right, title or interest (including patent rights, copyrights, trade secret rights, mask work rights, trademark rights and all other intellectual and industrial property rights of any sort throughout the world) in that intellectual property."

In addition to this limitation the consulting agreement clearly restricts the consulting activity to the following specific areas based on Dr. Liotta's professional expertise as a Board Certified Pathologist and a Biomedical Engineer. "Consulting services will relate to general professional knowledge in medical diagnostic technology, clinical sample acquisition, preparation, fractionation, separation, storage and stability, regulatory filings and regulatory inspections related to clinical pathology laboratories [e.g. CAP (College of American Pathologists), CLIA, GMP inspections, and 510(k) or PMA filings for new diagnostic tests] relying upon knowledge obtained as a Board Certified Pathologist with CAP laboratory certification and expertise as a biomedical engineer. Consulting services will also relate to general scientific expertise in diagnostic devices and microfluidics as applied to the analysis of protein and biological mixtures and the classification of biologic states through complex mixture analysis of biological fluids." Services will exclude anything related to analysis of mass spectroscopy output spectra data." It is also understood that Dr. Liotta will not represent Biospect, directly or indirectly through any matter that is the subject of dealings with the U.S. Government.

Drs. Liotta and Petricoin have informed me that the only new development in this approved outside activity is a request by Biospect for Drs. Liotta and Petricoin to reduce the number of consulting hours per month.

Based on my review, I am satisfied that the ongoing consulting activities with Biospect do not overlap with the ongoing CRADA activities with Correllogic Systems.


J. Carl Barrett, Ph.D.

TAB 9

REQUEST FOR APPROVAL OF OUTSIDE ACTIVITY*

(Ref.: HHS Standards of Conduct Regulations)

☒ Initial request
☐ Revised Request
☐ Renewal

1. NAME (Last, First, Initial) PETRICORN, EMANUEL F		2. ORGANIZATIONAL LOCATION (Operating Division, Bureau, Division) DTP/OTRR/CEER/BSA	
3. TITLE OF POSITION SENIOR INVESTIGATOR		4. GRADE AND SALARY (Federal) TITLE 42	
*5. NAME, ADDRESS AND BUSINESS OF PERSON OR ORGANIZATION FOR WHOM OUTSIDE SERVICES WILL BE PERFORMED BIOSPECT, INC. 951 GATEWAY BLD. SOUTH SAN FRANCISCO, CA 94080		6. LOCATION WHERE SERVICES WILL BE PERFORMED	
7. NATURE OF ACTIVITY (Indicate type of activity, e.g., teaching, consultative services, and give full description of specific duties or services to be performed. Specify, when possible, the scheduled days of week and hours of day proposed activity will be performed.) Consulting services limited to scientific expertise on complex biological mixture analysis, predictive identification of target biological status by predictive analysis of biological tissues and fluids.			
8. ESTIMATED TIME INVOLVED			
a. PERIOD COVERED FROM October 1, 2002 TO October 1, 2004		b. ESTIMATED TOTAL TIME DEVOTED TO ACTIVITY (If on a continuing basis, give estimated time per year) 4 DAYS / MONTH	
c. WILL WORK BE PERFORMED ENTIRELY OUTSIDE USUAL WORKING HOURS? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF "NO," INDICATE ESTIMATED NUMBER OF HOURS OR DAYS OF ABSENCE FROM WORK 1 DAY / MONTH Will take annual leave for all time absent			
9. DO YOUR OFFICIAL DUTIES RELATE IN ANY WAY TO THE PROPOSED ACTIVITY? <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES (Describe) Invited because of my scientific expertise			
*10. IF PROVIDING CONSULTATIVE OR PROFESSIONAL SERVICES, ARE YOUR WOULD-BE ASSOCIATES RECEIVING OR WILL THEY SEEK, A GRANT OR CONTRACT FROM A FEDERAL AGENCY? <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES (Describe)			
11. METHOD OR BASIS OF COMPENSATION <input checked="" type="checkbox"/> FEE <input type="checkbox"/> HONORARIUM <input type="checkbox"/> PER DIEM <input type="checkbox"/> PER ANNUM <input type="checkbox"/> ROYALTY <input type="checkbox"/> EXPENSES <input type="checkbox"/> OTHER (Specify)		12. WILL COMPENSATION BE DERIVED FROM A HHS GRANT OR CONTRACT? <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES (Describe)	
13. THIS REQUEST IS MADE WITH FULL KNOWLEDGE OF DEPARTMENT AND OPERATING DIVISION POLICY AND PROCEDURES ON OUTSIDE ACTIVITIES. THE STATEMENTS I HAVE MADE ARE TRUE, COMPLETE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF.			
14. SIGNATURE OF EMPLOYEE 		15. DATE 9/22/02	16. ADDITIONAL INFORMATION ATTACHED <input type="checkbox"/> YES <input type="checkbox"/> NO
17. ACTION RECOMMENDED BY REVIEWING OFFICIAL			
a. <input checked="" type="checkbox"/> APPROVAL <input type="checkbox"/> DISAPPROVAL	b. SIGNATURE 	c. TITLE Director, DTP	d. DATE 9/30/02
18. ACTION TAKEN			
a. <input checked="" type="checkbox"/> APPROVAL <input type="checkbox"/> DISAPPROVAL	b. SIGNATURE 	c. TITLE DIRECTOR, DIVISION OF MANAGEMENT SERVICES	d. DATE 10/7/02

*See reverse of form
HHS 520 (1/82)

(INSTRUCTION ON BACK OF FORM)

Prepared by: Tonya Staley Fax No.: 301-480-0853 Phone No.: 301-496-8906

REQUEST FOR APPROVAL OF OUTSIDE ACTIVITY*

Ref.: HHS Standards of Conduct Regulations + NCI/NIH Rules

☒ Initial Request
☐ Revised Request
☐ Renewal

1. NAME (Last, First, Initial) <u>LIOTTA, Lance A.</u>	2. ORGANIZATIONAL LOCATION <u>DHHS, NIH, NCI, CCR LP, SP</u>
3. TITLE OF POSITION <u>Chief, Laboratory of Pathology</u>	4. GRADE AND SALARY (Federal) <u>602 - 6 \$ 125,335</u>
5. NAME, ADDRESS AND BUSINESS OF PERSON OR ORGANIZATION FOR WHOM OUTSIDE SERVICES WILL BE PERFORMED <u>Carol A. Dahl, Ph.D., Biospect Inc., 6701 Democracy Blvd. Bethesda, MD 20817</u>	6. LOCATION WHERE SERVICES WILL BE PERFORMED <u>6701 Democracy Blvd. Bethesda, MD 20817</u>

7. NATURE OF ACTIVITY (Indicate type of activity, e.g., teaching, consultative services, and give full description of specific duties or services to be performed. Specify, when possible, the scheduled days of week and hours of day proposed activity will be performed.) Also answer (a), (b), (c), and (d) below.

B-1
Consultative services: Provide advice on public domain diagnostic testing methods applied to animal and human toxicology and correlation with tissue pathology.

TAB 10

Only published and publicly available information and data will be discussed. For consulting, DHHS rules regarding consulting will be observed.
 Employee(s): (a.) yes (circle one) a project officer; (b.) has (circle one) extramural responsibilities;
 (c.) has (circle one) CRADA or MTA-CRADA responsibilities;
 (d.) Branch Office has (circle one) grants or contracts with this organization.

8. ESTIMATED TIME INVOLVED

a. PERIOD COVERED FROM <u>Oct. 31, 2002</u> TO <u>Oct. 31, 2003</u>	b. ESTIMATED TOTAL TIME DEVOTED TO ACTIVITY (If on a continuing basis, give estimated time per year) <u>192 hrs/year</u>
--	---

c. WILL WORK BE PERFORMED ENTIRELY OUTSIDE USUAL WORKING HOURS? IF NO, COMPLETE THE FOLLOWING:
☒ YES ☐ NO I currently have 81 DAYS/HOURS of unused annual leave. If this request is approved, I will use the following time for the activity: DAYS/HOURS: 1

9. DO YOUR OFFICIAL DUTIES RELATE IN ANY WAY TO THE PROPOSED ACTIVITY? Related to professional competence, but not an official responsibility for use of government funds
☒ NO ☐ YES

*10. IF PROVIDING CONSULTATIVE OR PROFESSIONAL SERVICES, DO YOUR WOULD-BE ASSOCIATES RECEIVE OR WILL THEY SEEK, A GRANT OR CONTRACT FROM A FEDERAL AGENCY? Services provided will not knowingly involve, directly or indirectly, preparation of material which could relate to any financial dealings between the outside organization and NIH
☒ NO ☐ YES (Describe)

11. METHOD OR BASIS OF COMPENSATION <input type="checkbox"/> HONORARIUM <input checked="" type="checkbox"/> FEE/ <input type="checkbox"/> NONE (See Attached) <input type="checkbox"/> ROYALTY <input checked="" type="checkbox"/> EXPENSES <input type="checkbox"/> OTHER (Specify)	12. WILL COMPENSATION BE DERIVED FROM A DHHS GRANT OR CONTRACT? <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES (Describe)
--	---

13. THIS REQUEST IS MADE WITH FULL KNOWLEDGE OF DEPARTMENT AND OPERATING DIVISION POLICY AND PROCEDURES ON OUTSIDE ACTIVITIES. THE STATEMENTS I HAVE MADE ARE TRUE, COMPLETE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF.

14. SIGNATURE OF EMPLOYEE <u>Lance A. Liotta, Ph.D.</u>	15. DATE <u>10-4-02</u>	16. ADDITIONAL INFORMATION ATTACHED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
--	----------------------------	--

a. <input checked="" type="checkbox"/> APPROVAL <input type="checkbox"/> DISAPPROVAL	b. SIGNATURE <u>[Signature]</u>	c. TITLE <u>Director CCR/NCI</u>	d. DATE <u>10-11-02</u>
17. ACTION RECOMMENDED BY REVIEWING OFFICIAL			
a. <input checked="" type="checkbox"/> APPROVAL <input type="checkbox"/> DISAPPROVAL	b. SIGNATURE <u>[Signature]</u>	c. TITLE <u>Deputy Ethics Counselor, NCI</u>	d. DATE <u>12/17/02</u>
18. ACTION TAKEN			

*See reverse of form HHS-520 3/8/98
 SEE REVIEWING OFFICIAL COMMENTS ON REVERSE

DO NOT WRITE IN THIS BOX

Approval Contingent on Compliance
with Notices on Reverse Side

Employee has been appraised of the rules
governing outside activities and use of official
title and NIH/NCI affiliation.

05/15/2004 SAT 11:45 FAX 3014960840

031

Print at: Tuesday, May 04, 2004 12:39:04 PM
Host: 31-WILSON-1
User: WilsonM

TAB 11

National Cancer Institute Data System

Employee Information and Form

Last Name: [REDACTED] First Name: [REDACTED] MI: [REDACTED]
HNO Code: [REDACTED] Status: [REDACTED]
Mandatory Files: [REDACTED]

Job Title: [REDACTED] Salary: [REDACTED]
Pay Plan: [REDACTED] Plan: [REDACTED] Job Status: [REDACTED] [REDACTED] [REDACTED] [REDACTED]

His/Her Date of Birth: [REDACTED]

View CRADA: [REDACTED] BIOPECT INC. [REDACTED]

Fee: [REDACTED] 182

CRADA	CRADA	CRADA	CRADA	CRADA	CRADA
1401122003	12072003	11	11	11	11
12072003	11	11	11	11	11

CRADA	CRADA	CRADA	CRADA	CRADA	CRADA
121-000/2004	2004	100222002	08/25/2003	08/25/2003	11
121-000/2004	2004	100222002	02/24/2004	11	11

NCI Review Check Biospect
Hrs/days this \$20: 192 hrs/yr Other 520s Yes X No ☐ Total 520 Hrs/days: 296
Humanas Press - Editor
CRADAs in immediate area? Yes X No ☐
Dr. Liotta was CRADA PI on the NCI-FDA-Correlogic Systems, Inc. CRADA 01403 expired 4/3/2004 (copy of COI analysis and CRADA documentation attached)
Money earned two Date: \$49,375 consulting fees - proposed annual rate of \$39,000 or \$3250/month
Organization Subsidiary Involvement Yes ☐ No X

Official Business Relatedness? Biospect and Correlogics do business in the same area, however, Dr. Liotta's consultation was limited per agreement with Dr. Barrett so that his consultation did not overlap with his official duties- this a very technical distinction.

Recommended

Based on legal analysis of an activities certified by the scientific director to be different from official duties of the employee this limited consultancy should be recommended, but it is a management decision as to any appearance of conflict of interest that approval will continue to raise.

05/14/2004 FRI 13:07 FAX 3014960840

002



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

TAB 12

May 14, 2004

The Honorable James C. Greenwood
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Greenwood:

As you know, I share your concerns that prior to February of this year, NIH employees, other than those who file public financial disclosure reports, were not required to fully disclose the compensation amounts of outside activities with pharmaceutical and biotechnology companies. As I testified before the Subcommittee on Oversight and Investigations May 12, I believe the NIH ethics program lacks sufficient transparency and disclosure. I have been working with the Subcommittee, the Office of General Counsel at the Department of Health and Human Services (HHS) and the Office of Government Ethics (OGE) to rectify this problem.

With the assistance of HHS, OGE approved our request on February 6, 2004, to require all Institute and Center Directors, Deputy Directors, Scientific Directors, and Clinical Directors to file public financial disclosure reports. Recently, we submitted a second request to OGE to require senior scientists and managers occupying 500 additional positions to file public disclosure reports. This increase in the number of public financial disclosure filers will significantly add to the level of transparency within the NIH ethics program.

I have also worked with HHS to resolve issues related to the Subcommittee's request for the compensation amounts connected to consulting arrangements between NIH employees and industry. We have been able to strengthen our ethics program by requiring all NIH employees, regardless of their position or salary, to provide consulting compensation amounts for current and future activities. These amounts were provided to the Subcommittee on March 19, 2004. But the collection of compensation amounts for past, closed activities was considered an action that could raise Privacy Act considerations, and I was advised that this could put the Federal Government at risk of litigation. Therefore, we initially proceeded to request the amounts on a voluntary basis.

In light of the insufficient response to the voluntary requests for information, again working with the Office of General Counsel at HHS, I have determined that the need of Congress to have this information, NIH's need for the information as it works to propose new or to revise existing policies and procedures, and the public interest in general, override the litigation risks involved in the mandatory collection of consulting compensation amounts. Therefore, I will instruct all

05/14/2004 FRI 13:07 FAX 3014960840


003

Page 2 - The Honorable James C. Greenwood

employees who had consulting arrangements since January 1, 1999, that are now closed to report the compensation amounts received pursuant to the consulting as a requirement and condition of their employment. These amounts will be provided upon collection to the Subcommittee, pursuant to the Subcommittee's request of December 8, 2003.

I hope this satisfies the Subcommittee's concerns regarding this matter. Please contact me if you have any additional questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Zerhouni", with a long horizontal flourish extending to the right.

Elias A. Zerhouni, M.D.
Director

05/14/2004 FRI 16:58 FAX 3014980840

002

MEMORANDUM

TO: IC Directors TAB 13

FROM: NIH Deputy Director and
NIH Deputy Ethics Counselor

SUBJECT: Changes to Outside Activity and Award Approval Process

On January 18, 2004, Dr. Zerhouni issued a memorandum regarding changes in the NIH Ethics Program which I forwarded to you in an e-mail message of the same day. The memorandum explained that I was appointed as the NIH Deputy Ethics Counselor (DEC), and as such, was given the additional DEC responsibilities for the IC Deputy Directors, Scientific Directors, Clinical Directors and Extramural Directors (those officials in the extramural program who report directly to the IC Director). I, as the NIH DEC, will continue to serve as the DEC for the IC Directors. The memorandum also discussed the newly established of the NIH Ethics Advisory Committee (NEAC). I now write to explain in more depth the process for submission and approval from the NEAC of outside activities and awards.

As you are aware, Dr. Zerhouni pledged to review all outside activities of NIH employees. To that end, all ongoing activities must be reviewed to determine if, consistent with applicable statutes and regulations, NIH employees should be allowed to continue to engage in these activities. Accordingly, all activities that fall within the NEAC's jurisdiction must be submitted to the NEAC for its review and recommendation. Based upon the NEAC's review, I, as the NIH DEC, will decide if the activity should continue. Furthermore, all other activities must be reviewed at the IC level. The employee's supervisor and the IC DEC together will determine whether or not the employee may continue to engage in the activity. Last, as explained below, the NEAC has jurisdiction over requests for approval of awards. These should be submitted to the NEAC for its consideration, where appropriate.

As outlined in Dr. Zerhouni's January 18 memorandum, the following activities and awards falls within the NEAC's jurisdiction:

- 1) NEAC will provide supervisory review and, if appropriate, approval for **all outside activity and award requests submitted by appointed or acting NIH OD Senior Staff and IC Directors**. The NIH DEC will serve as the final arbiter of these requests.
- 2) NEAC will advise the NIH DEC on **all outside activity and award requests submitted by IC Deputy Directors, Scientific Directors, Clinical Directors, and Extramural Directors**. The NIH DEC will serve as the final arbiter of these requests.
- 3) NEAC will advise the NIH DEC in relation to requests submitted by **any other NIH employee as follows**:

05/14/2004 FRI 16:58 FAX 3014960840

003

- requests to accept awards from non-governmental sources that include a cash payment and/or travel reimbursement equal to or in excess of \$2,500;
- any outside activity request involving a biotechnology or pharmaceutical company;
- any outside activity request that involves total anticipated compensation in excess of \$10,000, or which is expressed as a future income stream;
- any outside activity for which payment will be, entirely or in part, in the form of stock, stock options, or other equity position.

Please submit to the NEAC for its review a new outside activity approval packet for any outside activity in which you are currently engaged and wish to continue. Also, please inform your staff that they must submit new outside activity approval packets to either the NEAC (through the IC DEC) if the activity falls within the NEAC's jurisdiction, or to their supervisors and the IC DEC in order to continue with the activity. Failure to timely obtain new approvals for the activities will result in the cancellation of the previously obtained approvals. The attached memorandum may be used by you to inform your staff of the changes to the outside activity and award approval process. It details the NEAC's jurisdiction, the deadline for submissions to the NEAC or the IC for ongoing activities, and what information must be presented when seeking approval of ongoing or new outside activities, or awards.

Please contact me if you have any questions.

05/14/2004 FRI 16:59 FAX 3014960840

004

MEMORANDUM

TO: IC Employees

FROM: IC Director

SUBJECT: Procedure for Review of Ongoing and New Outside Activities and Certain Awards

As you know, outside activities in which NIH employees engage and certain awards given to NIH employees have recently received significant media and Congressional attention. To assure that these activities in no way negatively affect our mission to advance the public health, we are reviewing all ongoing outside activities, and subjecting some activities and awards to heightened review by the newly established NIH Ethics Advisory Committee (NEAC). I write to explain the NEAC's jurisdiction and the procedures for submitting requests for approval of ongoing or new outside activities, and certain awards.

The NEAC has the following responsibilities and authority:

- 1) NEAC will provide supervisory review and, if appropriate, approval for **all outside activity and award requests submitted by appointed or acting NIH OD Senior Staff and IC Directors**. The NIH DEC will serve as the final arbiter of these requests.
- 2) NEAC will advise the NIH DEC on **all outside activity and award requests submitted by IC Deputy Directors, Scientific Directors, Clinical Directors, and Extramural Directors**. The NIH DEC will serve as the final arbiter of these requests.
- 3) NEAC will advise the NIH DEC in relation to requests submitted by **any other NIH employee as follows**:
 - requests to accept awards from non-governmental sources that include a cash payment, and/or travel reimbursement equal to or in excess of \$2,500;
 - any outside activity request involving a biotechnology or pharmaceutical company;
 - any outside activity request that involves total anticipated compensation in excess of \$10,000, or which is expressed as a future income stream;
 - any outside activity for which payment will be, entirely or in part, in the form of stock, stock options, or other equity position.

The attached documents entitled "NIH Ethics Advisory Committee," and "Activity Requests Subject to the NIH Ethics Advisory Committee (NEAC) Jurisdiction" provide additional information.

05/14/2004 FRI 16:59 FAX 3014960840

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As explained more fully below, you are required to provide specific information with respect to compensation if you wish to continue an outside activity or have a new activity considered for approval. Therefore, please comply with the following deadlines for review of ongoing and new outside activities:

- 1) For ongoing activities, submit packets through supervisory channels to the IC DEC **no later than Tuesday, February 17, 2004**; and
- 2) For new outside activities, submit packets through supervisory channels to the IC DEC **at least six weeks in advance** of the anticipated start date of the activity.

If your activity is scheduled to occur prior to February 17, contact your IC DEC immediately for expedited review of the outside activity packet.

You should follow the already-established IC process for outside activity approval. That is, the IC Program Staff is available to help you with preparing the packet and the IC Ethics Staff is available to advise on the appropriateness of any undertaking. Your supervisor must still approve the activity and the IC DEC must review it before the packet is forwarded to the NEAC. (If the activity does not fall within the NEAC's jurisdiction, the activity will be reviewed and approved by your supervisor and IC DEC.) Once supervisory approval is obtained and the IC DEC review is completed, the IC DEC will forward those activities that fall under the NEAC's jurisdiction to the NEAC for action.

The following information must be submitted if you desire to have your request for approval considered or continued:

- **HHS Form 520.** This Form must now include information about the *amount* and *type* (e.g., cash, stock, or stock options) of income, compensation, fees, remuneration, expenses, or reimbursement that is to be received in connection with the ongoing or proposed activity. In addition, you must include, retrospectively, the cumulative amount of any income or other monetary receipts (including the type or method of payment) that was received by you from the outside source in connection with the ongoing activity for the past 5 years. We have been informed by the HHS Designated Agency Ethics Official that failure to provide the required information with respect to the amount and type of compensation will require the NIH DEC to cancel the ongoing outside activity or deny a request to begin a new one. The compensation information should be supplied in "Item Number 17" on the reverse of the HHS Form 520. Also, when reporting the period covered by the activity, the "from" date in box 8a of the Form 520 should reflect the date the activity originally started.
- **NIH Supplemental Information sheet to the HHS Form 520.** This supplemental sheet must include a thorough answer to question 3, "Explain how the proposed outside activity is different from the scientific activities performed as part of your official duties."

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- **NIH Form 2657.** This form must be completed by the employee and signed by the outside organization, where applicable.
- **Invitation Letter from Outside Organization.** Additional information that describes the activities and/or the organization may be included as well.
- **Your PD or Billet.** If you do not have a current PD or billet, please include a detailed explanation of your current job responsibilities.

Please note that any packet that is not complete will be returned, and approval will be held in abeyance until the packet is properly completed and the review can be performed.

If your request involves an already approved activity, you may reuse the previously submitted documents as long as all the required information is included, i.e., amend the previously submitted outside activity packets to include compensation information. You must, however, resign and redate the HHS Form 520.

If you have any questions, please contact [name], [IC name] DEC.

cc: [name], [IC name] DEC

Slobodin, Alan

From: Burton, Craig (HHS/OS) [Craig.Burton@hhs.gov]
Sent: Saturday, June 19, 2004 9:45 AM
To: Slobodin, Alan
Cc: Burton, Craig (HHS/OS)
Subject: RE: Moshell

TAB 14

Answers from NIH...:

Did Moshell receive ethics training from NIH? they'll check about past years and he has been recently counseled about the need to file a 520 for expert witness services.

Does Moshell confirm he performed consulting services? [Alan never asked about consulting services performed by Moshell, so we never looked into it. What specifically is he interested in?] - ANY CLEARER GUIDANCE YOU CAN PROVIDE FOR ME TO SEEK FROM NIH WOULD BE APPRECIATED.

When was Moshell counselled? In April or May from the NIH Ethics Office when a 520 was approved by the NIH DEC, and in June by his IC DEC.

Has he filed any 520s for his expert witness services? No. He did not think he had to because he filed a 520 for his private practice which he thought covered the expert witness service.

Is it NIH's position that Dr. Moshell should have disclosed his expert witness services to NIH? Yes. It is required by the HHS supplemental regs.

Should he have filed separate 520s for each time he testified as an expert witness? Yes. Each case requires a separate 520.

-----Original Message-----

From: Slobodin, Alan
 To: Burton, Craig (HHS/OS)
 Sent: 6/18/2004 7:54 PM
 Subject: RE: Moshell

Did Moshell receive ethics training from NIH? Does Moshell confirm he performed consulting services? When was Moshell counselled? Has he filed any 520s for his expert witness services? Is it NIH's position that Dr. Moshell should have disclosed his expert witness services to NIH? Should he have filed separate 520s for each time he testified as an expert witness?

Please fax me the 520 approving his clinical practice as dermatologist.

-----Original Message-----

From: Burton, Craig (HHS/OS) [mailto:Craig.Burton@hhs.gov]
 Sent: Friday, June 18, 2004 7:37 PM
 To: Slobodin, Alan
 Cc: Torres, Abelardo (HHS/OS); Flamberg, Gemma (NIH/OD)
 Subject: Fw: Moshell

From nih:

 Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: Flamberg, Gemma (NIH/OD) <FlambergG@OD.NIH.GOV>
 To: Burton, Craig (HHS/OS) <Craig.Burton@hhs.gov>
 CC: Smolonsky, Marc (NIH/OD) <SmolonsM@OD.NIH.GOV>
 Sent: Fri Jun 18 13:53:34 2004
 Subject: RE: Moshell

NIH's response on this issue.

Can you determine if a Dr. Moshell filed a 520 form for outside activity relating to serving as an expert witness?

In 1985, Dr. Moshell filed a 520 form, and obtained approval to conduct clinical practice as a dermatologist. The 520 did not specifically cover service as an expert witness, and Dr. Moshell has indicated that he did not believe that a specific 520 was needed for that purpose. To the best of our knowledge, Dr. Moshell was not specifically advised that he needed to seek separate authorization to perform services as an expert witness. Once Dr. Moshell's particular situation came to NIH's attention, we counseled Dr. Moshell to make sure that he is aware of the regulatory requirements regarding service as an expert witness as an outside activity.

In 1996, DHHS promulgated supplemental regulations which required employees to file a separate 520 form and obtain prior approval for any outside activity that involved service as an expert witness. At that time, however, NIH did not require the ICs to search their files to determine if there were activities that were approved previously that would require new approval.

Having reviewed Dr. Moshell's financial disclosure reports retained consistent with the 6 year record retention period, we note that he has consistently reported his private clinical practice, since at least 1998. His reports do not, however, make reference to law firms or other indicia of service as an expert witness. Without this information, it is unclear how his ethics official could have known that follow-up was necessary. Through the NEAC process, and additional directives, NIH is ensuring that both the ICs ethics staffs and individual employees are aware of all regulatory requirements.

637

Gemma Flamberg
Senior Legislative Analyst
Office of Legislative Policy and Analysis
National Institutes of Health
301) 496-3471
Fax (301) 496-0840
flamberg@od.nih.gov

APPROVAL FORM FOR AWARDS

Note: Regardless of market value, an award must be a bona fide award or incident to one that is given for meritorious public service or achievement.

Name of Employee: Richard D. Klausner, M.D.

Name of Award: 1997 Rabbi Shai Shacknai Memorial Prize

TAB 15

Date of Request: 2/7/97

1. This award is not being offered by an entity that has interests that may be substantially affected by the performance or nonperformance of the employee's official duties.

☒ If this is a correct statement, go to Statement 2.

☐ If this statement is not correct, the award may not be approved.

2. This award is not being offered by organization, the majority of whose members have interests that may be substantially affected by the performance or nonperformance of the employee's official duties.

☒ If this is a correct statement, go to Statement 3.

☐ If this statement is not correct, the award may not be approved.

3. This award is not a cash award and has a market value of less than or equal to \$200.

☐ If this is correct, the award may be approved without a written determination made by an agency ethics official.

☒ If this is not correct, go to Statement 4.

4. This award is a cash award or has a market value of more than \$200 or is an award of cash or investment interests.

☒ If this is correct, the award may only be approved upon a written determination by an agency ethics official that:

a. The award has been made on a regular basis:
Yes ☒ No ☐

b. The award recipients have been chosen pursuant to written guidelines or by a selection committee.
Yes ☒ No ☐

This form constitutes my written determination that:

☐ This award is not approved.

☐ This award is not a cash award or has a market value of less than \$200 and is approved.

☒ This award is a cash award or has a market value of more than \$200 and is approved.

Maurice D. Wilson
Deputy Ethics Official
Prepared by OSCE/NIH:3-10-93

2/10/97
Date

✓ Approval Ruth L. Kurosky ion to adequate to allow determination of the
Disapproval Director, NIH DATE Jan

3/10/97

000001

JUN 10 1997

APPROVAL FORM FOR AWARDS

Note: Regardless of market value, an award must be a bona fide award or incident to one that is given for meritorious public service or achievement.

Name of Employee: Richard D. Klausner, M.D.

Name of Award: Raymond Bourguine Award

Date of Request: 6/9/97

1. This award is not being offered by an entity that has interests that may be substantially affected by the performance or nonperformance of the employee's official duties.

☒ If this is a correct statement, go to Statement 2.

☐ If this statement is not correct, the award may not be approved.

2. This award is not being offered by organization, the majority of whose members have interests that may be substantially affected by the performance or nonperformance of the employee's official duties.

☒ If this is a correct statement, go to Statement 3.

☐ If this statement is not correct, the award may not be approved.

3. This award is not a cash award and has a market value of less than or equal to \$200.

☐ If this is correct, the award may be approved without a written determination made by an agency ethics official.

☒ If this is not correct, go to Statement 4.

4. This award is a cash award or has a market value of more than \$200 or is an award of cash or investment interests.

☒ If this is correct, the award may only be approved upon a written determination by an agency ethics official that:

a. The award has been made on a regular basis:
Yes ☒ No ☐

b. The award recipients have been chosen pursuant to written guidelines or by a selection committee.
Yes ☒ No ☐

This form constitutes my written determination that:

☐ This award is not approved.

☐ This award is not a cash award or has a market value of less than \$200 and is approved.

☒ This award is a cash award or has a market value of more than \$200 and is approved.

Reed H. Kucsko
Deputy Ethics Official

Prepared by OSCE/NIB:3-10-93

7/18/97
Date

[Attach Letter or award or other description to adequate to allow determination of the basis of award.]

Recommended for Approval: Maureen C. Wilson 7/26/97
Maureen C. Wilson, Ph.D.
Deputy Ethics Officer

Jun-19-04 08:25am From: House Energy & Commerce Cate Ford

202-226-2447

T-136 P.005/006 F-614

2/18
 got Karen's
 initials.

ROUTING AND TRANSMITTAL SLIP

DATE: February 6, 1998

TO:	Initial	Date
2 Karen Santoro, ASCE, NIH 31/3B63	hs	2/6
3 Office of the DDER, NIH 1/144		
4 Dr. Maureen Wilson, DEC, NCI 31/4A48		
1 Tom Dillon	MD	2/6
5		
6		
7		

X	Action	File	Note and Return
	Approval	For Clearance	Per Conversation
	As Requested	For Correction	Prepare Reply
	Circulate	For Your Information	See Me
	Comments	Investigate	X Signature
	Coordination	Justify	

Re: Klausner Recusal - SOMPS

Remark:

On behalf of Dr. Wilson, please sign the above-referenced for Dr. Klausner in association with his acceptance of the Raymond Bougine Award. The official file for this activity is maintained in the NCI Ethics Office.

Please return when complete.

Tom

This was approved prior to Ed Swindell's permanent OAE O designation. I conferred w/ Jake and we agreed it can go forward as is. Thank you. hs

From:	Georgia McIntyre, Ofc. Assist. Office of the Assistant Director, NCI	Location:	31/4A48	Phone:	6-1148
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DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health


National Cancer Institute
Bethesda, Maryland 20902

September 28, 2001

TAB 16

MEMORANDUM

TO: Yvonne Maddox, Ph.D.
Acting Deputy Director, National Institutes of Health.

Through: Stephen Benowitz 
Director, Human Resources
National Institutes of Health

FROM: J. Carl Barrett, Ph.D.
Director, Center for Cancer Research
National Cancer Institute

SUBJECT: Special Volunteer Designation for Richard D. Klausner, M.D.

Issue

On October 1, 2001, National Cancer Institute (NCI) seeks to designate Richard D. Klausner, M.D. as a Special Volunteer under my supervision. This will facilitate continuity of this extraordinarily promising National Institutes of Health (NIH) research program related to Von Hippel-Lindau Disease. It also will serve the needs of the Department of Health and Human Services (DHHS) by overcoming the statutory post-employment limitations found at 18 USC § 207 that otherwise may affect necessary communications between Dr. Klausner and the Agency.

Background

The position of Director, NCI, is Presidentially appointed, but does not require Senate confirmation. As such, the post-employment provisions applying to former NCI Directors are those applied to "senior employees" of the Executive Branch. Such employees are subject to lifetime or two year bars on communications with the intent to influence the Government in specific party matters as described in the attachment. In addition, such employees are subject to a one-year "cooling off period" from knowingly having any communication with the intent to influence their former agency. Because Dr. Klausner was not a Senate-confirmed appointee, the scope of this restriction is limited to the NIH (18 USC § 207(c)). This restriction does not apply to acts done in carrying out official duties as an employee of and on behalf of a state or local government; an accredited, degree-granting institution of higher education; or a non-profit hospital or medical research organization. Dr. Klausner's new employer, the Case Foundation, is a private family foundation not covered by this exemption.

