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NIH REFORM ACT OF 2006: PROGRESS, CHALLENGES, AND NEXT STEPS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

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NIH REFORM ACT OF 2006: PROGRESS, CHALLENGES, AND NEXT STEPS

TUESDAY, SEPTEMBER 9, 2008

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

The subcommittee met, pursuant to call, at 10:05 a.m., in room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. (chairman) presiding.

Members present: Representatives Pallone, Eshoo, DeGette, Baldwin, Schakowsky, Matheson, Deal, Myrick, Murphy, Burgess, Blackburn, and Barton (ex officio).

Staff present: Melissa Sidman, Jessica McNiece, Carly Hepola, Lauren Bloomberg, Chad Grant, and Aarti Shah.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. The meeting of the subcommittee is called to order, and today we are having a hearing on NIH reform, "NIH Reform Act of 2006: Progress, Challenges, and Next Steps," and I will recognize myself initially for an opening statement.

First, I guess I would like to welcome back all my colleagues from the 5 week district work period. I have to say, to me it felt like we were here yesterday but I know it was a busy time, hopefully a productive time.

The subcommittee, as I said, is meeting to discuss the progress, the challenges, and the work that still needs to be done to meet the expectations outlined in the NIH Reform Act that was passed in 2006, and I know that our ranking member of the full committee, the gentleman from Texas, Mr. Barton, was very much involved in that legislation and specifically requested that we have the hearing today.

For over a century, the National Institutes of Health has played a fundamental role in the advancement of biomedical, behavioral and population-based research. NIH translates cutting-edge research into practical applications. This work has led to the development of new diagnostic tools which have permitted early detection of numerous diseases and have produced innovative treatments that have saved millions of lives and profoundly improved the lives of many others. Federal investment in NIH research has led to groundbreaking discoveries in the fight against cancer, diabetes, heart disease, and numerous other conditions that impact the lives

of all American families. For the most part there is a mutual understanding of the importance of this research and public education, which up until recent years was reflected in a bipartisan effort to double funding for the NIH. Democrats and Republicans were united in ensuring NIH had the resources it needed to continue its mission. This, however, or unfortunately is no longer the case as the priorities of this Administration have shifted towards broad tax cuts and increased funding for defense and the war in Iraq. There is not enough money to fund domestic priorities including the vital research conducted by the NIH.

The President's fiscal year 2009 budget proposal was no different. He has yet again requested flat funding for the NIH, which if adjusted for inflation, would represent a 14 percent cut in funding, and has threatened to veto any domestic spending bill that exceeds his request. This Administration is willing to spend $12 billion each month on the conflicts in Iraq and Afghanistan but has abandoned the commitment, in my opinion, to the medical research that will help provide lifesaving treatment to our returning veterans and millions of other Americans. While one-third of veterans returning from Iraq and Afghanistan suffer from debilitating mental illness and while the rate of suicide among our national heroes is now double that of the general population, mental health research has remained relatively flat for years. I have to say, during the Democratic Convention, our New Jersey delegation had a visit during one of our breakfasts by Congressman Patrick Kennedy from Rhode Island, and he specifically talked about how the amount of funding for mental illness and suicide prevention has really effectively gone down.

We also have a great need for further research into traumatic brain injury. It is estimated that 10 to 20 percent of Iraq and Afghanistan veterans have experienced traumatic brain injury from exposure to roadside bomb blasts but show no outward signs of the condition, and this coupled with our current limited understanding of the condition and its symptoms is resulting in many of our military personnel suffering with little hope of getting better. We have an obligation, in my opinion, to our war heroes and to all Americans to ensure that this lack of investment in medical research ends. We must increase the funding levels for NIH to improve diagnosis and treatment of these debilitating injuries and diseases.

I think we are in danger of losing ground to other nations that are making medical and biotechnical research more of a priority, and this cannot continue without devastating results. We must recommit to provide the NIH the funding it needs to continue the innovative research that has brought hope to so many Americans.

Now, in the 2006 Act, Congress asked the National Institutes of Health to report on their work and required them to reorganize and use limited funds in a more effective and efficient way. We also required them to release a biannual report detailing this activity and laying out the Institute's progress. The first report was just released a few weeks ago and today we will be hearing from Dr. Zerhouni, director of the NIH, on how the requirements laid out by Congress in 2006 are being implemented. I am eager to hear about the organizational changes and strategic planning activities that

have taken place at NIH since the passage of the Act as well as the cross-institute initiatives that have been implemented.

As we discuss the next steps in our continued effort to improve NIH, it is vital that we all work together to make sure it is strong and effective, not only through organizational change but also through a renewed commitment to providing the funding necessary to continue the great work of the agency, and I hope that we can all work together to further this mission.

I do want to specifically mention, as I already have, the efforts of Mr. Barton and also Mr. Deal. I know that they worked on this quite a bit and Mr. Barton was actually the sponsor of it when we were in the Majority and so I note he cares a great deal and that is really the reason that we are having the hearing today.

I yield now to our ranking member of the subcommittee, Mr. Deal.

OPENING STATEMENT OF HON. NATHAN DEAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. DEAL. Thank you, Mr. Chairman, for holding this very important hearing to examine the NIH Reform Act of 2006 and its implications on biomedical research at the National Institutes of Health, and thank you, Dr. Zerhouni, for being with us today. We look forward to your testimony.

As we all agree, the NIH is a critical component of the puzzle in the healthcare delivery mission of our Nation. They lead research, paving the road for biomedical developments of our future and actively engage in preserving the health of all Americans through research and innovation. I am looking forward to hearing what Dr. Zerhouni will say regarding the NIH Reform Act of 2006 and the improvements at NIH which have subsequently resulted. I believe this legislation laid an appropriate foundation to fund trans-NIH research, revolutionizing the way interdisciplinary science shares information of common interest. The Common Fund authorized by this Act laid the groundwork for transformational healthcare research at the National Institutes of Health. Additionally, the Act called for great transparency so taxpayers know exactly how their hard-earned dollars are being spent. It also required greater accountability on the part of NIH to ensure that these needed dollars are being spent appropriately.

While NIH has modernized its structure and operational objectives, there is still much yet to be accomplished. For example, how does the Institute determine a fair share of research dollars for certain disease-specific issues? Do appropriators account for the outside private revenue-generating capacity which some enjoy while others fall very short. Even last week, celebrities banded with three major television networks to host a nationwide telethon in support of the fight on cancer. Musicians, actors, reporters and businesspeople alike joined forces and managed to raise over $100 million for the American Cancer Society. This is fantastic and represents the power of the American people when we all come together for a common cause.

There are, however, many research-worthy conditions which do not enjoy this type of support, many of which whose budgets are modest yet critically underfunded, are forced to abandon research

due to monetary constraints. How are these specific circumstances mitigated to ensure every disease is given at least some degree of scrutiny through their NIH dollars? Furthermore, research is only beneficial to the public when information is shared among scientists and healthcare professionals. How do we stimulate cross-disciplinary sharing of this critical research data, which is so critical to our fight against disease? As we move forward, I am hopeful we can address these apparent concerns and continue to push NIH toward innovation and development and not back to the ways of our past.

Again, I am encouraged by the developments made since the implementation of the NIH Reform Act of 2006 and foster an appreciation of the cross-cutting innovative research at NIH upon which we, our families, and our constituents depend as a result of the passage of this legislation. By giving the director the tools to implement strategic research planning and to promote cross-institutional research, barriers to medical innovation are being broken, and I thank you, Mr. Chairman, and I thank Dr. Zerhouni for being with us today and we look forward to this hearing.

Thank you. I yield back.

Mr. PALLONE. Thank you, Mr. Deal.

I next recognize for an opening statement the gentlewoman from California, Ms. Eshoo.

Ms. ESHOO. Good morning, Mr. Chairman. It is good to be back. Welcome, Dr. Zerhouni. I am going to submit my statement for the record and reserve the time for questions. Thank you.

[The prepared statement of Ms. Eshoo follows:]

PREPARED STATEMENT OF HON. ANNA G. ESHOO

Thank you Mr. Chairman for holding this hearing on the NIH Reform Act. As the first reauthorization of the NIH in 13 years, it's a significant piece of legislation that will transform the way the NIH operates for years to come.

Our oversight NIH, which I call the "National Institutes of Hope," is, I believe, the crown jewel in the jurisdiction of the Energy and Commerce Committee. The legislation we're discussing today was endorsed by some of the most important stakeholders and experts in healthcare, including Dr. Zerhouni.

Last February, Dr. Zerhouni flew to my Congressional District to participate in a Healthcare Forum at Stanford University, to join Speaker Pelosi, John Chambers, CEO of Cisco, and leading experts to discuss innovations in healthcare. Dr. Zerhouni spoke to our tendencies to manage the short term when it comes to medicine. What we need is a clear vision, to look into the future 15 and 20 years from now. He gave us a wonderful analogy of our efforts to combat polio more than 50 years ago. It could have been our strategy in 1954 to improve the iron lung, to make it very productive, very effective, and very efficient and forget about a vaccine for polio. If that were the case, we'd have terrific iron lungs today and no vaccine for polio.

The NIH serves a crucial mission to the American people. We trust the NIH to acquire new knowledge and conduct basic research that will enable us to prevent, detect, diagnose, and treat diseases from the rarest genetic disorder to the common cold. We make investments in the NIH because it represents hope for the future.

There are many, many important elements to this law. The establishment of the common fund should serve to stimulate trans-NIH research in areas of emerging scientific opportunities. The creation of a new infrastructure at NIH to evaluate and report on the research portfolio will make it easier for the public to gain access to all the work that's being done under NIH grants.

What the bill does not address is the very real issue of funding. While the bill authorizes a 5% increase a year, we have not seen this happen, and after adjusting for inflation, the NIH is actually losing money. After years of significant funding increases for NIH, we've come to a complete halt in growth, with President Bush requesting a $5 million decrease for Fiscal Year 2009.

I look forward to learning more about how the NIH Reform Act has been implemented, what barriers and successes have been discovered, and how we can continue to improve the National Institutes of Health.

Mr. PALLONE. Thank you.

Our ranking member of the full committee, Mr. Barton, is recognized.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Thank you, Mr. Chairman, and I thank the full committee, Chairman Dingell for holding this hearing. You know it is important to me if I am actually here on time, so I am here today and I was here, let the record show, at a little before 10:00. I want to thank Dr. Zerhouni for his attendance. He has done an outstanding job as director of the NIH.

I did request both informally and formally to Chairman Dingell that we hold an oversight hearing on the NIH Reform Act of 2006 and I am very pleased and honored that Chairman Dingell and Chairman Pallone would honor that request.

The law that we are reviewing today represents the first thorough, complete reauthorization of NIH in over 13 years at the time it was done in 2006. Reforming NIH was a top priority of mine as the chairman of this illustrious committee and the writing of this specific legislation proved to be a very long and arduous process. The bill that we are reviewing today or the law that we are reviewing today was literally the last act of the last Congress. It passed at, my recollection, about 3:00 in the morning and Congress adjourned about 3:15. So it took to the very last to get this done. Having said that, I think the last 2 years have shown that passing this Act was the right thing to do. Changes are being made. I think the NIH and the research community that it represents are better today because of the law that we are reviewing today.

In some respects, I think it is safe to say now in hindsight that the old NIH was stuck in the past. This law gave it the flexibility to adopt new research opportunities. It actually gave the director, in this case, Dr. Zerhouni, some real clout. It made him more than a figurehead. It gave him the ability to do oversight within the NIH. It gave the director's office the ability to coordinate research responsibilities that spanned a very many number of institutes and centers that constitute in total the NIH. The division of program coordination, planning and strategic initiatives was established under this Act to give focus to new areas of emerging scientific opportunity, allowing the NIH to coordinate and plan in a cross-NIH way new research initiatives that had not been allowed to do and able to do in the past.

As we all know, much of the research that the NIH does is disease-specific, and that is as it should be, but we know that if we focus only on one disease, sometimes researchers were blinders to advances in other areas that might be of help to them. Under the old NIH system, the director presided over this type of research but had no ability to systematically inform other scientists of other researchers' discoveries in other areas in a different institute. That was a major problem. Everyone who has looked at the new system,

the new coordination role that we have under the new law, agrees that this new system gives enhanced opportunities to make new and necessary medical advances in a more timely fashion.

I am particularly proud of what is called the NIH Roadmap for Medical Research. This is funded through another of the new funds that we now have, a fund that is called the Common Fund. The roadmap is a set of trans-NIH research activities designed to support high-risk, high-impact research in emerging areas of scientific or public health areas. The new law requires transparency so that Congress and the public can know what the NIH is doing, how the dollars are being spent and what the results of those spending decisions are.

There is one thing that I hope we can explore today, Mr. Chairman. As we all know, the very structure of the NIH, these institutes that are somewhat isolated, kind of the silo style approach, lends itself sometimes to pigeonholing new knowledge. If this is not managed correctly, the NIH centers, as good as they are on an individual basis, not only do they not share information, sometimes they actually fight other institutes for high-priority funding. That is understandable if unfortunate. That is why I think it is so important and why I fought so hard in the last Congress to put in this Common Fund approach to get it its own line item and to encourage the Appropriations Committee to actually fund the Common Fund, which they are doing and I am very pleased about that. I feel very strongly that the Congress should not micromanage the NIH by dictating which disease or which disorder gets the highest priority in funding. I want scientists, not politicians, as well intentioned as we can be, and not advocates, as well intentioned as they can be, to figure out who gets the most money for the newest disease on the block that is the highest priority. I am proud to say that so far this Common Fund approach appears to be working.

Having said that, there are some of the stakeholders with the best of intentions that don't understand the new system or perhaps they don't want to understand the new system. In any case, once again in this Congress, this committee has numerous disease-specific bills before it, all clamoring with some justification that they should be the newest highest priority for Congress to fund. The whole purpose of the NIH reform bill in some ways was not to say we should never fund new research or give a higher priority to a different area but that we should let the experts, let the people who are most responsible to actually do the research in collaboration working within this new structure decide where to put the highest priority.

Mr. Chairman, again, I want to thank you for holding this hearing. I look forward to participating to the fullest degree possible and trying to make sure that the Congress and the people of America understand what the NIH is doing.

Mr. PALLONE. Thank you, Mr. Barton.

I next recognize the—well, first I have to thank the gentlewoman from Colorado for such a nice convention that we had, and I had a chance to go look at the Colorado Springs and Golden and Boulder. It was really nice, I have to tell you. I recognize the gentlewoman.

Ms. DEGETTE. Thank you. I hope you spent large amounts of money when you were in Colorado.

Mr. PALLONE. I did, unfortunately.

Ms. DEGETTE. Mr. Chairman, I want to thank you for having this hearing on the NIH Reform Act of 2006, of which I was also a strong supporter. I want to welcome Dr. Zerhouni and his senior staff, who worked so hard. I will waive my opening statement in favor of more time for questioning. Thank you.

Mr. PALLONE. And next is the gentlewoman from Tennessee, Ms. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Ms. BLACKBURN. Thank you, Mr. Chairman. I want to thank you for holding the hearing. I want to say welcome to our guest. We are so glad that you are here. I will put my full statement in the record, but briefly, I was pleased with provisions in the NIH Reform Act that cut bloated administrative costs and ordered to focus more on funding on research activities. In addition, the legislation aimed to improve best practices at NIH, and I am looking forward to learning how the NIH has cut the bureaucracy, has increased the transparency, has streamlined the interagency communication since the NIH Reform Act became law. And I know that communication component was one that had kind of stumbled, so I am looking forward to hearing about that.

NIH must have the autonomy and tools with which to set and develop the Nation's biomedical and behavioral research priorities. Often this committee considers disease-specific legislation which directs research funding and activities instead of allowing NIH to do the job, and I will continue to urge Congress to move away from cherry-picking research dollars since it is the responsibility of the NIH, and I do not believe it is the responsibility of Congress to dictate those research priorities.

I also want to say thank you for giving us the report. Nice way to receive that, and I hope that this is an indication of the transformation that we have seen in your communication and your technology capabilities, and I yield back.

Mr. PALLONE. Thank you.

I would like to ask unanimous consent that the statement of our chairman, Mr. Dingell, be included in the record. Without objection, so moved.

[The prepared statement of Mr. Dingell follows:]

PREPARED STATEMENT OF HON. JOHN D. DINGELL

I commend Subcommittee Chairman Pallone for holding this hearing today. In the 109th Congress, under the Chairmanship of my good friend Joe Barton, this Committee worked in a bipartisan and diligent fashion to move legislation which reauthorized and reorganized the National Institutes of Health (NIH). When Congress passed, and the President subsequently signed into law, the "NIH Reform Act of 2006", it was only the third omnibus reauthorization in NIH's history.

Passage of the "NIH Reform Act of 2006" was a major accomplishment for the Congress and was achieved, thanks in large part to the dedicated work of Representative Barton. It was my sincere pleasure to work with Representative Barton and his staff on that legislation.

As with any major legislation, it is important that the committee of jurisdiction exercise its responsibility to oversee and evaluate the programs and activities created. That is why I am so pleased that the Subcommittee on Health is examining the implementation of the "NIH Reform Act of 2006". And I welcome Dr. Zerhouni, Director of the NIH, who has been an invaluable resource to the Committee. Thank you, Dr. Zerhouni.

The "NIH Reform Act of 2006" enhanced the authority and tools available to the NIH Director's Office to conduct strategic planning and to facilitate and fund trans-disciplinary, cross-Institute research initiatives. In addition, the law created more budgetary, organizational, and programmatic transparency at the NIH and standardized data and information management systems.

Although this law was a significant step in the right direction, the NIH still faces many hurdles. Challenges facing the agency—such as attracting and keeping young scientists, creating opportunities for trans-disciplinary research that cut across Institute boundaries, and managing the portfolio of extramural and intramural research—are only being compounded by insufficient funding.