000032

However, post-employment limitations do not apply to services performed on behalf of or in service to the U.S. Government. Therefore, designating Dr. Klausner in the capacity of Special Volunteer during specified periods of leave from his new employer will allow him to provide input as described below without violation of 18 USC § 207.

Proposed Special Volunteer Services

On October 1, 2001, Dr. Klausner will be considered an Adjunct Investigator under my supervision. He will have access to resources, space, and personnel as consistent with the title and under the appointment of Special Volunteer. While Dr. Klausner will be able to conduct research efforts, travel as deemed necessary, and provide input in a number of issues defined by his appointment; he will be unable to supervise NIH personnel or make commitments on behalf of the NCI. The following serves as a summary of his ongoing research activities and the services Dr. Klausner is expected to perform while a Special Volunteer.

1. Conduct research studies in the area of :

- Von Hippel-Lindau (VHL) tumor suppressor genes. This project is directed at understanding a tumor suppressor gene, VHL, and the cell biology of the VHL gene products and its role in development of Von Hippel-Lindau Disease, a hereditary cancer syndrome, that places VHL patients at-risk of developing bilateral, multifocal renal tumors and cysts, cerebellar and spinal hemangioblastomas, retinal angiomas, tumors in the inner ear (endolymphatic sac tumors), pheochromocytomas, pancreatic cysts and neuro-endocrine tumors, and epididymal cystadenomas.
- Role of VHL in the Regulation of Hypoxia-Inducible Genes. This research focuses on the interaction between HIF (hypoxia inducible factor) and VHL. VHL binds to HIF and targets the HIF protein for proteasomal degradation. When the cell loses VHL, the HIF protein levels increase and thus cause increased transcription of VEGF, GLUT1, erythropoietin and other hypoxia inducible genes.
- The use of micro array technology to study gene expression patterns in late stage (metastatic) renal cell carcinoma. Using statistical analysis is being used to identify groups of genes that are predictive of survival. Once genes are established as most highly correlated with survival, findings from the arrays will be validated and applied to early stage tumors and possibly other types of cancer. Intracellular pathways existing between the identified genes will also be established.
- The relationship between VHL and the met receptor. These studies explore the effects of activating the met receptor with hepatocyte growth factor (HGF) on in vitro invasive cell growth.

000033

2. Attend national, international, and domestic meetings, conferences, and workshops, to exchange scientific information as consistent with the NCI mission and my approval. Participation in such events is essential to facilitate Dr. Klausner's research and to ensure effective and continued scientific liaison between the NCI and professional, advocacy, and other organizations. Thus, travel expenses associated with these events will be Federally supported.
3. To provide scientific and technical advice to the duly appointed DHHS delegates to the Irish Cancer Consortium and the Middle East Cancer Consortium. In this role he will be asked to draw upon his experience as a former DHHS representative to both international consortia.
4. To provide scientific and technical advice in a variety of areas of importance to DHHS at the request of the Secretary, DHHS.

Dr. Klausner's research accomplishments and liaison roles for DHHS, as noted above, have had an important impact on the National Cancer Institute, particularly in its interactions with outside organizations. As a Special Volunteer in the Center for Cancer Research, NCI, both the Institute and the Department will continue to benefit from his scientific and diplomatic skills.

Recommendation

Dr. Klausner's designation as a Special Volunteer is in the interest of the public, as his research activities contribute significantly to improving global health. Thus, I recommend that you approve this designation.

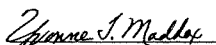

J. Carl Barrett, Ph.D.

Action Requested

Concur ☒

Non-Concur ☐

Date 9/28/01


Yvonne Maddox, Ph.D.
Acting Deputy Director, NIH

attachment

cc: Honorable Tommy G. Thompson, Secretary, DHHS
Barbara McGarey, NIH Legal Advisor, NIH, OGC, DHHS
Gretchen Hirschauer, NIH Ethics Counsel, ED, OGC, DHHS
Maureen O. Wilson, Deputy Ethics Counselor, NCI, NIH, DHHS

000034

Letter from the Editors TAB 17

The field of molecular medicine is moving beyond genomics to proteomics, the goal being the characterization of the cellular circuitry and the understanding of the impact of disease and therapy on cellular networks. In the future, entire cellular networks, not just one dysregulated protein, will be the targets of therapeutics. It will soon be possible to analyze the state of protein signal pathways in the disease-altered cells, before, during, and after therapy. This can herald the advent of true patient-tailored therapy, and provide a rational basis for targeted therapeutics.

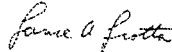
An immediate application of clinical proteomics is disease detection and monitoring. Proteomic technologies promise to dramatically alter the landscape of clinical chemistry and pathology. Proteomics applied to clinical samples will uncover new individual biomarkers that can offer mechanistic insights into disease pathophysiology. Pattern recognition and artificial intelligence computer tools are leading to the discovery and use of diagnostic patterns comprised of dozens, or even hundreds, of simultaneous biomarkers.

With these objectives in mind, investigators are developing highly sensitive, biosensors, protein arrays, and mass spectrometry platforms that can be applied to clinical samples. Nanotechnology, biofluidics, labs-on-a-chip, electrochemical sensors, and pattern recognition algorithms, are all components of this new field.


A key feature of *Clinical Proteomics* will be its commitment to rapid scientific review and timely publication of submitted manuscripts. This will be achieved by requesting that papers be submitted on disk and by utilizing pdf and e-mail technology to ensure quick turnaround during peer review and galley proof correction.

We hope that you will join us in our efforts to fill a critical unmet need in translational medicine.

Sincerely,



Lance A. Liotta, MD, PhD • Editor
National Cancer Institute
National Institutes of Health, Bethesda, MD



Emanuel Petricoin, PhD • Editor
Food and Drug Administration
Rockville, MD

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Predicant 00608

XDomain: thefoleys.com
 Date: Tue, 25 Jun 2002 15:27:39 -0400
 From: cdahl <cdahl@earthlink.net>
 Subject: Liotta/Petricoin
 To: jim tananbaum <jim@prospectventures.com>, Foley Pete <pete@thefoleys.com>, heller jonathan <rellehj@yahoo.com>, John Stults <stults@sbcglobal.net>, Rick Klausner <rick@gatesfoundation.org>
 Reply-to: cdahl@earthlink.net
 X-Mailer: EarthLink MailBox 5.0.6.9 (Windows)
 X-EM-Version: 5, 0, 0, 0
 X-EM-Registration: #3003520714B31D032830

TAB 18

Hi,
 A couple of updates...

I spoke with Lance Liotta yesterday at the NIH Biosensors meeting. I mentioned the possibility of consulting with us. He is very interested and thought Chip would be as well. The situation with government ethics is the following. They can not consult for a group with which they have any sort of collaborative arrangement. That would include a CRADA and Lance thought MTA as well. This might mean that if we have them consult we can not access our samples through them, at least as long as they are in an active consultant agreement with us.

With that said, my impression from discussions with Chip, Lance and from Lance's presentation at the meeting is that they are getting their samples from other sources anyway. There are specialized groups and centers around the country that have provided samples to them. I gather for the ovarian samples it was the group at Northwestern and for prostate a group in North Carolina.

I think they could be useful as consultants, in terms of providing more detail about what they have done as well as assisting in thinking through issues like sample collection and preparation. If we were to have them consult my guess is that they could supplement the input from Rick (and myself) about other sources with whom we might form collaborations to access the biological samples. We could then contact those potential sources directly.

Rick, I have included you on this email to specifically solicit your feedback on this topic. Could you share your thoughts?

I think this is a subject for the next Biospect call when Jim returns.

I saw George at the meeting as well. He will be seeing Coifman in a couple of weeks at a meeting and plans to follow up on the discussion Jonathan and I had with Coifman. I let him know that we were working on putting an NDA in place with Coifman to facilitate that discussion. He also seems to think we should consider whether we might want to buy their group.

I also ran in to one of my former contractors who happens to be a toxicologist at U. of Michigan. I was probing him about contract organizations doing toxicology. He had some strong opinions as he just went through a review of these groups in order to select one to work on a subcontract from his group. He said he would share this information with me, so hopefully this will provide a useful starting point for identifying a group with whom we want to work. If it looks useful when I get it I will send it around.

646

Page 2 of 2

Best,
Carol

Predicant 01061

XDomain: thefoleys.com
 Date: Tue, 25 Jun 2002 17:25:04 -0400
 From: cdahl <cdahl@earthlink.net>
 Subject: RE: Liotta/Petricoin
 To: jim tananbaum <jim@prospectventures.com>, Foley Pete <pete@thefoleys.com>, heller jonathan <rellehj@yahoo.com>, John Stults <stults@sbcglobal.net>
 Reply-to: cdahl@earthlink.net
 X-Mailer: EarthLink MailBox 5.0.6.9 (Windows)
 X-EM-Version: 5, 0, 0, 0
 X-EM-Registration: #3003520714B31D032830

TAB 19

FYI. I just got off the phone with Rick. He confirms the ethic limitations for Lance and Chip. He concurs that it would be better to use them as consultants and then we can go to the original (non-govt/academic) sources to try and get the samples.

Carol

----- Original Message -----

From: cdahl
 To: Rick Klausner, John Stults, heller jonathan, Foley Pete, jim tananbaum
 Sent: 25/25/2002 3:27:38 PM
 Subject: Liotta/Petricoin

Hi,
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I spoke with Lance Liotta yesterday at the NIH Biosensors meeting. I mentioned the possibility of consulting with us. He is very interested and thought Chip would be as well. The situation with government ethics is the following. They can not consult for a group with which they have any sort of collaborative arrangement. That would include a CRADA and Lance thought MTA as well. This might mean that if we have them consult we can not access our samples through them, at least as long as they are in an active consultant agreement with us.

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Best,

Predicant 01058

Carol

Department of Health and Human Services
Employment by Title 42 Authority
May 2004

TAB 20

1. *How many employees are receiving compensation under any of the Title 42 authorities? Please provide a breakdown the number of employees compensated under each Title 42 authority and please provide a breakdown of the number of Title 42 employees by agency.*

Table 1 below shows the use of Title 42 hiring authorities by Operating Division across HHS.

Table 1: Title 42 Employment by Operating Division								
OPDIV	2000(h) (Special Consultants)	2009(h) (Fellows)	2009(a) (SBR)	2009(a) (Special Experts)	2009(a) (Special Experts)	2009(a) (Special Experts)	2009(a) (Special Experts)	Total
AHRQ	1	36	0	0	7			44
FDA	217	351	41	0	0			609
HRSA	0	7	0	0	0			7
OS	1	19	0	0	0			20
SAMHSA	1	0	0	6	0			7
CDC/ATSDR	119	362*	61			287	100	929
NIH	1,396	2,434	127					3,957
Total	1,735	3,209	229	6	7	287	100	5,574

* CDC total in this column includes service fellows hired under section 209(h) as well.

2. *Since Title 42 compensation authority was broadened in 1999, how many employees at HHS agencies have converted from federal civil service positions to Title 42 employment? What is the distribution of employee salaries for each Title 42 compensation level? What is the range of salary increases (the differences between the previous federal civil service salaries and the new Title 42 salaries) for those employees who converted? What has been the total cost of the differences between the increased Title 42 salaries and the previous federal civil service salaries for all of the HHS-agency employees who converted from federal civil service to Title 42?*

Table 2 shows conversions to Title 42 by OPDIV since 1999, along with salary ranges, the range of salary increases accompanying the conversions, and the increased salary costs due to the conversions to Title 42.

OPDIV	Number of Conversions	Title 42 Salary Range	Range of Salary Increase	Cost Increase of Conversions
AHRQ	2	\$54,427 – \$130,970	\$3,318 – \$14383	\$17,701
FDA	164	\$74,729 – \$194,028	\$0 – \$34,800	\$1,536,954
HRSA	0	N/A	N/A	\$0
OS	0	N/A	N/A	\$0
SAMHSA	1	\$184,250	\$6,800	\$6,800
CDC/ATSDR	56	\$94,991 – \$112,594	\$5,439 – \$24,359	\$1,198,716
NIH	737	\$22,344 – \$200,000	\$0 – \$64,103	\$11,654,645
Total	960			\$14,414,816

3. How many new employees were hired under a Title 42 authority? How many employees hired since 2000 have converted to Title 42?

New hires to Title 42 positions and conversions are shown by Operating Division in Table 3.

OPDIV	New Hires to Title 42 Positions	Number of Conversions
AHRQ	0	0
FDA	461	5
HRSA	5	0
OS	1	0
SAMHSA	0	0
CDC/ATSDR	701	1
NIH	3,446	74
Total	4,656	80

Since July 1, 1999, how many retention bonuses have been given? What has been the total cost of these retention bonuses?

Table 4: Retention Allowances Paid to Title 42 Employees		
OPDIV	Number of Retention Allowances	Total Cost of Retention Allowances
AHRQ	0	\$0
FDA	205	\$2,001,766
HRSA	0	\$0
OS	0	\$0
SAMHSA	0	\$0
CDC/ATSDR	3	\$52,325
NIH	236	\$2,773,656
Total	444	\$4,827,747

Total retention allowances for NIH and FDA count each time an allowance is renewed, not the number of individual receiving a retention allowance. Retention allowances are authorized for no more than one year at a time, therefore the continuation of an employee's retention allowance is counted as a separate authorization.

NIH Information

- How many employees are receiving compensation under any of the Title 42 authorities? Please provide a breakdown the number of employees compensated under each Title 42 authority and please provide a breakdown of the number of Title 42 employees by institute or center.

The following table shows NIH's Title 42 employment by Institute and Center for each Title 42 Authority.

Table 5: NIH Use of Title 42 Authorities by Institute / Center				
Institute/ Center	Title 42(f) (Special Consultants)	Title 42(g) (Staff Fellows)	SBRS (Senior Biological Research Scientist)	Total
CC	500	103		603
CIT	7	15		22
CSR	32	0		32
FIC	5	1		6

Table 5: NIH Use of Title 42 Authorities by Institute / Center

Institute / Center	Title 42(D) (Special Consultants)	Title 42(G) (Staff Fellows)	SBRS	Total
NCCAM	8	4		12
NCI	216	678	48	942
NCHMD	2	0		2
NCRR	6	0		6
NEI	10	49	2	61
NHGRJ	25	79		104
NHLBI	41	163	6	210
NIA	22	70	2	94
NIAAA	13	43	1	57
NIAID	136	257	8	401
NIAMS	11	49	2	62
NIBIB	5	0		5
NICHD	60	129	23	212
NIDA	15	33		48
NIDCD	10	42		52
NIDCR	20	59	6	85
NIDDK	66	128	20	214
NIEHS	39	102	5	146
NIGMS	35	18		53
NIMH	37	135	2	174
NINDS	33	144	2	179
NINR	2	0		2
NLM	14	118		132
OD	25	1		26
ORS	1	14		15
NIH Total	1,396	2,434	127	3,957

2. Since Title 42 compensation authority was broadened in 1999, how many employees at NIH have converted from federal civil service positions to Title 42 employment? What is the distribution of employee salaries for each Title 42 compensation level? What is the range of salary increases (the differences between the previous federal civil service salaries and the new Title 42 salaries) for those employees who converted? What has been the total cost of the differences between the increased Title 42 salaries and the previous federal civil service salaries for all of the NIH employees who converted from federal civil service to Title 42?

Information on NIH conversions is shown below and in Table 2, above.

OPDIV	Number of Conversions	Title 42 Salary Range	Range of Salary Increases	Total Increase for Conversions
NIH	737	\$22,344 - \$200,000	\$0 - \$64,103	\$11,654,645

3. How many new NIH employees were hired under a Title 42 authority? How many NIH employees hired since 2000 have converted to Title 42?

Information on NIH Title 42 hires is shown below and in Table 3, above.

OPDIV	New Hires to Title 42 Positions	Number of Conversions
NIH	3,446	74

4. Since July 1, 1999, how many retention bonuses have been given? What has been the total cost of these retention bonuses?

NIH information on retention allowances is shown below and in Table 4, above.

OPDIV	Number of Retention Allowances	Total Cost of Retention Allowances
NIH	236	\$2,773,656

NIH response to Title 42 data request

1. What are the required credentials to be eligible for Title 42 compensation?

Answer: Title 42 provides the flexibility needed to allow NIH to attract and retain individuals with outstanding scientific, technical, and clinical skills. Other than clinical staff such as nurses, to be eligible for a T-42 appointment, whether under (f) or (g), the individual must have a doctorate in a biomedical or related field, and must be engaged in scientific research, or science management, science administration, or science policy. In rare instances, an exception may be granted by the Deputy Director for Intramural Research or the Deputy Director for Extramural Research to waive the doctorate based on a finding that the individual's education and experience is equivalent to a doctorate.

2. For each calendar year starting with 2000, what percentage of new NIH employees were hired as Title 42 employees?

Answer: See first worksheet in the attached chart.

3. Please provide a listing of each employee at HHS or HHS agency receiving Title 42 salaries, including names, agency, when hired, salary, retention bonuses (if any) qualifications for Title 42 compensation (degrees, board certifications, etc.).

Answer: See second worksheet in the attached chart.



Percent of New
Hires under Tit...

**Percent of New NIH
Employees Hired under
Title 42* by Calendar
Year
Percentage
of New
Employees
Hired under
Title 42**

CY	Title 42
2000	21.5%
2001	25.4%
2002	27.5%
2003	32.2%
Average	26.7%

*Includes only AD and RS pay plans

List of Pfizer - NIH Consultants from 1999 to Present

NAME	DATE	DESCRIPTION OF SERVICES	AMOUNT	REMARKS
Bax, Adrian	6/7/00 - 6/7/01	to assist Pharmacia & Upjohn in the development of improved NMR pulse programs	\$15,000 per year plus travel expenses	See note above. No other payments made to this date.
	6/7/01 - 6/7/02	to assist Pharmacia & Upjohn in the development of improved NMR pulse programs	\$15,000 per year plus travel expenses	See note above.
	7/6/02 - 6/6/03	to assist Pharmacia & Upjohn in the development of improved NMR pulse programs	\$15,000 per year plus travel expenses	\$2,000 on 12/2/03 for consulting fee
Bernick, John		General clinical scientific support		\$81.50 expenses reimbursement on 11/7/99
NIAD	6/1/01 - 11/30/01	consulting services in conjunction with the Visual Basic Advisory Committee Meeting	\$1,000 per meeting and up to \$1,000 for travel	\$271.43 travel reimbursement on 9/28/01
Barnes, H. Bryan Jr.		General consulting services		\$1,000 on 8/28/01 for consulting fee
NIH				\$10,000 on 8/27/01 for consulting fee
				\$84 on 10/2/02 for expenses reimbursement
				\$1,650 on 4/28/02 for consulting fee
				\$793 on 6/1/02 for expenses reimbursement
				\$15,000 on 9/1/02 for consulting fee
				\$1,000 fee on 9/28/02 for Advisory Board Meeting
				\$20,000 on 4/15/04 for consulting fee
				\$300 on 4/15/04 for Advisory Board Meeting
Chasen, Bruce	10/99	provides guidance to Pharmacia Upjohn on the planning and ongoing progress of the Pfizer-Schering-Plough Advisory Board meeting on 10/5/99.	\$1,000 honorarium plus travel expenses	See note in Pharmacia payments above
Cilinski, John	10/22/00	3 days of general consulting services for Pharmacia Upjohn	\$1,000 plus travel expenses	\$64,000 to Pharmacia Upjohn above
Dyke, Christopher Kent		Symyx Speaker		\$900 honorarium on 8/7/01
NIH				\$900 honorarium on 10/30/01
				\$1,650 on 10/22/01 for travel reimbursement
				\$500 honorarium on 3/1/02
				\$2,000 on 4/23/02 for consulting fee
Feris, Frederick L.	6/00 - 6/01	general per diem consulting for Pharmacia & Upjohn	\$2,000 per diem plus travel expenses	See note in Pharmacia payments above
Fennell, Albert, Jr.	2/17/04 - 2/18/04	2000 dollars travel and checkbooks with a check on speciality and laboratory supplies.	\$2,000 for 2-day plus travel expenses	\$2,000 honorarium on 2/18/04
	4/28/04 - 4/28/05	NIH doctors, staff and checkbooks with a check on speciality and laboratory supplies.	\$2,000 per day of consulting plus travel expenses	

TAB 21

CONFIDENTIAL

June 6, 2004

1

List of Pfizer - NIH Consultants from 1999 to Present

Stanzler, Frank J.	NCI	10/18/2002	General consulting services	\$4,500 plus travel expenses	\$1,200 honorarium on 8/12/03 \$2,000 speaker fee on 1/16/03 \$16,122 expense reimbursement on 08/03 \$1,000 honorarium on 10/18/03 \$95,000 expense reimbursement on 12/20/03 \$7,831.22 consultant fee on 6/15/01
Harris, Curtis C.	NCI	4/101 - 5/31/02 4/102 - 5/31/04	As visited Pizar's Drug Safety Evaluation Program regarding the manufacturer of potent tumor treatment with Pizar compounds (to visit Pizar's Drug Safety Evaluation regarding its proprietary program pursuant to 41001 grant) Participation in May 2003 Pizar/NCI conference Review of Pizar/NCI data and literature	\$18,000 for 3 days of 24 hours plus travel expenses \$5,000 per day of consulting plus travel expenses	\$11,800 consulting fee on 8/12/02 \$11,800 consulting fee on 8/16/03 \$11,000 NCI consulting fee on 9/18/03 \$300 honorarium on 12/18/02
Hausman, Frances P. NCIHD			Synopsis Speaker to review and read of Pharmacokinetics & Update in the strategic planning of discovery and development of chemoprevention drugs, participate in the evaluation of new product opportunities and due diligence reviews, and in formulating regulatory strategies.	\$350/hr. for a maximum of 22 work days or 253 hours per 12-month period	See note re Ph. needs payments above \$1,000 honorarium on 6/28/03 \$326.50 expense reimbursement on 8/20/03
Levy, David	NHLBI	7/19/99 - 10/19/99	officer, with Pardo-Oliva is an Accepted study and to serve as a member of the NCI/NIH Expert committee.	\$42,500 plus expenses	See note re Pharmacokinetics \$1,000 honorarium on 8/4/99 \$350.00 expense reimbursement on 8/4/99 \$1,000 honorarium on 8/5/99 \$1,000 honorarium on 10/5/99 \$1,000 honorarium on 10/11/99 \$1,000 honorarium on 11/10/99 \$37 expense reimbursement on 5/5/00 \$3,000 honorarium on 3/22/00 \$47 expense reimbursement on 6/4/01 \$1,000 honorarium on 8/4/01 \$1,000 honorarium on 8/11/03 \$360 honorarium on 3/12/03 \$360 honorarium on 3/12/03

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List of Pfizer - NIH Consultants from 1999 to Present

						\$1,000 honorarium on 6/26/03
						\$1,000 honorarium on 7/25/03
						\$1,000 honorarium on 7/29/03
						\$1,000 honorarium on 8/1/00
						\$76.84 expense reimbursement on 8/28/03
						\$1,000 honorarium on 9/22/03
						\$468 expense reimbursement on 9/24/03
						\$226 expense reimbursement on 10/28/03
						See note re Pharmacia payments above
						\$1,500 consulting fee on 2/15/02
						\$697 expense reimbursement on 3/4/02
						\$3,784 honorarium and travel fees on 4/8/01 for advisory results review
						\$4,000 consulting fee on 2/7/01 for FDA review
						\$5,871 consulting fee on 10/9/01
						\$1,175 consulting fee on 1/27/01
						\$16,000/day for 6-hr, at other fees: \$40/hr. Total fees re:to exceed \$10,000. Travel expenses.
						\$750 honorarium on 8/22/99
						\$5,000 consulting fee on 8/18/01
						\$680 seminar series honorarium on 5/6/03
						See note re Pharmacia payments above
						See note re Pharmacia payments above
						\$16,000 consulting fee on 2/28/01

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List of Pfizer - NIH Consultants from 1999 to Present

[illegible]

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List of Pfizer - NIH Consultants from 1999 to Present

NAME	DATE	DESCRIPTION	AMOUNT	REMARKS
	5/1/02 - 5/1/03	Presented to several Pfizer in the study of Neurobiology of neurological disease	\$15,000 per session plus travel exp.	TOTALS FOR 2002: \$6,372.70 consulting fees; \$94,600 honoraria; \$40,708.10 expenses reimbursed.
	11/1/02 - 11/1/03	presented to several Pfizer in the study of Neurobiology of Alzheimer's Disease.	\$45,000	TOTALS THROUGH JUNE 4, 2004: \$25,000 consulting fees; \$45,000 honoraria; \$7,103.12 expenses reimbursed
Taylor, Simon	10/98 - study completion	acted in development and execution of protocol involving use of Prilosec in health in treating diabetic patients who have problems with sedation and insulin metabolism.	\$240/hr, plus travel exp.	See note re Pharmacia payments above
Wersich, Steven	8/02 - 8/03	consulting for Pharmacia & Upjohn related to insulin and its relation to other endocrine and metabolism	\$1,000 per day for 2 days plus travel exp.	See note re Pharmacia payments above
Weinberger, Daniel R.	did not end date	general consulting services for Pharmacia & Upjohn	\$2,000 honorarium on 1/1/00 for 1 day	See note re Pharmacia payments above
Weinberg, John M.	8/99 end date	general consulting services	\$175 expense reimbursement on 2/28/03	See note re Pharmacia payments above

Footnote: Payments listed may not necessarily correspond to the Agreed Compensation figures because there may be other arrangements with a consultant for which we do not have a written agreement.

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Slobodin, Alan

From: Burton, Craig (HHS/OS) [Craig.Burton@hhs.gov]
Sent: Friday, June 18, 2004 9:51 PM
To: Slobodin, Alan
Cc: Flamberg, Gemma (NIH/OD); Torres, Abelardo (HHS/OS)
Subject: Fw: NEAC Totals



NEAC Totals.doc

TAB 22

Here you go

 Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: Flamberg, Gemma (NIH/OD) <FlambergG@OD.NIH.GOV>
To: Burton, Craig (HHS/OS) <Craig.Burton@hhs.gov>
CC: Smolonsky, Marc (NIH/OD) <SmolonsM@OD.NIH.GOV>; Jaffe, Holli Beckerman (NIH/OD) <JaffeHB@OD.NIH.GOV>
Sent: Fri Jun 18 18:43:39 2004
Subject: FW: NEAC Totals

<<NEAC Totals.doc>> This is in response to Alan's question, as follows:

Because the NEAC does not approve or deny requests, were any of the NEAC recommendations not followed by the approving official? If so, please provide background information on each of those individual instances.

Attached are statistics tallying the activities that the NEAC reviewed, and noting the couple of cases where the NIH DEC's (Dr. Kington) decision was different. I know Alan asked for the details of those cases. There are only 2, and I will get them for you as quickly as I can, but it doesn't look like it will be tonight because the keeper of the files has gone home.

Activities Reviewed by NEAC

Totals

Activities and Awards Reviewed by NEAC: 317*
NEAC Recommended Approval: 234

Approval Recommendations by NEAC

NEAC Recommended Approval & NIH DEC Approved: 231
NEAC Recommended Approval & Activities are Pending: 3

Disapproval Recommendations from NEAC

NEAC Recommended Disapproval & NIH DEC Approved: 2
NEAC Recommended Disapproval & NIH DEC Approved, but for No Compensation: 2
NEAC Recommended Disapproval & Employee Withdrew the Activity: 6
NEAC Recommended Disapproval & the Activity is Still Pending: 23
NEAC Recommended Disapproval & Dr. Kington disapproved the activity: 2

NEAC Requested More Information after Initial Review

Employee Withdrew Activity before Final Recommendation: 4
Still Pending (NIH DEC Has Not Given Final Approval): 34

Awards

NEAC recommended approval for 10 Awards. NIH DEC approved those 10 Awards.
Two of the Awards were Lecture Awards.

*When I looked closer at the spreadsheets, 4 activities that I counted last time were not found to be within NEAC's jurisdiction when they were presented to the Committee, so the Committee declined to review them.

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Frank	Joseph A. Frank	CC	NINDS	8/26/1997	12/22/1999	Phase II Pilot Study of CEP-151 in M.S. Patients	Cephalon, Inc.
Frank	Joseph A. Frank	CC	NINDS	12/12/1997	8/2/2002	Baseline to Treatment, Crossover, Clinical MRI - Phase II Trial of CGP 77116 in MS Patients	Neurocrine Biosciences, Inc.
Frank	Joe Frank	CC	NINDS	10/11/1999	10/5/2005	Application-Based Technical Development of Magnetic Resonance (MR)	GE Medical Systems
Marincola	Francesco Marincola	CC	CC	6/25/2002	6/25/2003	Evaluation of Mechanisms of Action of Aldara in the Induction of Apoptotic and Inflammatory Changes When Administered to Basal Cell Carcinoma In Situ	3M Pharmaceuticals, Inc.
Eckelman	William Eckelman	CC	CC	10/24/1997	4/6/2000	Development and Preparation of Radiopharmaceutical Grade I-124 for Applications Using PET	Memorial Sloan-Kettering Cancer Center
Alter	Harvey Alter	CC	CC	11/21/1997	4/29/2000	Isolation and Characterization of a Novel Hepatitis Agent(s)	Sentinel Biosciences
Klein	Harvey Klein	CC	CC	1/27/1994	1/27/2001	Collaborative Development of a Core Laboratory for Cell Processing and Gene Therapy+	Nexell Therapeutics
Pastan	Ira H. Pastan	NCI	NCI	12/24/1998	12/24/2002	Breast and Prostate Cancer Vaccines	IDEC Pharmaceuticals Corporation
Keefer	Larry K. Keefer	NCI	NCI	7/16/1999	10/26/2004	Development of Nitric Oxide (NO) Generating Therapeutic Devices	Medtronic AVE

Data as of 5/26/2004

TAB 23

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Rosenberg	Steven A. Rosenberg	NCI	NCI	3/23/2000	4/7/2005	Development of TAPETm Based Immunotherapies Targeted Against Cancer	Vion Pharmaceuticals Inc
Berzofsky	Jay A. Berzofsky	NCI	NCI	2/1/1999	3/29/2003	Semi-Allogeneic Cell Hybrids for the Immunotherapy of AIDS	HybVax
Berzofsky	Jay A. Berzofsky	NCI	NCI	6/14/2000	6/14/2004	Development of an HIV Vaccine using LEAPS and CTL Epitope Constructs	Cel-Sci Corporation
Hewitt	Stephen Hewitt	NCI	NCI	5/19/2000	6/30/2005	Development and Automation of Layered Expression Array Platform	20/20 Gene Systems, Inc.
Oppenheim	Joost J. Oppenheim	NCI	NCI	6/25/2001	6/25/2003	Development and Evaluation of Chemokine or Chemokine Receptor Neutralizing Antibodies for their Anti-Angiogenic Effects and Potential as Treatments for Cancer	Algenix, Inc.
Dean	Michael Dean	NCI	NCI	2/22/1999	3/14/2005	ATP-Binding Cassette Gene (ABC1) Target Validation/Mechanism of Action and Identification and Characterization of new ABC Family Member Genes Involved in Familial High Density Lipoprotein (HDL) Deficiency (FHD)	Aventis

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Libutti	Steven K. Libutti	NCI	NCI	11/10/2000	11/10/2005	Development of SeICDs™ and Thalomid-Based Therapies for Cancer	Celgene Corp.
Pastan	Ira H. Pastan	NCI	NCI	10/27/2000	3/21/2003	Development of Anti-EGFR Immunotoxins for the Treatment of Malignant Brain Tumors	Baker Norton Pharmaceuticals
Lowy	Douglas R. Lowy	NCI	NCI	12/14/2001	12/14/2004	Development of Papillomavirus Pseudovirion-Based Vaccines	Wyeth-Lederle Vaccines and Pediatrics
Waldmann	Thomas A. Waldmann	NCI	NCI	7/21/2001	7/21/2005	Phase I Study of Localization of Tumor Pretargeted by Murine B9E9Antibody/Streptavidin Fusion Protein (BE9 Fusion) in Patients With Refractory or Relapsed Non-Hodgkin's Lymphoma	NeoRx
Narayanan	Ven Narayanan	NCI	NCI	12/20/2000	12/3/2006	Utilization of BIOACTIV™ Technology for the Development of Compound Derivative	Albany Molecular Research
Nelson	David Nelson	NCI	NCI	10/25/2001	10/25/2005	Development of BLYS for the Treatment of Common Variable Immunodeficiency Disease Recombinant	
Rosenberg	Steven A. Rosenberg	NCI	NCI	2/8/2002	2/8/2005	Development of CTLA-4 Antibody-Based Immunotherapies Targeted Against Cancer	Medarex, Inc.
Pavliakis	George N. Pavliakis	NCI	NCI	2/4/2002	2/4/2005	Optimization of HIV DNA Vaccines	Wyeth-Lederle Vaccines

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Shaw	J. St Shaw	NCI	NCI	10/30/2001	7/12/2005	Prediction and Validation of Sites of Phosphorylation of Human Proteins and the Effects of Phosphorylation on Protein-Protein Binding	AxCell Biosciences
Pastan	Ira H. Pastan	NCI	NCI	6/8/1994	6/8/2001	Development of LMB-7 Immunotoxin	Roche Diagnostics GmbH
Pastan	Ira H. Pastan	NCI	NCI	7/6/1992	11/8/1999	MDR Gene Expression in Hematopoietic Stem Cells	Genetix Pharmaceuticals
Kwak	Larry Kwak	NCI	NCI	10/21/1994	10/21/1999	Novel Therapeutic Vaccines for B-Cell Lymphomas	MedImmune, Inc.
Arbuck	Susan Arbuck	NCI	NCI	5/14/1992	5/14/2000	CRADA for the Clinical Development of Taxotere	Aventis
Hearing	Vincent J. Hearing	NCI	NCI	11/2/1995	3/12/1999	Scientific and Commercial Development of Diagnostic and/or Therapeutic Agents for Hyperpigmentary Lesions	Beiersdorf AG
Restifo	Nicholas Restifo	NCI	NCI	5/10/1996	5/10/2001	Development of Anti-Cancer Vaccines Using the Accell Gene Delivery System (Gene Gun)	PowderJect Vaccines, Inc.
Schlom	Jeffrey Schlom	NCI	NCI	12/23/1996	12/23/1999	Functional Analysis of CD8+ Lymphocytes Redirected Against TAG-72 Positive and/or CEA Positive Tumors by MHC-Unrestricted, Chimeric Antigen Receptors	Cell Genesys, Inc.

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Pastan	Ira H. Pastan	NCI	NCI	1/16/1997	1/16/2001	Generation of immunotoxins Targeted to the CD 22 Antigen for the Treatment of B Cell Leukemias and Lymphomas	Royal Free Hospital School of Medicine
Liotta	Lance A. Liotta	NCI	NCI	3/5/1997	3/5/2002	Development of a Clinical Pathology Laser Capture Microdissection System for Routine Clinical Use	Arcturus Engineering, Inc.
Kwak	Larry Kwak	NCI	NCI	2/10/1994	5/23/2002	Lymphoma Vaccine Formulation and Evaluation	Bionira USA, Inc.
Gonzalez	Frank Gonzalez	NCI	NCI	4/17/1998	4/17/2000	The Production of Mice Expressing Human Cytochrome P450 CYP2D6 and CYP3A4	Pfizer, Inc.
Keefer	Larry K. Keefer	NCI	NCI	4/2/1997	1/13/2000	Properties of NO Donors Formulated in Fluorocarbons for Use With Partial Liquid Ventilation	Alliance Pharmaceutical Corp.
Restifo	Nicholas Restifo	NCI	NCI	9/8/1998	9/9/2000	Development of Therapope-Based Vaccines Targeted Against Human Melanoma	Virus Research Institute
Rosenberg	Steven A. Rosenberg	NCI	NCI	12/27/1998	10/27/2001	Development of Recombinant DNA-Based Cancer Vaccine	Vical, Inc.
Dean	Michael Dean	NCI	NCI	4/20/1999	10/20/2001	Analysis of Gene Expression Related to HIV Infection and AIDS	Alfymetrix, Inc.
Keefer	Larry K. Keefer	NCI	NCI	10/9/1998	6/18/2002	Nitric Oxide Releasing Compounds for Treatment of Male Erectile Dysfunction	NitroMed

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Reynolds	Craig Reynolds	NCI	NCI	9/23/1998	6/18/2002	Targeting of Angiogenesis Using Antibody-Drug Toxin Conjugates	ImClone Systems, Inc.
Pastan	Ira H. Pastan	NCI	NCI	9/7/1999	9/7/2003	Clinical Development of the Recombinant Immunotoxin Anti-Tac (Fv)-PE38 As an Anticancer Agent	AlbaPharm, Inc.
Pastan	Ira H. Pastan	NCI	NCI	9/7/1999	9/7/2003	Clinical Development of the Recombinant Immunotoxin RFB4-(dsFv)-PE38 As an Anticancer Agent	AlbaPharm, Inc.
Harris	Curtis Harris	NCI	NCI	7/30/1992	10/26/2001	Development of Screening Tests for Carcinogenic or Anticarcinogenic Compounds	Nestec, Ltd.
Pastan	Ira H. Pastan	NCI	NCI	5/19/1999	5/19/2003	Drug and Method for the Therapeutic Treatment of Ovarian Cancer and Mesotheliomas (ss(dsFv)-PE38	NeoPharm, Inc.
Pastan	Ira H. Pastan	NCI	NCI	4/24/2003	4/24/2005	Recombinant Immunotoxin in the Treatment of AIDS	IVAX Corporation
Pastan	Ira H. Pastan	NCI	NCI	1/5/2004	1/5/2006	Development of Mesothelin Antibodies for Cancer Therapy	Morphotek Inc.
Keeler	Larry K. Keeler	NCI	NCI	1/10/2003	1/10/2006	The Manufacture of Extracorporeal Blood Processing Devices with Nitric Oxide-Releasing Polymers	MC3, Inc.

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Dean	Michael Dean	NCI	NHLBI	5/8/2003	5/8/2006	Development of inhibitors to ATP-Binding Cassette Transporter Genes Using siRNA Methodologies	GenoFunction, Inc.
Berzofsky	Jay A. Berzofsky	NCI	NCI	8/29/2003	8/29/2006	Antagonists to Transforming Growth Factor Beta in Cancer Therapy	Genzyme Corporation
Roberts	Anita B. Roberts	NCI	NCI	8/29/2003	8/29/2006	Antagonists to Transforming Growth Factor Beta in Cancer Therapy	Genzyme Corporation
Pastan	Ira H. Pastan	NCI	NCI	2/3/2003	8/22/2006	Development of LMB-9 as a Cancer Agent	IVAX Corporation
Schlom	Jeffrey Schlom	NCI	NCI	1/27/1995	8/7/2000	The Use of Monoclonal Antibodies and Development of Novel Recombinant Immunoglobulin Forms for Radioimmunoguided Surgery of Cancer	Neoprobe Corporation
Pastan	Ira H. Pastan	NCI	NCI	12/11/2003	12/11/2006	Development of Anti-Mesothelin Immunotoxins as Therapeutic Agents for the Treatment of Cancer.	Enzon Pharmaceuticals, Inc.
Libutti	Steven K. Libutti	NCI	NCI	5/19/2000	6/30/2005	Development and Automation of Layered Expression Array Platform	20/20 Gene Systems, Inc.
Waldmann	Thomas A. Waldmann	NCI	NCI	9/9/2003	11/7/2006	Phase I Trial of MEDI-507 in CD-2 Positive Lymphoproliferative Disease.	Medimmune, Inc.

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Trent	Jeffrey M. Trent	NHGRI	NHGRI	9/9/1997	9/9/2003	Quantitative Analysis of Genome Composition and Gene Expression by Micro-Arrays	Agilent Technologies, Inc.
Bitner	Michael Bitner	NHGRI	NHGRI	9/14/1999	9/14/2002	Catalyzed Reporter Disposition (CARD) Signal Amplification Methodology for Accurate Gene Expression Profiling	NEN Life Science
Nussbaum	Robert Nussbaum	NHGRI	NHGRI	9/23/1999	9/23/2002	Single Nucleotide Polymorphism Genotyping by Mass Spectroscopy	Sequenom Industrial Genomics
Bitner	Michael Bitner	NHGRI	NHGRI	8/6/1999	8/6/2002	Improved Detection of Analytes in Nucleic Acid Hybridization-Based Detection Assays Using Fluorescent Quantum Dot Particles	Quantum Dot
Trent	Jeffrey M. Trent	NHGRI	NHGRI	8/6/1999	8/6/2002	Improved Detection of Analytes in Nucleic Acid Hybridization-Based Detection Assays Using Fluorescent Quantum Dot Particles	Quantum Dot
Trent	Jeffrey M. Trent	NHGRI	NHGRI	6/10/1999	2/8/2003	Cloning of Major Susceptibility Loci for Hereditary Prostate Cancer (HPC)	Genzyme, Inc.
Blaese	Michael Blaese	NHGRI	NHGRI	2/14/1995	6/29/1999	Viral Vectors for Gene Therapy	Genetic Therapy, Inc.
Trent	Jeffrey M. Trent	NHGRI	NHGRI	5/7/1996	7/10/2001	Quantitative Analysis of Gene Expression by Micro-Arrays	Research Genetics, Inc.

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Bitner	Michael Bitner	NHGRI	NHGRI	7/30/1997	7/28/1999	Multicolor Fluorescent Detection Reagents for Detection of Biological Analytes	Belov Faenza Scientific
Trent	Jeffrey M. Trent	NHGRI	NHGRI	7/30/1997	7/28/1999	Multicolor Fluorescent Detection Reagents for Detection of Biological Analytes	Belov Faenza Scientific
Blaese	Michael Blaese	NHGRI	NHGRI	7/2/1998	1/8/2000	Development and Testing of Adeno-EIAV Hybrid Viruses as Transcomplementing Agents for the Production of EIAV Vectors	Oxford Biomedica, Ltd.
Brewer	H. B. Brewer	NHLBI	NCI	2/22/1999	3/14/2005	ATP-Binding Cassette Gene (ABC1) Target Validation/Mechanism of Action and Identification and Characterization of new ABC Family Member Genes Involved in Familial High Density Lipoprotein (HDL) Deficiency (FHD)	Aventis
Young	Neal S. Young	NHLBI	NHLBI	1/25/1999	1/25/2002	Development of a Capsid Antigen Based B19 Parvovirus Vaccine	Medimmune, Inc.
Kotin	Robert M. Kotin	NHLBI	NHLBI	10/5/2000	10/5/2002	Development of Novel Chimeric Gene Therapy Vectors Comprising an Adenovirus Vector Harboring AV-ITRs	GenVec, Inc.

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Dunbar	Cynthia Dunbar	NHLBI	NHLBI	11/16/2000	11/16/2001	Rhesus Monkey Autologous Transplantation Experiments Designed to Optimize Gene Transfer into Hematopoietic Stem Cells	Immunex Corporation
Keefer	Larry K. Keefer	NHLBI	NCI	5/9/2003	5/9/2006	Incorporation of Nitric Oxide Donors in Lotions to be Applied to the Skin	
	MC3, Inc.						
Brewer	H. B. Brewer	NHLBI	NHLBI	5/8/2003	5/8/2006	Development of Inhibitors to ATP-Binding Cassette Transporter Genes Using siRNA Methodologies	GenoFunction, Inc.
Barrett	Austin J. Barrett	NHLBI	NHLBI	11/4/2003	11/4/2004	Ex Vivo Selective Depletion of Host-Reactive Donor T-Lymphocytes Using TH9402 and Photodynamic Cell Purging: Pre-clinical Evaluation and Optimization of the Clinical Scale Process	Celmed Biosciences Inc.
Pohl	Lance Pohl	NHLBI	NHLBI	12/24/2003	12/24/2006	Murine Model for Prediction of Hepatotoxic Potential of New Drugs	GlaxoSmithKline
Mcveigh	Elliot Mcveigh	NHLBI	NINDS	10/11/1999	10/5/2005	Application-Based Technical Development of Magnetic Resonance (MR)	GE Medical Systems
Schlessinger	David Schlessinger	NIA	NIA	5/16/2001	5/16/2006	Altered Expression of Developmentally Regulated Genes	Vaccinex LP

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Lakatta	Edward G. Lakatta	NIA	NIA	1/23/2002	6/7/2004	Systolic and Pulse Pressure Hemodynamic Improving by Restoring Elasticity: The Sapphire Study	Alteon, Inc.
Lakatta	Edward G. Lakatta	NIA	NIA	4/4/1996	3/28/2002	Use of Facitaxel and Other Microtubule-Stabilizing Agents for the Prevention of Restenosis and Other Vascular Diseases" AMENDMENT #5:	Angiotech Pharmaceuticals, Inc.
Rapoport	Stanley I. Rapoport	NIA	NIA	11/14/1997	11/14/1999	Mechanism and Drug Treatment of Alzheimer's Disease: Excitatory Amino Acids and Energy Metabolism	Bearsden Bio
Lakatta	Edward G. Lakatta	NIA	NIA	2/2/1999	2/2/2000	Precinical Development of Gene Delivery System Therapeutics for the Treatment or Prevention of Genetic and Acquired Vascular Diseases	Megabios Corporation
Barry	Clifton E. Barry	NIAID	NIAID	1/25/2001	1/25/2004	Development of New Drugs for the Treatment of Tuberculosis	
Miller	Louis H. Miller	NIAID	NIAID	3/8/2001	3/8/2004	Merozoite Surface Protein 1 Expressed in Insect Cells: Process Development, Pre-Clinical and Initial Clinical Evaluation	Novavax, Inc.

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Shevach	Ethan M. Shevach	NIAID	NIAID	9/13/2000	7/13/2003	Analysis of Gene Expression in Immunoregulatory T Cells That Co-Express the CD4 and CD25 Surface Markers	Genetics Institute, Inc.
Malech	Harry Malech	NIAID	NIAID	9/13/2001	9/13/2004	Study of Low Intensity Preparative Regimen Followed By HLA-Matched Transplantation for Chronic Granulomatous Disease	Nexell Therapeutics, Inc.
Kehrl	John Kehrl	NIAID	NIAID	11/21/2001	11/21/2002	Discovery and Characterization of Novel Non-Cytolytic Antiviral Factors Derived from CD8+ T Cells of Certain HIV-Infected Individuals	Ciphergen Biosystems
Ribeiro	Joss Ribeiro	NIAID	NIAID	3/11/2002	3/11/2005	Evaluation of DNA Vaccines Based on Sand Fly Salivary Proteins to Control Leishmania Infantum Infections in Dogs	Merial Limited and Merial S.A.S.
Miller	Louis H. Miller	NIAID	NIAID	10/24/2001	8/2/2005	Novel, Polyspecific Malaria Vaccine Development Based on P1EMP1 Using Molecular Breeding TM Directed Molecular Evolution Technologies	Maxygen, Inc.
Lane	H. Clifford Lane	NIAID	NIAID	10/30/1992	10/30/2000	Adoptive Transfer of Human T Cell Clones for Treatment of Immunologically Mediated and Infectious Diseases	Cell Genesys, Inc.

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Malech	Harry Malech	NIAID	NIAID	9/30/1994	3/30/2001	Development of An Ex Vivo Stem Cell Gene Therapy System to Provide Both Short and Long Lasting Correction for the Genetic Defects in Chronic Granulomatous Disease (CGD)	Nexell Therapeutics, Inc.
Purcell	Robert H. Purcell	NIAID	NIAID	4/4/1994	4/4/2000	Development of Hepatitis A Vaccine	SmithKline Beecham Pharmaceuticals
Seder	Robert Seder	NIAID	NIAID	4/14/1994	4/14/1999	Evaluation of the Interaction-15 and CD4+ T Cells	Immunex Corporation
Purcell	Robert H. Purcell	NIAID	NIAID	4/1/1994	10/1/2000	Development of Hepatitis C Vaccine	GlaxoSmithKline
Purcell	Robert H. Purcell	NIAID	NIAID	4/5/1996	10/5/2000	Development of a Safe and Effective Vaccine Against Hepatitis E Virus (HEV)	GlaxoSmithKline Biologicals S.A.
Strober	Warren Strober	NIAID	NIAID	10/30/1997	10/30/1999	Using Anti-Murine IL-12 Antibodies, P40 and P70, to treat TNBS Colitis in a Mouse Model	Genetics Institute, Inc.
Prussin	Calman Prussin	NIAID	NIAID	4/2/1998	4/2/2000	Use of rhIL-12 as an Adjuvant in Allergen Immunotherapy	Genetics Institute, Inc.
Prussin	Calman Prussin	NIAID	NIAID	5/25/1999	5/25/2001	Phase II Efficacy Study of Aerosolized Recombinant Human IL-4 Receptor in Adults with Asthma	Immunex Corporation
Moss	Bernard Moss	NIAID	NIAID	11/8/1999	11/8/2000	A Study of the Binding of IL-8 to Poxvirus/Fc Fusion Proteins	Immunex Corporation

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Strober	Warren Strober	NIAID	NIAID	3/8/2001	3/8/2002	A Study to Determine the Effect of Human TRAIL on Autoimmune Lymphoproliferative Syndrome (ALPS) in the MRL/lpr mouse and its Effect on Colonic Inflammation in the Murine TNBS Colitis Model	Genentech, Inc.
Collins	Peter L. Collins	NIAID	NIAID	4/10/1996	2/19/2002	Production of Live Attenuated RSV and PIV Vaccine Viruses from cDNA	Lederle Praxis (Biological Div of American Cyanamid)
Inman	John K. Inman	NIAID	NCI	8/3/2000	11/20/2003	Development of Optimized Inhibitors of Protein Zinc Finger Domains	Achillion Pharmaceuticals, Inc.
Lipsky	Peter E. Lipsky	NIAMS	NIAMS	9/16/2002	9/16/2004	A Phase I Open-Labelled, Dose-Ascending Clinical Trial of Immunotherapy of MRA, A Humanized Anti-IL 6 Receptor Monoclonal Antibody, in Patients with Systemic Lupus Erythematosus	Chugai Pharmaceuticals, Inc.
O'shea	John J. O'shea	NIAMS	NIAMS	4/3/1996	4/3/2001	JAK3 Structure and Function Analysis: Molecular Basis to JAK3 Interactions with IL-2R-GAMMA	Pfizer, Inc.
Plotz	Paul Plotz	NIAMS	NIAMS	9/23/2002	9/23/2006	Randomized, Double Blind, Placebo-Controlled Trial of Infliximab in Patients with Dermatomyositis and Polymyositis	Centocor, Inc.

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Plotz	Paul Plotz	NIAMS	NIAMS	11/7/2003	11/7/2005	Enzyme Replacement Therapy for Pompe Syndrome	Genzyme Diagnostics
Klein	David Klein	NICHD	NICHD	8/9/1996	5/27/2000	Serotonin N-Acetyltransferase: Distribution, Biochemistry, and Pharmacology	Institute DeRecherches Internationales Servier
Baum	Bruce J. Baum	NIDCR	NIDCR	4/16/2003	4/16/2006	Adeno-Associated Virus Mediated Gene Transfer to Salivary Glands for Systemic Gene Therapeutic Applications	Genetic, Inc.
Chiorini	John A. Chiorini	NIDCR	NIDCR	4/16/2003	4/16/2006	Adeno-Associated Virus Mediated Gene Transfer to Salivary Glands for Systemic Gene Therapeutic Applications	Genetic, Inc.
Bugge	Thomas H. Bugge	NIDCR	NIDCR	1/9/2004	1/9/2006	Protease activated pro-cytotoxins for cancer targeting	Onco Tac Pharmaceuticals Aps
Wess	Jurgen Wess	NIDDK	NIDDK	8/4/1997	11/1/2000	Creation and Analysis of Muscarinic Receptor "Knock Out" Mice	Eli Lilly and Company
Lewis	E. Ne Lewis	NIDDK	NIDDK	9/7/1998	9/7/2000	Vibrational Spectroscopic Imaging Studies of Biomolecular Systems	Imperial Chemical Industries
Levin	Ira Levin	NIDDK	NIDDK	9/7/1998	9/7/2000	Vibrational Spectroscopic Imaging Studies of Biomolecular Systems	Imperial Chemical Industries
Jacobson	Kenneth A. Jacobson	NIDDK	NIDDK	2/9/2001	2/9/2004	Development for A3 Modulation of the P2Y1 Receptor	Gilead Sciences, Inc.

Data as of 5/26/2004

Standard CRADAs by PI's IC at time of execution

Last Name	NIH PI	PI's Original Institute	Lead IC	Effective Date	Modified Expiration Date	Title	Collaborator
Shloach	Joseph Shloach	NIDDK	NIDDK	2/13/2001	2/13/2003	Development of a Purification Process Using Different Types of Expanded Bed Resins	Amersham Pharmacia Biotech
Jacobson	Kenneth A. Jacobson	NIDDK	NIDDK	10/14/1994	10/14/1999	Adenosine Receptor Agonists in Cerebral Ischemia	Gilead Sciences, Inc.
Bennett	Peter Bennett	NIDDK	NIDDK	10/14/1994	10/14/1999	Genetic Determinants of Non-Insulin-Dependent Diabetes Mellitus	Glaxo Research Institute
Yeh	Herman Yeh	NIDDK	NIDDK	5/1/1998	5/1/2000	Precinical Research Development of Small Molecular Weight Antiangiogenic Compounds; Thalidomide, Cyclophosphamide and their Analogues	EntellMed, Inc.
Jacobson	Kenneth A. Jacobson	NIDDK	NIDDK	12/10/1998	12/10/1999	Adenosine Receptor (A ₂) Gene Knockout Mice	Merck & Co., Inc.
Wess	Jurgen Wess	NIDDK	NIDDK	5/1/1986	5/1/2000	Analysis of Receptor/G Protein Coupling Mechanisms in Yeast	American Cyanamid Company
Blackshear	Perry J. Blackshear	NIEHS	NIEHS	12/17/1998	12/17/2000	Studies of Tristetraprolin (TTP) and Related C/EBP Proteins	Zeneca
Weinberger	Daniel Weinberger	NIMH	NIMH	5/21/2002	5/21/2003	Determination of Expression of Novel G-Protein Coupled Receptor Family SREB in Normal and Diseased Human Brain	Yamanouchi Pharmaceutical
Merril	Carl Merrill	NIMH	NIMH	8/18/1994	8/18/1999	Enhanced Bacteriophage Anti-Bacterial Therapy	Exponential Biotherapies, Inc.

Data as of 5/26/2004


TAB 24

IC	Awardee's Last Name	First Name	Cash Amt	Selecting Org	Was Selecting Org a grantee of the Institute?	Subtotals by I/C	Subtotals by largest recipient per I/C
NCI	Abraham	Jame	\$350	Washington Society for the History of Medicine	N		
NCI	Aziz	Noreen	\$20,000	Susan G. Komen Foundation	N		
NCI	Cheng	Sheueyann	\$4,100	American Thyroid Assoc.	N		
NCI	Feldman	Elizabeth	\$100	American College of Surgeons, Washington DC Chapter	Y		
NCI	Figg	W. Douglas	\$75	Assoc. of Military Surgeons of the US	N		
NCI	Finkelstein	Steven	\$525	ACOS/DC Chapter	N		
NCI	Finkelstein	Steven	\$500	American College of Surgeons, Washington DC Chapter	N		
NCI	Finkelstein	Steven	\$1,500	American College of Chest Physicians	N		
NCI	Ford	Leslie	\$1,000	Association of Community Cancer Centers	N		
NCI	Fraumeni	Joseph	\$1,000	Yale University, Cancer Center	Y		
NCI	Greenwald	Peter	\$2,500	American Society of Clinical Oncology	N		
NCI	Harris	Curtis	\$2,763	International Society of Gastroenterological Carcinogenesis	N		
NCI	Jaffe	Elaine	\$2,434	Massachusetts General Hospital	Y		
NCI	Jaffe	Elaine	\$1,000	Memorial Sloan Kettering Cancer Center	Y		
NCI	Jaffe	Elaine	\$1,500	University of Illinois, Chicago College of Medicine	Y		
NCI	Jaffe	Elaine	\$500	University of Pennsylvania, Medical Center	Y		
NCI	Kingma	Douglas	\$1,000	Clinical Cytometry Society	N		
NCI	Klausner	Richard	\$4,000	Van Andel Institute	N		
NCI	Klausner	Richard	\$3,000	Arizona Cancer Center	Y		
NCI	Klausner	Richard	\$3,000	American Society of Cytopathology	N		
NCI	Klausner	Richard	\$20,000	American Society of Clinical Investigation	N		
NCI	Klausner	Richard	\$10,000	American Academy of Dermatology	N		
NCI	Klausner	Richard	\$15,000	Ohio State University, Arthur James Cancer Hospital & Center	Y		
NCI	Klausner	Richard	\$40,000	University of Pittsburgh	Y		
NCI	Klausner	Richard	\$50,000	Service Oncologie Medicate Pite Salpetriere	N		\$145,000
NCI	Lee	Kyung	\$2,000	Society of Biomedical Research	N		
NCI	Liotta	Lance	\$5,000	University of Texas, MD Anderson Cancer Center	Y		
NCI	Liotta	Lance	\$4,500	West Virginia University, Mary Babb Randolph Cancer Center	Y		
NCI	Liotta	Lance	\$750	American Association of Clinical Chemistry	N		
NCI	Liotta	Lance	\$1,250	Clinical Ligand Society	N		
NCI	Lowy	Douglas	\$10,000	American Academy of Dermatology	N		
NCI	Milner	John	\$500	University of Missouri - Columbia	Y		
NCI	Misteli	Thomas	\$3,500	Union of Swiss Societies of Experimental Biology	N		
NCI	Mitchell	James	\$2,000	University of Pennsylvania, Medical Center	Y		
NCI	Neelapu	Sathva	\$1,000	AACR	N		
NCI	Phan	Giao	\$1,500	AACR	N		
NCI	Posada	Edwin	\$1,500	Amer. Society of Clinical Oncology	Y		
NCI	Ried	Thomas	\$5,000	American Society of Biochemistry & Biology (additional \$20,000 designated for research laboratory)	N		
NCI	Rimer	Barbara	\$3,000	Arizona Cancer Center	Y		
NCI	Rosenberg	Steven	\$51,385	American-Italian Cancer Foundation	N		
NCI	Rosenberg	Steven	\$6,000	University of Texas, MD Anderson Cancer Center	Y		
NCI	Sedelnikova	Oiga	\$1,543	Intl. Congress of Radiation Research	N		
NCI	Solomon	Diane	\$3,000	American Society of Cytopathology	N		
NCI	Streuwing	Jeffrey	\$2,500	Association of Military Surgeons of the US	N		
NCI	von Eschenbach	Andrew	\$3,000	American Urological Association	N		
NCI	Waldmann	Thomas	\$2,000	American Society of Microbiology	Y		
NCI	Yuspa	Stuart	\$1,000	Society for investigative Dermatology	N		
NCI	Yuspa	Stuart	\$1,000	Society for investigative Dermatology	N	\$298,775	
NHGRI	Collins	Francis	\$5,000	March of Dimes	No		
NHGRI	Collins	Francis	\$3,000	University of Pennsylvania, School of Medicine & the Children's Hospital of Philadelphia	Y		
NHGRI	Collins	Francis	\$7,500	Museum of Science	N		
NHGRI	Collins	Francis	\$19,500	The Gardner Foundation	N		

IC	Awardee's Last Name	First Name	Cash Amt	Selecting Org	Was Selecting Org a grantee of the Institute?	Subtotals by I/C	Subtotals by largest recipient per I/C
NHGRI	Collins	Francis	\$1,500	Child Neurology Society	N		
NHGRI	Collins	Francis	\$1,500	University of North Carolina at Chapel Hill	Y		
NHGRI	Collins	Francis	\$2,500	Harvard University, Massachusetts General Hospital - a part of Partners Health Care facilities	Y		
NHGRI	Collins	Francis	\$4,000	Van Andel Institute	N		
NHGRI	Collins	Francis	\$5,000	Loma Linda University	N		
NHGRI	Collins	Francis	\$5,000	American College of Obstetricians & Gynecologists	N		
NHGRI	Collins	Francis	\$4,000	University of Wisconsin - Madison	Y		
NHGRI	Collins	Francis	\$25,000	American College of Surgeons	N		
NHGRI	Collins	Francis	\$3,000	American Society of Cytopathology	N		
NHGRI	Collins	Francis	\$1,000	American Academy of Otolaryngology, Head & Neck Surgery Foundation, Inc.	N		
NHGRI	Collins	Francis	\$1,000	Association of American Physicians	N		
NHGRI	Collins	Francis	\$10,000	Calvin College & Van Andel Institute			
NHGRI	Collins	Francis	\$2,000	American Heart Association	N		
NHGRI	Collins	Francis	\$5,000	Association for Molecular Pathology	N		
NHGRI	Collins	Francis	\$2,000	Bucknell University	N		
NHGRI	Collins	Francis	\$1,000	North Carolina State University, Departments of Statistics and Genetics	N		
NHGRI	Collins	Francis	\$2,000	University of North Carolina at Chapel Hill	Y		\$110,500
NHGRI	Green	Eric	\$500	Mount Desert Island Biological Laboratory	No		
NHGRI	Green	Eric	\$1,000	University of South Florida Health Sciences Center	No	\$112,000	
NHLBI	Burg	Maurice	\$2,000	University of Arkansas	N		
NHLBI	Leonard	Warren	\$10,000	American Association of Immunology, Awards Committee	N		
NHLBI	Schron	Eleanor	\$1,000	American Heart Association	N	\$13,000	
NIA	Mattson	Mark	\$8,383	Catedra Santiago Grisolia	N	\$8,383	
NIAAA	Salem	Norman	\$8,000	American Oil Chemists Society	Y	\$8,000	
NIAID	Berger	Edward A.	\$1,000	Indiana University, Department of Microbiology and Immunology	Y		
NIAID	Connors	Mark	\$2,000	Johns Hopkins University	N		
NIAID	Fauci	Anthony	\$10,000	RAND	Y		
NIAID	Fauci	Anthony	\$1,000	Georgetown University, Kennedy Institute of Ethics & Brennan Family	N		
NIAID	Fauci	Anthony	\$7,500	The American Society for Microbiology, ICAAC Scientific Program Committee	N		
NIAID	Fauci	Anthony	\$3,000	American Society of Cytopathology	N		
NIAID	Fauci	Anthony	\$2,000	The United States & Canadian Academy of Pathology, Inc.	Y		
NIAID	Fauci	Anthony	\$5,000	The American Association for Clinical Chemistry, Inc.	Y		\$28,500
NIAID	Germain	Ronald N.	\$1,000	Harvard University, Dana Farber Cancer Institute	Y		
NIAID	Kelsall	Brian L.	\$1,000	American Academy of Asthma, Allergy, and Immunology	N		
NIAID	Lane	Henry Clifford	\$1,000	University of Pittsburgh, Cancer Institute	Y		
NIAID	Moss	Bernard	\$1,000	University of Cincinnati, College of Medicine, Physician Scientist Training Program	N		
NIAID	Moss	Bernard	\$1,000	The Scripps Research Institute	Y		
NIAID	Moss	Bernard	\$2,000	St. Jude's Children's Research Hospital	N		

IC	Awardee's Last Name	First Name	Cash Amt	Selecting Org	Was Selecting Org a grantee of the Institute?	Subtotals by I/C	Subtotals by largest recipient per I/C
NIAID	Moss	Bernard	The University of Chicago	The University of Chicago	The University of Chicago Cancer Research Institute		
NIAID	Paul	William E.	\$2,000	American Academy of Microbiology	N		
NIAID	Sher	Alan	\$600	University of Connecticut, Health Center Committee	Y		
NIAID	Willems	Thomas E.	\$10,000	University of Chicago, Howard Taylor Ricketts Award Committee	N	\$51,100	
NIAMS	Kastner	Daniel	\$3,000	New York Academy of Medicine	N		
NIAMS	Plotz	Paul	\$2,500	Alpha Omega Alpha Honor Medical Society (award form incorrectly dated 4/9/02)	Y		
NIAMS	Plotz	Paul	\$3,000	New York Academy of Medicine	N	\$8,500	
NICHD	Weinrich	Michael	\$1,500	College of Applied Life Studies at the University of Illinois at Urbana-Champaign	Y; no active NCMRR grants	\$1,500	
NIDCR	Baum	Bruce	\$1,000	New York University, College of Dentistry	N		
NIDCR	Baum	Bruce	\$5,000	American Dental Association	Y		
NIDCR	Stevkin	Harold	\$1,500	Columbia University, School of Dental and Oral Surgery	Y	\$7,500	
NIDDK	Bax	Adriaan	\$500	Temple University	N		
NIDDK	Bax	Adriaan	\$15,000	The Protein Society	N		
NIDDK	Bax	Adriaan	\$5,000	American Chemical Society	N		
NIDDK	Bennett	Peter	\$25,000	Novartis	N		
NIDDK	Bogardus	Clifton	\$500	Columbia University, College of Physicians & Surgeons (additional \$100,000 designated for research fellow support)	N		
NIDDK	Cushman	Samuel	\$2,000	American Diabetes Association	N		
NIDDK	Daly	John	\$11,748	Swedish Academy of Pharmaceutical Sciences	N		
NIDDK	Felsenfeld	Gary	\$6,200	The Great Plains Society for Molecular Biology & Genetics	N		
NIDDK	Gershengorn	Marvin	\$4,300	Cedars-Sinai Medical Center	N		
NIDDK	Jacobson	Kenneth	\$2,120	Chemical Society of Washington (DC)	N		
NIDDK	Jensen	Robert	\$1,500	University of California - Los Angeles	N		
NIDDK	Kohn	Leonard	\$2,000	American Thyroid Association	N		
NIDDK	Philpott	Caroline	\$6,189	University of Kansas	Y		
NIDDK	Rehermann	Barbara	\$5,000	University of Kansas	Y		
NIDDK	Rice	Kenner	\$10,000	The College on Problems of Drug Dependency	Y		
NIDDK	Schermann	Jurgen	\$10,000	American Society of Nephrology	N		
NIDDK	Spiegel	Allen	\$2,000	The Endocrine Society	N	\$109,057	
NIMH	Charney	Dennis	\$15,000	Collegium Internationale Neuro-Psychopharmacologicum (CINP)	no		
NIMH	Charney	Dennis	\$15,000	Collegium Internationale Neuro-Psychopharmacologicum (CINP)	no		
NIMH	James	Regina	\$5,000	American Academy of Child & Adolescent Psychiatry	No		
NIMH	Lebowitz	Barry D.	\$2,500	Gerontological Society of America	Y		
NIMH	Mishkin	Mortimer	\$25,000	Metropolitan Life Foundation (additional \$100,000 designated for NIMH for Alzheimers' research)	N		
NIMH	Ungerleider	Leslie G.	\$1,365	University de Montreal Faculte de Medecine	N		
NIMH	Weinberger	Daniel R	\$3,000	American Psychiatric Association	N	\$66,865	
NINDS	McFarland	Henry	\$12,500	International Multiple Sclerosis Foundation	N	\$12,500	

IC	Awardee's Last Name	First Name	Cash Amt	Selecting Org	Was Selecting Org a grantee of the Institute?	Subtotals by IC	Subtotals by largest recipient per IC
NINR	Phillips	Janice	\$4,000	Oncology Nursing Society	N	\$4,000	
NLM	Galperin	Michael	\$2,250	Purdue University, Department of Chemistry	N		
NLM	Lindberg	Donald	\$5,000	Cosmos Club	N		
NLM	Ostell	James	\$1,000	Society for Investigative Dermatology	N		
NLM	Parascandola	John	\$3,500	American Chemical Society		\$11,750	
TOTAL			\$712,930			\$712,930	

Jun-21-04 06:28am From- T-261 P.002/003 P-611
 May-07-2004 03:07pm From-Assistant Secretary for Legislation 202-690-7380 T-025 P.002/004 P-768

DEPARTMENT OF HEALTH & HUMAN SERVICES
 Office of the Secretary
 TAB 25
 The General Counsel
 Washington, D.C. 20201

APR 16 2002

The Honorable W. J. "Billy" Tauzin
 Chairman
 Committee on Energy and Commerce
 House of Representatives
 Room 2125, Rayburn House Office Building
 Washington, D.C. 20515

Dear Mr. Chairman:

The purpose of this letter is to clarify the role of this Department's attorneys with respect to the investigative interviews of employees of the Food and Drug Administration (FDA) being conducted by the Subcommittee on Oversight and Investigations. On March 21, 2002, you forwarded a letter to Dr. Lester Crawford, Deputy Commissioner, FDA, indicating that the subcommittee is investigating the conduct of ImClone Systems, Inc., in developing Erbitux, a colorectal cancer drug. Your letter noted that investigative interviews of FDA employees would be necessary because the subcommittee's inquiry concerns FDA policies and procedures pertinent to the Erbitux matter, as well as other issues broadly related to the FDA approval process for drugs and biologics. Further, your letter specifically stated that arrangements could be made with the Department's Office of General Counsel to provide "personal counsel" to the employees being interviewed.