After years of significant funding increases for NIH in its fight against disease, this Administration has consistently chosen to flat fund or decrease NIH's budget. For instance, the President's FY2009 budget requested a decrease of $5 million below the FY2008 program level. This budget decrease could significantly harm the country's principal medical research agency. This is simply unacceptable.

I look forward to hearing Dr. Zerhouni's testimony about the implementation of the NIH Reform Act and I welcome his views about how to respond to challenges that lie ahead.

Mr. PALLONE. And the next recognized for an opening statement, the gentlewoman from Illinois, Ms. Schakowsky.

OPENING STATEMENT OF HON. JAN SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you so much, Mr. Chairman, and thank you, Dr. Zerhouni. I wanted to give you a personal thank you for being helpful to me and my family when we needed help, and I appreciate the opportunity to discuss the direction and priorities of the NIH, ensuring that the agency continues to expand its life-saving research in the interest of all Americans. I want to applaud your leadership on these issues as well as the other issues designed to advance the cause of biomedical research and improve healthcare quality.

The NIH is our Nation's leading research institution and we look to it to develop cutting-edge cures for debilitating diseases like heart disease, diabetes, cancer, and so many other illnesses that are families are struggling with every day. And yet over the past 5 years the Administration has refused to make NIH funding a priority. From fiscal year 2003 to fiscal year 2008, the NIH budget has steadily declined. Yet President Bush proposed another reduction in NIH dollars in his fiscal year 2009 budget, representing a 14 percent decrease from the fiscal year 2003 levels. We are on the verge of many breakthroughs in treating and preventing serious illnesses and yet it seems we are moving backwards.

When we passed the NIH Reform Act, I and many of my colleagues were on record expressing our concerns with the annual 5 percent increase in NIH funding as provided for in the legislation, saying that it was insufficient to keep pace with the rate of inflation. We tried to include an amendment that would authorize the NIH with a real 5 percent increase that accounted for inflation and rising costs of conducting this invaluable work and were defeated despite having the backing of numerous research and patient advo-

cacy organizations. We never imagined that we would be fighting back gradual cuts to the program and it is time that we corrected the focus of this committee and of the Congress.

NIH budget cuts damage the agency's ability to support dynamic new research projects and recruit talented and creative new investigators. A report authored earlier this year by prominent university presidents and professors highlighted a long list of adverse effects of the flat NIH budget including an 8 percent decrease in the overall success rate for vital NIH research projects. We can't possibly maintain our standing as the world's leader in first-rate innovative medical research with statistics like those.

So Dr. Zerhouni, I commend you for continuing to move forward with our research priorities on a diminishing budget, and it is my sincere hope that the President and this Congress will step up to the plate and provide NIH with adequate resources to continue your work. Thank you so much for being here again. I appreciate it.

Mr. PALLONE. Thank you.

I next recognize the gentleman from Pennsylvania, Mr. Murphy.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Thank you, Chairman Pallone and Ranking Member Deal for this hearing today, and thank you, Dr. Zerhouni, for the testimony we are going to hear today.

The research conducted at the National Institutes of Health is critical to improving healthcare for Americans and funding through medical research. As an adjunct faculty member myself on the University of Pittsburgh School of Medicine and the University of Pittsburgh School of Public Health, I witnessed firsthand many of the collaborative efforts that take place and much of the groundbreaking research.

I also want to make sure we thank Chairman Barton during his tenure as chairman for the work he did in moving this bill forward before and the ongoing work that Mr. Dingell and Mr. Barton have pushed for with NIH reforms. I think they paid off.

But I want to say that there are some areas that I think are so important for the future moving forward. The collaborative efforts or the latitude that you have or the NIH has in investing in research is vital. But one of the things that I want to make sure, at a time when we are concerned about the $2 trillion expense of healthcare in America, that NIH can and I believe should play a leadership role in pushing for major reforms that can come out of collaborative research. That is practical and applied research that is aimed at patient safety and patient quality that reduces cost such as disease management, such as integrating mental health care with other medical care to treat diseases faster, more effectively and less costly. We know, for example, that those with chronic illness and untreated depression have double the medical costs of those without depression or those with treated depression and yet many times, and I know researchers will get caught in a little box and we want to follow that linear thinking but it is important that in your role as the head of NIH that you push for people to

ask the people in the cubicle or the office next door, how does this work and how does this apply. That is where great breakthroughs can come through.

One particular area is that the Centers for Disease Control and Prevention reported that healthcare-acquired infections in clinics and hospitals contribute to between 90,000 and 100,000 deaths in the United States each year, which adds over $50 billion to annual medical costs. So far this year, from January 1, this means 1,210,000 infections, 59,891 deaths and $30,273,000,000 in costs. And every time Congress looks at the costs of healthcare and Medicare and Medicaid and the VA and private insurance, it is vitally important that we think not just in terms of who is paying but what we are paying for and what can we do to improve quality. This is an area that I hope NIH plays a strong an active leadership role in improving healthcare quality in America.

With that, I look forward to hearing your testimony today and I yield back my time.

Mr. PALLONE. Thank you, Mr. Murphy.

The gentlewoman from Wisconsin, Ms. Baldwin, is recognized.

OPENING STATEMENT OF HON. TAMMY BALDWIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WISCONSIN

Ms. BALDWIN. Thank you, Mr. Chairman, and thank you for holding this hearing this morning. Also, I thank you, Dr. Zerhouni, for being here today. I really look forward to your testimony and the discussion that I expect will follow.

As my fellow members of this committee have heard many times before, I represent south central Wisconsin in the Congress and I am honored to have the University of Wisconsin—Madison as one of the Nation's premier research institutions as a part of the district that I represent. Much of the university's success has been fueled by NIH funding, so I am eager to have a review and a discussion of the reauthorization passed last session in Congress.

These are really exciting times for scientific research as we continue to learn more and more about the way that the world works and about how the human body functions. We are coupling these discoveries with advances in technology and the research possibilities are truly exploding. The ability to conquer a variety of different diseases is truly within our reach at this time. I am really continually amazed at the incredible research that is done at the University of Wisconsin and the depth of expertise that they house in so many different areas of research. From the initial discovery of how to grow and sustain stem cells made by Dr. Jamie Thompson in 1998 to more recent discoveries in virus transmission and vaccine development, the UW has been a leader in a number of very exciting research fields. Today the university is also paving the way for more goal-oriented and interdisciplinary research through its new Discovery Center, which will focus on nanotechnology, biotechnology and information technology, and in addition, through the NIH's clinical and translational science awards, we are training the next generation of clinical and translational researchers. This is a type of progress that I am incredibly proud of in my district and I strongly feel that we as members of Congress and as

government officials should do everything that we can to aid and encourage these researchers and not discourage them or tie their hands.

Despite this potential for amazing progress right now, the NIH continues to struggle with a shortfall in funding. Because federal funding has not kept pace with inflation since 2003, the purchasing power of NIH has decreased 13 percent. My colleague, Ms. Schakowsky, just outlined some of the consequences. I wanted to highlight two others. While it affects all aspects of biomedical research, it has a particularly strong effect on one group and that is young researchers. Since 1990, the average age at which a researcher receives his or her first major NIH grant has increased 4 years from 39 years of age to 43 years of age. In addition, the percentage of major NIH research grants that go to first-time investigators has decreased from 29 percent to 25 percent. So I am interested to hear today how the NIH is coping in this very difficult environment.

Dr. Zerhouni, thank you again for coming here. I welcome the opportunity to talk about the NIH and look forward to the questions that will follow your testimony.

Mr. PALLONE. Thank you, Ms. Baldwin.

Next recognized for an opening statement, the gentleman from Texas, Mr. Burgess.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Mr. Chairman. Dr. Zerhouni, welcome back to our humble committee. Every time I hear you talk—and I have stolen this line from you and used it so many times I almost embraced it as my own, but you talk about medicine becoming more personalized, and because it is more personalized, it is going to be more predictive, and because it is more predictive it can be more preventive, and has to be more participatory, and really, those are the guideposts for me whenever we talk about healthcare policy in this Congress. I want to make certain that we do nothing that will deflect you from that path because I believe that to be the correct one.

I was really very proud and pleased to be part of this committee in 2006 when we hammered out the compromise that we now know as the NIH Reform Act. I am grateful to Chairman Barton for putting so much emphasis on that in the 109th Congress. Part of your problem is us, and we come to you and say this has to be a priority and this has to be a priority, and when everything is a priority, nothing is a priority, and the Reform Act was to try to inject some measure of sanity into your world and I am anxious to see whether or not we have done that. I am interested to hear about the gains we have made in the translational research at the National Institutes of Health. I am interested to hear about the research that has been funded and the new demonstration programs that allow you to allocate funds and award grants and contracts and engage in other transactions for high-impact, cutting-edge medical research.

And then finally, this year we lost one of the giants in medical research, Dr. Michael DeBakey, at the age of 99, and shortly before

his passing, I had an opportunity to talk to Dr. DeBakey and he talked about how the world had been transformed by the NIH, and when he was a young man and graduated from medical school, he had to go to Europe to get the credential to be a researcher and now the world is a different place and researchers come to the United States to get the credentials to go into careers in research, and he empathically pointed out to me that Congress did that by its activity in the 1940s and 1950s transforming the NIH, and if it was a priority for the Congress in the 1940s and 1950s, there is no reason that it shouldn't be a priority for the Congress of the 21st century.

So I look forward to hearing your testimony today and I assure you that we will work with you to make certain that we all achieve the goals that you talk about so frequently, and I will yield back.

Mr. PALLONE. Thank you, Mr. Burgess.

The gentleman from Utah is recognized for an opening statement, Mr. Matheson.

OPENING STATEMENT OF HON. JIM MATHESON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF UTAH

Mr. MATHESON. Thank you, Mr. Chairman. I will be very brief.

I want to thank you for the hearing. We all certainly value the efforts of NIH, and Dr. Zerhouni, I appreciate your taking the time to be with us today. Funding is an important issue, you have heard a lot of people on this committee mention that, but it is also important that we know that our programs are being implemented effectively, and that is really the purpose of this hearing to get an update from you on the Reform Act and I think this is wholly appropriate that we are having this discussion today and I look forward to your remarks.

Mr. PALLONE. Thank you. I think that concludes our opening statements by the members so we will now move to our first and only panel and our only witness, Dr. Zerhouni. Let me just take a minute here to first welcome you, and mention that you of course are the director of the National Institutes of Health. This is Dr. Elias A. Zerhouni, who is also a medical doctor. We have a 5-minute opening statement. Since you are the only person though, I am certainly not going to stick to that, and I know you said you would like to talk a little longer so please proceed. You know your statement becomes part of the record, and in the discretion of the committee we may submit additional brief and pertinent statements in writing for inclusion in the record. Thank you for being here and thank you for what you do.

STATEMENT OF ELIAS A. ZERHOUNI, M.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Dr. ZERHOUNI. Thank you, Mr. Chairman. First of all, I would like to thank you and thank Mr. Deal for this committee meeting. I thought it was appropriate that we met with all the members to really report to you on the progress of the Reform Act of 2006, which passed about 18 months ago.

But before I do that, I would like to personally and publicly thank Chairman Barton, who at the time single-handedly led the effort at the beginning and then crossed the aisle and worked in

an extraordinary bipartisan fashion with Chairman Dingell and members in the Senate to make this happen really at the last minute of the last 109th Congress. I want to thank you personally because it has made a huge difference in the outlook for science and the outlook for health in the country.

And today what I would like to do is to show you why it is important to understand what are the mega trends, what are the real trends in science and why is the Reform Act fitting with what is happening on the ground in science. So my testimony, my oral testimony will be focused on that, but I have also submitted a full written testimony for the record, Mr. Chairman.

When you think about where we are in science, I would like to stress and direct your attention to the slides. We provided also hard copies for you. There are four fundamental points. First and foremost, I have never witnessed in my career such a rapid pace of new and extraordinary discoveries which truly are changing the way we see medicine in the future to an era of medicine that will be personalized. And it will affect health and the way we manage health, we pay for health, we pay in the 21st century, and how our costs are going to be affected because of the ushering in of this new era. This new era can only be here because scientific progress over the past 20 years has led us to realize that diseases as we knew them and disciplines of science as we knew them are actually not parallel to what the discoveries are. In fact, we are noticing today an enormous convergence of science. Fields of cancer research have had a huge impact on HIV/AIDS. Fields in cardiac research have had a huge impact on cancer research and one of the most successful treatments for cancer, Gleevec, actually came from research initially in the cardiovascular system. In addition, this convergence tells us that we have to cross boundaries. You cannot be bound by boundaries. You have to be without boundaries going forward in the life sciences.

We also know that it is essential that we match our organizational changes to where the science is rather than fit the science into your organizational structures so that if you look strategically from the standpoint of the NIH director, you really have an obligation to look at how is the agency, as complex as it is, doing its work in the short term. What are the tools to manage the agency in the medium term and what are the tools that you need to manage the agency in the long term. Agencies don't change every year. They change over several years. Where was the mechanism to do that? Programs don't happen in a month. They happen over 2, 3 years. Where was the mechanism to make sure that those were coordinated and were strategic. That's what the NIH Reform Act has done, and my testimony will essentially tell you where is the science, what is the rationale for this convergence of science, which means that our patients today are likely to suffer from more diseases and mechanisms of disease that affect them across institutes and across the missions of different institutes.

The NIH Reform Act of 2006 really, in my view, solved a fundamental problem as well explained by Mr. Barton, which was to address the medium- and long-term issues and how do you adapt an agency as complex as the NIH for its mission. So I would like to just take you back for a second in terms of what has happened in

science over the past 20 years. Fundamentally, all of us scientists have gone from observing disease from the outside to try to go to the real essence of biology, so we have gone from the surface of the cell and then we have gone to the nucleus of the cell and eventually in 1953, the first discovery of the structure of DNA told us that DNA was important. But it took us about the last 20 years to unravel the chromosomes: we have 23 pairs of chromosomes, the very long, 3 billion basis of the DNA of humans. We had completed the human genome in 2003 and we had said that this would be the basis of a true revolution in science. Why is that? Why is that long stretch of DNA bases telling us that this in fact is a key to the mysteries of biology today?

[Slide shown.]

So what I would like to do is, if you will allow me, to give you a little bit of a sense of how we see it. On the left-hand side is DNA. DNA essentially is a code, an instruction book that each part of the DNA may code for a particular gene product which usually is a protein. So in this case, I am showing you five proteins, A, B, C, D and E, but what we didn't understand is that all of these proteins don't act in isolation. They all interact. For example, we now have what we call networks and pathways of molecules which are very complex. So in this case, for example, I show you molecule C, which has the ability, for example, with that bar that goes back with a stop sign to stop the production of protein A and may encourage the production of protein D, and all of that in health is what you need to do as a physician. You need to maintain your patient within what I call the homeostasis zone, where everything is in balance.

Now, we know that disease means that all of these networks are out of balance. How do we unravel that complex? The human genome gave us a key and many, many other advances give us the ability to study proteins to study RNA and DNA in detail. But now let me show you what has happened in the past 3 years that has changed the world. Clearly, when we look at the DNA sequence, what we are looking for are in the disease state. Perhaps a misspelling, a mutation, as you see that star sign there, that has affected protein C. Well, that mutation is going to change the way the protein functions, is going to change usually its shape, and in this case, you can see that C is no longer functional, and look what happens. If C is not functional, then A is going to grow, and if C is not functional, D is going to go down, and all of that basically creates a dysfunction. So what you see all of a sudden is in the disease state you have more A than you should, more cholesterol, for example, more of a protein that you shouldn't have, which is what we look for when we want to diagnosis a disease. We say, "Does this patient have high cholesterol, what type of cholesterol, how is it related to heart disease?" That is what we do. And the reason I am giving you this background is to now show you what has happened to me in my career here at the NIH over the past 6 years and to the world of science.

On this table, I am showing you the 23 chromosomes of humans from one to the last chromosome. We have a pair of each one of these, and what we have at the NIH is a map that we developed with the National Human Genome Research Institute, all the insti-

tutes, and I asked all the institutes to report to me any finding that they have made that may explain a dysfunction in one of these networks that I showed you of molecules. In 2005, there was one discovery which related to macular degeneration, which is a major cause of blindness. Then I waited and waited for the reports, and in 2006 I had three new reports related to heart disease, inflammatory bowel disease, very surprising discoveries actually, and we invested in 2005 in a large effort across all NIH to try to find out more of these markers of disease states. Look at what happened. In the first quarter of 2007, all of a sudden I got more reports of discoveries than I had in the previous 2 years. Second quarter, it doubled. Third quarter, it increased again.

By the fourth quarter of 2007, I knew I had a real problem because all of these discoveries meant a complete rethinking of how NIH was going to address these problems. But thanks to the Reform Act, we had a mechanism with the Common Opportunity Fund to get together and say how are we going to tackle this. We had a retreat of all the directors and we talked about our new strategies, and sure, we should have because look at what happened in 2008, first quarter, and the second quarter. This, members of the committee, is an explosion of knowledge. I have never witnessed such an explosion in my entire career. I didn't think that we would witness this so fast.

I will give you an example. We spent years of research trying to find out, as Mr. Murphy was pointing out, the complex causes of chronic diseases because chronic diseases like diabetes and heart disease are the main diseases, and we never found out. Ten years ago we had no inkling as to exactly what was wrong in diabetes. Today we have 16 genes that we know we are going to investigate like detectives. These are clues. We are going to go after them. Autism is another disease that is very worrisome in terms of its presence, its increase, the impact it has on families. We were searching around and we decided to invest in a project where we would go around the world and do a comparison of patients with autism and patients without autism, using these modern methodologies, and guess what? We discovered just last month six new genes. Those are clues.