Subsequently, investigative interviews with five FDA employees were scheduled and on April 9, 2002, an attorney from the Department's Office of General Counsel accompanied an FDA employee to the first of these interviews. Prior to the start of the interview, the committee staff members conducting the interviews apparently expressed some concern about the attorney from the Department being there. Specifically, there seemed to be some question as to the role of the attorney with respect to the interview process. While the majority committee staff member and the minority committee staff member opted to proceed with the interview, they requested a letter from the Department explaining the role of attorneys from the Office of General Counsel with respect to interviews of FDA employees in the Erbitux matter.

At the outset, it is important to note that the Department recognizes that the subcommittee has the right to investigate matters that fall within its jurisdiction and that these inquiries may involve interviews of Department personnel. Because this inquiry involves conduct of Department personnel acting within the scope of their duties, the Department offered to represent these individuals in their personal capacity, as provided for in your March 21, 2002, letter.

Jun-21-04 06:28am From: 1-201 P.003/004 P.001
 May-03-2004 03:07pm From: Assistant Secretary for Legislation 202-690-7380 T-025 P.003/004 F-759

Page 2 - The Honorable W. J. "Billy" Tauzin

I would like to address any concerns the subcommittee may have about counsel from the Department attending interviews of FDA employees in this particular matter. It is important to stress that Department attorneys represent employees in their personal capacity. Thus, Department attorneys who accompany an employee of FDA to an investigative interview will not inform any Department officials about the substance of the interview. Pursuant to an existing agreement with the Committee, moreover, an attorney who accompanies an FDA employee to these investigative interviews will not advise any other FDA employee scheduled to be interviewed of the content of any prior interviews. Also, the employees who have already been interviewed were advised of their right to retain personal counsel prior to their interviews. Any other FDA employees who are scheduled to be interviewed will also be advised of their right to retain personal counsel.

Additionally, the Department agrees that with respect to the interviews of FDA employees in this matter, no one from the FDA Office of Chief Counsel will represent an FDA employee during these interviews.

I believe that the guidelines set forth above should address the subcommittee's concerns about Department attorneys being present at these investigative interviews. Moreover, it is my understanding that the terms I have outlined are very similar to past arrangements made by the Department with respect to interviews of FDA employees in other subcommittee investigations.

Sincerely,



Alex M. Azar II

cc: The Honorable John D. Dingell
 Ranking Member

The Honorable James C. Greenwood
 Chairman
 Subcommittee on Oversight and Investigations

The Honorable Peter Deutch
 Ranking Member
 Subcommittee on Oversight and Investigations

TAB 26

Turnover Rates for NIH Scientific Staff for FY1994- FY2003	
FY	Turnover Rate of Scientific Staff
1994	6.56%
1995	10.67%
1996	9.04%
1997	9.86%
1998	10.42%
1999	10.56%
2000	10.10%
2001	9.37%
2002	8.75%
2003	7.08%
Avg:	9.24%

Turnover Rates of Title 42* Employees for FY2000-2003	
FY	Title 42 Turnover Rate compared to NIH Onboard Count
2000	2.4%
2001	2.4%
2002	2.1%
2003	2.5%
Avg.	2.4%

*Includes AD and RS pay plans only



TAB 27

HOME**OUR MISSION****ABOUT US****ADVISORS****TOOLS & SERVICES****PUBLICATIONS****CONGRESSIONAL****NEWS****SITE GLOSSARY****CONTACT US****Our Mission**

The founders of Correlogic Systems, Inc. envision a world where the ability to detect the relationship between a few seemingly inconsequential bits of data out of trillions may change the future of mankind.

Correlogic's mission is to advance the early identification of various cancers and other diseases, and to accelerate the new drug discovery process by applying its proprietary software to the development of proteomic and other biomarkers. We have created patent-pending diagnostic software for use by both the scientific research and pharmaceutical research communities and the clinical diagnostic market. Through licensing, joint ventures and strategic alliances, we seek to work with manufacturers of protein separation and sequencing tools, diagnostic kit manufacturers, pharmaceutical companies, the academic research community and others to create turn-key diagnostic systems that will revolutionize the disease testing and screening market. Equally important, we also provide pattern discovery solutions to biotech and pharmaceutical companies for use in genomics, molecular biology, protein sequencing, and in new drug identification and toxicity evaluation.

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Correlogic Systems, Inc. is a clinical proteomics company engaged in the development of tools and processes for proteomic and genomic-based clinical diagnostic systems and new drug discovery. Correlogic has developed a patent-pending, scientifically validated methodology for the early detection of various cancers and other diseases through the use of high throughput bioassays and pattern discovery software. Our technologies have a wide range of applications for the creation of disease diagnostic models, biomarker discovery, and new drug discovery processes.

Correlogic is also a clinical laboratory regulated under the Clinical Laboratory Improvement Amendments of 1988, designated to perform high complexity testing. Correlogic has entered into agreements to provide an ovarian cancer testing service in cooperation with the nation's two premier diagnostic laboratories, Laboratory Corporation of America and Quest Diagnostics.

Latest News...

On April 22, Peter Levine, President and CEO of Correlogic, appeared at the Biomedical Marketing Association's 26th Annual Conference in Boston, MA. He presented "The Importance of Partnerships in Technology Development and Commercialization in the Diagnostics Industry: A Case Study of Correlogic (OvaCheck™)".

On April 19, the *Philadelphia Inquirer* writes about Correlogic's work on ovarian cancer detection in the article, **Progress From Unraveling Proteins**.

On April 14, the *Miami Herald* writes about Correlogic's work on ovarian cancer detection in the article, **New Jersey Oncologist Says Ovarian Cancer Test May Catch Disease Early**.

The peer-reviewed journal *Endocrine-Related Cancer*, has accepted for publication "High-Resolution Serum Proteomic Features for Ovarian Cancer Detection", a paper co-authored by Correlogic's Chief Science Officer, Ben Hitt, along with researchers at NCI/FDA and others. This research, including the continued use of Correlogic's technology, was a further extension of our previously reported ovarian cancer results.

Correlogic's poster presentation "High-Throughput Multidimensional Mass Spectrometry Analysis for the Detection of Early Stage Epithelial Ovarian Cancer: A Serum Test for Ovarian Cancer." appeared at the Society of Gynecological Investigation conference in Houston, TX on March 25, 2004. The poster presented results that were 97 percent sensitive and 94 percent specific in validation.

February 10, 2004, Mitsui and Co., Ltd., Tokyo, Japan, makes equity investment in Correlogic. The companies will explore the creation of a joint venture in Japan. **Read press release.**

On January 12, 2004, Judith Reichman, M.D., medical contributor of the Today Show, profiled OvaCheck™, a blood test for the early detection of ovarian

cancer. **New Tests and Therapies May Help Enhance the Lives of Women. View the interview with NBC's Ann Curry.**

On December 1, 2003, Peter Levine, President and CEO of Correlogic, addressed Rep. Steve Israel's (D-NY) Cancer Task Force. He spoke about the upcoming ovarian blood test and other technology. The event was attended by 50 representatives from cancer advocacy and support organizations, local government representatives and healthcare providers.

Genome News Network covers Correlogic's proteomic pattern technology to detect ovarian cancer in its earliest stage. **Diagnosing Ovarian Cancer by Proteomics**, November 14, 2003.

The Wall Street Journal covers Correlogic's work on prostate and ovarian cancer detection. **Tiny Protein May Lead To Better Screen Test For Prostate Cancer**, November 4, 2003.

On October 28, 2003, Peter Levine presented the latest developments on the ovarian cancer blood test. He spoke at LabCorp's Analysts and Institutional Investors Meeting - *"Improving Patient Care Through Scientific and Technological Leadership."*

On September 19, 2003, Peter Levine addressed the Sixth Annual Ovarian Cancer National Alliance Advocacy Conference in San Francisco.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health**TAB 28**November 5, 2002
VIA FEDEXOffice of Technology Transfer
National Institutes of Health
6011 Executive Boulevard
Rockville, MD 20852

Peter J. Levine
President
Correlogic Systems, Inc.
6701 Democracy Blvd., Suite 3000
Bethesda, Maryland 20817

Re: Approval of co-sublicense to LabCorp and
Quest Diagnostics of exclusive license
agreement between PHS and Correlogic
Systems, NIH Ref. No. L-121-01/0

Dear Peter:

This is to provide our approval of the proposed co-sublicense agreement between Correlogic Systems and co-sublicensees Quest Diagnostics and LabCorp. Copies of the fully executed sublicense agreements were earlier provided to OTT as required by the exclusive license between PHS and Correlogic referenced above.

As required by Paragraph 4.02 of the license agreement between PHS and Correlogic, Paragraphs 5.01-5.04, 8.01, 10.01, 10.02, 12.05, 13.07-13.09, and Appendix E, Section (a) and (b) are attached to the sublicense agreement, and the agreement obligates LabCorp and Quest Diagnostics to abide by their requirements when applicable. Exhibit G of the sublicense agreement includes certain qualifications to these provisions, which generally clarify the respective responsibilities of Correlogic, Quest Diagnostics and LabCorp as to their implementation. We considered these qualifications prior to approving the sublicense agreement.

We understand that the sublicense agreement with LabCorp and Quest Diagnostics will facilitate the development and delivery of a high-throughput diagnostic apparatus that will apparently be capable of detecting ovarian cancer in its earliest stages using a single drop of blood from the patient. Because of this, and in view of the substantial benefit to the public health that will arise from the rapid development, testing and implementation of the technique, we are pleased to grant our approval of the sublicense agreement.

We look forward to continuing to work with you on this very important public health issue.

Sincerely,

Steve Ferguson, M.B.A.
Deputy Director
Division of Technology Development and Transfer

Message

Page 1 of 8

Norman Clark

From: Peter J. Levine [plevine@correlogic.com]
Sent: Thursday, May 22, 2003 9:18 AM
To: Lance A. Liotta (Lance@helix.nih.gov); 'Petricoin, Emmanuel'
Subject: FW: info on Biospect -- FYI Rick Klausner

Lance and Chip,

FYI --

Peter

Peter J. Levine
 President
 Correlogic Systems, Inc.
 6701 Democracy Blvd. Suite 300
 Bethesda, Maryland 20817
 Tel: 301 983-1376
 Fax: 301 983-2966
 E-mail: plevine@correlogic.com

-----Original Message-----

From: Vince Simmon [mailto:vincent.simmon1@cox.net]
Sent: Wednesday, May 21, 2003 4:15 PM
To: plevine@correlogic.com
Subject: info on Biospect

Peter: it was nice talking with you today. Here is some info on your new competition. I'll be in touch.
 Vince

Biospect, Inc.

THE COMPANY:

Biospect is a new company based in South San Francisco, California focused on becoming the world leader in complex mixture analysis of biological fluids to improve preclinical drug development and to inform the detection, diagnosis, monitoring, and treatment of human disease. Biospect will implement a new class of analyses based on the identification of predictive patterns for specific biological states. To this end, Biospect will apply proprietary separation, detection, and informatics technologies to define those distinct biological states.

MANAGEMENT

James B. Tananbaum - CEO and Chairman

Jim is a Managing Partner of Prospect Venture Partners. Prior to establishing Prospect Venture Partners II, Jim served as the founding CEO of Theravance, Inc. (formerly Advanced Medicine, Inc.) from 1997 through 2000. Theravance is a private pharmaceutical company

based in South San Francisco, employs 250 people, and has raised over \$300 million.

From 1994-1997, Jim was a partner at Sierra Ventures where he played a key role in the healthcare technology group and led their healthcare service and health care information enterprises effort. During this period, he led investments and served as a Director of Intensiva HealthCare Corporation (NASDAQ:IHCC) and NovaMed EyeCare Management (NASDAQ:NOVA), and lead investments in Healtheon (NASDAQ:HLTH) and Amerigroup (NASDAQ:AMGP). >From 1991 to 1994, Jim held a series of management positions at Merck & Company, Inc. In 1991, Jim co-founded GelTex Pharmaceuticals (NASDAQ:GENZ) and served as a Director through 1997. In 2000, GelTex was acquired by Genzyme in a transaction valued at approximately \$1.8B. Most recently, Jim helped found and served as start-up CEO for three Prospect Venture Partners portfolio companies: Infinity Pharmaceuticals, Biospect, and Concurrent Pharmaceuticals.

He is a founding member of the Harvard/MIT Health Sciences and Technology Advisory Group, Vice Chairman of the Harvard Medical School Cell Biology and Pathology Advisory Council, a member of the board of directors of the California Healthcare Institute, and a member of the Young Presidents' Organization and the World Economic Forum Global Leaders of Tomorrow.

Jim serves or has served on the Board of Directors of Theravance, Biospect, Concurrent Pharmaceuticals, GelTex Pharmaceuticals, Infinity Pharmaceuticals, Intensiva HealthCare, NovaMed EyeCare, and several other privately-held companies.

Jim received an M.D. from Harvard Medical School, an M.B.A. from Harvard Business School, and B.S.E.E. and B.S. degrees from Yale University.

Carol Dahl - Vice President, Strategic Partnerships

Dr. Dahl most recently served as a consultant to the National Academies (National Academy of Science, National Academy of Engineering, and National Research Council), a consultant to Prospect Venture Partners, and Vice President of Science and Technology Initiatives at the Case Institute for Health, Science, and Technology. From 1990 to 2001 Dr. Dahl was at the National Institutes of Health serving as Assistant to the Director of the National Cancer Institute (NCI) in the area of strategic technologies where she established the Office of Technology and Industrial Relations (OTIR) and served as the first Director; Program Director of the Sequencing Technology Branch at the National Center for Human Genome Research (NCHGR); and Guest Researcher at the Advanced Technology Program (ATP) in the National Institutes of Standards and Technology, Department of Commerce. During her tenure in the federal government Dr. Dahl initiated pioneering technology programs totaling several hundred million dollars that are having a significant impact on the development of genomics, transcriptome analysis, and proteomic technologies; nanotechnology based tools; in vitro and in vivo molecular monitors; molecular imaging; and the integration of biomedical information science and technology into biomedical research.

Dr. Dahl was previously on faculty of the University of Pittsburgh and the Pittsburgh Cancer Institute. Dr. Dahl received a bachelors degree with Honors from the University of Iowa, and a masters and doctorate from the University of Wisconsin-Madison. She received postdoctoral training at the Karolinska Institute in Stockholm, the Pasteur Institute in Paris, and the Immunobiology Research Center at the University of Minnesota.

Pete Foley - Vice President, Engineering

Mr. Foley has over 20 years of industry experience in systems design, product planning and development, ASIC and microprocessor design and development. He recently founded nBand Communications, a fabless semiconductor startup developing programmable baseband and MAC solutions for the broadband wireless market. He was President & CEO and acting VP Systems Engineering at nBand, raised \$21M in two rounds, and grew the team to 48.

Prior to nBand, he was an Entrepreneur-in-Residence at Benchmark Capital, where he founded Travertine Systems, a company specializing in home networking technology over POTS twisted pair, which was subsequently acquired by Epigram (now Broadcom).

Prior to Travertine, he played key technical and management roles at Chromatic Research, SuperMac Technology, and Apple. He served as acting VP Marketing at Chromatic, and later ran Systems Engineering. While at SuperMac, Mr. Foley created the IC Technology group and as Director of Graphics Products oversaw the development of one of the industry's first Rambus based graphics controllers.

At Apple he was an early member of the Newton team where he served as principal Newton hardware architect and the program manager for the Hobbit microprocessor development. While a graduate student at U.C. Berkeley, he led the micro-architectural design of SOAR (Smalltalk On A RISC). He holds a BSEE degree from Rice University and an MSCS from U.C. Berkeley.

Jonathan Heller - Vice President, Information and Project Planning

Dr. Heller was most recently Director of Informatics at SurroMed, a company focused on biomarker discovery. Previously, he led the data mining group at Exelixis, a model-organism genetics company. Dr. Heller received a bachelors degree with Honors in Applied Mathematics from Harvard University. He did his doctorate at University of California, Berkeley in Biophysics, where he was a Howard Hughes Pre-doctoral Fellow.

John T. Stults - Vice President, Analytical Sciences

Dr. Stults widely recognized for his contributions in mass spectrometry and proteomics. He was a Senior Scientist and the head of the Research Mass Spectrometry Laboratory at Genentech from 1987 to 2002. During that time, he developed methods for peptide sequencing, disulfide determination, glycosylation and phosphorylation analysis, and 2D gel electrophoresis. He was co-recipient of the 2002 ASMS Distinguished Contribution Award for his pioneering work in protein identification from gels by mass spectrometry. He has published 70 papers and book chapters, and he is a member of the editorial boards of Molecular & Cellular Proteomics and the Journal of Proteome Research. He received a B.A. in Chemistry from the College of Wooster (Ohio) and Ph.D. in Analytical Chemistry from Michigan State University.

Dan Miller - Vice President, Finance and Administration

Mr. Miller most recently served as Vice President, Finance and Administration of Photuris (a Greylock company) where he managed all fund raising and administrative efforts. Photuris completed 2 rounds of private financing and raised over \$80 million. Photuris has successfully launched its products worldwide.

From 1997 to 2000, Mr. Miller served as Corporate Controller of Extreme Networks where he managed all areas of finance including financial planning, treasury, order management, manufacturing accounting, accounting services, and international operations. While at Extreme, the company raised two rounds of private financing totaling \$33 million as well as a \$130 million initial public offering and a \$600 million secondary offering.

Prior to Extreme Networks, Dan held a senior treasury position at Genentech where he managed all aspects of treasury and was involved in strategic tax issues. In addition, he led many business development deals involving the licensing or acquisition of technology through either cash or equity investment.

Dan began his career with the Deloitte & Touche. He is a C.P.A. and holds an M.B.A. from Carnegie-Mellon University and B.A. from John Carroll University.

BOARD OF DIRECTORS

James Tananbaum, Chairman

Richard Klausner, Director

Dr. Richard D. Klausner has been named Executive Director of the foundation's global health program. Dr. Klausner is the former Director of the National Cancer Institute (NCI) where he led the nation's cancer program.

As director of NCI, Dr. Klausner led one of the world's largest research and health agencies creating successful national and international programs aimed at applying science and technology to improving the public health. NCI oversees one of the largest clinical trial, drug development and surveillance and epidemiology programs worldwide. NCI also administers the second largest HIV/AIDS programs worldwide. At NCI, Dr. Klausner, along with Dr. Anthony Fauci, oversaw the creation and development of the Vaccine Research Center. As NCI's director, Dr. Klausner managed a \$4.5 billion budget and a staff of 5,000 employees.

Most recently, Dr. Klausner served as Senior Fellow and Special Advisor to the Presidents of the National Academies for Counter Terrorism and Liaison to the White House.

Dr. Klausner is well known for his work in cell and molecular biology. Dr. Klausner has served as chief of the cell biology and metabolism branch of the National Institute of Child Health and Human Development. He has served on numerous advisory committees and is the past president of the American Society for Clinical Investigation. He is the author of more than 280 scientific articles and several books, and has received numerous awards and honors. He is a member of the National Academy of Sciences and the Institute of Medicine.

Russell Hirsch, M.D., Ph.D., Director

Russell is a Managing Partner of Prospect Venture Partners. Prior to establishing Prospect Venture Partners II, Russell was a member of the Health Care Technology Group at Mayfield. He joined Mayfield in 1992, served as a Venture Partner from 1993 to 1994 and as a General Partner from 1995-2000. Russell played a key role in Mayfield's investment activities in the biotechnology and medical device sectors. As an Associate, he participated actively in the incubation of Millennium Pharmaceuticals and as a General Partner he was responsible for the incubation of Intuitive Surgical Devices both of which are now publicly traded. (NASDAQ: MLNM), (NASDAQ:ISRG).

Prior to Mayfield, Russell was at the University of California San Francisco from 1984-1992 where he was engaged in biomedical research. His work, published in a variety of respected journals, focused on important aspects of hepatitis B viral replication. His descriptions of the reverse transcription and packaging functions of polymerase gene products merited publication in Nature.

Russell serves or has served on the Board of Directors of Intuitive Surgical, Sunesis, Valentis (NASDAQ: VLTS), Alsius, Orquest, Infinity Pharmaceuticals, Genpath and several other privately-held companies. Russell serves on the Boards of the Bay Area Bioscience Center

6/8/2004

and Interplast.

Russell holds an M.D. and Ph.D. in Biochemistry from the University of California, San Francisco and a B.A. in Chemistry from the University of Chicago.

Richard Zare, Director

Richard N. Zare is the Marguerite Blake Wilbur Professor in Natural Science at Stanford University. He is a graduate of Harvard University, where he received his B.A. degree in chemistry and physics in 1961 and his Ph.D. in chemical physics in 1964. In 1965 he became an assistant professor at the Massachusetts Institute of Technology, but moved to the University of Colorado in 1966, remaining there until 1969 while holding joint appointments in the departments of chemistry, physics and astrophysics. In 1969 he was appointed to a full professorship in the chemistry department at Columbia University, becoming the Higgins Professor of Natural Science in 1975. In 1977 he moved to Stanford University.

Professor Zare is renowned for his research in the area of laser chemistry, resulting in a greater understanding of chemical reactions at the molecular level. By experimental and theoretical studies he has made seminal contributions to our knowledge of molecular collision processes and contributed very significantly to solving a variety of problems in chemical analysis. His development of laser induced fluorescence as a method for studying reaction dynamics has been widely adopted in other laboratories.

George Whitesides, Director

Dr. Whitesides received an A.B. degree from Harvard University in 1960 and a Ph.D. from the California Institute of Technology (with J.D. Roberts) in 1964. He was a member of the faculty of the Massachusetts Institute of Technology from 1963 to 1982. He joined the Department of Chemistry of Harvard University in 1982, and was Department Chairman 1986-9. He is now Mallinckrodt Professor of Chemistry at Harvard University. He received an Alfred P. Sloan Fellowship in 1968; the American Chemical Society (ACS) Award in Pure Chemistry in 1975; the Harrison Howe Award (Rochester Section of the ACS) in 1979; an Alumni Distinguished Service Award (California Institute of Technology) in 1980; the Remsen Award (ACS, Maryland Section) in 1983; an Arthur C. Cope Scholar Award (ACS) in 1989; the James Flack Norris Award (ACS, New England Section) in 1994; the Arthur C. Cope Award (ACS) in 1995; the Defense Advanced Research Projects Agency Award for Significant Technical Achievement in 1996; the Madison Marshall Award (ACS) in 1996; the National Medal of Science in 1998; the Sierra Nevada Distinguished Chemist Award (Sierra Nevada Section of the ACS), The Wallace Ory Innovation Award in High Throughput Screening (the Society for Biomolecular Screening) in 1999, and the Award for Excellence in Surface Science (the Surfaces in Biomaterials Foundation) in 1999; and the Von Hippel award (Materials Research Society) in 2000. He is a member of the American Academy of Arts and Sciences, the National Academy of Sciences, and the American Philosophical Society. He is also a Fellow of the American Association for the Advancement of Science and the New York Academy of Science, a foreign fellow of the Indian National Science Academy, and an Honorary Fellow of the Chemical Research Society of India.

Judith Swain, Director

Dr. Judith L. Swain is the Arthur L. Bloomfield Professor of Medicine and Chair, Department of Medicine, Stanford University School of Medicine. Dr. Swain came to Stanford in December, 1996 from the University of Pennsylvania where she was the Herbert C. Rorer Professor of

Medical Sciences, Professor of Genetics, and Director of Cardiovascular Medicine. Dr. Swain received her undergraduate education at the University of California, Los Angeles, and her medical education at the University of California, San Diego, before moving to Duke University to complete training in Internal Medicine and Cardiovascular Medicine. She then joined the faculty at Duke where she became widely known in the field of molecular cardiology, and pioneered the use of transgenic animals to understand the genetic basis of cardiovascular development and disease. She has held continuous research funding from the NIH for over 20 years, and holds an NIH M.E.R.I.T Award for her work on the developmental biology of the cardiovascular system. Her research interests are centered on the role of growth factors in angiogenesis.

Dr. Swain has served in numerous national leadership roles. She was elected President of the American Society of Clinical Investigation in 1995, and that same year was appointed to the Advisory Council of the National Heart Lung and Blood Institute. She has served on the NIH Director's Standing Committee on Clinical Research, on the Advisory Council of the Director of the NIH, and as the Chair of the National Heart, Lung, and Blood Institutes Director's Review Committee. Dr. Swain also served as Director of the US/Russia Cardiovascular Biology Program at the NIH. Dr. Swain currently serves as a member of the NIH National Advisory Research Resources Council, and as a member of the National Research Councils Committee on Space Biology and Medicine of the Space Studies Board. She has served on the Scientific Advisory Board of the Pharmaceutical Research Institute of Bristol-Myers Squibb Pharmaceutical Company and the Donald W. Reynolds Foundation, and currently serves on the Scientific Advisory Boards for the Wellcome Trust (International Advisory Committee), Burroughs Wellcome Foundation (Chair of Translational Medicine Committee), the Doris Duke Charitable Foundation, and the Pasarow and Kirsch Foundations. Dr. Swain has been elected to a number of honorary societies including the Association of American Physicians, the American Society for Clinical Investigation, the Association of University Cardiologists, the American Clinical and Climatological Society, and the Institute of Medicine.

William Perry, Director

William J. Perry, Hoover Institution senior fellow, is the Michael and Barbara Berberian Professor at Stanford University, with a joint appointment in the School of Engineering and the Institute for International Studies. His previous academic experience includes professor (half-time) at Stanford from 1988 to 1993, during which time he was codirector of Stanford's Center for International Security and Arms Control. He also served as a part-time lecturer in the Department of Mathematics at Santa Clara University from 1971 to 1977.

Perry was the nineteenth United States secretary of defense, serving from February 1994 to January 1997. His previous government experience includes deputy secretary of defense (1993–94) and undersecretary of defense for research and engineering (1977–81).

Perry's business experience includes laboratory director for General Telephone and Electronics (1954–64); founder and president of ESL (1964–77); executive vice-president of Hambrecht & Quist (1981–85); and founder and chairman of Technology Strategies and Alliances (1985–93). He serves on the board of directors of United Technologies, Hambrecht Quist, the Boeing Company, and a number of emerging high-tech companies.

He received his B.S. and M.S. degrees from Stanford University and his Ph.D. from Pennsylvania State, all in mathematics. He is a member of the National Academy of Engineering and a fellow of the American Academy of Arts and Sciences. From 1946 to 1947,

Perry was an enlisted man in the Army Corps of Engineers and served in the Army of Occupation in Japan. He joined the Reserve Officer Training Corps in 1948 and was a second lieutenant in the army reserves from 1950 to 1955.

Bryan Roberts, Director

Bryan Roberts joined Venrock in 1997 and is now a General Partner involved with the firm's activities in healthcare based in Menlo Park, CA. Prior to joining Venrock, Bryan worked at Kidder Peabody & Co., Inc. in investment banking. Bryan is responsible for Venrock's investments in Illumina and Nanosys, and currently serves on the boards of several private companies including athenahealth, Biospect, Concurrent Pharmaceuticals, First Genetic Trust, Microbia, Surface Logix and Xenoport.

Bryan received his Ph.D. in Chemistry and Chemical Biology at Harvard University and graduated from Dartmouth College, where he obtained a B.A. in Chemistry.

Robert V. Gunderson, Jr., Director

Bob is a Senior Partner, Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP. Bob Gunderson is a founding partner of one of the pre-eminent law firms for emerging growth companies, with offices in Menlo Park, CA; Austin, TX; Boston, MA; and New York, NY. Since it's founding in 1995, the firm has been responsible for more than 100 public offerings, over 1,000 venture and other private financings, 800 strategic alliances, and 151 mergers and acquisitions. Mr. Gunderson is a nationally recognized authority in the areas of venture capital and the private and public financing of technology companies. Mr. Gunderson holds a JD degree from the University of Chicago, where he is currently a member of the Law School's Visiting Committee and was Executive Editor of The University of Chicago Law Review. Mr. Gunderson received an MBA in finance from The Wharton School of the University of Pennsylvania and an MA from Stanford University. Mr. Gunderson currently serves as a member of the Board of Directors of several private technology companies.

Ken Nussbacher, Director

Ken Nussbacher is currently a Fellow at Affymetrix, Inc. and a consultant to Versant Ventures. He joined Affymetrix in 1995 as Executive Vice President and Chief Financial Officer and was subsequently head of Business and Legal Affairs. Mr. Nussbacher joined Affymax N.V. (the pioneer of combinatorial chemistry and parent of Affymetrix) in 1989 and served as Executive Vice President until the sale of Affymax to Glaxo Wellcome in 1995. His prior work experience included two high technology companies and a major law firm. Mr. Nussbacher has been a Director of Symyx Technologies (SMMX), a combinatorial materials science company, since 1995 and of Xenoport, Inc., a privately held biotechnology company with expertise in engineered bioavailability, since 2000. He joined the Board of Biospect in 2002. He holds a J.D. from Duke University and a B.S. in Physics from The Cooper Union.

Norman Clark

From: Peter J. Levine [plevine@correlogic.com]
 Sent: Thursday, July 03, 2003 5:11 PM
 To: 'Brand, Kevin (NIH/NCI)'
 Cc: 'Liotta, Lance (NIH/NCI)'; 'Petricoin, Emmanuel (FDA/CBER/O)'; 'whiteleyg@ncicrf.gov'; Reid G Adler
 Subject: RE: MOU

Kevin,

The consensus on our side is that we prefer to stick with the agreement that was negotiated last August, and memorialized in Karen Maury's letter to me of mid-September, 2002. However, in the spirit of cooperation, we are once again re-negotiating the same issues. Unless there is a clear and convincing legal reason why our language cannot be included, then it should be, or, we should revert to the original agreement of August/September 2002.

Have a great 4th.

Peter

Peter J. Levine
 President
 Correlogic Systems, Inc.
 6761 Democracy Blvd, Suite 300
 Bethesda, Maryland 20817
 Tel: 301 983-1376
 Fax: 301 983-2966
 e-mail: plevine@correlogic.com

-----Original Message-----

From: Brand, Kevin (NIH/NCI) [mailto:brandk@mail.nih.gov]
 Sent: Thursday, July 03, 2003 11:42 AM
 To: 'plevine@correlogic.com'
 Cc: Liotta, Lance (NIH/NCI); Petricoin, Emmanuel (FDA/CBER/O); 'whiteleyg@ncicrf.gov'
 Subject: MOU

Peter:

The MOU revisions were looked over by everyone in the group, and I believe the consensus is that we prefer at this point to use the previous version I had prepared. We feel the previous version addressed the need to maintain open rapport between the parties in a way that clearly does not restrict our need to drive the device validation process. Note that we are sensitive to your business dealings that you might be conducting separately, and in no way wish for you to be left out of this process to your detriment. Your version does have language which is indeed true; that the focus of our efforts is to incorporate components which will speed the device approval process and which show the most scientific promise. We also wish to ensure that Labcorp/Quest are made aware of the process, as your sublicensees are critical to bringing this device to the market. This being the case, is there any way that Correlogic can consider the MOU version I prepared?

Thanks, Kevin

Norman Clark

From: Brand, Kevin (NIH/NCI) [brandk@mail.nih.gov]
Sent: Monday, July 07, 2003 2:47 PM
To: 'plevine@correlogic.com'
Subject: MOU

Peter, I took the time to share your feelings on the MOU with the NCI/FDA group, but their feelings are that it is absolutely critical that we drive the device validation process. Irrespective of the favorable language changes you recently made (i.e., recognizing that the choosing of components is done with the public interest perspective in mind), we feel uncomfortable with the language you propose. We feel that the FDA would not recognize the distinction you propose in section 2 of the MOU, and thus it makes us uncomfortable with that language you are suggesting. To put this matter to be for everyone's sake, might you reconsider?

Kevin

Norman Clark

From: Peter J. Levine [plevine@correlogic.com]
Sent: Monday, July 07, 2003 5:45 PM
To: Brand, Kevin (NIH/NCI)
Cc: Reid G Adler
Subject: RE: MOU

Kevin,

I bumped into Chip and Lance as they were exiting a meeting in my building this afternoon (which raises another issue, but I will leave that for another time), and there seems to be some confusion. Both Chip and Lance said that they did not have a problem with our language, as long as Correlogic was not making the final decision unilaterally. Nothing in our proposed language suggests or implies that Correlogic would be the final arbiter of the submission to FDA. Rather, the clear intent (and I believe language) of what we drafted explicitly states that if the PI's can't agree, that the matter gets bumped upstairs to the individuals who signed the MOU. It is the essence of due process. How can that be a problem?

Peter

Peter J. Levine
 President
 Correlogic Systems, Inc.
 6701 Democracy Blvd. Suite 300
 Bethesda, Maryland 20817
 Tel: 301 983-1376
 Fax: 301 983-2966
 E-mail: plevine@correlogic.com

-----Original Message-----
From: Brand, Kevin (NIH/NCI) [mailto:brandk@mail.nih.gov]
Sent: Monday, July 07, 2003 2:47 PM
To: 'plevine@correlogic.com'
Subject: MOU

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Kevin

Norman Clark

From: Brand, Kevin (NIH/NCI) [brandk@mail.nih.gov]
Sent: Tuesday, July 08, 2003 8:32 AM
To: 'Peter J. Levine'
Cc: Reid G Adler
Subject: RE: MOU

Let me check on this. My earlier discussions showed otherwise, but let me clarify with the group and get back with you.

-----Original Message-----
 From: Peter J. Levine [mailto:plevine@correlogic.com]
 Sent: Monday, July 07, 2003 5:45 PM
 To: Brand, Kevin (NIH/NCI)
 Cc: Reid G Adler
 Subject: RE: MOU

Kevin,

I bumped into Chip and Lance as they were exiting a meeting in my building this afternoon (which raises another issue, but I will leave that for another time), and there seems to be some confusion. Both Chip and Lance said that they did not have a problem with our language, as long as Correlogic was not making the final decision unilaterally. Nothing in our proposed language suggests or implies that Correlogic would be the final arbiter of the submission to FDA. Rather, the clear intent (and I believe language) of what we drafted explicitly states that if the P's can't agree, that the matter gets bumped upstairs to the individuals who signed the MOU. It is the essence of due process. How can that be a problem?

Peter

Peter J. Levine
 President
 Correlogic Systems, Inc.
 6701 Democracy Blvd. Suite 300
 Bethesda, Maryland 20817
 Tel: 301 983-1376
 Fax: 301 983-2966
 E-mail: plevine@correlogic.com

-----Original Message-----
 From: Brand, Kevin (NIH/NCI) [mailto:brandk@mail.nih.gov]
 Sent: Monday, July 07, 2003 2:47 PM
 To: 'plevine@correlogic.com'
 Subject: MOU

Peter, I took the time to share your feelings on the MOU with the NCI/FDA group, but their feelings are that it is absolutely critical that we drive the device validation process. Irrespective of the favorable language changes you recently made (i.e., recognizing that the choosing of components is done with the public interest perspective in mind), we feel uncomfortable with the language you propose. We feel that the FDA would not recognize the distinction you propose in section 2 of the MOU, and thus it makes us uncomfortable with that language you are suggesting. To put this matter to be for everyone's sake, might you reconsider?

Kevin

Norman Clark

om: Peter J. Levine [plevine@correlogic.com]
 Sent: Tuesday, July 08, 2003 9:25 AM
 To: 'Brand, Kevin (NIH/NCI)'
 Subject: RE: MOU

Kevin,

One more thought: I submit that the central issues on the government side should not be decided by Lance and Chip, much less outside contractors like Gordon. These are policy and legal issues that have far reaching ramifications for Correlogic, the NCI, the rapid deployment and commercialization of the test and, indeed, the very nature and future of public-private sector partnerships. I was not aware that either by title, position nor experience that these gentlemen are in a position to potentially detail a project that has had such public exposure and Congressional interest.

Just a thought.

Peter

Peter J. Levine
 President
 Correlogic Systems, Inc.
 6701 Democracy Blvd, Suite 300
 Bethesda, Maryland 20817
 Tel: 301 983-1376
 Fax: 301 983-2966
 E-mail: plevine@correlogic.com

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 Sent: Tuesday, July 08, 2003 8:32 AM
 To: 'Peter J. Levine'
 Cc: Reid G Adler
 Subject: RE: MOU

Let me check on this. My earlier discussions showed otherwise, but let me clarify with the group and get back with you.

-----Original Message-----

From: Peter J. Levine [mailto:plevine@correlogic.com]
 Sent: Monday, July 07, 2003 3:45 PM
 To: Brand, Kevin (NIH/NCI)
 Cc: Reid G Adler
 Subject: RE: MOU

Kevin,

I bumped into Chip and Lance as they were exiting a meeting in my building this afternoon (which raises another issue, but I will leave that for another time), and there seems to be some confusion. Both Chip and Lance said that they did not have a problem with our language, as long as Correlogic was not making the final decision unilaterally. Nothing in our proposed language suggests or implies that Correlogic would be the final arbiter of the submission to FDA. Rather, the clear intent (and I believe language) of what we drafted explicitly states that if the FI's can't agree, that the matter gets bumped upstairs to the individuals who signed the MOU. It is the essence of due process. How can that be a problem?

Peter

Peter J. Levine
President
Correlogic Systems, Inc.
701 Democracy Blvd. Suite 300
Bethesda, Maryland 20817
Tel: 301 963-1376
Fax: 301 963-2966
E-mail: plevine@correlogic.com

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Sent: Monday, July 07, 2003 2:47 PM
To: 'plevine@correlogic.com'
Subject: MOU

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Kevin

Norman Clark

From: Brand, Kevin (NIH/NCI) [brandk@mail.nih.gov]
Sent: Wednesday, July 09, 2003 12:15 PM
To: 'plevine@correllogic.com'
Subject: MOU



MOU 7-8-03.doc
(26 KB)

Peter, from the last email, the group recommended further clarifications to the MOU. Please let me know if this is something all parties can accept. If so, I would like to go ahead and get this CRADA scheduled for NIH CRADA Subcommittee review.

Thanks, Kevin

<<MOU 7-8-03.doc>>

Norman Clark

From: Petricoin, Emanuel [petricoin@cber.FDA.gov]
Sent: Thursday, July 10, 2003 8:33 AM
To: 'liottai@mail.nih.gov'; 'PLEVINE@correlogic.com'; 'brandk@mail.nih.gov'
Subject: Correlogic-NCI MOU

Dear Kevin,

It had a nice chat with Peter yesterday concerning our response to Correlogic's suggested changes and additions in the MOU wording. I think we were both able to understand better each other's points of view. I expressed our concerns that we cannot accept wording which explicitly gives them final say in any part of the process. Peter expressed their concerns that as the commercial partner, their wishes and requirements must be better addressed if a dispute arises. To that end (I did not see any revisions that you may have made and passed on, Kevin) I propose the following wording that could replace the entire language in question:

On an ongoing basis, and well before the setting of any final product system design goals and specifications, NCI and Correlogic shall discuss in good faith and seek to agree on such goals and specifications. Given the great public health benefit expected by the Parties in the rapid approval and commercialization of the product, both parties will act in good faith to resolve any disputes and will rely on GMP and scientific merit to weigh design specifications and selection of specific components. Both parties acknowledge that Federal Law such as 21CFR320.30 and 21CFR320.30(e) will need to be adhered to for all clinical applications. And in no event will any Party set, submit or announce any design goals and specifications, including the selection of component devices, that have not first been proposed and reasonably agreed to by the other Parties. All parties to this CRADA acknowledge that reaching agreement on such decisions will substantially impact the speed at which approved products can be commercialized. Thus, if the CRADA Principal investigators and management teams formed under Federal Regulations cannot reasonably agree on the final product system design goals and specifications, the signatories to this CRADA shall meet to resolve in good faith any such disputes...

Continue as per the original language

Chip

 Sent from my BlackBerry Wireless Handheld

Sent: Friday, July 18, 2003 10:21 AM
 To: Brand, Kevin (NIH/NCI)
 Cc: Reid G Adler
 Subject: RE: Silence

Kevin,

A little confusion, apparently. First, with the endless stream of "tweaks" and additional language coming from both sides, I do not believe that we have ever fully agreed to anything (other than the August/September 2002 agreements). Obviously, when one side adds a sentence here or there, it has potential impact across the document. Second, with different versions of the documents, it was clear from our "compare documents" sheet that terms and wording that had been in previous versions had been dropped, not as a result of an interim agreement to drop a particular phrase, but that language simply disappeared. So, the version that we sent to you on Monday morning, July 14, is our "final" version, containing what we believe had been informally agreed to in earlier versions, our edits of your and Chip's most recent versions, and a few minor technical edits.

Hope that this helps.

Have a great weekend.

Peter

Peter J. Levine
 President
 Correlologic Systems, Inc.
 6701 Democracy Blvd, Suite 300
 Bethesda, Maryland 20812
 Tel: 301 983-1376
 Fax: 301 983-2966
 E-mail: plevine@correlologic.com
 -----Original Message-----
 From: Brand, Kevin (NIH/NCI) [mailto:brandk@mail.nih.gov]
 Sent: Friday, July 18, 2003 10:10 AM
 To: 'Peter J. Levine'
 Subject: RE: Silence
 Hi, my email on Monday is below. My question is that section 2 and 3 I believe we had previously agreed to, but the latest revision had different language.

Peter, looking over what you sent in light of earlier versions of the MOU, most of the highlighted text in articles 3 and 4 we had previously agreed to. As I now look at the version I was sent from you dated June 17th, much of the highlighted items did not exist in that version of the agreement. Thus my understanding was that articles 3 and 4 were pretty much ironed out; only article 2 was still being contended.

Also, I want to confirm that all the parties wish to retain the following sentence in section 2: "Accordingly, all Parties shall have the right to provide input insofar as defining and suggesting what components become part of the contemplated marketed product, and choosing the manufacturer(s) of the product."

Kevin Brand
 Technology Transfer Specialist
 National Cancer Institute
 6120 Executive Blvd., Suite 450
 Rockville, MD 20852-7161
 ph. (301) 451-4566; (301) 846-5423
 fx. (301) 401-2117

-----Original Message-----
 From: Peter J. Levine [mailto:plevine@correlologic.com]
 Sent: Thursday, July 17, 2003 9:01 PM
 To: Brand, Kevin (NIH/NCI); Brand, Kevin (NIH/NCI)
 Subject: Silence

707

Kevin,

the silence is very loud. What's happening?

Peter

Peter J. Levine
President
Correllogic Systems, Inc.
6701 Democracy Blvd. Suite 300
Bethesda, Maryland 20817
Tel: 301 983-1370
Fax: 301 983-1968
E-mail: plevine@correllogic.com

Norman Clark

From: Peter J. Levine [plevine@correlogic.com]
Sent: Tuesday, July 22, 2003 7:57 AM
To: 'Petricoin, Emanuel'; 'brandk@mail.nih.gov'
Cc: 'rgadier@comcast.net'; 'lottai@mail.nih.gov'
Subject: RE: Silence



Correlogic's DVComparison_NCI
 omments on parag. rev MOU 7-10-...

Dear Chip -- thanks for your e-mail and candid expression of your feelings. Frankly, I am equally frustrated with what seem to me to be an unending series of changes from NCI and FDA over the past twelve months -- which would unacceptably narrow Correlogic's ability to commercialize the product. Regardless of who's at (greater) fault, these exchanges of "track changes" haven't resolved several issues because the document as a whole has been a moving target. And I suspect that one of our documents (NCI's or ours) omitted some key changes to Paragraphs 3 & 4 while we all focused on "Section 2" -- but they weren't discussed with Kevin or agreed to by us.

Please understand that Correlogic cannot agree to a CRADA (or MOU) in which the Clinical Proteomics Reference Laboratory has the final authority to decide about component selection, notwithstanding the merits of Correlogic's views. This is a huge and fundamental issue for us. Discussions in "good faith" are not sufficient if this permits SAIC or an SAIC advisory committee (that we didn't even know was to be convened) to impose their own views about what components are appropriate. Correlogic has a broader responsibility under its license from PHS to develop a device that is not only appropriate but is also amenable to expeditious practical application. The bottom line for us is that if the Principal Investigators cannot agree on the platform, then the signatories to the CRADA will have to resolve such questions. This was acceptable last August to NCI and FDA, as reflected in Karen Maurey's September 12 letter -- why is it a make or break issue for NCI/FDA today?

Also, Correlogic cannot agree to a CRADA in which it does not attend meetings with the FDA, nor have a true voice in determining regulatory strategy. Attendance by Correlogic is not, to my knowledge, proscribed by FDA regulations and it should be helpful to all parties. Frankly, it will be critical for Correlogic to attend, given its responsibility for commercializing the approved device. This doesn't diminish NCI's authority or responsibility as the "Applicant." And, as you will recall, Karen Maurey's letter accepted this proposition last September, reflecting agreement at that time by FDA's Bea Broke. Ten months later, why is this also become a make or break issue for NCI/FDA?

For both of these issues, it seems clear to us that NCI and FDA technology transfer policies can best serve the public good only if they accommodate CRADA collaborators. Unfortunately, we didn't have an opportunity yesterday to discuss them with Dr. Anna Barker.

In many respects, the bulk of negotiations on CRADA Amendment #1 and the MOU have been completed for several weeks. I've attached a Word document that reiterates the changes we need to see in two paragraphs of NCI/FDA's prior draft MOU. Our "red-line" of July 14 to the entire MOU is also attached for convenience. With the hope that NCI and FDA will re-think and accept our position on these two issues, for purposes of fine-tuning the final language, I'm wondering whether the principals and their counsel might meet for pizza and beer early next week, and agree that the text has to be completed before we run out of food? That might get us to closure faster than another round of track changes. I'd love to have the CRADA committee review our case in August!

Respectfully,

Peter Levine

Peter J. Levine
President
Correlogic Systems, Inc.
6701 Democracy Blvd, Suite 300
Bethesda, Maryland 20817
Tel: 301 963-1376
Fax: 301 963-2966
E-mail: plevine@correlogic.com

-----Original Message-----
From: Petriccin, Emanuel (mailto:petriccin@cber.FDA.gov)
Sent: Monday, July 21, 2003 4:26 PM
To: 'plevine@correlogic.com'; 'brandk@mail.nih.gov'
Cc: 'rgadler@comcast.net'; 'liottal@mail.nih.gov'
Subject: Re: Silence

Wow, this really seems twilight zone to me. I basically thought that the mour and crada issues- fda meetings, etc, Had been agreed to, and that the only issue was what happens if the parties disagree on the platform. The language vis a vis fda meetings I thought had been beat to death already, and the changes already implemented by dozens of rounds of track changes. The agreed to language had references where the nci would talk with correlogic before any fda meeting and provide them with an meeting summary within a set and short period of time thereafter- this language was in previous documents and not objected to by Correlogic-although it now seems like this is new (to me)- why wasnt this brought up before in the last draft??????????????

Chip

Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: Peter J. Levine <plevine@correlogic.com>
To: 'Brand, Kevin (NIH/NCI)' <brandk@mail.nih.gov>
Cc: Reid G Adler <rgadler@comcast.net>; 'Petriccin, Emanuel' <petriccin@cber.FDA.gov>
Sent: Mon Jul 21 15:25:35 2003
Subject: RE: Silence

Kevin,

I will look at the language in more detail, but on the point of Correlogic attending FDA meetings, this was explicitly stated in Karen Maurey's September 12 letter; Beatrice Broke of the FDA was a participant in the August 15, 2002 meeting where these points were agreed to (and she is a "cc" on that letter), and, if NCI is intending to transfer the 510K/PMA to Correlogic (and obviously FDA knows this, even now), on what basis would they object to our attendance at such meetings?

Peter

Peter J. Levine
President
Correlogic Systems, Inc.
6701 Democracy Blvd, Suite 300
Bethesda, Maryland 20817
Tel: 301 963-1376
Fax: 301 963-2966
E-mail: plevine@correlogic.com

-----Original Message-----

Norman Clark

From: Petricoin, Emmanuel [petricoin@cber.fda.gov]
 Sent: Thursday, March 14, 2002 4:55 PM
 To: PLEVINE@correllogic.com; lance@helix.nih.gov; bhitt@correllogic.com
 Subject: News from California

Hi Peter

How do you anticipate that this will affect the immediate concern of analyzing the ovarian and prostate data which we are now running samples on as well as the modeling stuff.

I am afraid that the news out there is very scary. I talked to the new scientist who is taking over for George Wright and he claims it cannot happen this because we would have seen it in the sequences. That they have patents filed three years ago on what is basically patent number 2 and that they have a paper "in the final stages of review" for prostate cancer. I am sure that George Wright will see our paper and ban it. There are several groups doing very similar things at UC, the Fred Hutchinson group through the edrn claims that they are building a supervised and unsupervised system that is analyzing serial data for the edrn and will give groups that they are going to give out to the community for free. I do not believe them either, and who knows. Very tricky meeting and emotionally draining. Everyone is shooting for it and the tsunami is now at the shore. I am very afraid that slowing down analysis of the ovarian is going to kill it.

Chip
 Emanuel Petricoin, Ph.D.
 Co-Director
 FDA-NCI Clinical Proteomics Program

 Sent from my BlackBerry Wireless Handheld (www.BlackBerry.net)

Norman Clark

From: Petricoin, Emmanuel [petricoin@cber.fda.gov]
 Sent: Friday, April 19, 2002 6:21 PM
 To: 'plevine@correlogic.com'; 'bhitt@correlogic.com'; Petricoin, Emmanuel; 'lance@helix.nih.gov'
 Subject: Re: Thanks

Publish it so who cares.

Chip
 Emanuel Petricoin, Ph.D.
 Co-Director
 FDA-NCI Clinical Proteomics Program

 Sent from my BlackBerry Wireless Handheld (www.BlackBerry.net)

-----Original Message-----
 From: plevine@plevine@correlogic.com
 To: Ben Witt <bhitt@correlogic.com>; Emanuel F Petricoin <petricoin@cber.fda.gov>; Lance
 Liotta <lance@helix.nih.gov>
 Sent: Fri Mar 15 12:00:59 2002
 Subject: Fw: Thanks

Peter J. Levine
 President
 Correlogic, Supreme, Inc.
 6701 Democracy Blvd, Suite 300
 Bethesda, MD 20817

301 214-4131 (Tel)
 301 242-1666 (Tel)

----- Original Message -----
 From: "Leon, Dr. Jorge" <LeonJ@questdiagnostics.com>
 To: "plevine" <plevine@correlogic.com>
 Sent: Friday, April 18, 2002 10:08 AM
 Subject: RE: Thanks

> Peter,
 >
 > Did you see the write up on LUNICITY?? What do you think?? They
 > claim they have an Ovarian Cancer tests more advanced than the NIP??
 > I am meeting with them today so learn more, I will let you know.
 >
 > I am looking forward to your document and is looking to see soon.
 >
 > regards
 >
 >
 > Jorge
 >
 > -----Original Message-----
 > From: plevine (mailto:plevine@correlogic.com)
 > Sent: Friday, April 18, 2002 9:16 AM
 > To: Leon, Dr. Jorge
 > Cc: Ben Witt
 > Subject: Re: Thanks
 >
 >
 > Jorge,

Norman Clark

From: Petricoin, Emmanuel [petricoin@cber.fda.gov]
Sent: Monday, August 05, 2002 6:59 AM
To: 'plevine@correlogic.com'; Petricoin, Emmanuel
Cc: 'bhitt@correlogic.com'
Subject: Re: BD

Hi Peter

We can talk with them. However, we have had some very fruitful discussions with api, and they probably are the ones we would go with to build a "soup to nuts" system- if we went down that route. Tim Veenstra knows many of their top scientists very well, and since they are the worlds preminenet mass spec company- they may be the best bet.

We could talk with them, though. I am gone from this thursday until the 16th. We will still have the crada meetings, as long as it fits Ben and your schedule. Just email Heather on thursdays to let her know if you can make it down.

Chip
 Emanuel Petricoin, Ph.D.
 Co-Director
 FDA-NCI Clinical Proteomics Program

 Sent from my BlackBerry Wireless Handheld (www.BlackBerry.net)

-----Original Message-----
From: Peter J. Levine <plevine@correlogic.com>
To: Emanuel F Petricoin <petricoin@cber.fda.gov>
CC: Ben Hitt <bhitt@correlogic.com>
Sent: Fri Aug 02 18:23:07 2002
Subject: BD

Chip,

Rick Ivey from BD called, asking to resume our dialog about how they can work with us (he wanted to meet). I told Rick that I could not discuss the licensing of any diagnostic tests or our technology related to diagnostic tests for the time being as I have just signed a "stand still" agreement in that regard. However, I did tell him that we (Correlogic FDA/NCI) are still very interested in finding an equipment manufacturer that can put together a workable alternative to SELDI-TOF.

Rick mentioned that BD had extensive talks with both Ciphergen and Lumicyte and concluded that they would not work with either company because of the fight over the IP. He also said that BD had found several other "platforms" from smaller companies that he believes may work. I suggested that we could talk about this, particularly if you and/or Lance were part of the discussion. So, what does next Thursday look like?

Peter

I suggested that
 Peter J. Levine
 President
 Correlogic Systems, Inc.
 6701 Democracy Blvd. Suite 300
 Bethesda, Maryland 20817
 tel: 301 963-1376
 fax: 301 963-1966
 E-mail: plevine@correlogic.com

Norman Clark

From: Petricoin, Emmanuel [petricoin@cber.fda.gov]
 Sent: Tuesday, June 17, 2003 7:37 AM
 To: 'whiteleyg@ncicrf.gov'; 'lance@helix.nih.gov'; Petricoin, Emmanuel; Fusaro, Vincent *;
 'ardekani@cber.fda.gov'; 'veenstra@ncicrf.gov'; 'conrads@ncicrf.gov'; Johann, Don *; Ross,
 Sally; 'mckeonk@ncicrf.gov'; 'rgsaul@comcast.net'; 'plevine@correlogic.com';
 'bhitt@correlogic.com'; 'jsmith@correlogic.com'; 'wwiggins@correlogic.com';
 'tchen@correlogic.com'; 'tcoleman@correlogic.com'; 'brandk@mail.nih.gov';
 'pturner@correlogic.com'; 'jeffreyt@mail.nih.gov'; Rajapakse, Vinodh (NIH)
 Subject: Re: Friday's CRADA

We are going to have a crada meeting this Friday at 10 am in building 29A even though
 Gordon is on vacation. The topic will be an update and data presentation from Tim Coleman
 on the ad'ison work.

Chip

 Sent from my BlackBerry Wireless Handheld

Norman Clark

om: Sybert, Kathleen (NIH/NCI) [sybertk@otd.nci.nih.gov]
sent: Thursday, October 03, 2002 3:59 PM
To: 'Peter Levine'
Subject: FW: Invitation to participate on a proposed panel for the Biotechnology Industry Organization (BIO) 2003 annual meeting

Importance: High

> -----Original Message-----
> From: Sybert, Kathleen (NIH/NCI)
> Sent: Thursday, October 03, 2002 3:55 PM
> To: Liotta, Lance (NIH/NCI); Droke, Beatrice A (FDA); Berkley, Dale
> (OD); 'Peter J. Levine'
> Subject: Invitation to participate on a proposed panel for the
> Biotechnology Industry Organization (BIO) 2003 annual meeting
> Importance: High
>
> Dear Lance, Bea, Dale, and Peter,
>
> I would like to propose a panel to the BIO 2003 meeting organizers to
> discuss the NIH/FDA/Correlologic collaboration for the detection of
> ovarian cancer. The BIO 2003 meeting is being held June 22-25, 2003
> in Washington D.C.
>
> I envision the panel as follows:
>
> A title something like: The Case of Small Business & Big Government v.
> Ovarian Cancer.
>
> Kathy: moderating
> Lance: a description of the science and technology
> Bea: a discussion of the CRADA mechanism
> Dale: a discussion of the licensing of background and CRADA inventions
> Peter: a discussion of how the collaboration contributed to the
> company's development and how it meshes with its future business
> strategy
>
> Would each of you be interested in participating? I think it would be
> a very well attended session!
>
>
> Kathleen Sybert, Ph.D., J.D.
> Chief, Technology Transfer Branch
> National Cancer Institute
> National Institutes of Health
> Suite 450
> 6120 Executive Boulevard
> Bethesda, Maryland 20892-7181 (USPS)
> Rockville, Maryland 20852-4909 (FedEx, UPS, etc.)
> Phone: (301)496-0477
> Facsimile: (301)402-2117
> e-mail: sybertk@mail.nih.gov
> web site: http://ttb.nci.nih.gov
> My Secretary is Chelly Johnson
>

Norman Clark

From: Sybert, Kathleen (NIH/NCI) [sybertk@otd.nci.nih.gov]
Sent: Thursday, October 03, 2002 4:23 PM
To: Peter J. Levine
Subject: RE: Invitation to participate on a proposed panel for the Biotechnology Industry Organization (BIO) 2003 annual meeting

WONDERFUL! I'll be back in touch when I know more.

-----Original Message-----

From: Peter J. Levine [mailto:plevine@correlogic.com]
 Sent: Thursday, October 03, 2002 4:21 PM
 To: Sybert, Kathleen (NIH/NCI)
 Cc: Lance Liotta; Berkley, Dale (OD); Droke, Beatrice A (FDA)
 Subject: Re: Invitation to participate on a proposed panel for the Biotechnology Industry Organization (BIO) 2003 annual meeting

Dear Kathleen,

Yes! I think that this is an excellent idea. The Correlogic/NCI/FDA story is remarkable on many, many fronts (not the least of which is the Herculean effort on everyone's part to get the original CRADA in place, and the ongoing efforts to modify it to reflect what we are actually doing and will be doing).

I would love to be a participant, and would be pleased to assist in helping refine ideas for the panel.

Best regards,
Peter

P.S. We very much enjoyed working with Svetlana Shtrom, and will miss her enthusiastic and always helpful manner of dealing with complex issues.

Peter J. Levine
 President
 Correlogic Systems, Inc.
 6701 Democracy Blvd. Suite 300
 Bethesda, Maryland 20817
 Tel: 301 983-1376
 Fax: 301 983-2966
 E-mail: plevine@correlogic.com

----- Original Message -----

From: "Sybert, Kathleen (NIH/NCI)" <sybertk@otd.nci.nih.gov>
 To: "'Peter Levine'" <plevine@correlogic.com>
 Sent: Thursday, October 03, 2002 3:58 PM
 Subject: FW: Invitation to participate on a proposed panel for the Biotechnology Industry Organization (BIO) 2003 annual meeting

>
 >
 > -----Original Message-----
 > > From: Sybert, Kathleen (NIH/NCI)
 > > Sent: Thursday, October 03, 2002 3:55 PM
 > > To: Liotta, Lance (NIH/NCI); Droke, Beatrice A (FDA); Berkley, Dale
 > > (OD); 'Peter J. Levine'
 > > Subject: Invitation to participate on a proposed panel for the
 > > Biotechnology Industry Organization (BIO) 2003 annual meeting
 > > Importance: High
 > >
 > > Dear Lance, Bea, Dale, and Peter,

From: Jim Tananbaum
Sent: Friday, October 4, 2002 2:50 PM
To: Carol Dahl, ExecStaff
Subject: RE: Agreement **TAB 29**

I am happy with the result here. Correllogic hopefully will not present too many problems.

-----Original Message-----
From: Carol Dahl [<mailto:cdahl@biospect.com>]
Sent: Wednesday, October 02, 2002 1:21 PM
To: ExecStaff
Subject: FW: Agreement

FYI. The answer to an earlier question that came up regarding Chip and Lance and their existing affiliations. I think the only area of concern is the Correllogic agreement. I emphasized to Chip that they need to be sure that information about the two companies does not become intertwined in any way or transferred. Let me know if you have any other concerns. Their agreements are in the last stages of ethics review at the NCI and the FDA.
Carol

-----Original Message-----
From: Petricoin, Emmanuel [<mailto:petricoin@cher.fda.gov>]
Sent: Wednesday, October 02, 2002 11:42 AM
To: 'Carol Dahl'
Subject: RE: Agreement

>
> Hi Carol-
>
> Here is a list of other relationships that Lance and I have in place
> with
> other companies (we only have outside activities that are together,
> not
> independently):
>
> Inside activity:
>
> 1. CRADA relationship with Correllogic Systems, Inc. for bioinformatic
> analysis of mass spectra
> 2. Pending CRADA relationships with two companies for protein array
> technology developed in US government proteomics program
>
> Outside activity Topics:
>
> 1. Consulting relationship with local biotechnology company on

disposable

- > point-of-care single analyte immunoassays
- > 2. Pending consulting relationship with local biotechnology on activity
- > screening for isolated kinase targets and their inhibitors
- >
- > Chip
- >

RE: catching up

Page 1 of 2

Slobodin, Alan

From: Larry Parnell [parnell@cshl.org]
Sent: Tuesday, November 19, 2002 4:54 PM
To: Jeff Livingstone
Subject: RE: catching up

TAB 30

Jeff,

Thanks for the info. I'll have to look into all that. With regards to lunch - I'll get back to you in a day or two so that we can set a date.

On Tue, 19 Nov 2002, Jeff Livingstone wrote:

> I was wondering what had happened to you!
 >
 > I assume this is the position:
 >
 > http://216.239.37.100/search?q=cache:JL9nqBiXj-cC:www.gmds.de/stellenboe+rse/innsbruck_0209.pdf+biocrates&hl=en&lr=lang_en&ie=UTF-8
 >
 > That's good you have a lead. I am assuming you are eager to move to
 > Europe. With the slash and burning going on in US bioinformatics
 > sently, it's probably an excellent move.
 >
 > Check out a similar company called Correlologic which couples LCM and M/S
 > as well as Ciphergen, which you know of already. I would also think of
 > Sequenom in terms of competition.
 >
 > Note the Chip Petricoin and Lance Liotta are now on our Scientific
 > Advisory Board. If you need any feedback on Biocrates, I would be happy
 > to ask them if they know anything.
 >
 > See: http://ccr.cancer.gov/tech_initiatives/clinical_proteomics.asp
 >
 > In another small world story, we recently added Cliff Hendrick, the COO
 > of GZMO to our Board of Directors, along with Jack Douglas, the SVP and
 > General Counsel of MLNM. Coincidentally, it was Cliff who orchestrated
 > the purchase and closure of PharmaGenics by Genzyme. His reflection of
 > the former PharmaGenics CEO, Mike "Sherm the Worm" Sherman is quite
 > coincident with that of Bruce's. It was funny to hear.
 >
 > Mon-Tues-Wed of next week are good for me. I'd be happy to meet you for
 > lunch here. We can go to Isabella's a couple of miles away from here,
 > in downtown Dedham.
 >
 > Larry - Do you know that Signet is what Cambridge Research Labs became
 > 1989 when approximately 1/2 of CRL was moved to Ortho in NJ? The
 > rest was taken private by Ron Casciato (my boss) the former General
 > Manager of CRL. I asked Ron if he remembered Charles "Chuck"

6/20/2004

RE: catching up

Page 2 of 2

> Rittershaus. He does, but he doesn't know where he went to after CRL
> formally "closed" in 1989.

ee our new corporate web site at www.signetlabs.com. I actually
> created most of the content for the site.