What happens after you have made these discoveries is, you need to explore them and you cannot sit back. You have to be nimble. The pace of change is so fast that we needed the instruments to react quickly and the NIH Reform Act frankly, has done that for me and for the NIH and for all of science because it allows us to have a conversation that is proactive rather than reactive. So if you look, for example, at the plan, what is the NIH plan? The NIH plan is after these discoveries are made, these are clues. We are going to study more populations, more genes. We are going to try to understand how these complex networks work. That will give us leads, real leads, and those will lead to targets once we prove that they are indeed, like cholesterol being high, that is a real target, and that will then be translated through centers like the Centers for Clinical and Translational Science and other things we are doing into either diagnostics to be more predictive or prevention to preempt disease or treatments. That is the fundamental trend of science. But that tells you I have not used the word of any one dis-

ease, any one institute, any one organization. You are going to have to cross borders and to fertilize across borders, across disciplines, across all types of sciences, physical as well as biological sciences.

So how is that embedded in the future? It means that medicine will have to become much more personalized, much more predictive, much more preemptive, but it will require us to go from a system of healthcare to a system of health. That is the fundamental change going forward.

Now, how has that worked for us? Let me just describe for you what has happened at the NIH and how the institution has responded to this. First, as I said, all the directors, myself included, sat together and said we need to be more nimble, we need to streamline the way we make decisions. We had 63 committees, 24 appropriations, institutes. Everybody had to get their OK, and frankly, it wasn't as functional and we wanted it to be in an era where everything is converging. It was fine 20 years ago. It is not fine today. So the first thing we did is, we streamlined governance. And this is essentially the governance of NIH with a central steering committee of 10 directors that have the authority to basically advise the NIH director, and once those decisions are made, they are really decisions that we all abide by. That has created a level of coordination that we didn't really have but this only takes care of short-term issues and we have five management committees. We eliminated 63 separate committees that had a say in the affairs of the NIH. That has streamlined things, made it more functional. But in 2006 we were able to add, through the Reform Act, the element that allows you to manage in the medium term, and that is this Division of Program Coordination, Planning, and Strategic Initiatives. It allows us to have resources to look at what is happening in science, where are the gaps, where are the opportunities. Let us move quickly in that direction. This is really what I think the Reform Act has given us.

Let me show you the impact of that. So I would like to show you what the mechanisms would have been before the Reform Act. If you had an idea, you would have to convince 24 separate institutes that this was important to them. But you know in science, bold ideas don't get adopted by 24 people at once. It doesn't happen this way. So typically what happens is, you get convinced when the game is over basically, yes, we have already made that, it is pretty clear that it is a good investment, like the genome. The Human Genome Project was one of the most controversial projects started at the NIH. It was opposed by large majority of individuals who said this is just a lot of mechanics but not science. Once it became successful, there is not an institute that doesn't have a genomics program. So science can't wait for the consensus of so many. It needs to be bold. It needs to be gutsy. It needs to move fast. In the past we had obviously the ability to do that but it would take longer because you have to go through the process, then accumulate the dollars.

Now, in good times when the budgets are rising, there are more dollars to give to bold initiatives but what happens when budgets are not so generous as they have been generous over the past 5 years. You have to really make priority decisions. How do you

make those priority decisions? Well, do you take away from cancer and give to something that may not have anything to do with cancer? That is a difficult proposition, and that is where the system really slowed down in an era where convergence occurred. We tried an experiment. We said, look instead of having this, let us use a small percentage of the NIH budget and put it in a common fund and let us discuss then about the most exciting opportunities in science, and that is what the roadmap prototype was and I was really pleased to see that in fact it was adopted and the directors contributed and we had some projects that were initialled immediately and implemented in a way that a lot of people said we couldn't have done it without a Common Opportunity Fund, if you will. And that was enshrined in the Reform Act and this is what I think as an institutional mechanism this committee has done. You have enabled us to separate the question of monies, opportunities and 24 different opinions about where science is, to a more nimble organization where now the appropriators have appropriated a Common Opportunity Fund which allows us to basically function in a very different way. Now if you have an idea, it goes through this very high-level analysis with lots of experts across all fields. It doesn't relate to one institute or one disease. They look at the entire portfolio. They invite scientists from all areas of science and then they make a priority call, and if there is a priority call, it goes through this NIH Common Opportunity Fund, 1.8 percent of the budget, and then it goes back to an institute that says I am going to take the lead. So we are supplementing the institutes' budgets depending upon science, not depending upon an appropriation process that is not related to the scientific priorities.

So I am just going to give you one example of a breakthrough that occurred because of that. When we had the Common Opportunity Fund, we decided to provide what we call molecular libraries, compounds that only pharmaceutical companies had in the past. Scientific researchers in academia did not have access to that. And we did it because we had advances in robotics and advances in basic technologies that allowed us to test 1.5 million compounds against a disease target in less that a week. It would have taken a year and a half before.

Now, let me just show you just one example of how that has changed one disease, schistosomiasis. It affects 200 million people around the world. We had a scientist, Dr. Williams at the University of Illinois, who for 20 years had been researching it and was hoping that he could test a compound that he thought would work. Within a week, he worked with the NIH center and he has the first compound that the WHO is saying is the number one discovery in tropical diseases in the last 50 years. So this is what has happened thanks to the Reform Act.

But going forward, what we are going to do is to continue what the other part of the Reform Act that I don't think is well understood that is written in law. And that is that NIH has to continue to innovate despite all of the environmental difficulties, challenges, budgets. America has to invest in high-risk, high-impact research. So we did. We have committed over $1 billion, in these budget times, trust me, it is not so easy to do, $1 billion to what we will call high-risk, high-impact innovation research, transformative re-

search. This could not have happened before the implementation, the passing of the Reform Act. Trust me. We couldn't have done it. For example, we have implemented what we call the Transformative RO1, what we call Discoveries Without Boundaries, and I am showing you a little cartoon about what Discoveries Without Boundaries is not, and that is, "I will be happy to give you innovative thinking, just give me the guidelines." No guidelines. That is what we wanted. This allowed us to, for the first time, establish a program with no boundaries, and it is implemented now. We will see what happens. We will learn from it.

Last but not least is transparency. You have asked us to be more transparent. We intend to be. We have implemented an automated system to report to you exactly what we spend on what disease, how much we spend on it, and you will have the basis of that information. We are distributing this electronically. You can search it on your computer. If you have any question, you can go back to this and find out what NIH is doing.

This is the first biennial report. We decided that this was a lot tougher to understand and nowadays you can plug that into your computer, put the words you want, and you will find out exactly what NIH is doing. Now, it is not perfect. Let me just make sure we don't oversell this. This is new technology. It is knowledge management. It is looking at all of our data. We are going to learn from it, but at least we are biting the bullet of transparency and we want to do it in a way that I think will satisfy you and satisfy the Act.

Last but not least is the sense that "long term" needs to be taken care of and long term means continuous improvement to look at the agency over years. We never had a mechanism to do that. Every time Congress wanted to reform, they would form an ad hoc committee that didn't really know what happened before and had no stake in what would happen next. So the idea, and I want to credit again Chairman Barton for that, was to create a very empowered Scientific Management Review Board and this Board has been impaneled and the role of this Board is to advise the NIH Director to conduct continuous, and the world "continuous" is important. Comprehensive organizational reviews of NIH and report these findings no less than every 7 years to the HHS and Congress, so that you have a mechanism that is accountable about understanding these changes and proposing changes that are buttressed by facts.

Mr. Chairman, I know I have abused the time and I apologize for going over time but I thought it was important to see the connection between why the Reform Act was important in the context of science that is changing so fast. Again, thank you very much, Mr. Chairman.

[The prepared statement of Dr. Zerhouni follows:]

Testimony
Before the
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives

"The NIH Reform Act of 2006: Progress, Challenges, and Next Steps"

Statement of
Elias A. Zerhouni, M.D.
Director
National Institutes of Health
U.S. Department of Health and Human Services

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In 1944, Congress passed the Public Health Service Act, which laid the foundation for a modern National Institutes of Health (NIH) to support biomedical research through extramural grants, largely to academic research institutions. This basic system remains in place and has served the Nation – indeed the world – very well. With over a half century of advances supported by the Agency, NIH is comprised of 27 Institutes and Centers based on the burden of disease; race, gender and demographic disparities; and individual organ systems of the human body. The field of biomedical research burgeoned as life was extended, diseases were conquered and knowledge was expanded.

These past 64 years have been a distinctive period in the history of scientific inquiry. Yet what lies ahead in the near future will likely be even greater scientific and medical advancements. As the Director of NIH, I am witnessing an unprecedented explosion of research advances and discoveries.

The field of medical research is breaking down human biology into its basic components as never before. We have sequenced the human genome, giving us our biological instruction book. We can increasingly track molecular pathways, providing more precise understandings of how disease develops. We are acquiring new information about DNA and proteins and their role in disease processes.

We have the ability to obtain biological data, and integrate and manage new knowledge faster and with more accessibility. We are seeing and understanding cellular interactions, causes and effects that are leading us to a transformation of medical treatment, where disease will be preempted before symptoms appear and suffering begins.

One major breakthrough is new knowledge indicating commonalities among diseases. For example, we are discovering similar genetic variations occurring among multiple diseases, such as cancer and type 2 diabetes. This convergence of science strongly suggests that cross-cutting, multi-disciplinary research, unencumbered by arbitrary structures and narrow approaches, is the critical way of advancing medical research. Cellular mechanisms involving genes, molecules, proteins and other biological components of the human body are the underpinnings of all disease. They must be better understood before discoveries are applied to individual diseases, and with our new knowledge and tools, comprehension will increase.

The approaches mandated by the NIH Reform Act of 2006, P.L. 109-482, will require NIH to seek new ways of conceptualizing and addressing scientific questions. The translation from discovery to patient care will be better facilitated.

The scientific boundaries between NIH's Institutes and Centers have become blurred by the interdisciplinary coordination among them. The functional integration required by the Act has helped this process. As you consider NIH issues in the future, I caution you that it would be a

grave mistake to go backwards in mandating disease-specific research at a time when barriers need to be torn down, not rebuilt.

The timing of the consideration and passage of the Act intersected quite well with the convergence of science. The Act contains authorities and mechanisms that are facilitating and speeding trans-NIH research. It requires greater transparency from the Agency. It calls for innovation, particularly in the area of high-risk, high-reward research, and across scientific disciplines in both the life and physical sciences. And it requires more accountability. The Act was an elegant response to the science of our day to the opportunities of this moment in the annals of medical research, and a stimulus for experimentation with new and bold approaches to science and public health.

Two years after passage of the Act, I am here to tell you that the vision of its crafters is being fulfilled. We are using new authorities to enable and expedite trans-NIH research, funded through the new Common Fund, an appropriations line item authorized by the Act. We have issued a new Biennial Report, required by the Act, which explains NIH programs to Congress in one consolidated and transparent publication. We are moving ahead on an open and electronic disease funding report, as required by the Act. And today, I am announcing the composition of the Scientific Management Review Board, a panel mandated by the Act, which I believe will be an effective mechanism for continuously monitoring and improving NIH's organization and performance over time, thus avoiding the ad hoc approaches of the past.

The following is a summary of the implementation status of the various provisions of the NIH Reform Act:

Trans-NIH Research

Prior to the Act's establishment of a Common Fund to support Trans-NIH research, NIH had established the Roadmap for Medical Research, which was funded through voluntary contributions from NIH's Institutes and Centers and supplemented by direct appropriations from the Office of the Director (OD) of NIH. Funding for the Roadmap consisted of $131.9 million in FY04 (of which $38.4 million was OD funding), $239.7 million in FY05 (of which $64.0 million was OD funding) and $352.6 million in FY06 (of which $85.3 million was OD funding). Following enactment of the NIH reauthorization, in FY07 $483 million was provided for the Common Fund, and $498.2 million was provided in FY08. The President's budget request for FY09 includes $534 million for the Common Fund. We are using the Common Fund to specifically support high-risk and potentially high-reward, cross-cutting, innovative research that no single Institute or Center could accomplish alone. Research supported by the Common Fund is focused on moving medical discoveries from the bench to the bedside to improve health outcomes, and will fill vital gaps in our knowledge of human biology. Also, it allows NIH to be nimble and more responsive to emerging issues and opportunities. Common Fund projects include:

- **The Human Microbiome Project (HMP).** Within the body of a healthy adult, microbial cells are estimated to outnumber human cells by a factor of ten to one. These hidden communities of cells are the unexplored planets of human biology. They are largely unstudied, and their effect on human development, physiology, immunity, and nutrition is unknown. This research is the next step after the sequencing of the human genome. To take advantage of recent technological advances developed for the human genome project and to create new ones, the NIH Roadmap initiated the HMP with the mission of generating resources enabling comprehensive characterization of the human microbiota and analysis of its role in human health and disease. The knowledge gained from this initiative will dramatically enhance our understanding of disease interactions, possibly leading to new and more effective treatments. This project took less than two years from concept to launch. The authorities contained in the Act helped NIH to continue to move quickly.

- **The Epigenome Project.** The Human Genome Project provided the sequencing of genes. The Epigenome Project will determine the factors, such as the environment, that regulate or turn genes on and off. In order to explore this emerging frontier of science, NIH will launch an integrated series of initiatives beginning this very month. Upon completion, we expect the Project will produce a map of the epigenomes of normal human cells to serve as a reference for diseased cells; develop an integrated Data Coordinating Center to enhance data sharing worldwide; discover novel regulators of epigenomic structure; and compare epigenomes from normal and diseased cells.

- **The Structural Biology Roadmap.** The Structural Biology Roadmap is a strategic effort to create a comprehensive gallery of three-dimensional shapes of proteins in the body. This research investment involves the development of methods to produce protein samples that scientists can use to determine the three-dimensional structure, or shape, of a protein. This effort will catalyze what is currently a hit-or-miss process into an organized, coordinated, systematic and streamlined routine, helping researchers clarify the role of protein shape in health and disease. During the first phase of the Structural Biology Roadmap (FY2004-2008), the NIH funded two Centers for Innovation in Membrane Protein Production that enabled interdisciplinary groups of scientists to develop innovative methods for producing large quantities of membrane proteins. In addition, a number of small exploratory and regular research grants were awarded to individual investigators to broaden the base of innovative ideas under development. These investments in Centers and in investigator-initiated research projects have produced considerable advances in methods and several important solved structures, including that of the beta-2 adrenergic receptor. This protein is the target of numerous drugs and a prime example of a large family of important cell regulatory molecules known as G-protein coupled receptors (GPCRs). Just last month, we discovered the structure of the voltage dependent anion channel, a protein that plays a key role in the life and death of cells by controlling the flow of electrically-charged particles across all cell membranes.

- **Clinical and Translational Science Awards.** A major goal of the NIH Roadmap was the reengineering of the clinical research enterprise in the United States by bringing diverse areas of science into an integrated system through innovative approaches that will speed

the translation of basic discoveries to clinical treatment. The centerpiece of this effort was the Clinical and Translational Science Awards program which has continued on after the conclusion of the Roadmap. Using the Common Fund and support from NIH's National Center for Research Resources, NIH is funding a consortium of clinical research centers at medical schools across the country. A requirement of funding is that the centers expand their areas of expertise and scope, the most dramatic change in clinical research in 50 years. Working together, these sites will serve as discovery engines that will improve medical care by applying the latest scientific advances to real world practice. Among the goals of the program are the training of a new generation of clinical investigators, enhancement of the clinical research enterprise, more effective methods of translational research, and linkages through the most modern systems of bioinformatics.

Transparency and Accessibility

NIH wholly supports the Administration's goal for Federal agencies to be more transparent organizations. For example, every grant we support is available for public viewing. But some of our reporting methods have sometimes lacked sufficient transparency and accessibility. One area in which the Act has mandated improvements is reporting of disease funding. The Act directs the Agency to "establish an electronic system to uniformly code research grants and activities" of all NIH programs.

This provision is intended to correct long-standing deficiencies, such as lack of uniformity and transparency, associated with disease funding collection and reporting. Our response to the

statutory mandate is the creation of the Research, Condition, and Disease Categorization (RCDC) system, a computer based tool that will apply a uniform process of accounting accompanied by fully transparent lists of grants underlying and supporting the amounts for each reporting area. NIH will unveil the first RCDC reports as part of the release of the President's 2010 budget request.

Conceptually, RCDC development had begun prior to the Reform Act but has been greatly enhanced as a result of the new authority. Such an undertaking is a venture into uncharted territory for NIH. Using computer technology for the first time in an NIH-wide accounting of disease funding will help with consistently collecting data and producing reports, but inevitably as in any new data collection effort, will be imperfect at first. We expect the RCDC to evolve over several years as the system is refined and adjusted. Any inconsistencies and early flaws in the system will be identified and reported to Congress as we proceed. However, we expect the initial product to be an enormous improvement over past practices because it will, for the first time, have a uniform methodological basis, and will, also for the first time, be fully transparent.

The new system will generate web-based summary tables that the public can view and download. These data tables will include complete project listings of NIH research activities divided into hundreds of research areas, diseases and conditions. The RCDC will offer opportunities for dialogue with the public about refinements in the system over time.

We are particularly excited about the prospect of public input into the RCDC. Taxpayers must have access to reliable information about how public funds are used to finance biomedical

research, and we will welcome their participation in the evaluation of the new, congressionally mandated system.

The Act also consolidated NIH's various congressional reporting requirements, replacing dozens of individual reports with a single compilation, the NIH Biennial Report. The first Biennial Report has been completed and submitted to this and other committees of jurisdiction. As it is the first report, I expect subsequent Biennials to be even better. The Biennial Report clearly will enhance the ability of Congress to understand and oversee NIH's various research programs by bringing clarity to the process of information dissemination.