>
> Jeff
>

> -----Original Message-----
> From: Larry Parnell [mailto:parnell@cshl.org]
> Sent: Tuesday, November 19, 2002 3:55 PM
> To: Jeff Livingstone
> Subject: catching up
>

> Jeff,
>

> Sorry that I have been incommunicado the past few weeks, but I have been
> traveling a bunch and also quite occupied with my job search. For a
> while,
> I had lost your email address and when I did write to jitechnologies, it
> bounced. I just got back from 2 1/2 weeks in Bavaria and Austria where I
> interviewed for a director of Bioinformatics at an Austrian start up.
> The
> company is called Biocrates (www.biocrates.at) and is set to do
> mass-spec
> analysis to discover metabolomic info on diseases, candidate drugs and
> w
...indications of available therapeutics. On Wed, the founders will meet to
> discuss my candidacy...
>

> Anyhow, it would be great if we could get together some time soon. This
> week is getting a bit tight as I have three phone interviews on the next
> three successive days. How about next week? I can easily drive out to
> Dedham to meet you if you'd like, if you can.
>

> And in the curiosity dept. - Is a Charles Rittershaus working for you?
> He
> and I worked together at Cambridge Research Labs, an off-shoot of Ortho
> Diagnostics, itself a subsidiary of J&J back in '84 & '85.
>

> Hope all is well!
> Larry
>
>
>
>
>

6/20/2004

RE: Inquiry

Page 1 of 3

Slobodin, Alan

From: Liotta, Lance (NIH/NCI) [liotta@mail.nih.gov]
Sent: Friday, November 15, 2002 5:11 PM
To: 'Jeff Livingstone'
Subject: RE: Inquiry

TAB 31

Sorry I have to follow government rules of course and an outside company can not use my official government affiliation. I can not obtain approval until the ethics office reviews and approves the company, its financial sources, the mission of the company and my role in the company, and specified in my contract with the company. My company role must be completely different from what I do in my official duties. I'm sorry this paperwork will cause a delay. It may be best for you to remove my name from consideration, in light of your concerns listed below.

Lance

> -----
> From: Jeff Livingstone
> Sent: Friday, November 15, 2002 3:37 PM
> To: Liotta, Lance (NIH/NCI)
> Cc: Petricoin, Emanuel F (FDA)
> Subject: RE: Inquiry

> Dear Lance -
>
> I am sorry, but I am a little caught off guard by this. This is the
> first I am hearing that consultancy agreements need to be in place prior
> to proceeding with Ethics Board approval.
>
> As far as I am aware, the detailed materials I provided Chip over a
> month ago were given to the Ethics Board and have been in review since
> that time. It was my understanding that you were aware of this.
>
> I spoke to Chip when he was here in Boston a couple of weeks ago and he
> told me he had not yet received approval notification yet, that this was
> still under review by the Board.
>
> We are aware we cannot officially release any information regarding your
> or Chip's involvement until this is cleared. We have been very careful
> to fulfill this request and so have been circumspect in this regard.
>
> We are also aware that the relationship we are interested in is through you
> and Chip as individuals, not as representatives of the NIH. The NDAs I
> previously sent had NIH addresses listed on them. This was an error on
> my part. As I discussed with Chip when he was here, I now wish to send
> you and him modified NDAs with your home addresses on them, which he
> indicated was the correct thing to do.
>

6/20/2004

RE: Inquiry

Page 2 of 3

> It is not clear to me that consultancy agreements need to be put in
 > place prior to execution of an NDA. As far as I can gather, we cannot
 > approach you as a consultant until we are provided clearance by the
 > ethics Board. Hence, it makes sense to execute NDAs first so at least
 > we can bring you up to speed as to what we are doing internally, prior
 > to your participation as a SAB member - for which compensation would be
 > given.
 >
 > If I am confused as to the correct procedures to follow or am forgetting
 > something or most importantly, my understanding of our current standing
 > with the Board is wrong, then please let me know what I need to do as
 > soon as possible so that you and Chip can legitimately and without
 > liability on your part, participate on Signet's SAB.
 >
 > Of course, the above assumes that you and he still have an interest in
 > participating. If this is not the case, then please advise me as soon
 > as you can.
 >
 > Thank you for your interest and thank you for your help in securing the
 > appropriate path through the necessary regulations.
 >
 > I have copied Chip on this email.
 >
 > Yours,
 >
 > Jeff

-----Original Message-----

> From: Liotta, Lance (NIH/NCI) [mailto:liottal@mail.nih.gov]
 > Sent: Friday, November 15, 2002 3:12 PM
 > To: 'Jeff Livingstone'
 > Subject: RE: Inquiry
 >
 > Dear Jeff
 > Sorry for any inconvenience, but you can not use my name on your
 > scientific
 > advisory board because I am not yet approved by our government ethics
 > office
 > to serve on your board. Moreover you and I have no signed consulting
 > agreement in place. I need this document to provide to ethics so that I
 > can
 > even apply for approval. The same applies for Dr. Petricoin.
 > Lance
 >
 > > -----
 > > From: Jeff Livingstone
 > > Sent: Friday, November 15, 2002 3:00 PM
 > > To: Lance A Liotta
 > > Subject: Inquiry
 > >
 > > <<File: image001.jpg>>
 > > Lance -
 > >

6/20/2004

RE: Inquiry

Page 3 of 3

>>
>>
➡> I need to send personal NDA's to all the members of the SAB
acknowledging
>> they are representing themselves and not their respective institutions
> in
>> this regard.
>>
>>
>>
>> Can you please provide me with your home address so I can add it to
> your
>> document prior to sending? Thank you.
>>
>>
>>
>> Jeff
>>
>> _____
>> <<File: image002.jpg>> Jeff R. Livingstone, PhD
>>
>> Vice President, Business Development
>>
>> Signet Laboratories, Inc. (800) 223-0796, ext. 2024
>>
>> Rustcraft Road, Ste. 140 (781) 461-2456 (fax)
➡>
Dedham, MA 02026 (508) 954-3441 (mobile)
>>
>> www.signetlabs.com
>>
>> Proteopathology(tm)
>>
>>
>>
>
>
>

6/20/2004

Re: SAB and Meeting you next week

Page 1 of 3

TAB 32**Slobodin, Alan**

From: Petricoin, Emmanuel [petricoin@cber.fda.gov]
Sent: Thursday, August 01, 2002 7:09 AM
To: jlivingstone@signetlabs.com; lance@helix.nih.gov
Subject: Re: SAB and Meeting you next week

Hi Jeff

Both Lance and I are interested in talking with you about this. Perhaps a conference call this afternoon would be helpful to us so that we could understand better what you envision our roles to be, a bit more about your Magellan technology, and how we could get ethics clearance. Note that both lance and I work with Correlomics as a crada partner within our us government jobs.

Best,

Emanuel
 Emanuel Petricoin, Ph.D.
 Co-Director
 FDA-NCI Clinical Proteomics Program

 Sent from my BlackBerry Wireless Handheld (www.BlackBerry.net)

-----Original Message-----

From: Jeff Livingstone <jlivingstone@signetlabs.com>
 To: lance@helix.nih.gov <lance@helix.nih.gov>
 CC: Petricoin Emmanuel <petricoin@cber.fda.gov>
 Sent: Wed Jul 31 15:11:55 2002
 Subject: SAB and Meeting you next week

Dr. Liotta -

You may be aware I have been in correspondence with Dr. Petricoin, and have invited him to be a member of a new Scientific Advisory Board we are putting together. He in turn has suggested that we extend an invitation to you as well.

We are very aware of your excellent work in pathology and proteomics, and of course your background is an ideal fit for the new technology we will be launching at the DDT meeting this coming Sunday. My only concern is there may be a conflict of interest between companies you are working with at present (e.g. Correlologic) and/or companies you may intend to start.

6/20/2004

Re: SAB and Meeting you next week

Page 2 of 3

personally. Out of professional courtesy, I did not wish to put you in such a situation. We meant no slight; I trust you will understand.

However, if this is not the case, and you are interested, then please let me know. We would be honored to have your expertise and perspective available for the development of our Magellan platform.

Please note I have sent a binder to Dr. Petricoin containing an overview of our company and the technology, along with his invitation to the SAB. Please feel free to review it if you wish.

I note you be participating in the DDT meeting (see below announcement). I intend to be at this meeting on Sunday (our presentation is at 12:16pm) and all day Monday. I would be happy to meet with you in person, if you had the time. If you are interested in visiting Signet while you are here, please let me know. We would like to extend this invitation to Dr. Petricoin as well, if he will be here for the meeting.

Thank you for your consideration

Jeff

CONFERENCE UPDATES: New Addition to the NCI Panel - We are happy to announce the following addition to the NCI Panel on Tuesday, August 6 from 10:30 am - 12:00 pm: Lance A. Liotta, M.D., Ph.D., Chief, Laboratory of Pathology, National Cancer Institute/NCI

Jeff R. Livingstone, PhD

Vice President, Business Development

Signet Laboratories, Inc. (800) 223-0796, ext. 2024

craft Road, Ste. 140 (781) 461-2456 (fax)

Dedham, MA 02026 (508) 954-3441 (mobile)

6/20/2004

725

Re: SAB and Meeting you next week

Page 3 of 3

Proteopathology(tm)

ch our presentation on this exciting new technology platform at the Drug
Discovery Technology Symposium - Startup Showcase August 4, 2002 in Boston.

6/20/2004

RE: SAB Query

Page 1 of 2

Slobodin, Alan

From: Jeff Livingstone [jlivingstone@signetlabs.com]
Sent: Friday, June 28, 2002 4:55 PM
To: Petricoin, Emmanuel
Subject: RE: SAB Query

TAB 33

Emmanuel -

Thank you very much for your kind reply.

We are aware of Dr. Liotta's excellent work in proteomics and LCM, and his work with Ben Hitt at Correlogic. I agree he would be an excellent person to contact in this regard.

At present, Signet is a privately owned, small business. The core business is profitable; however the capital necessary for the commercialization of our new technology will require outside financing. Our plans are to use outside investment to double our size and research activities.

We will be starting our "road show" next month to raise approximately \$15 MM for the successful commercialization of our technology. We expect this will be done through a combination of corporate and venture investments. Some of our corporate partners (i.e. Zymark, Corning Life Science, Anvil, Genomics Collaborative) have expressed an interest in contributing.

In order to preserve capital, we are intending to offer equity compensation to those who serve as members of the SAB. Obviously, once we close on our first round of financing, this will convert to a cash or cash + equity basis, depending upon the interest of that particular SAB member.

Jeff

-----Original Message-----

From: Petricoin, Emmanuel [mailto:petricoin@cber.fda.gov]
Sent: Friday, June 28, 2002 3:49 PM
To: 'Jeff Livingstone'
Subject: RE: SAB Query

Hi Jeff-

I would be interested in learning more about this, and would like to recommend my colleague Dr. Lance Liotta at the NCI for consideration for the SAB. I can provide you his contact info if you wish. I highly recommend him. We would have to receive outside activity OK from ethics. Can you tell me what kind of compensation the SAB members would receive for their time?

Best,

Emmanuel

> -----

> **From:** Jeff Livingstone
> **Sent:** Friday, June 28, 2002 11:59 AM
> **To:** petricoin@cber.fda.gov

6/20/2004

RE: SAB Query

Page 2 of 2

> Subject: SAB Query
>
> <<File: Corporate Summary - Front Sheet + SDI.pdf>>
> Dear Dr. Petricoin:
>
>
>
> We are currently working on a new tissue-based screening platform
> technology, which we intend to commercial for biopharmaceutical target
> discovery and lead validation, among other applications. Our efforts will
> be showcased at the Drug Discovery Technology Symposium - Start-Up
> Showcase on August 4th, in Boston.
>
>
>
> As part of this strategy, we are assembling a Scientific Advisory Board to
> include experts who can provide key, critical insight toward this pursuit.
> I am preparing formal invitation letters and wish to know if you would be
> interested and available. We expect the SAB to meet at most for one day,
> once a quarter.
>
>
>
> As an introduction, I am attached a one-page overview of Signet's history
> and mission.
>
>
>
> Thank you in advance for your help and interest.
>
>
>
> Yours,
>
>
>
> Jeff
>
> _____
> Jeff R. Livingstone, PhD
>
> Vice President, Corporate Development
>
> Signet Laboratories, Inc. (800) 223-0796, ext. 2024
>
> Rustcraft Road, Ste. 140 (781) 461-2456 (fax)
>
> Dedham, MA 02026 (508) 954-3441 (mobile)
>
>
>
>

6/20/2004

From: Carol Dahl <cdahl@predicant.com>
Sent: Monday, March 31, 2003 9:09 AM
To: Petricoin, Emmanuel; liottal@mail.nih.gov
Cc: Svetlana Shtrom; John Stults; Jonathan Heller
Subject: RE: Follow up and could you be available to meet?

TAB 34

Chip and Lance,
 I'm glad the 23rd works for you. We will book a conference room and look forward to seeing you here at our offices on Democracy.

We would also welcome a report on the glycosylated hemoglobin A1C detection for diabetes. The 23rd would be OK, but in advance of the 23rd would allow us to read it before our meeting and perhaps provide for a more interesting discussion.

The suggestions on consultants for 510K would be very useful.

Talk to you soon,
 Carol

-----Original Message-----

From: Petricoin, Emmanuel [mailto:petricoin@cber.FDA.gov]
 Sent: Monday, March 31, 2003 8:06 AM
 To: Carol Dahl; Petricoin, Emmanuel; liottal@mail.nih.gov
 Cc: Svetlana Shtrom; John Stults; Jonathan Heller
 Subject: Re: Follow up and could you be available to meet?

Hi Carol

The 23rd at 3 pm would be good for us.

We would be happy to give to you a report of glycosylated hemoglobin A1C detection for diabetes. We could give you this report on hhe 23rd if you wish. We think this would be a very promising route for you to take for a 510K- and very profitable. We will pull together the information on the predicate device and analyte as well. Also, we will provide you this week with some names for potential consultants that can give you 510k guidance.

Chip and Lance

 Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: Carol Dahl <cdahl@biospect.com>
 To: Petricoin, Emanuel F (FDA) <petricoin@cber.FDA.gov>; Liotta, Lance (NIH/NCI) <liottal@mail.nih.gov>
 CC: Svetlana Shtrom <sshtrom@biospect.com>; John Stults <jstults@biospect.com>; Jonathan Heller <jheller@biospect.com>

Predicant 00013

Sent: Fri Mar 28 10:24:30 2003
Subject: Follow up and could you be available to meet?

Hi Chip and Lance,

Chip, nice to see you in Santa Clara, Lance, sorry you could not join us. Thanks for the discussion. During the discussion you mentioned an application for diabetes monitoring that seemed potentially of interest. Is it possible that either one or both of you could flesh that out a bit and provide some sense of the specific tests that exist and that might be appropriate against which to demonstrate equivalency for a 510K application? It would be great if you could find any of the FDA approval background on those tests as well. We continue to be interested in your suggestions of possible applications with reasonable markets that might be appropriate for a "home brew" type of introduction or 510K.

I also want to thank you for the guidance document on Application Specific Reagents. We would like to learn more about the "home-brew" route. If you have any suggestions of others we should speak with on that subject, or consultants who are well qualified in that area that would be extremely useful. We are particularly interested in speaking with people who have been successful in going through that introduction process.

John Stults will be here in the DC area for the NCI meeting on proteomics at Westfields on April 22 or 23. I am under the impression that one or both of you will also be attending. We were wondering if you could be available for a meeting at Biospect on April 23 around 3 PM with John, Svetlana and me?

Talk to you soon,

Carol

Predicant 00014

From: Petricoin, Emmanuel <petricoin@cber.FDA.gov>
Sent: Friday, March 28, 2003 11:53 AM
To: Jonathan Heller; Petricoin, Emmanuel; liottal@mail.nih.gov
Cc: Svetlana Shtrom; John Stults; Carol Dahl
Subject: Re: Follow up and could you be available to meet?

TAB 35

Yes, as pointed out on the website. If you wish to get access to the spectra you must contact Mr. Kevin Brand at the OTT, who will send to you a non-negotiable CDA. Once this is signed, then we will provide you a one time use password to ftp download the data. Please let me know if you have any questions. Kevin's email is: brandk@mail.nih.gov (also should be on the web site).

Best,

Chip

Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: Jonathan Heller <jheller@biospect.com>
To: Petricoin, Emanuel F (FDA) <petricoin@cber.FDA.gov>; Liotta, Lance (NIH/NCI) <liottal@mail.nih.gov>
CC: Svetlana Shtrom <sshtrom@biospect.com>; John Stults <jstults@biospect.com>; Carol Dahl <cdahl@biospect.com>
Sent: Fri Mar 28 11:15:16 2003
Subject: RE: Follow up and could you be available to meet?

Chip,

One other question. At dinner, you mentioned that you thought you would be able to get us access to the new, high resolution data that you were now acquiring. I checked out your new web site and it has a lot more information on it - that is great. But I don't think there is a link to the high res data still. Can we access that data?

Thanks,
Jonathan

-----Original Message-----

From: Carol Dahl
Sent: Friday, March 28, 2003 7:25 AM
To: 'Petricoin, Emanuel F (FDA)'; 'Liotta, Lance (NIH/NCI)'
Cc: Svetlana Shtrom; John Stults; Jonathan Heller
Subject: Follow up and could you be available to meet?

Hi Chip and Lance,

Predicant 00015

Chip, nice to see you in Santa Clara, Lance, sorry you could not join us. Thanks for the discussion. During the discussion you mentioned an application for diabetes monitoring that seemed potentially of interest. Is it possible that either one or both of you could flesh that out a bit and provide some sense of the specific tests that exist and that might be appropriate against which to demonstrate equivalency for a 510K application? It would be great if you could find any of the FDA approval background on those tests as well. We continue to be interested in your suggestions of possible applications with reasonable markets that might be appropriate for a "home brew" type of introduction or 510K.

I also want to thank you for the guidance document on Application Specific Reagents. We would like to learn more about the "home-brew" route. If you have any suggestions of others we should speak with on that subject, or consultants who are well qualified in that area that would be extremely useful. We are particularly interested in speaking with people who have been successful in going through that introduction process.

John Stults will be here in the DC area for the NCI meeting on proteomics at Westfields on April 22 or 23. I am under the impression that one or both of you will also be attending. We were wondering if you could be available for a meeting at Biospect on April 23 around 3 PM with John, Svetlana and me?

Talk to you soon,

Carol



TAB 36

October 22, 2002

Dr. Lance Liotta
8601 Bradley Blvd
Bethesda, MD 20817

Dear Lance,

On behalf of Biospect, Inc. I am pleased to extend to you a consulting agreement. As you know, we consider your scientific expertise in medical diagnostic technology, clinical sample acquisition and stability, regulatory filings and regulatory inspections related to clinical pathology laboratories relying upon knowledge obtained as a Board Certified Pathologist with CAP laboratory certification and expertise as a biomedical engineer to be of great value and we believe your input could be of great assistance in our research and development activities. Anticipated consulting services will include teleconference and electronic communications, on site meetings at Company facilities, and off site meetings as requested including during normal business hours, as well as the review and preparation of written materials. General consulting services that may be requested by the Company from time to time will relate to the Company's research and development. We expect those services to average approximately 4 days per month.

We are very enthusiastic about the opportunity to engage your expertise through consulting. Please indicate your acceptance of this offer with your signature. Upon completion of your signature, keep a copy for yourself and return the signed original to me at:

Biospect, Inc.
6701 Democracy Blvd.
Suite 300
Bethesda, MD 20817

We look forward to working with you.

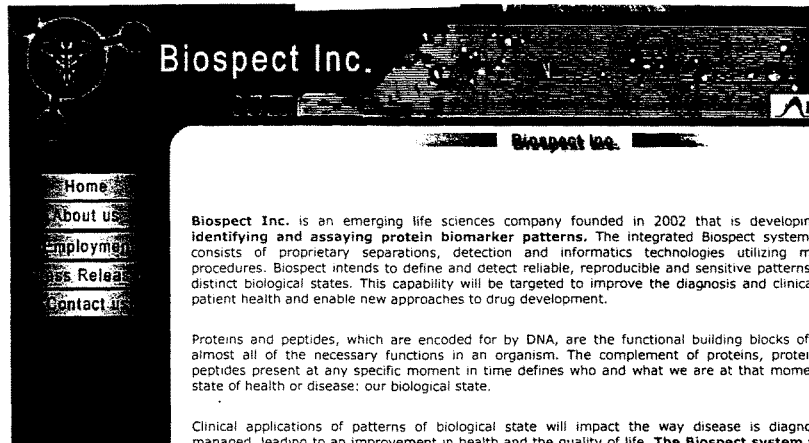
Sincerely,

A handwritten signature in black ink, appearing to read 'Carol A. Dahl'.

Carol A. Dahl, Ph.D.
Vice President
Strategic Partnerships

TOTAL P. 02
TOTAL P. 02

TAB 37



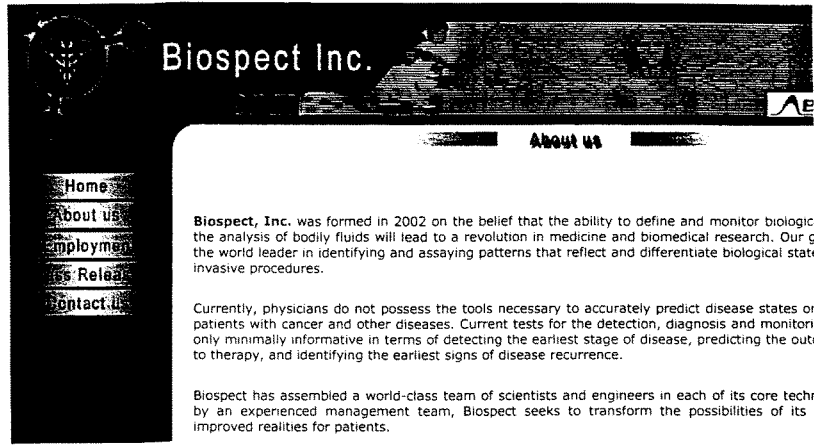
The image is a screenshot of the Biospect Inc. website. At the top, there is a header with the company name "Biospect Inc." and a logo on the left. Below the header, there is a navigation menu on the left side with links: "Home", "About us", "Employment", "Press Release", and "Contact us". The main content area on the right contains the following text:

Biospect Inc. is an emerging life sciences company founded in 2002 that is developing **identifying and assaying protein biomarker patterns**. The integrated Biospect system consists of proprietary separations, detection and informatics technologies utilizing mass spectrometry procedures. Biospect intends to define and detect reliable, reproducible and sensitive patterns of distinct biological states. This capability will be targeted to improve the diagnosis and clinical patient health and enable new approaches to drug development.

Proteins and peptides, which are encoded for by DNA, are the functional building blocks of almost all of the necessary functions in an organism. The complement of proteins, protein peptides present at any specific moment in time defines who and what we are at that moment of health or disease: our biological state.

Clinical applications of patterns of biological state will impact the way disease is diagnosed and managed, leading to an improvement in health and the quality of life. **The Biospect system will provide a foundation for the discovery and detection of patterns of proteins, protein fragments and peptides that reflect and differentiate various states of health and disease.**

ATTENTION: We have moved effective 12/22/03. Our new address and contact information is on the next page



The screenshot shows the 'About Us' page of the Biospect Inc. website. The header features the company name 'Biospect Inc.' and a navigation menu with links for Home, About Us, Employment, Press Release, and Contact Us. The main content area includes a paragraph about the company's mission, a paragraph about its current capabilities, a paragraph about its team, and a paragraph about its funding.

Biospect Inc.

About Us

Home
About Us
Employment
Press Release
Contact Us

Biospect, Inc. was formed in 2002 on the belief that the ability to define and monitor biological processes through the analysis of bodily fluids will lead to a revolution in medicine and biomedical research. Our goal is to become the world leader in identifying and assaying patterns that reflect and differentiate biological states without the need for invasive procedures.

Currently, physicians do not possess the tools necessary to accurately predict disease states or monitor patients with cancer and other diseases. Current tests for the detection, diagnosis and monitoring of disease are only minimally informative in terms of detecting the earliest stage of disease, predicting the outcome of therapy, and identifying the earliest signs of disease recurrence.

Biospect has assembled a world-class team of scientists and engineers in each of its core technology areas. By an experienced management team, Biospect seeks to transform the possibilities of its technology into improved realities for patients.

Funded by top-tier venture capital firms, Advent Venture Partners, Prospect Venture Partners, Versant Ventures, Biospect raised first round funding of over \$27 million.

TAB 38**EXHIBIT A**

SERVICES General consulting services that may be requested by Company from time to time relating to Company's research and development and other business activities, averaging one (1) full day per week. Company's research and development and other business activities are defined by the missions of the Company. The Company's mission is to become the world leader in complex mixture analysis of biological fluids/tissues to inform the detection, diagnosis, monitoring and treatment of human disease through the application of proprietary separation, detection, and informatics technologies.

Consulting services will relate to general professional knowledge in medical diagnostic technology, clinical sample acquisition, preparation, fractionation, separation, storage and stability, regulatory filings and regulatory inspections related to clinical pathology laboratories [e.g. CAP (College of American Pathologists), CLIA, GMP inspections, and 510(k) or PMA filings for new diagnostic tests] relying upon knowledge obtained as a Board Certified Pathologist with CAP laboratory certification and expertise as a biomedical engineer. Consulting services will also relate to general scientific expertise in diagnostic devices and microfluidics as applied to the analysis of protein and biological mixtures and the classification of biologic states through complex mixture analysis of biological fluids. Services will exclude protein microarrays, tissue microdissection, and serum proteomic pattern analysis using genetic algorithms and self-organizing maps. Services will include teleconference and electronic communications, on site meetings at Company facilities, and off site meetings as requested including during normal business hours, as well as the review and preparation of written materials.

If the consultant's name is used in the Company's public documents, it will be stated "The consultant is an employee of the US government and is performing this consultation as an approved outside activity." The Company will review the language with the consultant so that the description of the consultant conforms to government outside activity guidelines.

FEES Flat fee of \$5,000 per month, payable within 7 days after timely completion of service required that month, averaging 2 days per month. Consultant may be asked to provide documentation of hours of service.

EXPENSE REIMBURSEMENT Limited to (1) required, reasonable telephone expenses and long distance coach class (or equivalent) travel (transportation, lodging and meals) authorized in writing by company in advance, and (2) payable only 30 days after itemized invoice (and delivery of receipts).

INVOICES All invoices and receipts should be submitted to:

Dan Miller
Biospect, Inc.
Vice President, Finance and Administration
951 Gateway Blvd.
South San Francisco, CA 94080
650-952-4350 x 100 (phone); 650-952-0911 (fax)

From: Petricoin, Emmanuel <petricoin@cber.FDA.gov>
Sent: Monday, April 21, 2003 8:17 PM
To: Jonathan Heller
Subject: Re: CDA with Biospect **TAB 39**

Let me check. Worst case is that I can give the burned cd to carol on wednesday.

Chip

Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: Jonathan Heller <jheller@biospect.com>
To: Petricoin, Emmanuel <petricoin@cber.FDA.gov>
Sent: Mon Apr 21 19:03:04 2003
Subject: RE: CDA with Biospect

Chip,
I have not received the data yet - not sure if it got lost or has not been sent yet. Could you let me know?
Thanks,
Jonathan

-----Original Message-----

From: Jonathan Heller
Sent: Friday, April 04, 2003 1:49 PM
To: 'Petricoin, Emmanuel'
Subject: RE: CDA with Biospect

Thanks Chip. Our address is:

Biospect
Attn: Jonathan Heller
951 Gateway Blvd.
South San Francisco, CA 94080

Phone number is 650 952 4350 ext 105.

Jonathan

-----Original Message-----

From: Petricoin, Emmanuel [mailto:petricoin@cber.FDA.gov]
Sent: Friday, April 04, 2003 12:26 PM
To: Petricoin, Emmanuel (NIH); 'Brand, Kevin (NIH/NCI)'

Predicant 00725

Cc: Jonathan Heller
Subject: RE: CDA with Biospect

John-

Please send me a mailing address so that we can FedEx a disk with the data.

Chip

> -----
> From: Brand, Kevin (NIH/NCI)
> Sent: Friday, April 4, 2003 12:02 PM
> To: Petricoin, Emmanuel (FDA/CBER/O)
> Cc: 'jheller@biospect.com'
> Subject: CDA with Biospect
>
> At your convenience, feel free to share the proteomic data with Dr.
> Heller.
> The agreement is currently being forwarded to the FDA for final signature.
>
> Kevin
>
>

Burton, Craig (HHS/OS)

From: Flambert, Gemma (NIH/OD)
nt: Wednesday, June 16, 2004 2:15 PM **TAB 40**
o: Burton, Craig (HHS/OS)
Cc: Smolonsky, Marc (NIH/OD); Torres, Abelardo (HHS/OS)
Subject: Additional document re: Biospect

This should have been included in the package I sent yesterday. If it hasn't gone forward yet, can you include it please?
 Thanks! Sorry for not sending it yesterday, I just received it.

-----Original Message-----

From: Wilson, Maureen (NIH/NCI)
Sent: Wednesday, June 16, 2004 1:53 PM
To: Pugach, David (NIH/NCI)
Subject: FW: Biospect 520

-----Original Message-----

From: Liotta, Lance (NIH/NCI)
Sent: Wednesday, May 05, 2004 3:31 PM
To: Wilson, Maureen (NIH/NCI)
Subject: RE: Biospect 520

I do confirm this is on hold.
 Lance

From: Wilson, Maureen (NIH/NCI)
Sent: Wednesday, May 5, 2004 12:23 PM
To: Liotta, Lance (NIH/NCI)
Subject: FW: Biospect 520

See below

-----Original Message-----

From: Jaffe, Holli Beckerman (NIH/OD)
Sent: Wednesday, May 05, 2004 10:44 AM
To: Wilson, Maureen (NIH/NCI)
Subject: RE: Biospect 520

please also confirm with him that while he has not received any payments since february (in other words, he was last paid in february), he has not consulted with Biospect since February -- the arrangement has been put on hold until he receives approval from dr. kington. i know i'm beating a dead horse, but i want to be very clear on the facts. it's in his best interest that we have all the facts and no uncertainty. thanks for your help.

Holli Beckerman Jaffe, J.D.
 Director, NIH Ethics Office
 National Institutes of Health
 2 Center Drive
 Bldg 2, Rm BE-211
 Bethesda, MD 20892
 Phone (301) 594-9555
 Fax (301) 480-2281

-----Original Message-----

From: Wilson, Maureen (NIH/NCI)

Sent: Wednesday, May 05, 2004 9:40 AM
To: Jaffe, Holli Beckerman (NIH/OD)
Subject: FW: Biospect 520

-----Original Message-----

From: Liotta, Lance (NIH/NCI)
Sent: Tuesday, May 04, 2004 4:30 PM
To: Wilson, Maureen (NIH/NCI)
Subject: RE: Biospect 520

OK will do. thanks again

From: Wilson, Maureen (NIH/NCI)
Sent: Tuesday, May 4, 2004 3:31 PM
To: Liotta, Lance (NIH/NCI)
Subject: RE: Biospect 520

So you have a verbal agreement to perform 2 days of work per month for a total of \$3250. You should get a letter to that effect for your own protection and theirs in case anyone questions the rate or hours as inconsistent with the written contract.

-----Original Message-----

From: Liotta, Lance (NIH/NCI)
Sent: Tuesday, May 04, 2004 2:42 PM
To: Wilson, Maureen (NIH/NCI)
Subject: RE: Biospect 520

Hi Dr. Wilson

The original Biospect signed Consulting agreement was unchanged. A new consulting agreement was not signed. The original signed agreement remains active. This was stated in my latest NCI ethics renewal package. For this latest renewal for NCI Ethics, a new HHS form was signed by Biospect.

Reduction of the consulting stipend was a request made by Biospect, and I agreed. The Biospect request to reduce the stipend came before this last renewal so I added this fact as the only change in the outside activity (in my last Biospect renewal paperwork sent to NCI ethics). Let me know if you want me to go back to Biospect and get a formal letter covering only the change in the stipend.
Lance

From: Wilson, Maureen (NIH/NCI)
Sent: Tuesday, May 4, 2004 10:38 AM
To: Liotta, Lance (NIH/NCI)
Subject: Biospect 520
Importance: High

You advised me that money on the Biospect 520 was decreasing and that is indicated on the 520 itself . We have the original company consulting agreement that is open ended, but it should have an amendment that reduces your time/\$ agreement since the one on file indicates 2 days month at a rate of \$5000 and the 520 submitted indicates 192 hrs/year or 16/month=2 days @ \$3250. Did you forward an amended consulting agreement or exhibit A that updates your consulting agreement to reflect the new \$/time commitment? If so it is not in the current record. We have an executed NIH 2657, but if you have a copy of the excited current company consulting agreement we should make it part of the file.