Accountability, Effectiveness and Continued Improvement

While there have been various ad hoc assessments of NIH by Congress, the Institute of Medicine, the General Accountability Office and others over the past 50 years, there has not been a consistent, ongoing review of our programs by a permanent panel of experts in medical research and organizational effectiveness. This weakness has been addressed by the Act's creation of the Scientific Management Review Board (SMRB). The Act mandated that the Board conduct periodic organizational reviews, issue reports on organizational issues, and advise the NIH on the use of its management authorities. The SMRB was chartered in August 2007. For the past year we have been selecting and vetting the SMRB's members. I am pleased to announce today, for the first time, the membership of the Board, which is attached. As you can see, the members represent the brightest, most knowledgeable segment of medical research and management experts. And, based on their track records, they will be independent. While the

scope and breadth of their work will be determined by their own independent judgments, I would be willing to provide input on their planning and on topics of inquiry.

Innovation

The Act encourages NIH to support innovative research, particularly areas of inquiry that are high risk but will yield high rewards. NIH is striving daily to meet this goal. Following are some examples:

- **The NIH Director's New Innovator Award.** This award was launched last year to cultivate new investigators and support innovative ideas by encouraging and rewarding creativity. These investigators propose bold and highly innovative new research approaches that have the potential to produce solutions for broad, important problems in biomedical and behavioral research. The research proposed need not be in a conventional biomedical or behavioral discipline but must be relevant to the mission of NIH. The New Innovator Awards complement ongoing efforts by NIH and its Institutes and Centers to fund new investigators through R01 grants, which continue to be the major sources of NIH support for new investigators. In 2007, 20 new investigators were provided New Innovator Awards under the Roadmap to initiate their own new five-year research programs. The awards provide brilliant young scientists with the resources, time and freedom to pursue their creative ideas.

- **The NIH Director's Pioneer Award Program.** This program, first announced in 2004, is a high-risk research initiative. Pioneer Awards are designed to support individual scientists of exceptional creativity who propose pioneering – and possibly transforming approaches – to major challenges in biomedical and behavioral research. The term "pioneering" is used to describe highly innovative approaches that have the potential to produce an unusually high impact on a broad area of biomedical or behavioral research, and the term "award" is used to mean a grant for conducting research, rather than a reward for past achievements. An example of a scientific advance as a result of this program includes research by Dr. George Daley of Children's Hospital in Boston. Dr. Daley pioneered methods to establish non-embryonic stem cells from patients in an effort to accelerate research into a variety of human diseases. Dr. Daley and colleagues succeeded in converting skin cells from patients with a variety of genetic diseases, including Gaucher's disease, Duchenne muscular dystrophy, Down syndrome, Parkinson's disease, and others, into cells that look and act like embryonic stem cells. The resulting cell lines, called induced pluripotent stem cells (iPS), can potentially form any cell type in the body. iPS cells derived from patients allow a new way for scientists to model human diseases and may one day provide raw material for cell therapies to reverse leukemia, diabetes, Parkinson's disease, and paralysis, among other devastating conditions.

- **Transformative R01 Research Projects Program (T-R01).** The goal of this program, which we expect to launch this fall, is to provide support for individual scientists or collaborative investigative teams who propose transformative approaches to major

contemporary challenges. The primary objective of the T-R01 initiative is to create a program that is specifically designed to support exceptionally innovative, high risk, original and/or unconventional research with the potential to create new or challenge existing scientific paradigms. This program is a High Risk/High Reward Demonstration Project that will be supported by the Common Fund.

Summary

NIH has fully implemented the Reform Act. In some cases, such as the RCDC and the SMRB, it will be several more years before we know the full impact of implementation. But in most areas addressed by the Act, we have already seen the benefits. Trans-NIH research, in particular, is already producing research awards and results that will lift all medical research, regardless of the nature of disease or disability being studied. The Act has helped to facilitate greater collaboration across all Institutes and Centers while giving NIH new tools to be more strategic and adaptive. Consequently, the integration and convergence of life sciences research will occur at faster rates, as will discoveries, and we will further diminish the burden of disease here and across the globe.

Thank you for the opportunity to provide this information to you. I will be happy to answer any questions you may have.

ATTACHMENT

2008 Scientific Management Review Board Nominees

Norman R. Augustine has been nominated to serve as the board's first chairman. Mr. Augustine is chairman of the executive committee of Lockheed Martin Corporation.

Additional nominees to the SMRB Board are:

Jeremy Berg, Ph.D., Director, National Institute of General Medical Sciences
William R. Brody, M.D., Ph.D., Johns Hopkins University
Gail Cassell, Ph.D., Vice President, Scientific Affairs and Distinguished Lilly Research Scholar for Infectious Diseases, Eli Lilly
Anthony Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases
Dan Goldin, former NASA administrator
Richard Hodes, M.D., Director, National Institute on Aging
Stephen Katz, M.D., Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases
Thomas Kelly, M.D., Ph.D., Director, Sloan-Kettering Institute, Memorial Sloan-Kettering Cancer Center
Story Landis, Ph.D., Director, National Institute of Neurological Disorders and Stroke
Elizabeth G. Nabel, M.D., Director, National Heart, Lung, and Blood Institute
John E. Niederhuber, M.D., Director, National Cancer Institute
Deborah Powell, M.D., Dean and Assistant Vice President for Clinical Science, University of Minnesota Medical School
Griffin Rodgers, M.D., Director, National Institute of Diabetes and Digestive and Kidney Diseases
William Roper, M.D., Vice Chair of Health, former CDC and CMS head, University of North Carolina
Arthur Rubenstein, M.D., Executive Vice President, University of Pennsylvania for the Health System; Dean, University of Pennsylvania School of Medicine
Solomon H. Snyder, M.D., Professor of Psychiatry, Neurosciences and Pharmacology, Johns Hopkins University
Lawrence Tabak, Ph.D., Director, National Institute of Dental and Craniofacial Research
Harold Varmus, M.D., President, Memorial Sloan Kettering Cancer Center
Eugene Washington, M.D., Executive Vice Chancellor, Professor and Chair, Obstetrics, Gynecology, and Reproductive Sciences; and Professor, Epidemiology and Biostatics, University of California, San Francisco
Huda Zoghbi, M.D., Professor, HHMI Investigator, Baylor College of Medicine

Mr. PALLONE. Thank you. I did want to hear a full statement from you. That is why we had you as the only witness today, so thank you. And now we will have some questions and I will start with myself.

You mentioned in the Reform Act there were multiple changes in the administration, organization, and they created new initiatives and responsibilities for the agency including increased transparency, accountability, the trans-NIH research activities, which you said were so important, and in your testimony you outlined the progress NIH has made implementing these new provisions. However, as I mentioned in my opening statement, we know the funding for NIH has been decreasing in real terms in recent years. So can you elaborate on the challenges you face implementing these new initiatives, given the lack of funding increases?

Dr. ZERHOUNI. Right. So we have to be modest. The purchasing power of an agency depends obviously on its budget relative to inflation. So there is no doubt that you have to manage relative to inflation. Costs don't go down. The cost of oil doesn't go down. The cost of food doesn't go down. Everything has a certain ratio of inflation. So the way we have managed this is by truly identifying what are essential priorities of the agency. For example, one essential priority of the agency is the funding of the next generation of scientists. I think Mrs. Baldwin mentioned the fact that early stage investigators are funded later and later. We have initiatives to prevent that: high-risk, high-impact research. I showed you $1 billion committed to pioneer awards and new innovator awards so that we can sustain——

Mr. PALLONE. So tell me, that was another one of my questions, this new innovator award because, I mean, I know we hear a lot about the importance of ensuring that NIH attracts these young investigators. Why is that so important and what does this new innovator award do to accomplish that?

Dr. ZERHOUNI. So it is an award for really deep innovation by individuals who are less than 10 years from their doctoral degree. So it is the individual between 30 and 40 who is really trained, understands the issues and has a new idea. What happens if you do not do this in a period of constrained budgets, people become very conservative. They really don't want to present high-risk ideas because they are afraid that there won't be enough basis to be supported. So we want to dedicate dollars to those individuals. That is what you have to do in periods of stress when less than 20 percent of our applicants get funded.

Mr. PALLONE. And then one of the concerns I always have, even constituents will mention this if they are familiar with NIH, is that the translation from discovery to patient care. In other words, you have the basic biomedical research, which is what we think of NIH doing, but it has to translate into, you know, research to the patient's bedside. Do you want to comment on that at all? And again, given the new changes and the lack of funding how you deal with that.

Dr. ZERHOUNI. That is a crucial question, Mr. Chairman. You are putting your finger on probably the weakest, most difficult link to manage that we have. Let me show you, let me just tell you that if you look at the productivity of the pharmaceutical industry in

terms of new discoveries, it has gone down even though the pharmaceutical industry spends twice as much as NIH on research. What really needs to happen is an integration and a reinforcement both of our basic research according to what I showed you, which is understanding these complex connections, but understanding these complex connections cannot be just understood in the lab, they have to be understood in patients. Well, over the years what has happened is that it is more and more difficult to connect the basic scientists with the translational scientist who is going to do this and vice versa. So that response has been one that came from the ability to have a Common Opportunity Fund to make sure that the system does not come apart. It is not funding bench to bedside research alone. It is really to fund all of it. We believe that at NIH, about 60 percent of our budget should really be dedicated to basic discoveries but 40 percent should be applied research, and that applied research needs to focus on that translation in addition to all of the other things we do, for example, in vaccine development and so on. It is the connectivity that is the issue between those fields and the disciplines, unless you break the barriers, are not going to work with each other. And NIH's programs are designed to glue these components of the discovery process.

Mr. PALLONE. Is there anything that you suggest that we do? I mean, obviously today is not just about the past but about the future. Do you have any ideas for what we could do to deal with that problem or to make it easier?

Dr. ZERHOUNI. I think that if you really analyze the issue, NIH has taken the lead in terms of creating a home for translational science in conjunction with basic sciences. It is not exclusive of each other. In fact, we are trying to build the bridges here. But if you really think about new, young physician-scientists who are critical to this process, they are being run ragged, let us say, because the clinical service demands in their institutions are high, their training demands are high. They don't have the time to dedicate, and Dr. Burgess probably knows that very well, to 100 percent research at the translational edge. It is important if we are going to do this to find a way of funding these early-stage investigators not just through NIH but through Medicare, through Medicaid, through whatever R&D source we need to sustain that class of individuals, Ph.D.s and M.D.s who are dedicated to accelerating our discoveries in the human population. It is at risk. If you go to academic health centers, you will see that many departments are losing their best talent because we don't have the ability to sustain them at the right level. So that is what I would do. I would say, you know, preservation of the clinician scientists of the future, the next generation of scientists is a fundamental issue.

Mr. PALLONE. OK. Thank you very much.

Mr. Deal.

Mr. DEAL. That was a very impressive presentation. I am glad that we got to hear the full explanation of how you linked all this together. I think that is one of the best presentations explaining complex matters that I have heard.

Let me ask you this. Given that certain disease-specific research proposals receive significant private funding, and I use the example of the telethon-type environment that we saw that was very suc-

cessful for the cancer society last week, does NIH consider this fact, that is, the amount of privately raised revenue in making a decision as to what proposals will be funded within the NIH budget? In other words, how do you reconcile those two streams of funding?

Dr. ZERHOUNI. Right. So this is a very good question. The real question is, is that extra funding sustaining something that is very critical or is it just duplicative? That is the issue. And when we look at it in different fields, we realize—for example, cardiovascular research. If you look at all of the impact we have had on mortality, which has dropped 70 percent both for heart disease and stroke, you realize that we spend, every one of us, every American spends about $4 a year on cardiovascular research. If you look at cancer research, all of us spent about $9 over the past 30 years in the war on cancer, $9 a year. Everybody will tell you that even with philanthropy plus private funding, that we are still below where we need to be, particularly in cancer, because of the growth of—I mean, it is becoming the number one, it is the number one cause. So what we are trying to do is coordinate with the private foundations. For example, now we share our databases on what grants were accepted, what grants were not accepted so that we don't duplicate efforts. We have a transparent system with not just the cancer society but all funding agencies now. We open up through this transparent process our own databases for grants. That is one. The second is, we believe that because of this issue of early-stage investigators, that these private efforts are very important to maintain the next generation of scientists to be able to work on cancer, work on other things. I don't have that ability at the scale I would like it and so that is very important. So we work on two things: creating new talent, innovative talent, new people, new scientists and making sure we don't duplicate. Let me just assure you that with all of that, if you look at the productivity of pharma-spending twice as much as we do and not coming up with many, many targets, it tells you that more science according to the lines of what I described is going to be the key and that means more investments in people, talent, resources.

Mr. DEAL. I am sure that every other member of this subcommittee, like I, continue to receive requests from disease-specific groups for targeted legislation that would fund their particular disease, recognizing that some diseases obviously receive more outside funding than others. In order to balance your research among all disease-specific research proposals, would it be beneficial to establish a separate fund for less privately funded research proposals to ensure that they get adequate representation in the overall process of both private and publicly funded research?

Dr. ZERHOUNI. I think so. I think it is a good idea to have more open communications with the patient advocacy groups. I don't think it is a good idea to basically through different pressures to say, well, X goes to Y and Z goes to Z. Disease specific—what you understand as a disease today may be completely different 5 years from now, and diabetes is a good example. What we understood the disease to be 10, 15 years ago, a lack of insulin, now we understand in type 2 diabetes that it is really not the lack of insulin that is the problem, it is the resistance to insulin. Things change. So my sense would be that through this new division that we are imple-

menting to have that conversation of coordination and prioritization openly and transparently and not just through back channels and try to get separate legislation for each one. That only fragments the effort and it really, I think, disequilibrates the scientific progress.

Mr. DEAL. Well, I know that all of us are under that pressure and I think the fact that you have done such a good job of using the tools that are at your disposal under the 2006 Act has made it easier for many of us to resist those private groups saying we want you to just focus on us, and I wish that many of them could hear the explanation you have given us about how integrated all of the research really is. I think it would make them feel better if they really thought that they weren't totally being left out of the equation.

Thank you very much for your testimony today, and I yield back.

Mr. PALLONE. Thank you, Mr. Deal.

For questions, Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman, and Dr. Zerhouni, thank you for your outstanding presentation—cogent, highly instructive, encouraging, and it is an eloquent statement about your leadership at the NIH. I have always thought that this committee's jurisdiction of NIH is really the crown jewel of Energy and Commerce and I am very fond of saying to my constituents that NIH stands for the National Institutes of Hope, and I think that what you have presented to us today in detail is that much hope is being realized as a result of the legislation and so kudos to you, certainly to the ranking member of the committee when he was chairman as well as the rest of the committee for far-reaching legislation that ha brought us to what you presented to us today.

Now, earlier this year Dr. Zerhouni came to my congressional district, flew across the country to come to Stanford University where we had really an inspiring forum on technology and innovation and healthcare. At that time you reiterated many, many times the importance of a really clear vision for the future of healthcare and medicine, looking beyond managing the present and really protecting the future. I hope I am bringing some credit to the breadth of what we were attempting to examine that day, and I think that you said at the forum that we can't be short-term wise and long-term foolish. When 75 percent of our healthcare expenditures are related to chronic diseases, it raises the question of how do you think the NIH Reform Act addresses these long-term goals. That is my first question.

My second question is, having examined the efficiency now of being able to bring translational interpretation to what NIH is doing, I also know, we all know that it isn't any secret that the NIH needs more funding. The dollars will have the potential of fueling what you are doing. The fewer dollars there are, the harder it is to make progress even under the best of reorganization, and I think this is the best of reorganization. You gave us a statistic in February that for every year the NIH falls behind in terms of inflation and deinvestment decouple the NIH by $1 billion. We lose 6,000 scientists. I think these figures are correct. If they are not, I want you to correct them. It takes 20 years to train these 6,000 scientists. That is 120,000 years. I mean, that just takes my breath

away. It should take all of our breaths away. It takes $100,000 to train scientists effectively and that is $12 billion. So taking two steps forward and one step back I don't think is an effective way to fund the NIH. So my question is, when so much of our healthcare costs go toward managing chronic diseases, do you think that increasing—I guess it is a softball question, but it is the big question because I would like to see, as we have decoupled the bureaucracy from what needs to be done and gotten rid of the silos, and you have made the most magnificent presentation to us of the overall funding at the NIH is not where it should be. Tell us where you think we should go from there and how we do it.

So those are my two questions, and thank you again for your leadership. It isn't very often that we come to a hearing and leave, I think, on a high. But what you presented today is so encouraging and so hopeful for humanity, so thank you. Congratulations on your grandson's first birthday and taking his first steps on his own in life.

Dr. ZERHOUNI. Thank you. It happened just after the NIH Reform Act.

Ms. ESHOO. Well, good for us.

Dr. ZERHOUNI. First of all, thank you for having really a very good recall of our conversation there. I think what is essential is to understand the long-term impact of short-term decisions in something like science and health, which really goes over a long time. You don't train a scientist overnight. You train them over a long period of time. Once you have lost them, you have lost them. So the point I was making is sustainability and predictability of funding is essential, to have the talent to tackle the problems of chronic diseases. That is number one. So having these ups and downs, and the number I gave you is correct. In other words, if you really look at the impact, at the end of the day some people will have to leave the scientific workforce and they are. So we have young people right now who choose other careers because of the unpredictability. So predictability and reasonable inflation corrected rate of growth, is essential for anything. And that in science is even more important because you are talking about a 20-year cycle to train someone. And you have made all that investment and all of a sudden they go. So you need to sustain that.