Maureen O. Wilson, Ph.D.
Assistant Director
Deputy Ethics Counselor
NCI, NIH, DHHS
31 Center Drive, Bldg. 31, Rm. 3A18
Bethesda, MD 20892-2440

2:52 PM

06/16/04

Predicant Biosciences, Inc.
Vendor QuickReport
 January 1, 2002 through June 15, 2004

TAB 41

Type	Date	Num	Account	Clr	Amount
Liotta, Lance MD PhD					
Bill	12/27/2002	Dec fees	2010 - Trade accoun...		-5,000.00
Bill Pmt -Check	12/27/2002	5398	1010 - SVB Checking	X	-5,000.00
Bill	1/31/2003	Jan 03	2010 - Trade accoun...		-5,000.00
Bill Pmt -Check	2/12/2003	5522	1010 - SVB Checking	X	-5,000.00
Bill	2/28/2003	Feb 03	2010 - Trade accoun...		-5,000.00
Bill Pmt -Check	3/1/2003	5578	1010 - SVB Checking	X	-5,000.00
Bill	3/31/2003	Mar 03	2010 - Trade accoun...		-5,000.00
Bill Pmt -Check	4/1/2003	5683	1010 - SVB Checking	X	-5,000.00
Bill	4/30/2003	Apr 03	2010 - Trade accoun...		-5,000.00
Bill Pmt -Check	5/1/2003	5786	1010 - SVB Checking	X	-5,000.00
Bill	5/31/2003	May 03	2010 - Trade accoun...		-5,000.00
Bill Pmt -Check	6/1/2003	5901	1010 - SVB Checking	X	-5,000.00
Bill	6/30/2003	Jun 03	2010 - Trade accoun...		-5,000.00
Bill Pmt -Check	7/1/2003	6026	1010 - SVB Checking	X	-5,000.00
Bill	7/31/2003	Jul	2010 - Trade accoun...		-5,000.00
Bill Pmt -Check	8/1/2003	6163	1010 - SVB Checking	X	-5,000.00
Bill	8/31/2003	Aug	2010 - Trade accoun...		-5,000.00
Bill Pmt -Check	9/1/2003	6294	1010 - SVB Checking	X	-5,000.00
Bill	9/30/2003	Sep	2010 - Trade accoun...		-3,125.00
Bill Pmt -Check	10/9/2003	6437	1010 - SVB Checking	X	-3,125.00
Bill	10/31/2003	Oct	2010 - Trade accoun...		-3,125.00
Bill Pmt -Check	11/1/2003	6508	1010 - SVB Checking	X	-3,125.00
Bill	11/30/2003	Nov	2010 - Trade accoun...		-3,125.00
Bill Pmt -Check	12/1/2003	6624	1010 - SVB Checking	X	-3,125.00
Bill	12/31/2003	Dec	2010 - Trade accoun...		-3,125.00
Bill Pmt -Check	1/1/2004	6753 ✓	1010 - SVB Checking	X	-3,125.00
Bill	1/31/2004	Jan 04	2010 - Trade accoun...		-3,125.00
Bill Pmt -Check	2/1/2004	6903 ✓	1010 - SVB Checking	X	-3,125.00
Bill	2/29/2004	Feb	2010 - Trade accoun...		-3,125.00
Bill Pmt -Check	3/1/2004	7054 ✓	1010 - SVB Checking	X	-3,125.00
Bill	3/31/2004	Mar	2010 - Trade accoun...		-3,125.00
Bill Pmt -Check	4/1/2004	7207 ✓	1010 - SVB Checking	X	-3,125.00
Bill	4/30/2004	Apr	2010 - Trade accoun...		-3,125.00
Bill Pmt -Check	5/1/2004	7363 ✓	1010 - SVB Checking	X	-3,125.00

6753

BIOSPECT, INC.
 951 GATEWAY BLVD., 3B
 SOUTH SAN FRANCISCO, CA 94080
 (650) 952-4350

SILICON VALLEY BANK
 SANTA CLARA, CALIFORNIA 95054
 90-4039-1211

1/1/2004

TAB 42

PAY TO THE ORDER OF Dr. Lance Liotta

\$ **3,125.00

Three Thousand One Hundred Twenty-Five and 00/100*****

DOLLARS

Dr. Lance Liotta
 8601 Bradley Blvd.
 Bethesda, MD 20817

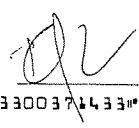
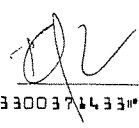
MEMO

⑈006753⑈ ⑆121140399⑆ 3300371433⑈ ⑈0000312500⑈

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 29-0037-4 Fiserv- San Leandro-#01
 01122004
 03107040146360
 01122004
 0620-0027-3 FRB BALTIMO
 ENT=0994 TRC=4003 PR=11

01010000000000000000
 001-0001250000
 001-0001250000

Predicant 00002

BIOSPECT, INC. 961 GATEWAY BLVD., 3RD FLOOR SOUTH SAN FRANCISCO, CA 94080 (650) 862-4350		SILICON VALLEY BANK SANTA CLARA, CALIFORNIA 95054 80-4039-1211		6903
PAY TO THE ORDER OF Dr. Lance Liotta		2/1/2004		
TAB 43		\$ **3,125.00		
Three Thousand One Hundred Twenty-Five and 00/100		DOLLARS		
Dr. Lance Liotta 8601 Bradley Blvd. Bethesda, MD 20817				
MEMO				
⑈006903⑈ ⑆121140399⑆		3300371433⑈		⑈0000312500⑈

000004 ⑈14596433
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 Fiserv-San Leandro-#14
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 ⑈21000002604⑈

⑈000004 ⑈14596433
 Processed
 Fiserv-San Leandro-#14
 ⑈21000002604⑈

To deposit only to
 Fiserv-San Leandro
 A/C # 0200002501

Predicant 00003

7054

BIOSPECT, INC.
 201 451 GATEWAY BLVD. 3B
 SOUTH SAN FRANCISCO, CA 94080
 (650) 952-4350

SILICON VALLEY BANK
 SANTA CLARA, CALIFORNIA 95054
 90-4039-1211

3/1/2004

PAY TO THE
 ORDER OF Dr. Lance Liotta

TAB 44

\$ **3,125.00

Three Thousand One Hundred Twenty-Five and 00/100*****

DOLLARS

Dr. Lance Liotta
 8691 Bradley Blvd.
 Bethesda, MD 20817

MEMO

⑈007054⑈ ⑆121140399⑆

3309371433⑈

⑈0000312500⑈

0152004 14360260
 0106074 Processed
 NT0214 TRF-14360260
 0117-0215004
 0117-0215004
 0122004
 0020-0027-R FBI BALTIMO
 ENT=0960 TRC=0980 PR=11

00000000000000000000
 001-2004-0000
 01000000000000000000

7054
 Safety Deposit Box
 Acct # 020002301

Predicant 00004

BIOSPECT, INC.
 201 551 GATEWAY BLVD, 3B
 SOUTH SAN FRANCISCO, CA 94080
 (650) 952-4350

SILICON VALLEY BANK
 SANTA CLARA, CALIFORNIA 95054
 950-4039-1211

4/1/2004

7207

PAY TO THE
 ORDER OF Dr. Lance Liotta

TAB 45

\$**3,125.00

Three Thousand One Hundred Twenty-Five and 00/100

DOLLARS

Dr. Lance Liotta
 8601 Bradley Blvd.
 Bethesda, MD 20817

MEMO

[Handwritten signature]

⑈007207⑈ ⑆121140399⑆ 3300371433⑈ ⑈0000312500⑈

4100004 14316571
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 NELL B. Liotta-San Leandro-#14
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Handwritten note:
 This is my 12
 Sandy Spring Bank
 Acct # 4800677806

PRESENTATION TO BIOSPECT

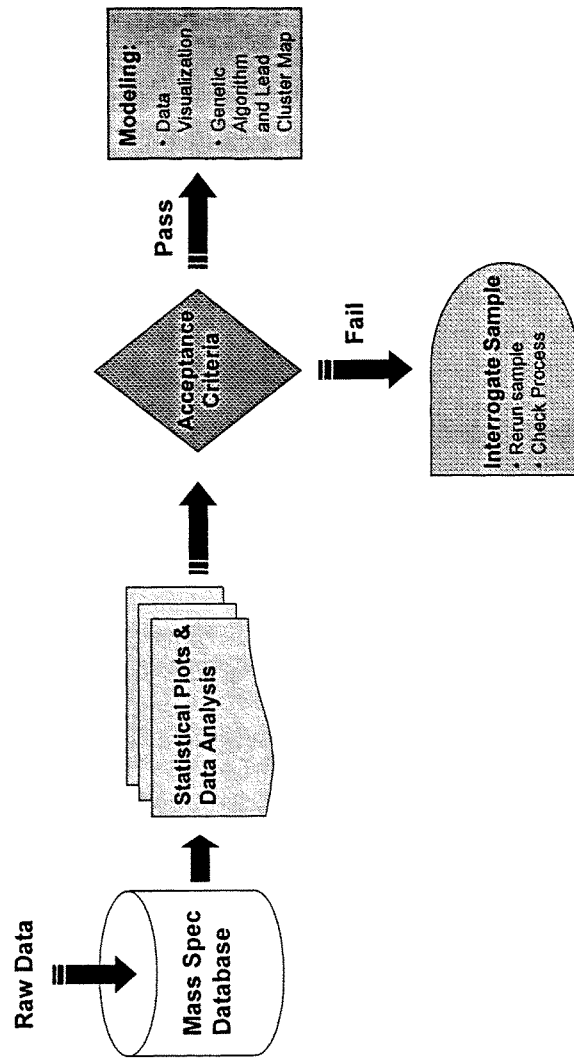
July 7, 2003

TAB 47

Agenda:

1. Overview of the field of opportunities in serum diagnostics
2. Package of material for presentation:
 - Public domain articles in cardiac markers and sepsis and regulatory routes for 510K.
 - PowerPoint overview of mass spec-based approaches (all information presented is in the public domain and US Government owned/patent pending)
 - Example competitive platform and companies

NCI-FDA Clinical Proteomics Statistical Sample Validation



Serum Proteomic Pattern Diagnostics

- TISSUE PATHOLOGIC STATES ARE REFLECTED IN HIDDEN SERUM PROTEOMIC PATTERNS UNCOVERED USING AN ARTIFICIAL INTELLIGENCE-BASED BIOINFORMATICS TOOL THAT LEARNS THE MOST FIT SOLUTION
 - WE HYPOTHESE THAT SERUM PROTEOMIC PATTERNS ARE PRODUCT OF THE UNIQUE TUMOR-HOST MICROENVIRONMENT AND REFLECT TUMOR AND HOST INTERACTION
- CURRENT STRATEGY:
- TWO INDEPENDENT TRACKS:
1. SCIENTIFIC INVESTIGATION INTO SPECIFIC SOURCE AND IDENTITY OF THE CLASSIFIERS
 2. NCI-BASED NATIONAL CLINICAL TRIAL ON SERUM PROTEOMIC PATTERN DIAGNOSTICS WHERE IDENTITY IS NOT NEEDED

Predicant 00592

NCI Proteomic Pattern Diagnostic Reference Lab: A Model for Moving Forward

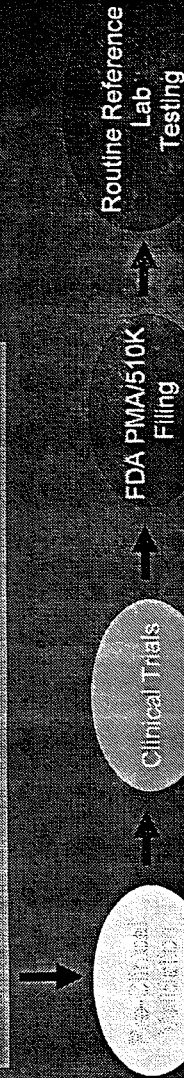
Developed under CRADA and Licensing Arrangement with Correllogic Systems, Inc.

RESEARCH AND DEVELOPMENT CORE:

- New platform/tech development/assessment
- New disease indication studies
- SOP optimization/validation
- New methods development

NCI CLINICAL REFERENCE LAB:

- 10,000 Sq. ft. Dedicated Space
- CLIA/CAP Certified: PI, Dr. Lance Liotta
- 3 ABI QqToF Hybrid MALDI-TOF
- 3 Liquid Robotic Sample Handling Stations
- Freezer space for clinical samples
- SGI-supported data storage
- Data visualization support Under separate collaboration with Brookhaven National Laboratories



Proteomic Pattern

FDA Filing Strategy

- Rigorously validate the method, including full QA and QC.
- Begin routine testing in a CAP-certified NCI clinical lab (Lab of Path)
- Initiate a 510(k) filing for a monitoring claim
- Gather the preclinical data and conduct comprehensive clinical studies to generate data to support a high risk screening indication
- NCI will file the PMA with extended claims
- If the PMA is approved, the NCI will bring the method to clinical reference laboratories (e.g. LabCore, Quest) through its CRADA partner Correlogic Systems.

Translating Bench Research to the Clinic: Important Developmental Milestones

- May 1998: Work begins using SELDI-TOF for proteomic fingerprinting of LCM-derived cells
- July 1998: Work begins using SELDI-TOF for proteomic fingerprinting of serum
- July 1999: Co-development of AI algorithms with Correlogic Systems, Inc. for pattern analysis of mass spectral fingerprints leading to first patent filing describing proteomic pattern diagnostics: PCT/US01/22447 "A PROCESS FOR DISCRIMINATING BETWEEN BIOLOGICAL STATES BASED ON HIDDEN PATTERNS FROM BIOLOGICAL DATA"
- July 2000: Cooperative research and development agreement (CRADA) with Correlogic Systems to develop Proteomic Pattern Diagnostics for clinical applications.
- February 2002: First publication showing potential clinical utility of proteomic pattern diagnostics "Proteomic Patterns in Sera Identify Ovarian Cancer", 2002, The Lancet, 359:572-77.
- July- September 2002: House and Senate Congressional Resolutions Passed supporting the potential for proteomic pattern diagnostic testing and health care Coverage for these test if demonstrated to be effective HR: 385/ SR:138
- November 2002: LabCorp and Quest Diagnostic partner with Correlogic Systems, Inc. for homebrew testing- opening up access to over 75% of the US reference lab market.
- November 2002: NCI begins development of world's first reference lab for clinical trials using proteomic pattern diagnostics
- Summer/Fall 2003: NCI begins clinical trials for ovarian cancer applications

Predicant 00602

From: Petricoin, Emmanuel <petricoin@cber.FDA.gov>
Sent: Tuesday, April 22, 2003 8:58 AM
To: Petricoin, Emmanuel; liottal@mail.nih.gov; Carol Dahl
Cc: Svetlana Shtrom; John Stults; Jonathan Heller
Subject: Glycosylated HGB material
Attach: 1143.pdf, 1147.pdf, checklist-f102.pdf, clia060501.pdf, fr0202ap.pdf, frclass2.pdf, k955087.pdf, parad510.pdf, H1c-diabetics.DOC; CLIA 1.DOC

TAB 48

Dear Carol-

Please find attached some information we have on CLIA guidelines, FDA/CDRH guidelines, and specific information on glycosylated hemoglobin approved testing for a potential Biospect 510k-based test.

We wanted to point out that there is a very good diabetes/proteomics meeting this Friday at the Natcher on the NIH :

> Proteomics in Diabetes April 24-25
> NIDDKK
> Reudi Aebersold
>
> <http://proteomics.niddk.nih.gov>
>

IT would be great if someone from Biospect could attend this conference. We will also attend. We could still meet with the team tomorrow at 3, although we would like to suggest that we meet next week after this conference is over and have even more information. Let us know.

Chip and Lance

<<1143.pdf>> <<1147.pdf>> <<checklist-f102.pdf>> <<clia060501.pdf>>
<<fr0202ap.pdf>> <<frclass2.pdf>> <<k955087.pdf>> <<parad510.pdf>>
<<H1c-diabetics>> <<CLIA 1>>

From: Liotta, Lance (NIH/NCI) <liottal@mail.nih.gov>
Sent: Friday, March 12, 2004 11:36 AM
To: Petricoin, Emanuel F (FDA); John Stults
Cc: Jonathan Heller; Svetlana Shtrom; Deborah J. Neff
Subject: RE: Biospect
Attach: Diabetes for Biospect.doc; Medical Cost of Diabetes.pdf; CRO for diabetes.pdf; Proteomics.diabetes.rfa.pdf

TAB 49

Dear John
 Enclosed please find the materials we compiled to answer your questions about Diabetes testing.
 Best Regards
 Lance and Chip
 <<Diabetes for Biospect.doc>>

<<Medical Cost of Diabetes.pdf>> <<CRO for diabetes.pdf>>
 <<Proteomics.diabetes.rfa.pdf>>

> -----
 > From: John Stults
 > Sent: Tuesday, March 9, 2004 2:54 PM
 > To: Petricoin, Emanuel F (FDA); Liotta, Lance (NIH/NCI)
 > Cc: Jonathan Heller; Svetlana Shtrom; Deborah J. Neff
 > Subject: RE: Biospect
 >
 > Good, we will plan on this Friday at 2PM EST. We would like to talk about
 > the diabetes project that I emailed to you last week.
 >
 > With regards to the reference, in my notes from the 2/20 call with Lance,
 > he indicated that you have tentatively identified four of the components
 > in the ovarian cancer pattern, and presented those results at a meeting
 > recently. If this is the case, we would like a copy of the presentation.
 >
 > John
 >
 > -----Original Message-----
 > From: Petricoin, Emanuel [<mailto:petricoin@cber.fda.gov>]
 > Sent: Tuesday, March 09, 2004 10:45 AM
 > To: John Stults; 'liottal@mail.nih.gov'
 > Cc: Jonathan Heller; Svetlana Shtrom; Deborah J. Neff
 > Subject: Re: Biospect
 >
 >
 > Yep, sounds great. Also, John- I need more info about the reference you
 > made
 > concerning the 4 markers? This was concerning some paper?
 >
 > Chip
 > Emanuel F. Petricoin, Ph.D.
 > Co-Director, NCI-FDA Clinical Proteomics Program
 > Senior Principal Investigator,
 > OCGT/CBER/FDA

> 8800 Rockville Pike
 > Bldg. 29A Room 2D12
 > Bethesda, MD 20892
 > Fax- (301) 480-5005
 > Office- (301) 827-1797
 > Mail code: HFM535
 > -----
 > Sent from my Wireless Blackberry
 >
 > -----Original Message-----
 > From: John Stults <jstults@biospect.com>
 > To: John Stults <jstults@biospect.com>; Petricoin, Emanuel
 > <petricoin@cber.FDA.gov>; liottal@mail.nih.gov <liottal@mail.nih.gov>
 > CC: Jonathan Heller <jheller@biospect.com>; Svetlana Shtrom
 > <sshtrom@biospect.com>; Deborah J. Neff <dneff@biospect.com>
 > Sent: Tue Mar 09 13:27:05 2004
 > Subject: RE: Biospect
 >
 > Dear Chip and Lance,
 > I cannot find a reply from you on a time for a conference call this week.
 > Are you available and planning on a call today at 4PM EST? It is actually
 > better for us if it is Friday at 2PM EST, if that time is available for
 > you.
 > Let me know.
 > John
 >
 > -----Original Message-----
 > From: John Stults
 > Sent: Friday, March 05, 2004 8:33 AM
 > To: 'Petricoin, Emanuel'; 'liottal@mail.nih.gov'
 > Cc: Jonathan Heller; Svetlana Shtrom; Deborah J. Neff
 > Subject: RE: Biospect
 >
 >
 > Ok to reschedule. How is Tues. March 9 at 4PM EST, or Fri. March 12 at 2PM
 > EST?
 > John
 >
 > -----Original Message-----
 > From: Petricoin, Emanuel [mailto:petricoin@cber.FDA.gov]
 > Sent: Thursday, March 04, 2004 2:49 PM
 > To: John Stults; 'liottal@mail.nih.gov'
 > Cc: Jonathan Heller; Svetlana Shtrom; Deborah J. Neff
 > Subject: Re: Biospect
 >
 >
 > John
 >
 > Lance will have problems getting together tomorrow because he is in the
 > midst of his own clia and cap inspection!!! Can we schedule next week?
 >
 > Chip
 > Emanuel F. Petricoin, Ph.D.
 > Co-Director, NCI-FDA Clinical Proteomics Program
 > Senior Principal Investigator,
 > OCGT/CBER/FDA
 > 8800 Rockville Pike
 > Bldg. 29A Room 2D12
 > Bethesda, MD 20892

Predicant 01008

> Fax- (301) 480-5005
 > Office- (301) 827-1797
 > Mail code: HFM535
 > _____
 > Sent from my Wireless Blackberry
 >
 > -----Original Message-----
 > From: John Stults <jstults@biospect.com>
 > To: Petricoin, Emanuel <petricoin@cber.FDA.gov>; liottal@mail.nih.gov
 > <liottal@mail.nih.gov>
 > CC: Jonathan Heller <jheller@biospect.com>; Svetlana Shtrom
 > <sshtrom@biospect.com>; Deborah J. Neff <dneff@biospect.com>; John Stults
 > <jstults@biospect.com>
 > Sent: Wed Mar 03 15:04:46 2004
 > Subject: Biospect
 >
 > Dear Chip and Lance,
 >
 > You have mentioned type II diabetes as a disease area where there is a
 > need
 > for improved diagnostics, and for which there is potentially a large
 > market.
 > We would like to learn more, and we would like you to do some research for
 > us. Questions to guide you in this project:
 >
 > 1. Give us a little background about how type II diabetes is currently
 > detected/diagnosed/monitored. Is this work done by a primary care
 > physician,
 > diabetologist, others?
 > 2. What is the need and how would a test be used? How is this need
 > currently being met, albeit inadequately? Is there more than one unmet
 > need, or could one test be used at more than one point in the
 > detection/diagnosis/monitoring continuum?
 > 3. Who would order the test? primary care physician? diabetologists?
 > others?
 > 4. What would be the treatment choices that the physician would make based
 > on the test result?
 > 5. What is the turn-around time needed for the test? POC? stat? 1-2 days?
 > 6. Based on the value added, other tests replaced, etc., what price might
 > be
 > justified from a health economic standpoint? \$20/test? \$100? \$500?
 > 7. What is the potential size of the market in terms of numbers of
 > tests/year?
 > 8. What size study would be necessary to validate this test?
 > 9. What are possible sources of samples for discovery and validation?
 >
 > We can discuss this project when we speak on Friday. We are also looking
 > forward to your written summary of the Biomarker conference.
 >
 > Best regards,
 >
 > John
 >
 >

From: John Stults <jstults@predicant.com>
Sent: Tuesday, March 23, 2004 2:27 PM
To: Jonathan Heller
Subject: FW: Stuff **TAB 50**
Attach: Literature for BiospectA.doc

fyi

-----Original Message-----
From: Liotta, Lance (NIH/NCI) [mailto:liottal@mail.nih.gov]
Sent: Tuesday, March 23, 2004 10:56 AM
To: John Stults
Cc: Petricoin, Emanuel F (FDA)
Subject: RE: Stuff

Hi John

Attached is a literature survey prepared for Biospect covering the last year 2003-2004 for all relevant proteomics, serum testing and immunoassay papers with links for each. Chip and I are also working on a list of disease categories which are in need of accurate and/or new diagnostic markers. Best regards

Lance

<<Literature for BiospectA.doc>>

> -----

> **From:** John Stults
> **Sent:** Monday, March 22, 2004 4:58 PM
> **To:** Thepetricoins@aol.com; Jonathan Heller; Svetlana Shtroum; Deborah J. Neff; Shawn Becker
> **Cc:** Petricoin, Emanuel F (FDA); Liotta, Lance (NIH/NCI)
> **Subject:** RE: Stuff

>

> Dear Chip,

>

> It turns out that tomorrow is not good for a conference call from our end.

> As far as "next week", do you mean April 1-2? If so, April 2 at 2PM EST

> is good for us. Let me know if that works for your schedule.

>

> Your email did not list the AACR sessions that you thought important. Will

> you resend?

>

> John

>

> -----Original Message-----

> **From:** Thepetricoins@aol.com [mailto:Thepetricoins@aol.com]
> **Sent:** Monday, March 22, 2004 12:51 PM
> **To:** John Stults; Jonathan Heller; Svetlana Shtroum; Deborah J. Neff; Shawn Becker
> **Subject:** Stuff

>

>

Predicant 00848

> Dear John

>

> Sorry I did not get back to you until now. If tomorrow is bad, let us
> know. We can do it next week, on thursday or friday if you wish. I would
> recommend the following sessions at the AACR.

> Please find attached the slide that I think you are referring to, as well
> as a paper that Lance and I dug up in investigating things for you. I
> think it is quite informative.

>

> Chip

>

>

From: Carol Dahl <cdahl@predicant.com>
Sent: Friday, January 31, 2003 1:25 PM
To: Jonathan Heller; John Stults; Dan Miller
Subject: FW: FDA filing strategy review
Attach: FDA_filingreview.ppt **TAB 51**

Might want to bring these to the discussion with Chip and Lance.

-----Original Message-----

From: Lance Liotta (<mailto:vze233d8@verizon.net>)
Sent: Sunday, January 12, 2003 12:41 PM
To: Carol Dahl
Subject: FDA filing strategy review

Dear Carol

Enclosed is a power point presentation that reviews the testing product filing strategy. I will be happy to stop by your Bethesda Office and review the steps and recommendations in detail.

Best regards
Lance

Medical Device Filings A Review

759

CFR Title 21, Volume 8

LAL 1-03

Predicant 00519

BACKGROUND

- Food and Drugs Act 1906 was the first FDA authority
- Food, Drug and Cosmetic act of 1938 extended control to cosmetics and therapeutic devices
- The Medical Device Amendment of 1976 was the first time diagnostic devices required registration
- The Regulations were updated in the Safe Medical Devices Act of 1990
- The Medical Device Amendments of 1992 instituted design control inspection as part of GMP
- June 1, 1998: Design control was fully effective

760

Medical Device Regulatory Levels

- Exempt
- Level 1 - 510(k)
- Level II - 510(k)
- Level III - PMA
- Licensed Biologicals

761

LAL 1-03

Predicant 00521

510(k)

- Demonstration of substantial equivalence to a device marketed prior to 1976 or to a device that FDA has determined to be substantially equivalent
- Equivalence is equal to or better than the performance characteristics of the predicate device.
- *Equivalence to a PMA product if there are “three of a kind” on the market

PMA

- Pre-market approval
- All class III devices are filed using this mechanism
- For new products or new product claims
- No predicate device currently on the market
- “180 days” after filing
- Must have a pre-market inspection for compliance with design control and GMP

Predicant 00523

PMA Steps

- Collect Pre-clinical data (basic initial data) 1,000-2500 samples. Assess sensitivity, specificity and precision.
- Obtain FDA approval for a proposed clinical protocol based on the pre-clinical data. Statistical projections and power calculations for the protocol are based on the preclinical results.
- Method development and characterization FDA data filing
- Clinical data FDA filing
- PMA inspection by FDA for compliance

Licensed Biological

- Limited to products that are for Blood Bank use
- Regulated by CBER, not by CDRH
- Treated as a “drug” because their are qualification screenings for injectables
- Eg: HIV, HBsAg etc.
- >3 year filing time

Controls for Medical Devices

- Class I - General Controls:
 - Registration and listing regulations 21CFR Part 807
 - Labeling regulations in 21 CFR Parts 801, 809 and/or 812
 - Reporting regulations in 21 CFR 803 and 804
 - Premarket notification (510(k)) in 21 CFR part 807
 - Quality Systems Regulation 21 CFR 820

Controls for Medical Devices

- Class II - General Controls and Special Controls:
 - All of previous controls
 - Special controls may be required such as special labeling, mandatory performance standards, patient registries and postmarket surveillance

Controls for Medical Devices

•Class III - General Controls and Premarket Approval:

- All Class I/II previous controls
- All requirements found in 21 CFR part 814
- 180 day approval period for FDA “approvable letter” status
- cGMP inspection performed for all original PMAs, and supplements requesting an alternate or additional manufacturing site.

Biospect Product

- Plasma/Serum diagnostic “device” consisting of a specimen processing method, a microfluidic chip, a specialized mass spec instrument, controlling software, robotic processor and controlling software, analysis software, classification software

What is required

- Calibration methodology
- Specimen handling per NCCLS guidelines
- Controls per CAP/CLIA regulations
- Specifications for all components
- Clinical data for filing
- Compliance demonstrated with all of 21CFR820 (Quality Systems)

Filing Strategy:

Three parts:

1. Generate “pre-clinical” data which will validate the method. This will permit the Company to run a clinical reference laboratory until FDA approval
2. File a 510(k) for a diagnostic as a liver function test, cardiac test, or a cancer recurrence marker. Use a limited claim of disease monitoring
3. File a PMA for a general screening claim

Quality System (21 CFR 820)

- Current Good Manufacturing Practices (cGMP)
- Incorporates all of the previous GMP requirements and adds design control

771

Predicant 00531

LAL 1-03

Quality System (21 CFR 820)

Subpart A

- Scope, definitions and “quality system”
- “Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical devices(s) designed or manufactured and that meets the requirements of this part.”

Quality System (21 CFR 820)

Subpart B - Requirements

•820.20 Management responsibility:

- Policy
- Organization
- Responsibility and authority
- Resources
- Representation and review
- Quality planning and system porcedures

Quality System (21 CFR 820)

Subpart B - Requirements

- 820.22 Quality audit:
 - Procedures for quality audits must be in place
 - Evidence of audits (reports)
 - Corrective actions including deficiency re-audits

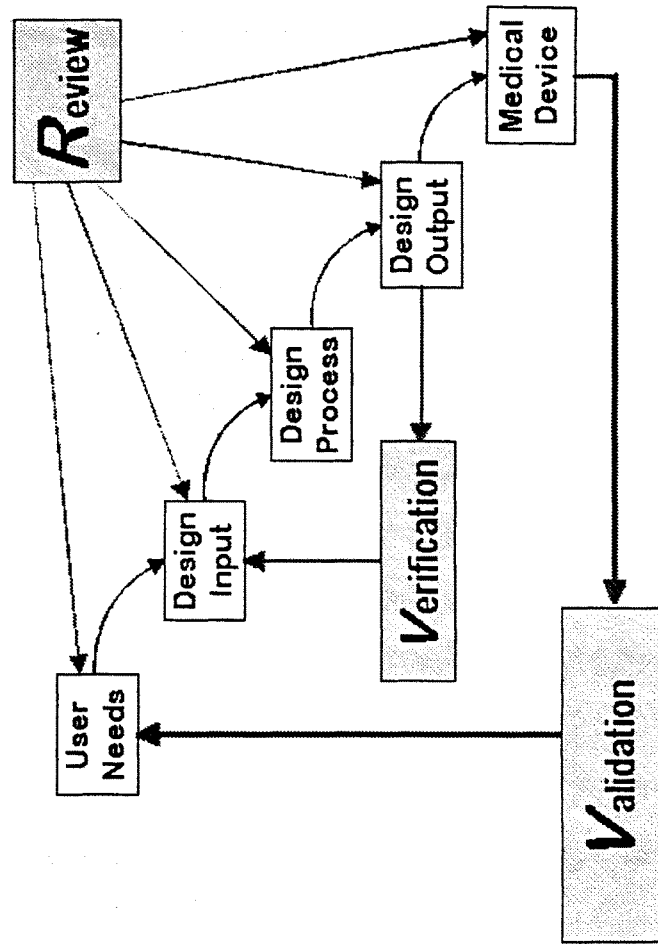
Quality System (21 CFR 820)

Subpart B - Requirements

•820.25 Personnel:

- Sufficient personnel with necessary education, background, training and experience. For CAP/CLIA certification the Laboratory Director must be a licensed Board Certified Pathologist.
- Procedures for and documentation of training
- Personnel who perform verification and validation activities must be aware of defects and result of defects

Waterfall Design Process



Predicant 00536

LAL 1-03

Quality System (21 CFR 820)

Subpart C - Design Control

•820.30 Design controls

- Design planning
- Design input must be documented
- Design review according to an established consistent procedure
- Design verification compares input to output
- Design validation confirms that design specifications are met

Quality System (21 CFR 820)

Subpart C - Design Control

•820.30 Design controls

- Design transfer ensures design is translated into the final specification
- Design changes must be done according to an established procedure
- Design History File must be established for each new product

Quality System (21 CFR 820)

Subpart C - Design Control

•820.30 Design controls

- Design planning
- Design input must be documented
- Design review according to an established procedure
- Design verification compares input to output
- Design validation confirms specifications are met

Quality System (21 CFR 820)

Subpart D - Document Controls

•820.40

- Document approval and distribution
- Document change control through a controlled procedure
- Often done today using standardized commercial software

Quality System (21 CFR 820)

Subpart E - Purchasing Controls

•820.50

- Establish requirements for all suppliers
- Evaluate and select potential suppliers based on their ability to meet quality requirements
- Establish and maintain a list of suppliers, contractors and consultants
- Purchasing data - includes contracts which outline change notification procedures

Quality System (21 CFR 820)

Subpart F - Identification and Traceability

•820.60 Identification

- Procedures for identifying product during all stages of receipt, production, distribution and installation to prevent mixups

Quality System (21 CFR 820)

Subpart F - Identification and Traceability

•820.65 Traceability

- Product must be traceable by lot number
- Subcomponent traceability

Quality System (21 CFR 820)

Subpart G - Production Controls

•820.70

- Documented instructions (SOP's)
- Production and process changes must be verified
- Environment controls
- Personnel training (must be documented)
- Contamination controls (must be documented and tracked)
- Buildings with suitable design and sufficient space

Predicant 00544

LAL 1-03

Quality System (21 CFR 820)

Subpart G - Production Controls

•820.70

- Equipment must be calibrated and certified
- Maintenance schedule maintained for all equipment
- Inspection per an SOP to ensure maintenance schedules
- Tolerances for instrument adjustment must be posted and readily available
- Any software used in production will be validated for its intended use with documentation of validation

Quality System (21 CFR 820)

Subpart G - Production Controls

•820.72 - Inspection, measuring and test equipment

- All inspection equipment must be suitable for its intended purposes
- Routine calibration, inspection and maintenance will be performed and documented

786

Predicant 00546

LAL 1-03

Quality System (21 CFR 820)

Subpart G - Production Controls

•820.75 - Process validation

- Applicable where verification of a process is not possible
- Process must be validated and approved according to an established procedure
- Changes require re-validation of the entire process

Quality System (21 CFR 820)

Subpart H - Acceptance Activities

- 820.80 - Receiving, in-process and finished device acceptance
 - Acceptance based on inspections, tests or other verification activities
 - Acceptance or rejection of a material (reagents, kits, microfluidic chips) shall be documented
 - In-process and final acceptance according to specifications
 - Product quarantined until release by authorized individual(s)
 - Activities shall be recorded as part of DHR

Quality System (21 CFR 820)

Subpart H - Acceptance Activities

- 820.86 - Acceptance status
- 820.90 non-conforming product
 - Documentation
 - Review and disposition
 - Retesting and re-evaluation possible but the revised product must meet all final specifications
- All steps must be documented in the DHR

Quality System (21 CFR 820)

Subpart J - Corrective and Preventative Action

- 820.100
- SOPs must be in place for CPA
- Investigation into the cause of nonconformities
- Verification and validation of action
- All activities must be documented

Predicant 00550

Quality System (21 CFR 820)

Subpart K - Device Labeling

•820.120

- Label integrity
- Inspection - responsibility for inspection and release before use
- Storage - to prevent mixups
- Operations - control to prevent mixups

Predicant 00551

Quality System (21 CFR 820)

Subpart K - Device Labeling

•820.130

- Packaging in order to protect the disposables from alteration or damage

Quality System (21 CFR 820)

Subpart L - Handling, storage, distribution and installation

•820.140

- Handling to prevent mixups, damage, deterioration etc.