Second, I have to give credit to my colleagues at the NIH. They all realize what is happening in science. They are the best of the best and truly have come together. So I will give you some examples beyond the Reform Act. Neural sciences and mental health issues are going to be very important to the chronic-disease burden of the country. Depression, as Mr. Murphy mentioned, is going to be a real challenge in the age between 25 and 44. So all the institutes that have to do with neural sciences came together for what is the NIH Neurosciences Blueprint. They came together spontaneously and said let us just work across that. As an example, they came then to the Common Opportunity Fund and said, the key to chronic-disease management is going to be behavior change, how do you change the behavior and how do you comply——

Ms. ESHOO. It operates like a venture capital fund, doesn't it?

Dr. ZERHOUNI. Exactly. It is a venture capital fund. So they came in and guess what? We have an initiative called the Science of Be-

havioral Change, because we realized we don't really know how to change people's behavior. So that is an investment that came from that concept of, how do you manage chronic diseases. The second is obesity. There is a trans-NIH obesity research plan. As you know, if we do not tackle this issue as a society, it is likely that life expectancy will decrease again. So we really want to work on these issues. But that is not just a NIH topic, it is a societal topic. But how do you get the people who are going to do that in a time where every year you tell them, well, your chances of getting funded are 20 percent, 15 percent, 10 percent. If you are a smart 25-year-old and you say I am going to work 10 years to finish my training in science, by age 35, like my son, have a child and try to get a job and then I am told, well, next year the budget may be this, may be that, you may get it, you may not, and then you don't get your first grant by age 42, it becomes daunting. So we have a fundamental issue. If you want to tackle chronic diseases, which are 80 percent of the cost, you have to have the workforce for it. Look at the issue of geriatrics. These are specialists who take care of the aged population. The number of geriatricians trained is actually going down at a time when the aging population is exploding. This is something that needs to be thought about and this committee really needs to look at the intricacies of how that happens. NIH is just the head of the fountain, but if there is no water in the fountain, trust me, you won't be able to solve the downstream problem.

Ms. ESHOO. Dr. Zerhouni, I want to work with you on legislation that is going to address this so that it is shaped and modeled to appeal regardless of what side of the aisle members may be on because this is, I think, one of the major areas for us to address and it is for future generations. We cannot have the spigot shut off. The costs are too high. We know what the challenges are. The best news today is, is that we can seize these challenges and really leapfrog way into the future. But we have to make sure that we have the appropriate funding stream that sustains and that it is not stop-start. So I want to work with you and with all of my colleagues on this, and thank you again for your brilliance and your leadership. This is a terrific hearing. Thank you.

Mr. PALLONE. Thank you.

Mr. Barton.

Mr. BARTON. Thank you, Mr. Chairman.

Thank you, Dr. Zerhouni. I appreciate the biennial report. I had it in the old form, the book, and I just got this. I need a port to put this in my brain. My problem is, my brain is analog and this is digital, so if you will have your scientists work on a way to input this directly, then I will see if we can't get funding for it. I do appreciate it.

I also want to compliment you on your kind words for me in your opening statement. You would think that you and I are related because you say nice things about me and I say nice things about you. As far as I know, there were no Zerhounis in Hill County, Texas, and I doubt there were very many Bartons in your neck of the woods, so we are not related, so this isn't a brother-in-law deal where we—like county commissioners sometimes get involved with.

You have done an outstanding job in implementing this Reform Act and it truly is reform and it truly is transformational. You paint such a positive picture. If you are even 60 percent correct, it is amazing what has happened in the last 2 years. I mean, it is really stunningly amazing what this Act has done. I wish that Chairman Dingell were here and hopefully he is watching and I know how busy he is and hopefully he is watching in his office on television the hearing because we intentionally set up the Act when we passed it 2 years ago to be a 3-year authorization. It has been 2 years so next year, 2009, we need to reauthorize the NIH if we want to continue the progress. So it is important that we have this hearing.

Now, my first question is, we required in the Act the establishment of an electronic system of coding to uniformly code research grants and activities so that they would be transparent, not only within the NIH but also to the public. This is a mandatory coding requirement and it is not voluntary. Could you comment on the implementation of this mandatory coding system and how it is being received and what the status is of it being fully implemented NIH-wide?

Dr. ZERHOUNI. Right. Dr. Krensky, who is the head of the Office of Portfolio Analysis and Strategic Initiatives, is here and has worked almost 2-and-a-half years. The first question that we resolved was, do we use manual coding, do we use an army of coders and then provide that to Congress like we have in the past in the 260 categories. We consulted widely, and it was very clear that in the age of Google, where you can have a search engine that can go in millions and millions of pages, that can extract information and present it to you, we thought we should adopt as a federal agency something that is the wave of the 21st century, and that is what we call knowledge management software. So all of the NIH system has been developing around this concept that you develop software and then you go into all of the grants and you identify through these automated search engines what it is that relates to diabetes or cancer or whatever you are looking for, and then you post it. In the past we had a judgment staff. People would say, well, this grant is 10 percent this, 20 percent that, and that is why advocacy groups were very frustrated with us and that is why you heard about the complaints of the advocacy groups saying we are not getting good information here, we don't know where the information is coming from, how is it analyzed. So we decided to embrace the 21st century for information management and it is a real, real breakthrough in terms of our ability to manage our portfolio. It is new, it is novel. The problem is that it doesn't give you the exact same results you used to see, and for institutes that had a long history of coding their own data according to their own priorities, it does present a problem, and how do you reconcile the new information with the old information the way you used to and how do you manage the coding that was there.

Obviously the new system is going to be evolving and it is not going to be perfect the first day. But how do you explain, for example, that an institute would have said, well, I am spending $100 million on this and our system searches this and says well, no, it is $80 million. How do you do the transition? So some institutes

have had difficulty with that, especially when you realize that the Reform Act gives the obligation to NIH to report on everything.

Mr. BARTON. Well, is it a technology difficulty or a human reluctance to implement?

Dr. ZERHOUNI. I think it is both. I think it is obviously cultural and control of information but also the sense that what these results are, this is a new system, knowledge management. What is that? Google search of your grant portfolio and then you are going to make that public and everybody can go in and say, gee, why is this grant here and not here? So you end up with a tremendous cultural change of——

Mr. BARTON. Would it be helpful if we gave some incentives to those institutes that meet the coding requirements sooner than others, or if you want to be punitive, disincentive to those that don't so you get more money next year if you are fully coded and implemented or less if you are not?

Dr. ZERHOUNI. I think this is so new, what I would do is, I would get the Scientific Management Review Board to look at that and to say, well, are we achieving our goal. Now, I will give you the statement that says don't think you are going to be happy day one. No one is going to be happy day one. But over time we will improve that.

Mr. BARTON. But if you had to put a percentage in terms of meeting the mandatory requirement for coding, would you say that overall the NIH has 70 percent implemented it, 50 percent implemented it, 25 percent?

Dr. ZERHOUNI. Right now?

Mr. BARTON. Yes, sir.

Dr. ZERHOUNI. Oh, 90 percent.

Mr. BARTON. Ninety percent?

Dr. ZERHOUNI. Ninety percent, yes. We have absolutely no issue. The only issue is when you want to go deeper in an area, how do you do it. So my decision was, look, you can report your coding as your coding. It doesn't comply with the Act but for the transition period I am find to see how you would walk the community through what the RCDC numbers are and what yours are as long as you are transparent. The problem is, in the past, we have had an issue, for example, in health disparities. Three, 4 years ago we had a scathing report from the National Academy of Sciences and when they re-looked at the source of the coding, they disagreed with our coding. So that is why the RCDC exists. That is why you have mandated it. And we are embracing it. I think at this point it is a matter of watching it for a while. I wouldn't decide to be punitive until I see it a little more. But I think the Committee and you as the governing oversight board have to stick to the line that we need an accountable, transparent automated system that can be followed over the years. Don't change the rules on me every 6 months, which is what the problem was. You cannot manage something you don't reliably know. This is the attempt to have the portfolio understood consistently and reliably.

Mr. BARTON. Mr. Chairman, I know my time has expired. Are we going to be allowed to ask additional questions?

Mr. PALLONE. I wasn't planning on having an additional round, Mr. Barton. I mean, if you want to ask——

Ms. DEGETTE. Mr. Chairman?

Mr. BARTON. No, I know the other people have waited a long time so I would just hope that after everybody asks one round, I am going to ask unanimous consent at that time if I could ask a few additional questions because this is my one shot to really focus and I appreciate the hearing but I don't want to abuse the prerogatives of the other members here.

Mr. PALLONE. OK. Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman. I was going to ask unanimous consent to give Mr. Barton 5 more minutes, but I will just go ahead.

Dr. Zerhouni, I always hate to use clichés about elephants but there is an elephant in the room and it is really the level of funding for the NIH. I want to explore that a little bit more in depth with you than just obviously the NIH could use substantially more resources. But I want to drill down a little bit with that, because what really struck me with your presentation, aside from the overall brilliance, were these two slides you had about the genome-wide association discoveries, how in 2005 you got this little blip and then by the second quarter of 2008 you had an explosion of discoveries. And I am wondering if you can describe for me if, for example, Congress made the kind of commitment that we had back in the 1990s, which was to double the NIH budget, if we made that kind of real commitment in the next term of Congress, what could we do from a concrete research standpoint to take those genome discoveries and move those along in your next matrix towards translation diagnostics, prevention strategies and therapeutics?

Dr. ZERHOUNI. I think personally that there are three priorities that need to be taken care of. First is the issue of the workforce. I think Congresswoman Eshoo was saying we should have a conversation about this. I think we need to have a conversation about that. I am very concerned. We have made projections. We are seeing the aging of the scientific workforce and we are seeing the absolute number of new investigators who come in not growing at the rate I would like it to grow. So the first thing we need to address is, how do we sustain the new generation of scientists who are going to solve these problems when we know the scope of the problems and also the scope of opportunities is much greater than it was before, and that is——

Ms. DEGETTE. Well, and just to interrupt you, the other problem, you know, I have a daughter who wants to potentially go into research who is a sophomore in college, and I look at her peers around her—it is not just the labor pool, it is the amount of debt burden these kids are going to have when they come out of their postgraduate programs.

Dr. ZERHOUNI. That is right. So you need to almost have a conversation that is way beyond NIH, the United States science and technology workforce trends and strategies to make sure we are competitive as you see the growth outside of the United States. We need to tackle that at the early entry stage. You don't have the bright minds to solve the problems if you don't take care of them at the beginning. So that I think is priority.

Ms. DEGETTE. And what do you mean concretely by that? Do you mean debt relief from loan relief and also salaries?

Dr. ZERHOUNI. I am not sure that I would be willing to say it is X, Y, or Z. I think we need to—it is a systems approach. You really need to look at it from science education all the way to funding. But you need to focus on that issue and perhaps you need to identify resources that are unrelated to whether or not inflation you say we have to invest in the talent pool first.

Ms. DEGETTE. I just might say on that, you might get your staff to work on some ideas more concretely around what those funding levels would look like and what we need to do.

Dr. ZERHOUNI. We have, and I am happy to share that for the record, if you wish, to tell you what our projections are. We have had long conversations across all institutes on this issue. The second is the issue that Chairman Pallone was raising and that is, you know, how do you sustain over time. I think predictability is very important there. So you can't in this sort of environment make ad hoc decisions. You need to really have a long-term plan, and the problem that we have is that it is hard to make long-term plans for anything. So one of the issues that I see in science management, not just NIH, is how we decide strategic investments that are more than 1 year or 2 years at a time, and how do you sustain that.

The third is very simple. As you think about it and you say what is it that really would stabilize the system, it is the success rate. And if the success rate goes way below a number, then you have a difficulty in sustaining the effort. People adapt to the new science. We have changed the kind of science we do all the time. NIH has been terrific at doing that. The problem is that if you do not have a reasonable success rate, you lose your talent pool. So what is a reasonable success rate, right? You are going to ask the question. I have thought about this for 6 years and I will tell you what the answer is. On average, we give a grant for 4 years, which means that if you are going to get renewed and maintain that research, you need a 25 percent success rate because you are going to renew it every 4 years, and if you don't have a quarter success rate, that is the bare minimum to just stay level. If you don't ensure that, you are losing. Ideally, you would want to sustain what you have and then fund those new ones, right?

Ms. DEGETTE. Right, right.

Dr. ZERHOUNI. Which means that your success rate has to be above 25, and historically, we have done extremely well in terms of adapting to new science when we are around the 30 percent range. So that is my technical opinion. Obviously that has implications. But those are the three things: new investigators, sustained success rate, and a predictable long-term path to investing in long-term issues that we deal with.

Ms. DEGETTE. I think as we move into the rest of the fall and since Congress will be leaving soon, it would be extremely helpful if your team could start to put some thought on price tags for that because when we come in to the next Congress, I think one thing we are going to be trying to look at is how we can commit ourselves to really making progress with these exciting new research breakthroughs that we are seeing, and in large part I think because of the Reform Act.

I just want to ask, you know I couldn't have you come here without talking to you about stem cell research, so I had my staff pull the budgets for stem cell research, and you know this as well as I do, the total stem cell research budget at the NIH for fiscal year 2007 was $650 million. Forty-two million dollars of that was for human embryonic stem cell research and the rest of it was for adult stem cell research, placenta, umbilical cord, et cetera. I am just wondering if that level of research dollars is really enough to sustain robust research, given some of the discoveries we have seen both in the private sector and around the world, or if it would really be helpful to get more dollars and of course less conditions?

Dr. ZERHOUNI. I asked myself that question, and as you know, we do not have a cap on dollars to fund human embryonic stem cell research. There is absolutely no limit. If you have a good proposal, they come in, we fund them if they pass review. What you see out there is, we fund pretty much all the good proposals that we get in human embryonic stem cell research but they have to do them with the stem cell lines that we have, and some researchers just don't feel that those lines are now appropriate for looking at the issues. What are the issues they are looking at? As you know, we have made great progress in induced pluripotent stem cells, adult stem cells. The other $610 million is invested in those areas. But let us remember one thing: Dr. Thompson from Wisconsin could not have made his breakthrough in understanding how to create induced pluripotent stem cells that are not human embryonic stem cells without the human embryonic stem cell research he has done. That is how we discovered the factors that take an adult cell and transforms it into pluripotent stem cells. So a lot of researchers are saying look, I understand the very first step to make something pluripotent, I still need to understand how it becomes a neuron or heart cell—I am simplifying—and a diabetes cell. We have had great breakthroughs over the past months and year so a lot of scientists are focusing on that. They are not really looking at embryonic but they are going to come back and say now, next step, I found the first four factors, what are the next five or the next 10 that do that. So I think you are going to see an up-and-down requirement for that funding but a lot of them fund that through private sources obviously.

Ms. DEGETTE. A lot of them, they think that pre-2001 cell lines are not effective so they are funding their funds for that research somewhere else.

Dr. ZERHOUNI. I have a diversity of opinion on that. Some people still use NIH stem cells and say that they are useful. Others say no, I really want to study new stem cells with new methods to look at the genes, how they are expressed so I can learn what factor. The goal right now is that people don't want to use embryonic stem cells in the long term. They want to really find the factors and then reprogram adult cells in the individual. That is the dream. It is not to take human embryonic stem cells. So I think that we need to fund all avenues of research. I think the $42 million is just the fact that you have that many researchers making good proposals. We have no bias in terms of one or the other.

Ms. DEGETTE. No, no, I know. Thank you.

Mr. PALLONE. Thank you.

Next for questions, Mr. Murphy.

Mr. MURPHY. Thank you, Mr. Chairman.

A couple areas here that I just want to let you know, a lot of my constituents have been talking lately about multiple sclerosis and cystic fibrosis and hoping that those areas are recognized, that a lot of major breakthroughs are coming through, and my hat is off to you and NIH and people who are doing the important research in that, and as those are chronic conditions, it leads me back to the discussion I had in my opening comments, and that is, in the areas of neural science and human development, which are part of the categories we look at here. You mentioned the key to disease management is behavior change. Could you elaborate on what you are finding with that?

Dr. ZERHOUNI. Right. So as we analyze the issue, we have deep conversations within the Office of Portfolio Analysis and Strategic Initiatives, this process that we now have, and there was a consensus that although we fund behavioral sciences, that we needed to have a more basic understanding of the science of behavioral change. We had papers that came out showing that if you understood that, you could actually change the proper level of control of blood sugar, for example, in diabetes. How do you maintain that? How do you encourage that behavior change and sustain it? Clearly, it is the key to chronic-disease management in what you could call non-communicable emerging diseases like obesity and heart disease and so on. We basically decided to invest in more fundamental research. I don't have the answer. I can tell you some anecdotes of what we are thinking about. We know, for instance, that if you look at public health measures, typically a passive public health measure works a lot better than an active public health measure. Let me be specific. If you look at seat belts, that is a public health measure. It took 50 years to get to 85 percent compliance. I mean, we knew about seat belts in the 1950s. That is an active act. It is a very simple one. It doesn't cost you anything, it is in the car, and yet you have difficulties in implementing it.

Mr. MURPHY. I would like to sit down with you, if I could, and spend a lot of time on this. With my background in psychology, I would like to follow up on that. I have a lot of questions, and I will submit more for the committee too. I would also like to know if it is OK with the chairman, I would like to yield the remainder of my time to Mr. Barton so he could follow up on some questions with you too.

Mr. BARTON. I will wait until the end. I will let every member ask their questions.

Mr. MURPHY. In that case, then I yield back, because I would like to follow up in excruciating detail with you.

Dr. ZERHOUNI. That is great, but I think you are on the most important issue, Congressman.

Mr. MURPHY. Thank you very much. I yield back now, Mr. Chairman.

Mr. PALLONE. Next for questions, Ms. Schakowsky.

Ms. SCHAKOWSKY. I have a question that is about a couple of specific programs. There was a $52 million cut to end the national children's study over Congress's objections and I have heard from medical researchers and academics as well as families that are

very concerned about this study, and I wondered if you know why the Administration wants to end this funding, what kind of data would be eliminated if the President succeeds in cutting the funding.

Dr. ZERHOUNI. Again, this is an issue of priorities. We looked at that study 3 years ago. It is a $3.2 billion study. Because of the other issues that we had to deal with and the flat budget, we thought that allocating that much money in these days, including the support of the National Institute of Child Health and Human Development, that the timing was not right and the priorities were different in terms of what we needed to dedicate dollars to.

Ms. SCHAKOWSKY. It just seems like it is so in line with the kind of priorities that you said doing this kind of longitudinal study beginning now of children, the environmental impact that cause disease. It seems like a real missed opportunity to get started in this kind of comprehensive look at what is affecting our children. It is disappointing.

I wanted to ask you about brain drain, about some researchers. I talked to one that was going to Dubai to look for funding, and if there is the feeling because not only the ability to recruit new investigators but we have heard that—it is not just not getting grants but that the grants have been cut in size, that some important research is going overseas to various countries.

Dr. ZERHOUNI. I hear that. On an anecdotal basis, yes. Then we look at the tracking of the numbers, we are not seeing an exodus of major scientists leaving. I mean, they would stay here. But it is true that we have had to be very stringent on increases in the budget so we have had, for example, no inflation for several programs, and when you look at that, the scientist has a choice: find new sources of funding, either through the private sector, or in many cases let people go. That is where the number 6,000 scientists leaving the workforce comes from at a time when the pharmaceutical industry is not expanding. It is also downsizing. And that gives an opportunity for other countries to take some of the talent that we had developed here. I don't see it today as a major exodus of talent but I am very concerned about it, and we cannot go on hoping that that won't happen. It will happen if we do not pay attention. Other countries are increasing their investment in research. China, for example, has a program specifically designed to recruit scientists from the United States to China. It is good for science. I mean, it is great that those scientists are not leaving science, but I don't think it is good for the integration that we described here as necessary to make progress.

Ms. SCHAKOWSKY. And the kind of continuity, I think that——

Dr. ZERHOUNI. That kind of continuity, yes.

Ms. SCHAKOWSKY. Tom Friedman wrote an article in the Sunday New York Times about innovation and promoting innovation as really being the future competitive comparative edge for the United States of America. You emphasize that as well, and I think a lot of us are concerned that we are losing these opportunities by a shortsighted view about the funding at NIH. I wanted to ask one other specific question. A few years back there were reports of senior officials at NIH receiving cash gifts from some of the same companies that received NIH funding. I wonder if you could tell us

what ongoing measures your office has implemented to safeguard against unethical practices.

Dr. ZERHOUNI. Right. Let me make sure that the record is clear. There were no senior officials getting money from anybody that was receiving grants. The issue——

Ms. SCHAKOWSKY. Some researchers?

Dr. ZERHOUNI. Researchers.

Ms. SCHAKOWSKY. OK. Sorry.

Dr. ZERHOUNI. At NIH, as you know, there is a firewall between the scientists who do research at NIH and the scientists who decide what grants get given. We have always maintained that firewall. I am not aware of a case in that—and Mr. Barton was actually overseeing that at the time where there was an official decision-making person who was getting that.

Ms. SCHAKOWSKY. I appreciate the distinction.

Dr. ZERHOUNI. Right. So now, in terms of scientists, we had undisclosed relationships that were not known to us that related to interactions with the pharmaceutical companies or others where, in fact, knowledge acquired through government resources, acquired through government employment, where it was used to gain private consulting fees and so on. We really tackled that in a very direct way. We just say that is just off limits. You can do it, we want you to work with industry, but on an official basis with a fully transparent agreement that know exactly all of the data. My philosophy is this: It is not all bad to work with industry. I mean, there are some good things that come out of it, especially when you are talking about new discoveries. The problem is the secrecy. So I want more sunshine in these relationships. You cannot manage what you don't know. So if it is not disclosed, how do you manage it? So that has been our philosophy. I think it has really not damaged NIH. Everybody predicted that our scientists would leave in droves. I think it has actually improved the ability to work with industry on a fair basis, understanding exactly what is given, what is received for what through formal overseeable agreements and peer reviewed through an independent conflict of interest committee.

So I feel that actually the NIH internally has done a terrific job. I would like to thank Dr. Kingston, who is the deputy director and is the director of ethics. It is been hard. He has been unpopular. It has been difficult, but now people as they see what is happening in the rest of the world, which is moving real fast, are actually thankful to have more clear rules that they can employ without preventing them from interacting but it has to be on an official duty basis, not a private basis.

Ms. SCHAKOWSKY. Thank you.

Mr. PALLONE. Mr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman.

Again, Dr. Zerhouni, thank you for spending so much time with us this morning. This has really been a pleasure to have a hearing that is based on success and achievement and to hear one of the rare good news stories that we hear come out of a federal agency, so I thank you for your presentation this morning.

You know, the subject of appropriations comes up, and I understood the philosophy of the Reform Act was to provide you with a

stable source of funding over the 5-year authorization of the bill. There was a lot of discussion as we did the bill, was a 5 percent increase year over year satisfactory or would the rate of biomedical inflation erode that. But the sad fact of the matter is, I don't know what you got in the appropriations process last year. I think it was about half of what we had authorized, and then this year of course, we have done no appropriations work at all so I presume that means we write our IOU in a few weeks. You will get what you got last year. So that activity has undermined the intent of the Reform Act of 2006, has it not?

Dr. ZERHOUNI. Well, in terms of priorities and choices to make, they were a lot harder, and as I said, there are still remaining areas of concern. The good thing is that the appropriators, after you passed the Reform Act in 2006 and the joint resolution, decided to fund entirely the Common Opportunity Fund. So that is no longer coming out of institutes. It really removed the friction there. But since then, things have been relatively flat for everyone. So it is really managing and making tough calls and priorities that has happened. Clearly, we would really be much better served not to have enormous increases one year and nothing the next, but have a predictable curve.

Mr. BURGESS. And again, it is a shame with all of the work we did on that that we didn't manage to follow through with the appropriations process. For your sake, I hope we do our job better in the future because I think that is so important.

You know, you talked about some of your templates for success, your benchmarks for success, and I just can't help but wonder, because in this committee we deal with the FDA, we deal with HHS and the Center for Medicare and Medicaid Services, are there any templates that would work in your world that would also work in other words of federal agencies? Are there going to be ways to apply what you have learned with this very great story that you presented to us today to be able—you talk about paying for health and not just healthcare. Are there going to be ways that we can real world, real time translate that to other federal agencies and make it a two-translational process, not just within your world but other areas where you intersect with other federal agencies?

Dr. ZERHOUNI. That is a very interesting question. I think the lesson that I learned is this: that typically Congress for good reasons makes decisions and appropriates in buckets. What is lacking—that makes strong fingers. Every bucket is a really strong finger. Everything you do is really justified. The problem is, you have these fingers but you have no palm. The mechanism that was created at NIH is a very experimental, innovative, new and working mechanism to create the glue. How you can translate that to other issues will resolve the issue that I hear all the time, in meetings with members, private and non-private, about how do we get more coordination, how do we get more synergy between the different areas of FDA, CDC, and frankly, that issue is inherent to the structure of how Congress authorizes agencies. I think thinking about mechanisms of gluing through maybe a common pool of resources that is managed jointly. That might be an experiment to expand, I believe. That is my personal belief. This is not an Administration view.

Mr. BURGESS. It is just a phenomenally interesting concept. One other thing, I just have to offer the observation, your slide where you showed the explosion of new information on the human genome, and of course, there are actually commercial applications out there that someone can go on the Internet today and have their genome sequenced for under $1,000. I mean, it is a phenomenal amount of information that we are putting at people's fingertips, so much so that the New England Journal of Medicine in one of its perspective articles a few months ago sort of talked about how does the average clinician now deal with a patient coming in and saying this is what I got, doc, what are you going to do. But it is truly a transformational time in medicine and I congratulate you for being able to be transformational in what is inherently a transactional process which is what we do here in the House of Representatives. I think we can all afford to be optimistic because of the work that you do, so thank you, sir.

Mr. PALLONE. Ms. Baldwin.

Ms. BALDWIN. Thank you, Mr. Chairman.

You have had quite a few questions about the challenges of dealing with tight NIH budgets. I want to focus on one particular category of awards, the clinical and translational science awards, because that is a program that really leverages the academic expertise found in particular institutions to shorten the distance between the clinical research and the patient care. I have heard anecdotal information that some of the grants have been or the awards have been much lower than anticipated, and of course, a factor of tight budgets, but recognizing that you are working with those tight budgets, can you tell me a little bit about the strategy of continuing to find more sites with smaller grants rather than contracting a number of sites and having a more adequate award amount? And I know these are tough decisions, but I would just like to hear your thinking in making those decisions.

Dr. ZERHOUNI. Yes, this was a tough set of decisions, and again, you have to balance what I believe is the mainstay of where discovery comes from, and that is investigator-initiated research. The real issue here is that we, through this process of analysis, that we go through now regularly, identified the need for re-engineering how clinical research and translational research is done. So the new program brought the investment from about $300 million a year to about $500 million in 2011–12 when we get to full spending. The idea there is that these CTSAs will have access to other sources of dollars from the institutes. So that the fact the CTSA is leveraging investment, you give the ability to the institute to really play at a different level, and some institutes have done it. You will see that, for example, University of Wisconsin is a terrific example. They have the facility to do translational science better than many other institutions. So the question is, do you look at this as a leveraging investment that will then accumulate other investments on a competitive basis or not. It is basically a resource grant that you give with no questions asked. We had to make the cut and we said $500 million is the envelope because of the budget being so flat. We had to set that tone. Now, the number of institutions is another issue and this is going to depend on our analysis of the effectiveness of the networks as we have them. As you know, we

funded 38. The number 60 came from the fact that we had a transition to manage between the old system to the new system. That decision is not fully made that we will go to 60. We will analyze it now that we have had 2 years of experience and that decision may be different downstream.

Ms. BALDWIN. You were just talking a little bit about in response to Dr. Burgess's questions about the palm that connects the fingers, and I know when we were discussing the NIH Reform Act last session, we were talking about the establishment of the new division of program coordination, planning and strategic initiatives, and there was some pushback from some advocates about how this would affect offices that were already conducting programs that crossed institutes and centers. So I am wondering with a little bit of experience now if you can talk a little bit about how the creation of this division has affected the operations of the program of offices such as the Office of AIDS Research and the Office of Research on Women's Health.

Dr. ZERHOUNI. Very good question, and remember the time the controversy occurred. You know, some people said no, we want to keep this, and people want to keep their thing and it is a very difficult transition to go from what you have to a new world that may be better but you have no proof that it will be better. So we have been very careful. We have moved in steps. And remember the Act says to preserve the authority of these offices. So the Office of AIDS Research is so large, so intertwined already that there is not a lot of need. I mean, they are doing a good job and it is 10 percent of NIH budget, AIDS research, so they need to continue to do this. We don't want to disturb that. Other institutes, other offices that are smaller, then found this to be a great way of leveraging their institute so the Office of Behavioral and Social Sciences Research, OBSSR, has been a real participant, bringing new ideas and trying to leverage what they have and try to push the Opportunity Fund to go into the behavioral sciences area, which his what we have done. So you see a difference there. I think it needs to evolve slowly. You don't want to break what isn't broken sort of philosophy, but over time, it will from the bottom up. We have the Office of Portfolio Analysis and Strategic Initiatives. Dr. Krensky is the director and is working real hard. We are trying to over a period of 18 months, 2 years then get to better integration, which will happen. So we have not touched the authorities of the existing offices of coordination because they are doing a coordination job that is decent in most cases.

Ms. BALDWIN. Thank you.

Mr. PALLONE. Thank you, Ms. Baldwin.

The gentlewoman from North Carolina is recognized for questions.

Ms. MYRICK. Yes, thank you very much, Mr. Chairman, and thank you, Doctor, for what you presented today but also what you do in thinking outside the box all the time. We appreciate it, and I think you have pretty much heard everybody agrees and supports your efforts in looking for ways to make it better.

Kind of following up on what Dr. Burgess was saying, you half answered what I was going to ask because I am curious about how the coordination between Department of Defense and Centers for

Disease Control because we know money goes into those areas that is not actually NIH money, but you know when you are talking about research-related activities between the two, is that pretty much the palm when you said the bucket is in the palm?

Dr. ZERHOUNI. Right.

Ms. MYRICK. And that is an area that we really need to take more seriously and see where we can expand on that relative to the value of the dollars.

Dr. ZERHOUNI. So again, I am glad that you bring that up because I have had internal conversations about what we can learn. I think there are two things that I would share with you, and again, this is my personal opinion, it doesn't represent the NIH view.

Ms. MYRICK. I understand.

Dr. ZERHOUNI. Two important components to this. One, don't create another layer. It is a mistake to create another layer, another institute that is going to coordinate everybody else or another agency that is going to coordinate everybody else. That is not the right thing to do. What I found very important is to understand the problem, allocate the dollars to it, but then have a streamlined decisionmaking process. But once you have made that decision, give the money to the agency best capable of accomplishing the task. So if we have a food safety issue, there should be some pool that doesn't get argued over for 24 months while we have a food safety issue. Give the money to the FDA to solve that problem, then you recirculate those dollars. That is what we have. You know, the money in the Common Opportunity Fund is never allocated forever to one goal, it is every 5 years you have to rotate. That is the beauty, I think, of the Reform Act. It gave us, for the first time, the ability to just put money in a bucket and never get it out, which is the typical problem with federal programs: it never sunsets. So this gives you, I think, a more traditional mechanism to keep adapting and responding in record time. I have to tell you, some of the programs we launched this year, the Microbiome to look at microbes in all humans, A.P. Genome to understand how the genome is controlled, those happened in a matter of months. In the old days it would take 4 years to get that. So that is my observation, Congresswoman.

Ms. MYRICK. Well, we appreciate it, and I think most everybody would be willing to work with you on that to try and bring about change because it is most important that we keep it moving, and I also share the other concerns that were raised, some that Anna raised and especially the ones with young people going into science and how we coordinate all of that because we are so far behind the rest of the world, and you mentioned China. I mean, China is just—they are doing everything they can in every area to move their country forward and we are going the other direction, and that is very scary to me, but thank you very much.

Thank you, Mr. Chairman. I yield back the balance of my time.

Mr. PALLONE. Thank you. Mr. Barton.

Mr. BARTON. Well, first of all, Mr. Chairman, thank you for the hearing again and thank you for allowing me the courtesy of asking a few questions. Dr. Zerhouni, I want to kind of go right at what would be the $64,000 question, if you remember that old quiz

show from the 1960s. There are not many of us that watched it, but I can remember it. Three years ago, the big push for a new institute and a new funding priority was autism. We had major bills in both the House and the Senate and we did pass an authorization bill creating some new specific structure for autism and we also enhanced the funding but we did subjugate the overall re-prioritization to the NIH Reform Act. In this Congress, the big push seems to be breast cancer and environmental research. There is a bill that the majority of this committee has sponsored and there is a major push to add some specificity of prioritization for that very high-profile and high-interest disease. My question to you, and hopefully we are at the stage where we are now as a Congress working to funnel these heartfelt requests for high-priority increases or at least re-prioritization to this new framework within the NIH. How would you think this new structure accommodate a Congressional and a stakeholder supported request for some sort of a re-prioritization of a specific disease or condition? Do you have an interagency task force mechanism or some sort of a mechanism with one of these new committees that instead of the Congress passing legislation, we can work within this new system to funnel this concern, which is legitimate. I am not downplaying the autistic concern of the last Congress or the breast cancer and environmental research concern of this Congress.

Dr. ZERHOUNI. Right. These are valid concerns, I agree with. I think if you pay attention, I mean, autism—I have a friend with an autistic child—you know the pain, you know it is hard, you know it is difficult, and you know we need a solution and we need to understand it better. So the human response is typically a positive one. You want to help, whether it be breast cancer or—the problem is, how do you do it in a way that does not create a locked-in sort of self-fulfilling concept of research that really never leads to that progress. In the past, as you know, you create a new unit, you create a new structure that never, never adapts to how science really evolves. That was the past. I think the Reform Act capped the number of institutes and issues, which was a good thing. I think in the next situation we really need to think better about how to take into account valid aspirations of disease groups and fit them into a process at the NIH where we can really analyze that. So in the case of autism, as you know, there is an interagency coordinating committee that is going to come up with a strategic plan in November. Once we have that, that will fit in the discussion of these program coordination and strategic initiative group that we now have. The downside is, we only have 1.8 percent of the budget in that Opportunity Fund. It is hard to do when you have to commit grants to 4 years, 5 years to an initiative. You can't change initiatives every other year, so you have to be steady. But at the end you recirculate the money in new priorities. That would be my recommendation, that maybe in the next situation or somehow that when a problem like this is identified, Congress will say look, we want you to develop a strategic plan, submit it to the priority-setting process of the entire agency if need be, or if it is very focused we can recommend, come back to you and say this really needs to be funded as a separate program.

Mr. BARTON. Under your current structure at the NIH, does the NIH have the ability if directed by the Congress either legislatively or informally through a letter signed by the chairman and members of the committee in the House and the Senate to create an interagency task force to focus on a high-priority need that hasn't been as focused on in the past?

Dr. ZERHOUNI. Absolutely. We do this informally.