•820.150

- Control of storage areas of final product
- SOP's to authorize receipt and dispatch from and to storage areas

Predicant 00553

LAL 1-03

Quality System (21 CFR 820)

Subpart L - Handling, storage, distribution and installation

•820.160

- SOP's for control and distribution of finished devices, and disposables to ensure only approved and released devices are shipped

•820.170

- “Installation” of a device to be done under SOP's
- Testing post-installation to ensure device is operating to specification

Quality System (21 CFR 820)

Subpart M - Records

•820.180

- All records are to be stored and accessible to FDA inspectors
- Records are to be legible
- Confidential records are to be labeled as such
- Retention period in for the product life or 2 years minimum

Quality System (21 CFR 820)

Subpart M - Records

- 820.181
 - Device Master Record (DMR)
 - Device specifications
 - Production methods, procedures and environment specifications
 - QA procedures and specifications
 - Packaging and labeling specifications
 - Installation, maintenance and servicing procedures and methods

Predicant 00556

Quality System (21 CFR 820)

Subpart M - Records

•820.184

•Device History Records (DHR)

- Date of manufacture
- Quantity manufactured
- Quantity released for distribution
- Acceptance records indicating adherence to the DMR
- Primary identification label and label for each production unit
- Device identification and control number(s)_{LC 1-03}

797

Quality System (21 CFR 820)

Subpart M - Records

820.186

- Quality System Record
- QSR shall include:
 - Location of procedures and all documentation of activities

Quality System (21 CFR 820)

Subpart M - Records

•820.198

- Complaint files
 - Documentation of all complaints
 - All processed in a uniform and timely manner
 - Reporting to FDA where applicable (803 and 804)
 - Investigations where necessary
 - CPR where applicable

Predicant 00559

Quality System (21 CFR 820)

Subpart N - Servicing

•820.200

•Where applicable:

- Analysis of service reports with appropriate statistical methodology
- Events reported as required (803, 804)

800

Predicant 00560

LAL 1-03

Quality System (21 CFR 820)

Subpart O - Statistical Techniques

- 820.250
 - Establish procedures for identifying valid statistical techniques required for controlling and verifying the acceptability of process capability and product characteristics
 - Sampling plans must be in place

801

Predicant 00561

LAL 1-03

Implications

- The Company or its Affiliate must have all design controls, Laboratory qualifications, and CAP/CLIA certifications in place at the time of PMA filing
- All design control must be implemented as soon as the Company demonstrates the feasibility of the testing system
- All improvements, refinements and revisions should be reflected in the evolving series of SOP's prepared as a necessary part of the design phase.



United States
Office of Government Ethics
 1201 New York Avenue, NW., Suite 500
 Washington, DC 20005-3917

TAB 52

May 27, 2004
 DO-04-011

MEMORANDUM

TO: Designated Agency Ethics Officials

FROM: Marilyn L. Glynn
 Acting Director

SUBJECT: Awards and Outside Consulting Activities

Attached is a statement that I delivered on May 18, 2004, before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce. The statement contains a discussion of the Office of Government Ethics (OGE) awards rule, 5 C.F.R. § 2635.204(d), as well as a discussion of various rules governing outside consulting activities. I am providing you with a copy of this statement because it sets out guidance on the subjects of awards and consulting that may be useful to ethics officials generally.

With respect to awards, the attached statement provides specific guidance on two issues. First, the statement addresses what constitutes an impermissible source for an award for meritorious public service or achievement. The specific question addressed is whether and under what circumstances the head of an agency or large agency component may accept an award from a source doing any business anywhere in that agency or office. In this connection, the statement does not provide a bright line test, but rather provides a list of factors for agency officials to consider in determining whether it is reasonable to assume that the office head may become involved in matters substantially affecting the interests of the particular source. Second, the statement addresses the subject of "lecture awards" and the distinction between a true award and a speaker's fee. As noted in the statement, this is an important distinction because the acceptance of bona fide awards is subject to different standards than the receipt of compensation or earned income for speaking activities. The statement sets out several criteria to assist agency officials in determining whether the primary purpose of the payment is to

Designated Agency Ethics Officials
Page 2

honor the employee for meritorious public service or achievement, or to compensate the employee for services as a speaker.

With respect to outside activities, the statement discusses the criteria that agencies should use in determining whether a proposed consulting arrangement is consistent with ethical requirements. In addition to the requirements in 5 C.F.R. § 2635.802(a), sections 2635.801(c) and 2635.802(b) require agencies to determine whether a proposed outside activity is consistent with other provisions in the Standards of Ethical Conduct for Employees of the Executive Branch (Standards), including the prohibition in 5 C.F.R. § 2635.702 against using public office for private gain. The statement sets out certain considerations that ethics officials should take into account when assessing outside consulting arrangements for potential appearances of using public office for private gain. We note that there is no specific rule on consulting in the Standards, although example 2 following section 2635.802 provides some guidance on consulting activities that involve the use of public office for private gain. See also 57 Federal Register 35006, 35040 (August 7, 1992) (many of same considerations applicable to teaching, speaking and writing apply to consulting activities). However, OGE is looking at the Governmentwide rules on outside activities to determine whether any changes are needed.

Finally, in light of certain reports in the media concerning other statements made at the recent House hearing, we want to take this opportunity to address the question of an ethics official's duty to handle so-called "appearance" questions. Accounts of certain statements made at the hearing have suggested that there is a distinction between "law" and Government "ethics," or between the provision of strictly legal advice and the provision of advice about appearances. What OGE fears may become lost in this discussion is the fundamental fact that Federal ethics regulations actually make appearance considerations part of the "law" and, therefore, the responsibility of every Federal employee and agency ethics official. See 5 C.F.R. § 2635.101(b)(14).

Attachment

805

OFFICE OF GOV'T ETHICS Fax:202-208-8039

Jun 17 2004 15:43 P.01



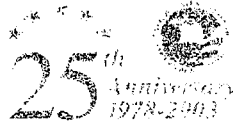
TAB 53

UNITED STATES
OFFICE OF GOVERNMENT ETHICS
1201 New York Avenue, NW, Suite 500
Washington, DC 20005-3917
202-482-9292
FAX 202-482-9240

**FACSIMILE TRANSMISSION
COVER SHEET**

DATE: June 17, 2004
TO: Congressman James Greenwood ATTN: JAG
PHONE NUMBER: _____
FAX NO: 225-9511
FROM: Jane Ley
COMMENTS: Attached please find a copy of
the responses prepared by the Acting Director,
Office of Government Ethics to questions posed
by Congressman Dingell in a letter to this
office on June 3, 2004.
NUMBER OF PAGES
(INCLUDING COVER SHEET): 15

IF YOU DID NOT RECEIVE THE TOTAL NUMBER OF PAGES, OR HAVE ANY
QUESTIONS, PLEASE CALL 202-482-9207.



Director

June 17, 2004

The Honorable John D. Dingell
 Ranking Member
 Committee on Energy and Commerce
 Washington, DC 20515-6115

Dear Mr. Dingell:

Enclosed are responses to the questions addressed to me in your letter dated June 3, 2004. Please let me know if I can be of further assistance.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Marilyn L. Glynn'.

Marilyn L. Glynn
 Acting Director

Enclosure

cc: The Honorable Joe Barton
 Chairman
 Committee on Energy and Commerce

The Honorable James C. Greenwood
 Chairman
 Subcommittee on Oversight
 and Investigations

The Honorable Peter Deutsch
 Ranking Member
 Subcommittee on Oversight
 and Investigations

1. After reading Mr. Swindell's testimony, one would be left to believe that the Department of Health and Human Services (HHS) has no authority or role in determining appropriate ethics practices or regulations for the National Institutes of Health (NIH). I was wondering if you agreed with his representation about the role that the Office of General Ethics (OGE) plays, and if you agreed with his representation about the lack of role that he asserts the Office of the General Counsel (OGC) plays?

Under the Ethics in Government Act, the Office of Government Ethics "exercises overall direction of executive branch policies related to preventing conflicts of interest on the part of officers and employees of any executive branch agency," and this certainly includes responsibility for developing rules of branch-wide applicability that would govern employees of HHS. However, Executive Order 12674 states that it is the responsibility of each agency head to "supplement, as necessary and appropriate, the comprehensive executive branch-wide regulations of the Office of Government Ethics, with regulations of special applicability to the particular functions and activities of that agency," subject to OGE approval. Furthermore, OGE regulations require each agency head to appoint a Designated Agency Ethics Official (DAEO) to coordinate and manage the agency ethics program, which includes periodic evaluations of the agency's regulations "to determine their adequacy and effectiveness in relation to current agency responsibilities." 5 C.F.R. § 2638.203.

2. Mr. Swindell squarely rests all blame regarding financial disclosure matters on the OGE's shoulders, noting that the "OGE has historically viewed the [financial disclosure] form as serving a conflicts of interest purpose rather than a disclosure purpose." He goes on to state that, "OGE did not historically believe that amounts of compensation were normally relevant to conflict analyses." Is it accurate to state that HHS has no role in making determinations about the significance or purpose of forms used in its agency and that this is the OGE's sole responsibility?

The information required from employees as part of an agency's prior approval process for outside activities commonly is addressed in the agency's supplemental standards of ethical conduct regulation, which is promulgated by the agency with OGE's approval. OGE has approved agency supplemental regulations that require information about the expected amount of compensation. See 5 C.F.R. § 6601.102(a)(2)(vi) (National Endowment for the Humanities); 5 C.F.R. § 6901.103(f)(1)(vi) (National Aeronautics and Space Administration).

3. Mr. Swindell notes that, "the OGE did not believe that the authorities in the Ethics in Government Act could support the collection of compensation amounts for completed and closed outside activities." Is it the sole responsibility of OGE to determine whether or not compensation amounts for completed and closed outside activities should be collected, and is it true that HHS had no role in making these sorts of judgments and no accountability for what decisions ultimately come out of OGE?

When Mr. Swindell first discussed this issue with OGE, it was in the context of the prior approval process at HHS/NIH; asking for compensation amounts about completed and closed activities could not be covered by that process. Subsequently, as noted in Mr. Swindell's testimony, his office and OGE concluded that there would be legitimate ethics program reasons for collecting compensation amounts about completed and closed activities. Deciding what information to collect in order to make a determination regarding the application of the Standards of Conduct would not be the sole responsibility of OGE; rather, as was the case here, the agency collecting the information would have a significant role in making that decision.

4. When discussing the issue of bona fide awards and barring agencies from receiving awards from entities that have matters pending under that individual's official responsibilities, Mr. Swindell notes that these decisions are, "ultimately a matter for OGE deliberation, that OGE has not formally opined on it, and that OGE may well choose a different approach than that of the Department," and that HHS is, "required to implement the OGE interpretation." So does this mean that HHS has no role in determining whether or not NIH employees should be allowed to accept bona fide awards from certain agencies, and that HHS's sole responsibility is to enforce whatever decisions OGE reaches?

The bona fide awards exception, found in 5 C.F.R. § 2635.204(d), is an OGE rule, and OGE expects agency ethics officials to follow the rule and any OGE interpretations of it. As with most rules, situations may arise in which an agency has questions as to the scope and applicability of the awards rule, and there will not always be an OGE opinion on point. In such cases, agencies have to decide how to interpret and apply the rule. Agencies certainly are welcome to consult with OGE on such occasions, either formally or informally, and OGE provides a desk officer for each agency to facilitate this consultative process. However, given the size of the executive branch and the number of

questions that agency ethics officials must handle, we recognize that agencies will not consult with OGE about every question that arises under the ethics rules and will exercise their own judgment in many cases.

5. Would OGE support a request from HHS to ban NIH employees from receiving outside activity income from drug and biotech firms?

OGE shares the concerns that have been raised concerning outside consulting activities of NIH employees. OGE believes that HHS would be justified in proposing new supplemental regulations addressing such concerns. OGE certainly could support restrictions on the receipt of outside compensation from drug and biotech firms, although we believe the agency would have to work out various details. Important questions for HHS would include, among others: What levels and types of employee positions would be subject to the restrictions? How would the rule define the prohibited sources, for example, how would the rule treat medical device manufacturers, or universities who have licensing agreements with industry? Should there be any exceptions for outside work to commercialize patents obtained by employees under the Federal Technology Transfer Act of 1986 and Executive Order 10096 (see Office of Legal Counsel, DOJ, "Application of 18 U.S.C. § 209 to Employee-Inventors Who Receive Outside Royalty Payments," September 7, 2000, <http://www.usdoj.gov/olc/209revised3.htm>)? How should the restrictions handle self-employed business activities with respect to biomedical products (compare with FDA restriction, 5 C.F.R. § 5501.106(c)(3))?

6. In your testimony you stated that, "Some outside consulting relationships may involve a subject matter that is so closely related to an employee's official work that the overlap would give rise to an appearance that the employee took advantage of his official position to obtain the outside consulting opportunity or that the employee is providing insights obtained on the job only to those willing to pay."

The attached Slide 10 demonstrates how Kenneth Korach, Chief at the Laboratory of Reproductive and Developmental Toxicology, at NIH's National Institute of Environmental Health Sciences, received \$78,180 to consult on biochemical and pharmacological actions of estrogens for Schering AG, another biotechnology firm. Doesn't consulting on the actions of estrogens seem to involve a subject matter very closely linked to his official duties at the Laboratory of Reproductive and Developmental Toxicology?

OGE is not in a position to comment on the specific circumstances pertaining to a particular individual. Moreover, OGE does not have sufficient familiarity with either the scientific issues involved in the outside activity or the duties of the employee position described in the inquiry to draw any conclusions with respect to the scenario. Nevertheless, we can discuss the general approach OGE takes with respect to such issues.

The reference to subject matter "overlap" in my written statement is illustrated by example 2 following 5 C.F.R. § 2635.802. This example concludes that an employee of the Occupational Safety and Health Administration (OSHA) would be prohibited from taking a paid consulting position with a firm to advise it with respect to compliance with OSHA safety standards on which he worked in the past and is expected to work again sometime in the future. In this example, the activity creates the appearance of using public office for private gain because the subject matter of the consultancy is the very agency standards in which the particular employee had been involved and is expected to be involved again in his official job.

We also have advised that agencies can find guidance in 5 C.F.R. § 2635.807--OGE's rule on teaching, speaking and writing--with respect to the kind of subject matter overlap that is likely to raise questions about the appearance of using public office for private gain in the context of outside consulting activities. See 57 Federal Register 35006, 35040 (August 7, 1992). Among other things, this rule states that an activity relates to an employee's official duties if it deals in significant part with matters to which an employee has been assigned during the previous one-year period or any current policy, program or operation of the employee's agency. This rule contains a textual note emphasizing that employees (other than certain high level political appointees) still may receive compensation for activities dealing with a subject within the employee's discipline or inherent area of expertise based on his educational background or experience even though the activity deals "generally" with a subject matter within the agency's area of responsibility. Of particular interest, given the focus of the Subcommittee, is example 2 following 5 C.F.R. § 2635.807(a)(2), which specifically deals with a situation involving an NIH scientist; the example states that the scientist could not be compensated for writing a book that focuses specifically on her own NIH cancer research, but that she could receive compensation for a textbook on cancer treatment, provided that the focus is not on recent NIH research and there are only brief references to publicly available NIH research among references to other recent cancer research. Additionally, in light of some of the issues that have been of concern to the

Subcommittee, we note that section 2635.807 restricts compensation for teaching, speaking or writing in other situations including when the payment is offered by a person with interests that could be substantially affected by the employee's duties or when the activity draws substantially on ideas or data that are nonpublic information.

7. In your testimony, you cite an important NIH standard which states that, "employees may not use their public office for their own private gain."

Does it surprise you to learn that in attempting to recruit potential scientists for NTH, some NIH officials and employees have sought to woo new employees by advertising outside consulting possibilities as a way for NIH employees to supplement their government salaries? Would you consider this a case of employees using their public office, and public titles, for their own private gain?

Although the inquiry refers to the prohibition on use of public office for private gain as an "NIH standard," it is important to remember that the principle is one of executive branch-wide applicability, pursuant to Executive Order 12674 and 5 C.F.R. § 2635.702. The inquiry refers to certain "advertising" activities conducted by NIH to recruit prospective employees. The Standards of Conduct are rules governing the conduct of individual employees, not rules intended to apply to official agency activities, including official agency decisions concerning recruitment methods. Having said this, we would have concerns if the advertisements suggested to prospective employees that they could use their official titles in a way that suggests agency endorsement of their outside activities or if the advertisements otherwise indicated that employees could engage in outside activities that would be impermissible under the standards discussed in my response to question #6 above. If such were the case, we would advise that the agency should correct any advertisements that reasonably could mislead prospective employees to believe that activities in violation of the ethics rules would be permissible.

8. Have any of OGE's audit activities, complete or non-complete, suggested that HHS has any kind of standard for reviewing the indirect effects of consulting relationships on NIH employees and their personal interests? For example, what about the potential that NIH employees, engaging in such consulting relationships, might be able to unfairly benefit companies who pay them, or damage the interests of competitors who don't?

We are not aware of any specific standards used by NIH particularly for the purpose of reviewing "indirect effects" of outside consulting activities, such as the impact on "competitors." This does not mean that NIH does not have such standards or that NIH does not use more general standards for assessing the potential for such effects, but only that OGE's program reviews have not focused on the specific issue of indirect effects on competitors. We do note that, in our most recent program review at NIH, we obtained a copy of a document titled, "Supplement to Form HHS-520," which apparently is to be completed both by the employee and the employee's prospective outside employer. Among other things, the form provides that the employee will not disclose nonpublic NIH information to the outside employer and that any NIH information disclosed will be provided on a "non-exclusive basis."

Given the Subcommittee's interest in this subject, we understand that some guidance on the subject of financial interests in "competing products" has been developed by the Food and Drug Administration for purposes of administering its ethics program for special Government employees. FDA, Waiver Criteria Document § I.B., <http://www.fda.gov/oc/advisory/conflictinterest/waiver.html>

9. Is there a model anywhere in the Federal Government for effective oversight of an employee's behavior in his or her private consulting work, after the outside activity has been approved? Would it be an appropriate use of government resources to require regular reports from the employee and his private sector employer as to the specific services/advice provided?

Some agency supplemental regulations specifically require employees to provide additional information or submit a new request for approval if there has been a significant change in either the employee's official duties or the outside activity. *E.g.*, 5 C.F.R. § 4501.103(b)(3) (Office of Personnel Management). In addition, some agencies have imposed a time limit on approvals for outside activities. *See* 5 C.F.R. § 6401.103(d) (Environmental Protection Agency-five years); 5 C.F.R. § 6901.103(g)(4) (NASA-three years).

OGE certainly believes that Government resources could be used to collect periodic reports from Federal employees concerning ongoing outside activities that are subject to agency approval requirements. Agencies, of course, have to make their own resource allocation determinations in administering their ethics programs, even as they do with any other agency program, and presumably an agency would weigh the benefits of such a requirement against the costs of administering the requirement. With respect to the question of whether agency resources could be used to require periodic reports from outside employers is a separate question that implicates authorities outside of OGE's jurisdiction, such as the Paperwork Reduction Act.

10. In your testimony you stated that the OGE standards permit agencies to promulgate blanket prohibitions on certain outside activities and that HHS has, in fact, promulgated certain supplemental prohibitions on outside activities.

Would the OGE have any objection if NIH were to ban the acceptance of outside activities involving pharmaceutical or biotechnology firms?

See my response to question #5 above. We note also that this inquiry, unlike question #5, is not specifically limited to compensated outside activities. Although some uncompensated outside activities may pose the potential for appearances of using public office for private gain, the element of compensation often enhances the risk. Thus, for example, OGE's rule on outside teaching, speaking and writing does not prohibit uncompensated activities, even if the subject matter is related to the employee's official duties. 5 C.F.R. § 2635.807(a). On the other hand, the HHS supplemental regulation governing FDA employees does cover uncompensated employment with significantly regulated organizations. 5 C.F.R. § 5501.106(c)(3)(ii). HHS would have to assess whether the same considerations would apply to NIH, which is primarily a research agency, as apply to FDA, which is a regulatory agency.

11. You note that a 1995 OGE review of the NIH ethics program discovered that NIH had a series of restrictions on outside consulting that were not promulgated in accordance with the procedures prescribed in the Executive Order and that the OGE directed that NIH either remove these restrictions or propose them for inclusion in the HHS supplemental regulation. You then said that, "At that time, NIH chose to remove the restrictions and did not propose any additional outside activity restrictions in the HHS supplemental regulation."

What were the special circumstances that led to the OGE order, and who at HHS made the decision not to submit restrictions on outside activities?

OGE's 1995 program review of NIH determined that NIH had a Policy Manual containing several substantive restrictions on the outside activities of certain employees. These restrictions were in addition to the uniform Standards of Conduct that OGE was directed to promulgate under Executive Order 12674. Pursuant to that Executive Order, as well as 5 C.F.R. § 2635.105, any agency ethical standards in addition to the uniform OGE standards are required to be promulgated, with OGE approval, as supplemental regulations, in keeping with the purpose of the Executive Order to promote consistency and uniformity in the application of ethical standards. OGE's 1995 report to HHS concluded that the NIH Manual should be revised to comply with the executive branch-wide OGE rules and that "[a]ny provisions that are broader than the executive branch standards may be included in HHS' proposed supplemental regulations for concurrence by OGE, if NIH wishes to maintain the restrictions." OGE has no independent knowledge of which official or officials at HHS made the decision not to submit the NIH restrictions on outside activities as proposed supplemental regulation provisions, and we would have to direct you to HHS for that information.

12. **It is our understanding that virtually all public disclosure requirements were removed in 1995 (94% of NIH employees became exempt), and that the agency even stopped collecting information on the consulting agreements for their internal private records. To what extent were those decisions mandated by OGE?**

We have no knowledge of circumstances in 1995 surrounding any removal of public financial disclosure requirements or any decision not to collect information about outside consulting activities. Certainly, nothing in OGE's 1995 program review at NIH pertained to the removal of public financial disclosure requirements. In 1998, however, OGE did issue an advisory letter to HHS concerning the public financial disclosure obligations of members of the Senior Biomedical Research Service (SBRS). In that letter, we concluded that their "rate of basic pay," as that phrase is used in the Ethics in Government Act, fell below the threshold for public filing status. We noted at that time that HHS could seek "equal classification" determinations for specific positions, pursuant to OGE's statutory authority under section 101(f)(3) of the Act, which would require the incumbents to file public financial disclosure statements. With respect to certain NIH positions, HHS submitted one such request in January of this year, which was granted in

February, and OGE currently is working with HHS on another request that was submitted in May. To the extent that the question deals with the collection of information about outside consulting activities as part of the NIH prior approval process, nothing in the 1995 program review report addresses the removal of information required under the agency's prior approval procedures. Likewise, nothing in OGE's 1998 SBRS opinion pertains to the collection of information as part of the agency's prior approval process for outside activities.

13. It appears that NIH, in conjunction with HHS, has consistently ignored and even fostered real or apparent conflicts of interest relating to NIH employees. Would similar conflicts of interest be condoned or ignored in other governmental agencies?

For instance, does the Department of Energy allow its employees to negotiate outside consulting arrangements with oil and gas companies such as Halliburton or Exxon?

Does the Labor Department allow its statisticians to work for the Chamber of Commerce? How about for the AFL-CIO?

Does the Department of Education encourage its technical employees to consult with, or accept awards and stocks from, school districts or the National Education Association?

OGE cannot speak for ethics officials at the three agencies named in the inquiry. However, our general observation, based on discussions with ethics officials across the executive branch, is that NIH's consulting issues are relatively unique, at least in magnitude if not also in kind. For one thing, we are not sure that employees at most other agencies have the same outside consulting opportunities as NIH scientists: not only are NIH scientists at the forefront of biomedical research, but there is great demand for this kind of expertise in the various research-intensive biomedical industries. Furthermore, as we found in our 1991 review of the NIH ethics program, the culture at NIH in general has always owed much to the academic model, and NIH scientists often assume that standards applicable to the activities of their colleagues in academia are applicable to themselves. See OGE, Review of the Ethics Program of the National Institutes of Health, November 1991, at 5. None of this, of course, excuses inattention to the ethical standards applicable to Government employees. To the contrary, the persistence of ethical concerns pertaining to outside activities at NIH suggests that, in addition to the Government-wide rules on outside activities, specific supplemental restrictions tailored to the unique circumstances of NIH may be needed.

14. If HHS came to you and asked for supplemental standards for ethics governing NIH employees, similar to those governing Food and Drug Administration (FDA) employees in 5 C.F.R. 5501, would your office have any objection to such a request?

See my responses to questions #5 and #10 above. Additionally, it should be noted that the FDA restrictions govern employment with "significantly-regulated organizations," a term that is defined by reference to the regulatory functions of FDA itself. See 5 C.F.R. § 5501.101(c)(2). This focus may not be a perfect fit for NIH. For example, FDA regulates entities, such as manufacturers of food and cosmetic products, that would not seem to pose the same potential for conflict for NIH employees. On the other hand, the FDA restriction does not address the potential for conflicts with universities that receive significant NIH funding. Furthermore, the FDA restriction on engaging in self-employed business activity with respect to FDA-regulated products could be an impediment to the commercialization of intellectual property as to which NIH employees have been permitted to obtain patent rights, pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 10096. See my response to question #5 above, in particular the Memorandum of the Office of Legal Counsel concerning "Employee-Inventors," which discusses the intent of Congress to promote commercialization of employee inventions.

15. As you are aware, 5 C.F.R. 5501 contains supplemental restrictions on FDA employees. Could you explain the additional restrictions on outside activities and financial interest applicable to FDA employees' dealings with firms regulated or likely to be regulated by that agency (e.g., start up biopharmaceutical firms)?

The interpretation and application of the HHS supplemental regulation is primarily the function of HHS, so questions concerning the scope of the regulation are best directed to HHS in the first instance. This is especially the case with respect to the FDA provisions in the regulation, because those provisions were largely modeled on FDA regulations that had been the subject of agency administration and interpretation since 1972. Generally, however, the regulation, with certain exceptions, restricts FDA employees from having financial interests in, or engaging in employment (including self-employment) with, organizations that are significantly regulated by FDA. OGE has no specific experience in applying the regulation to "start-up biopharmaceutical firms," but we note that the preamble to the rule states:

First, § 5501.104, like the prior FDA rule, distinguishes between interests in organizations that are significantly regulated by FDA, and interests in organizations that are only incidentally regulated by FDA. Only interests in "significantly regulated organizations" are restricted. "Significantly regulated organization" is defined, at § 5501.101(c)(2), to include any organization that derives ten percent or more of its annual gross sales from the sale of FDA-regulated products. The new rule adds a necessary modification to FDA's prior definition: companies that have no record of sales, but which are operating solely within a field regulated by FDA, also will be deemed to be "significantly regulated." This modification is necessary to cover companies that are subject to significant regulation by FDA but which do not yet have any products on the market. The rule would cover, for example, start-up biotechnology companies that may exist for several years before obtaining FDA approval to market any product.

61 Federal Register 39756, 39758 (July 30, 1996).

16. If an FDA ethics official approved an activity, such as a paid speech that included travel expenses, to address a drug or biotech or medical device firm's "scientific conference" as an "outside activity," would that official be approving a violative activity?

Would any consulting arrangement between a regulated firm and an FDA employee for professional services be violative on its face?

What is the legal liability, including criminal liability, for FDA employees who violate these restrictions?

What is the legal liability, including criminal liability, of firms that pay the funds?

What sanctions might apply to ethics officials that approve such activities, when it is clear that such payments from that entity are violative?

Questions concerning a specific interpretation of the FDA provisions in the HHS supplemental regulation are best addressed to HHS. Furthermore, inasmuch as the question pertains to what an "FDA ethics official" might do, we cannot speak to any internal standards, guidelines or interpretations on which such officials might rely.

As to the specific question about a paid speech to address a regulated company's scientific conference, we would point out that other ethics rules, besides the HHS supplemental regulations, also would have to be considered. For example, OGE's rule on speaking, teaching and writing prohibits the receipt of compensation for activities related to an employee's official duties, which includes activities that deal in significant part with ongoing or announced agency programs, policies or operations, as well as activities for which the employee would be compensated by an organization having interests that may be substantially affected by the employee's duties. 5 C.F.R. § 2635.807(a).

Based on our reading of the FDA provision in the supplemental regulation, we do not think that it could be said absolutely that "any consulting arrangement between a regulated firm and an FDA employee for professional services" would be "violative on its face." For one thing, not all FDA employees are subject to the restrictions of 5 C.F.R. § 5501.106(c)(3), but only those who are "required to file a public or confidential financial disclosure report pursuant to 5 C.F.R. part 2634." Furthermore, not all regulated firms are covered by the restriction, but only those that meet the definition of "significantly-regulated organization" in section 5501.101(c)(2). We also note that the rule itself has certain exceptions. See 5 C.F.R. § 5501.106(c)(3)(A) & (B).

With regard to the question about the legal liability of FDA employees for violations of the supplemental regulation, it is important to remember that these Standards of Conduct are agency rules, not criminal prohibitions. The latter can be imposed only by Congress through legislation. Nevertheless, employees who violate either the OGE ethics rules or any agency supplemental regulations may be subject to "appropriate corrective or disciplinary action." 5 C.F.R. § 2635.106. See, e.g., Suarez v. HUD, 2004 MSPB LEXIS 743 (May 26, 2004) (affirming agency removal of employee for violation of ethics rules, including OGE's rule on "appearances" of conflict). Of course, it is possible for the same conduct to violate both the administrative rules of ethical conduct as well as a criminal statute. For example, an FDA employee who engages in prohibited outside employment with a

significantly regulated organization might also violate the criminal conflict of interest provisions of 18 U.S.C. §§ 203 and 205 if the outside employment involved representing the organization before a Federal agency. In such cases, the employee could be subject to criminal prosecution, apart from any administrative action for violation of the supplemental regulations.

With respect to the liability of firms who pay funds to FDA employees in violation of the ethics regulations, there is no provision in the OGE Standards of Conduct for penalties against private persons. OGE is not aware of whether agencies such as the FDA may have other authorities to take action against private persons, such as debarment or other corrective action. There are certain criminal statutes, including two of the conflict of interest statutes, as well as the federal bribery and illegal gratuity statute, that carry criminal penalties for private persons who make certain payments to Federal employees. See 18 U.S.C. § 201; 18 U.S.C. § 203; 18 U.S.C. § 209. We are also aware that the Department of Justice, in appropriate circumstances, has proceeded against private parties for conspiracy and/or aiding and abetting with respect to the criminal conflict of interest statutes. See, e.g., United States v. Bordelon, 871 F.2d 491, 493 (5th Cir. 1989) (individual convicted of conspiracy and aiding and abetting employee's substantive violations of 18 U.S.C. § 208 and § 209).

As for agency ethics officials who may give incorrect advice or otherwise make incorrect determinations under the ethics rules, we would observe that the performance of any member of the civil service is subject to evaluation by supervisors. In this connection, we note that we intend to include a paragraph in our upcoming program review report to NIH to the effect that the position descriptions of deputy ethics counselors at that agency should be revised to contain a description of their ethics duties and that they should be rated annually on the ethics portion of their work. Where OGE encounters problems with agency ethics officials giving incorrect advice, we usually start by providing correct advice. Often, we also recommend that they attend one or more of the numerous training courses offered by OGE every year in various geographical locations. On the rare occasion when OGE has encountered an ethics official whose program has essentially broken down, OGE has contacted the individual's supervisors, sometimes including the agency head. Generally, it is important for OGE to be supportive of ethics officials as they struggle to complete their work within the limits of their available resources, but OGE can and does recommend that agencies take corrective action where management of the agency ethics program is deficient.