Mr. BARTON. You have that——

Dr. ZERHOUNI. It is not a formal process. It is an informal process. So autism, for example, we had already without the Act what we call the autism matrix where we identified what needs to be done. The real issue though is, how do you get to implementation but then you don't get into an implementation. We have created an entitlement forever in an area of research that will never be productive because things change. That flexibility is what I think the problem is in mandating things. I see the legislation that is coming down. Normally they mandate that we plan and we coordinate but they say oh, no, now we are going to appoint a committee that is going to tell NIH where to spend the money. That is an absolute mistake if we would go that route. Let me just be as clear as I can be. You should not separate the accountability and the authority.

Mr. BARTON. Now, as I said in my opening statement and as you have alluded to, this is a 3 year authorization bill. We are in the second year so we have got one more year. If Congress does its job, we should in the next Congress in the first year reauthorize for X more years so that we continue what we have done. What is the one thing when we do the reauthorization hopefully next year that we didn't do 3 years ago that we could do or should do next time around? If you had to point to one unfinished piece of business, what would that be?

Dr. ZERHOUNI. OK. First of all, this issue that you raised, we need to do a little more thinking about how to help Congress and help NIH tackle this issue of valid rising concerns of any one kind or another. How do we do this without trapping ourselves in a rigid system where, fundamentally, if you do this then the NIH is going to look like special interests at the end, and that is not what you want. So that I think is a very good question. We need to think more about it. The second is clarification. Authorities across the institutes are different and it is sometimes ambiguous and I think the Act has to, I think, in my view, equalize all the authorities across the institutes. I mean, why would an institute have authority X and not another institute. I think those authorities are good. I am not saying take anything away. I think you need to really equalize them and so that you don't end up with games that really prevent one institute from doing something and another one—I think a level playing field in terms of authorities would be a good idea. I don't believe that any one disease is superior to another, and all of them are really integrated now. You know, you don't have a patient that suffers just one thing at a time so we have to really take into account the fact that health has changed and level playing field and look at that.

The other is, I have to tell you, Mr. Chairman, I learned one thing. The way the process works does not allow us to do good medium- and long-term investments, 5, 10 years, capital invest-

ments. I am going to take an example from a non-NIH institute. The United States invests in long-term projects with other countries in fusion research, energy research, and with the process that we have, we have become an unreliable partner worldwide when we need to make long-term investments that are significant. That process, in my view, needs to be rethought. How do we make investment at NIH over 10 years' time for new capital, new resources, expensive resources? I can't do this if the next year I am going to be having a budget that is unpredictable so we need to have a management of long-term issues separately.

Mr. BARTON. I appreciate the chairman's patience with me. I want to end up on a very high note, so I want to ask this final question. You alluded in your comments to some breathtaking breakthroughs in research on diabetes. Do you believe it is possible, given the progress that is being made, that we could either cure diabetes in people that have it or prevent it for future populations?

Dr. ZERHOUNI. Absolutely. I am totally positive about this.

Mr. BARTON. What about Alzheimer's?

Dr. ZERHOUNI. That is a harder one for me to call. Diabetes, we can——

Mr. BARTON. Would you care to predict a time frame for a breakthrough on diabetes?

Dr. ZERHOUNI. That is dangerous to do, not advisable. If I was beginning my tenure, I would absolutely refuse to do that. Now I can probably do it and get away with it. I would definitely say that in diabetes, we will have ways of preventing, if implemented, the development of type 2 diabetes in a large number of individuals.

Mr. BARTON. In how many years?

Dr. ZERHOUNI. Ten years. Yes, I think it is clear. Alzheimer's disease, I have to tell you, I believe in the preemption approaches. I think it will take longer. It is not possible for me to see how we would reverse the progress of Alzheimer's disease. We can stop it. I don't think we will prevent it any time soon, 10, 15, 20 years maybe.

Mr. BARTON. Well, we are fortunate to have you as a public servant in the role that you play and we very much appreciate your attendance.

Again, Mr. Chairman and Chairman Dingell, I really appreciate the scheduling of this hearing and the way it has been conducted, and I yield back.

Mr. PALLONE. Thank you, Mr. Barton.

And of course, we are done today but I do want to thank you, Doctor, for first your presentation and answering the questions, and I think we did get the insight that we wanted to into what was happening at NIH and hopefully we can make some changes, although I still think the biggest problem is money and I guess I could say that about so many issues here. But thank you again. I guess I will mention that members may submit additional questions in writing. The way it works is, they are supposed to submit them to the clerk within the next 10 days and then we would notify you so you may get additional questions to answer and we appreciate the response.

Thanks again, and without objection, this meeting of the subcommittee is adjourned.

[Whereupon, at 12:20 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF HON. GENE GREEN

Mr. Chairman, thank you for holding this hearing today so we may revisit and assess the progress of the NIH Reform Act of 2006.

The NIH, the world's leading biomedical research institution, is one of the great success stories of the federal government. Our investment in this life-saving research has led to advances that have profoundly improved the length and quality of life for millions of Americans.

Information gained from NIH research is revolutionizing the practice of medicine and future directions of scientific inquiry.

Without a doubt, the work performed at the NIH is invaluable. The groundbreaking research supported by NIH has provided a lifeline of hope to countless Americans living with diabetes, cancer, HIV/AIDS and many other illnesses.

In 2006, this committee was led by a fellow Texan, Mr. Barton, who worked diligently on the NIH Reform Act of 2006. At that time Congress had not reauthorized the National Institutes of Health in more than a decade.

The bill created a Common Fund, through which the Director of the NIH could support the important research that involves several institutes and centers at the NIH.

The NIH Reform Act also ensured that this new Common Fund did not overshadow the important research being performed at the individual institutes and centers by stipulating that only 50 percent of funding increases appropriated by Congress each year can be dedicated to the Common Fund.

Unfortunately, nearly every year since the passage of the NIH Reform Act of 2006, the President has chosen not to adequately fund the NIH. Instead he has opted to ask Congress for meager increases in FY07 and FY08 and for flat level funding in FY09.

These funding levels do not even cover the cost of inflation and show a lack of commitment to research at the NIH.

I was proud to support the NIH Reform Act because my hometown of Houston is home to the world-class Texas Medical Center, which houses many facilities that conduct groundbreaking NIH research.

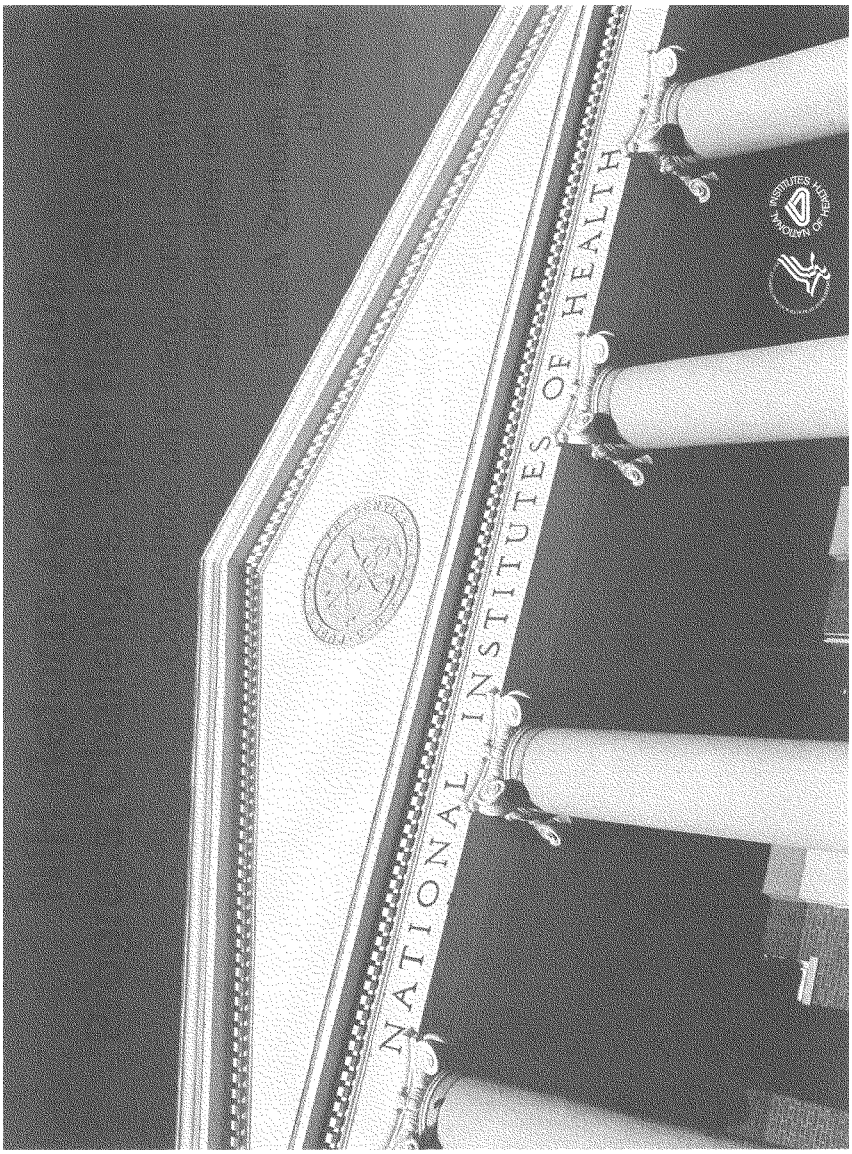
The Baylor College of Medicine and Texas Children's Hospital conduct more NIH pediatric research than any other NIH grantee.

The University of Texas's MD Anderson Cancer Center also conducts critical NIH research and is frequently recognized as the top cancer center in the country.

I believe it is crucial that the NIH be appropriated adequate funding level by Congress so that NIH research performed at the Texas Medical Center—and other impressive research facilities across the nation—will yield continued contributions to our understanding of disease and the development of effective treatments to improve the health and well-being of all Americans.

I want to thank Dr. Zerhouni for appearing before the Committee today. It is good to see you again.

Thank you Mr. Chairman, I yield back my time.

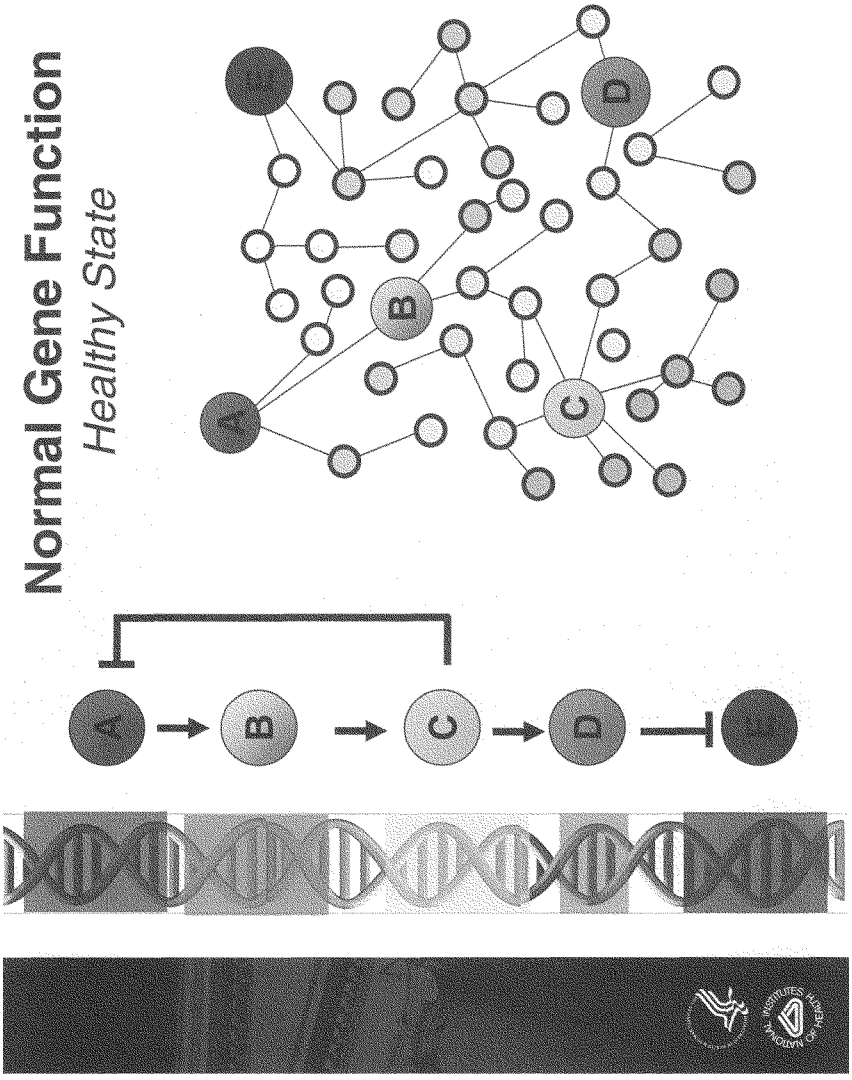

NATIONAL INSTITUTES OF HEALTH

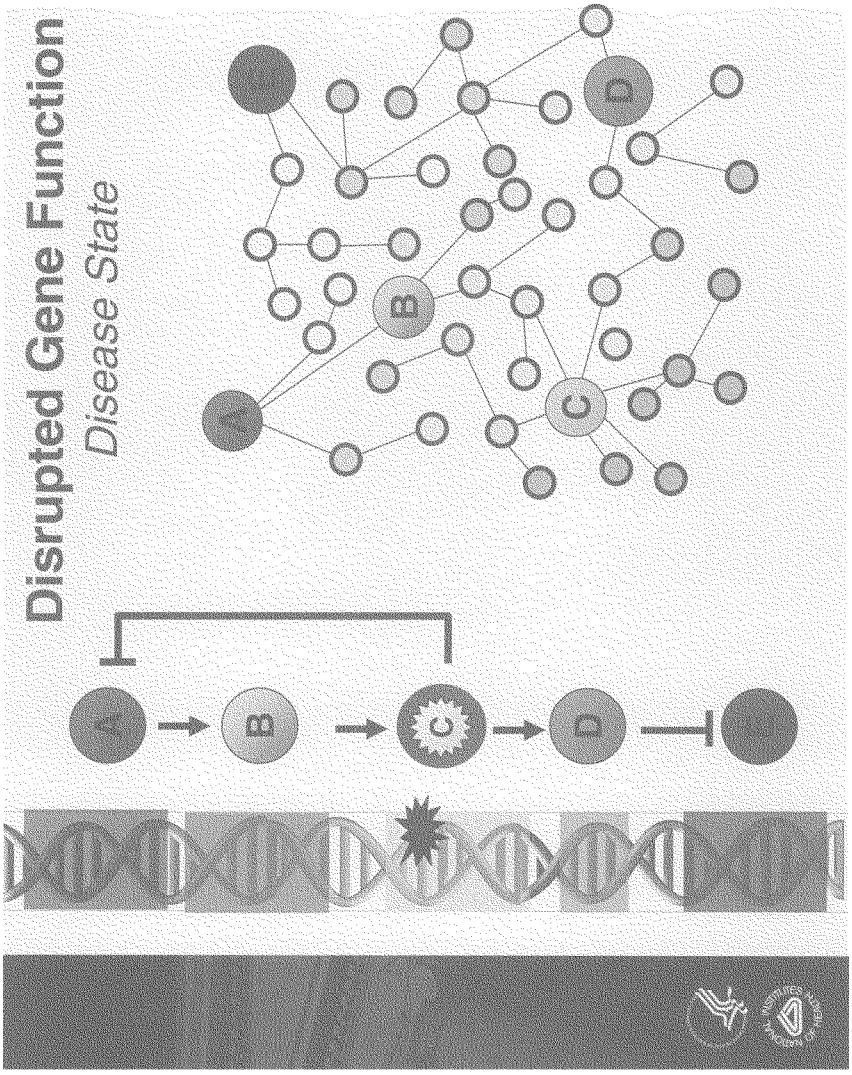
Major Trends in Science and Their Impact on NIH

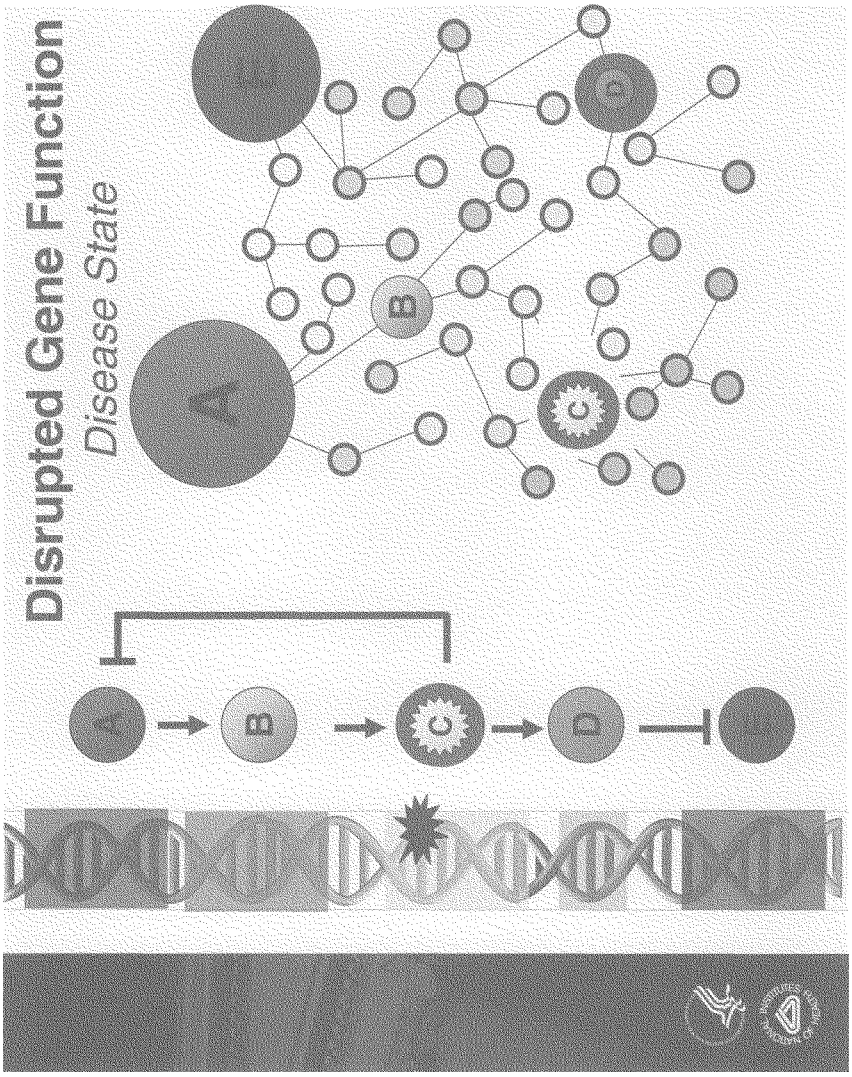
- Rapid pace of new and revolutionary discoveries open a new Era of Personalized Medicine and Health
- Convergence of science across boundaries of diseases and disciplines are forcing organizational changes
- NIH governance reforms addressed short-term issues
- NIH Reform Act of 2006 allows NIH to better address medium and long-term challenges in a more adaptive, transparent and proactive fashion



Toward a New Era in Medicine
Cell Nucleus Containing
23 Pairs of Chromosomes
Genes
Chromosomes
Bases
DNA Strand


Normal Gene Function
Healthy State
A
B
C
D
A
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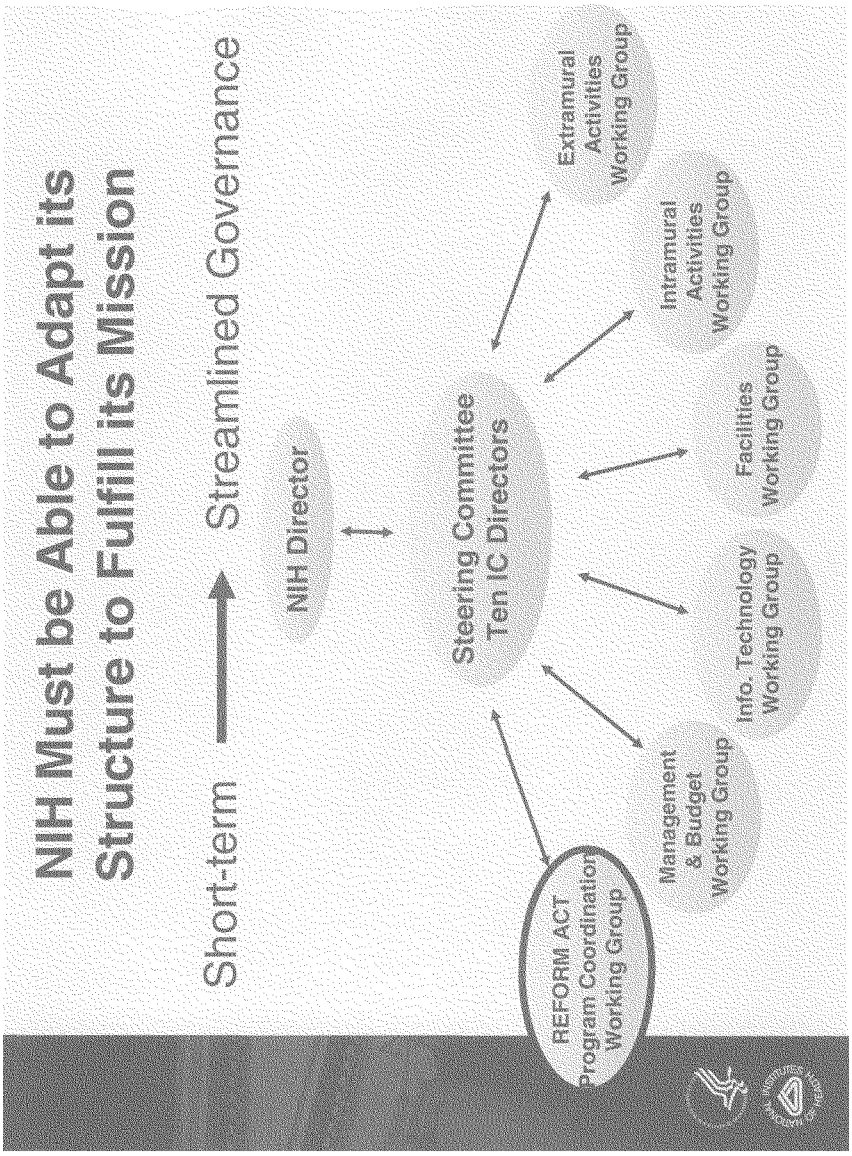

Disrupted Gene Function
Disease State
A
B
C
D


Disrupted Gene Function
Disease State
A
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Toward a New Era in Medicine:
Genome-wide Association Discoveries
Second quarter 2008
Manolio, Brooks, Collins, J Clin Invest 2008; 118:1590-605

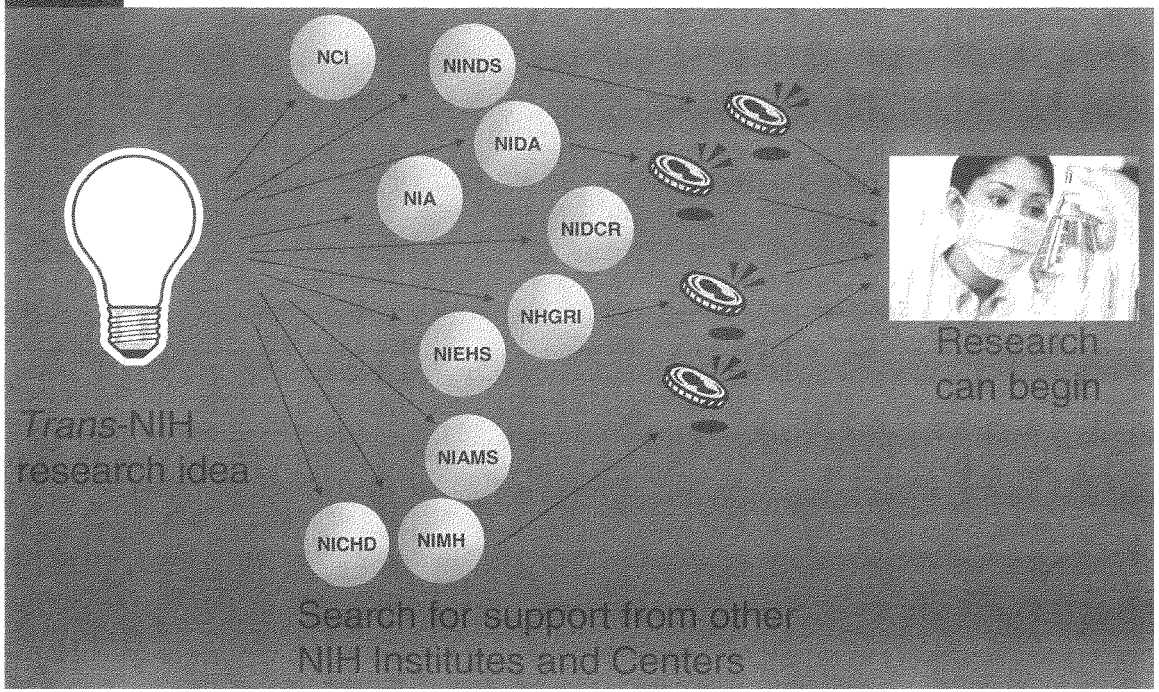
What Are the Next Steps?
How Do Scientists Unravel the Mystery?
Initial Genome-Wide Association Study
Clues
Analyzing More Populations and More Genes
Leads
Understanding the Biology
Targets
Translation
Diagnostics
Therapeutics
Prevention Strategies

The Future Paradigm: The 4 P's
Transform Medicine from Curative to Preemptive
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NATIONAL INSTITUTES OF HEALTH


NIH Must be Able to Adapt its Structure to Fulfill its Mission
Short-term
Streamlined Governance
NIH Director
Steering Committee
Ten IC Directors
REFORM ACT
Program Coordination
Working Group
Management
& Budget
Working Group
Info. Technology
Working Group
Facilities
Working Group
Intramural
Activities
Working Group
Extramural
Activities
Working Group

Funding for *Trans*-NIH Initiatives:

No Formal Mechanism for Trans-NIH Funding

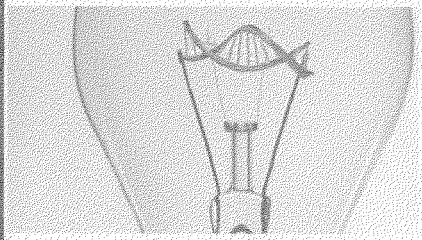


Funding for Trans-NIH Initiatives:
Roadmap Provided Prototype
Roadmap Initiative
$$$
$ Roadmap Fund
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NIDDK
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NIAAA
NLM
NIA
NHGRI
NEI
NIDA
NCI
NCCAM
FIC
NINR
NHLBI
NCMHD

Funding for Trans-NIH Initiatives:
After

Opportunities in Disease Research:
Molecular Libraries for New Treatments
200 million people are infected with Schistosomiasis
David Williams, an Illinois State University biological sciences professor, worked with NIH's Chemical Genomics Center to identify first new compound in 50 years
NCGC

Opportunities for Tomorrow:
NIH Investing in New, Transformative Ideas



NIH will commit $1 Billion over next 5 years to investigator-initiated high risk, high impact transformative research

- ✓ NIH Director's Pioneer Award
- ✓ New Innovator Award
- ▪ EUREKA Awards
- ✓ Transformative R01

The Transformative R01

Discovery Without Boundaries



"I'll be happy to give you innovative thinking. What are the guidelines?"

- Flexible award size
- Reviewed for potential impact and innovation
- Funded through NIH Roadmap
- Quickly moved from Award concept to Announcement

NIH Reform Act Increases NIH Transparency

Research, Conditions, and Disease Categorization (RCDC) system

- Provides uniform, automated and fully transparent report of NIH funding
- Released spring 2009

NIH Biennial Report

- Consolidated dozens of Congressional reports into single document
- Comprehensive description of research, priorities, and plans of the Institutes and Centers
- Submitted April 2008

NIH Must be Able to Adapt its Structure to Fulfill its Mission

How will NIH meet rising challenges?

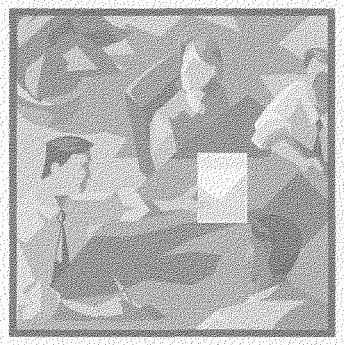
Short-term → Steering Committee

Medium-term → DPCPSI/Common Fund

Long-term → Scientific Management Review Board

NIH Reform Act Establishes:

Scientific Management Review Board

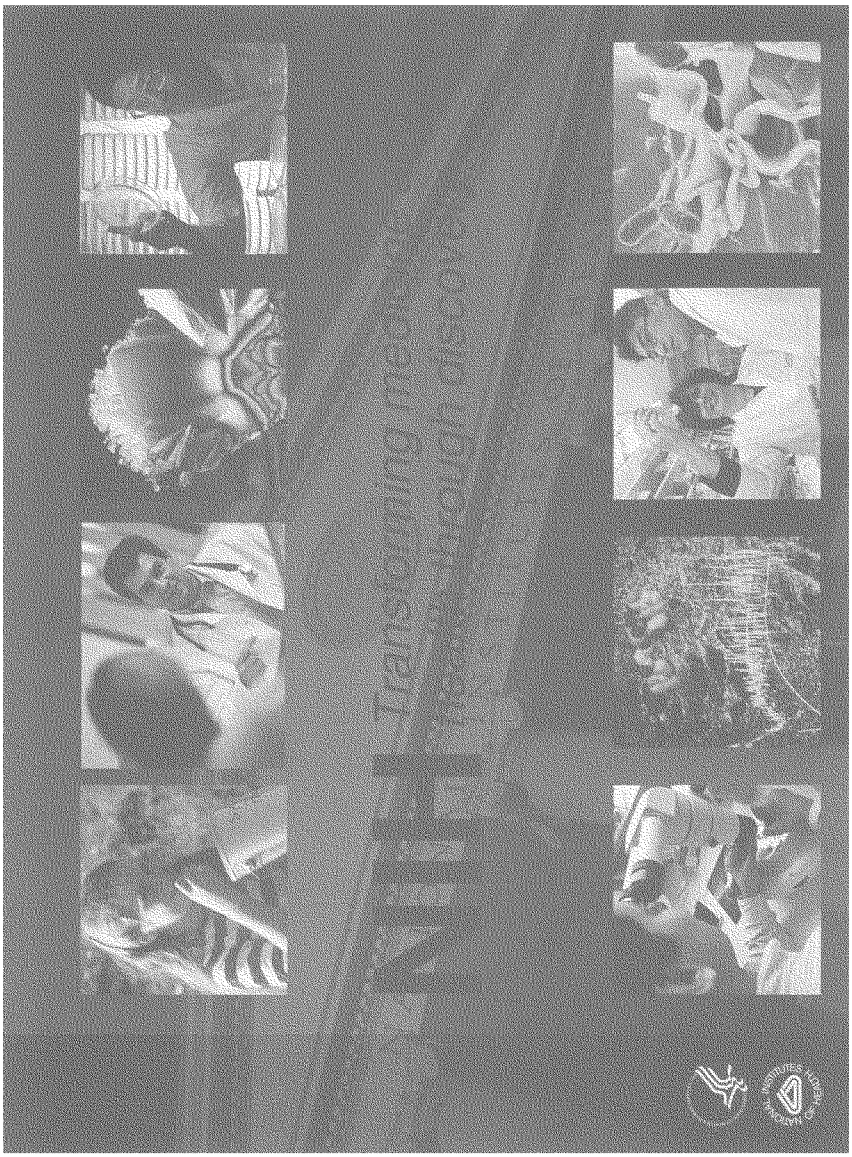


Mission:

- Advise the NIH Director
- Conduct continuous comprehensive organizational reviews of NIH and reports findings to DHHS and Congress at least every seven years

Composition:

- 21 Members
  - 9 Institute and Center Directors
  - 12 external research and management experts



DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DEC 12 2008

The Honorable John D. Dingell
Chairman, Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed are responses to the questions submitted by Representative Diana DeGette following up on the September 9, 2008, hearing entitled, "NIH Reform Act of 2006: Progress, Challenges, and Next Steps."

Thank you for the opportunity enabling Dr. Zerhouni to discuss implementation of the NIH Reform Act, its implications for biomedical research, and future efforts to improve the agency.

Sincerely yours,

Raynard S. Kington, M.D., Ph.D.
Acting Director

Enclosure

Enclosure—page 1

1. **To follow-up on our discussion during the hearing, what resources or investments are needed in order to ensure that the United States and the National Institutes of Health (NIH) remain a competitive leader in science worldwide, in terms of scholarships, student loan forgiveness, salaries, or otherwise?**

   The most important investment Congress can make in the NIH -- and in U.S. science in general -- is the investment of ongoing research support. Sustained research funding, at a reasonable inflation-adjusted rate of growth, provides institutions and individuals with the confidence to make long-term commitments to research.

   Sustainability and predictability are particularly important to investigators in training, whose career choices are invariably shaped by their perception of future prospects. For this reason, NIH has designed its career development and loan repayment programs to offer crucial support during critical periods of career transition, and provides stipends to offset the cost of living during the decade-long period of training typically required to prepare for a career in medical research.

   Stipends for graduate students and postdoctorates in research training, in particular, may require further resources in order to remain competitive. In 2000, a committee of the National Academy of Sciences found NIH stipend levels unduly low." The following year, NIH announced tentative stipend targets of $25,000 for graduate students and $45,000 for entry-level postdoctorates, and initiated annual stipend increases. As growth in the NIH budget slowed stipend adjustments were suspended. Today, NIH research training stipends remain below the target levels set in 2001.

2. **As we look to the next Congress, what are your projections on the level of funding necessary in order for NIH to make strategic investments of more than 1 year at a time and to facilitate a sustained success rate?**

   The biomedical research and development price index, developed by the Commerce Department's Bureau of Economic Analysis, estimates a 3.5% inflation factor for FY 2009. Between 1998 and 2003, increased support for NIH provided a framework for the recent pace of discovery in biomedical sciences and established the basis for future advances. During this time, research institutions throughout the country leveraged federal funds by investing their own resources in research facilities and science faculty.

   Since 2003, appropriations lower than the biomedical research index have resulted in the slower translation of basic science to medical practice as support for clinical trials struggles to keep pace with inflation. The research community has also observed an apparent reduction in incentives for the next generation of scientists to stay in the field. The Nation's return on investment has been diminished through less effective use of available capacity.

Inflation over the long-haul certainly has an effect on purchasing power for the biomedical research community. The FY 2009 request, however, will continue to move science forward. We will continue to invest in the best science and work with the community to use the resources provided to develop and translate scientific advances into therapies, cures, and diagnostics.

Regarding the second part of your question, a sustainable success rate would require an additional $5.2 billion. It assumes the average cost of a new grant receives the appropriate inflation adjustment as identified in the Biomedical Research and Development Price Index. It allows new awards the appropriate scientific purchasing power. It also assumes we maintain the balance within the NIH portfolio between Research Project Grants and other mechanisms.

