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**CANCER RESEARCH IN MINORITY AND
MEDICALLY UNDERSERVED POPULATIONS**

HEARING
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE
ONE HUNDRED SIXTH CONGRESS
FIRST SESSION
SPECIAL HEARING

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CANCER RESEARCH IN MINORITY AND MEDICALLY UNDERSERVED POPULATIONS

THURSDAY, JANUARY 21, 1999

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.
Present: Senators Specter and Stevens.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENTS OF:

DR. RICHARD D. KLAUSNER, DIRECTOR, NATIONAL CANCER INSTITUTE

DR. OTIS W. BRAWLEY, ASSISTANT DIRECTOR, OFFICE OF SPECIAL POPULATIONS RESEARCH, OFFICE OF THE DIRECTOR, NATIONAL CANCER INSTITUTE

NONDEPARTMENTAL WITNESSES

STATEMENTS OF:

DR. M. ALFRED HAYNES, CHAIR, INSTITUTE OF MEDICINE, COMMITTEE ON CANCER RESEARCH AMONG MINORITIES AND THE MEDICALLY UNDERSERVED

DR. LOUIS W. SULLIVAN, FORMER SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; PRESIDENT, MOREHOUSE SCHOOL OF MEDICINE

ARMIN D. WEINBERG, Ph.D., COCHAIR, INTERCULTURAL CANCER COUNCIL, DIRECTOR, CENTER FOR CANCER CONTROL RESEARCH, BAYLOR COLLEGE OF MEDICINE

OPENING REMARKS OF SENATOR SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The hour of 9:30 a.m., having arrived, the Appropriations Subcommittee on Labor, Health and Human Services, and Education, will now proceed.

We will hear this morning testimony on the Institute of Medicine study on cancer research on minorities and the medically underserved for fiscal year 1997. This subcommittee requested the Institute of Medicine to conduct a review of the status of research into

cancer among minorities and the medically underserved. That was formulated in September 1996 for fiscal year 1997.

We then expressed our concern in July 1997 questioning why it took some 9 months for the study to get under way, and then a contract was awarded in August 1997.

I mention that history very briefly to underscore the importance of prompt progress when the Congress, which adopted the recommendation of the subcommittee that this study be undertaken, that we really have to do it on an expedited basis.

My own sense is that every day we lose on making judgments on health care, it costs lives. We just went through the stem cell issue, which is a graphic illustration but I think it applies across the board. We really have to approach these health issues with a sense of urgency.

The scientific understanding of cancer control, prevention, detection, and treatment has improved dramatically in recent years, leading to 1998 being the first overall decline in the cancer mortality rate in the United States. And despite these scientific gains, however, not all segments of the United States population have benefitted to the fullest extent from the advances.

The Institute of Medicine found quite a number of problems with at least their contention on the National Institute of Health in the study and the National Cancer Institute, and we are here today to examine those and to hear the responses of the National Cancer Institute.

At 8:45 o'clock this morning, I was advised that the Republican Caucus had been set for 10 a.m., which looked impossible, but then was postponed till 10:30. So, we are going to be under a very tight time constraint today to conclude the hearing within 1 hour. Our customary allocation is to ask the witnesses to speak for 5 minutes, with the full statements being admitted to the record, and we will maintain that, but we would like to have you observe that time limit.

For expediting purposes, I am going to call on the first two panels together: Dr. Alfred Haynes, chair of the Institute of Medicine [IOM], Committee on Cancer Research Among Minorities and the Medically Underserved; Dr. Richard Klausner, Director of the National Cancer Institute; and Dr. Otis Brawley, assistant director of the Office of Special Population Research. A very distinguished panel.

Gentlemen, we thank you very much for joining us, and we will open with you, Dr. Haynes.

SUMMARY STATEMENT OF DR. ALFRED HAYNES

Dr. HAYNES. Good morning again, Senator Specter.

On behalf of the 15 members of the IOM committee, I am here today to present our report.

In accordance with your request to limit my testimony to 5 minutes, I have submitted full testimony in electronic form. I will, therefore, limit my remarks to a few of the most critical recommendations of the report.

This study was fully supported by NIH and received the full cooperation of the National Cancer Institute.

There is dynamic progress, dynamic change at NCI, and there was full agreement with some of our recommendations, partial agreement with others, and honest disagreement with a few.

There was full agreement with our recommendations to expand the SEER program to collect cancer information for groups not currently covered, including the medically underserved.

There was agreement with the recommendation to move towards a national registry for relating the work of the SEER program and the work of several State registries. That is assisted by the Centers of Disease Control and Prevention.

There was also agreement that a shift from an emphasis on racial classifications to ethnic groups would be more useful to cancer research. The committee commended the National Cancer Institute for its expanded program of behavioral research. That area has been too long neglected.

There was only partial agreement on our analysis of the institute's allocation of resources to research on minorities and the medically underserved. We disagree with the method of analysis by which the institute accounts for the second category which is based on the percentage of minorities involved in a research study. This method of analysis actually triggers criticism that the allocation is inadequate, with which the National Cancer Institute disagrees. But they do agree with our view that it would be better to account for minorities on the basis of whether or not the study is designed to answer questions pertinent to the problem of cancer in minority groups.

There is also partial disagreement about our assessment of priority setting. We agree with the view that scientific opportunity should have a high priority, but we argue that research opportunity must be taken in conjunction with the burden of cancer. If this is indeed the position of the institute, there has been a problem of communication because no member of the committee understood it to be so.

There was honest disagreement with a few of our views about planning. When we report that there was no evidence of a plan, it implies that the plan, if it existed, was not obvious to us. It is entirely possible that enough time had not elapsed for the design of the plan to be transparent.

PREPARED STATEMENT

Finally, there is one point on which we can all agree. The complexity of the problem of cancer is often misunderstood. Cancer is not a single disease. It is more than 100 diseases. This institute is important to all Americans and deserves our generous support so that it can meet the needs of all segments of our increasingly diverse population.

I will be happy to answer any questions.

Senator SPECTER. Well, thank you very much, Dr. Haynes, and thank you for undertaking the chairmanship of the Institute of Medicine Committee on Cancer Research among Minorities. You have brought to that position a very distinguished record: epidemiologist, former President and Dean of Drew Postgraduate Medical School, and former Director of Drew-Meharry-Morehouse Consortium Cancer Center. So, we thank you for your comments.

[The statement follows:]

PREPARED STATEMENT OF M. ALFRED HAYNES

Good morning Senator Specter and members of the Subcommittee. On behalf of the entire committee I am pleased to be here today to present our report.

One in four deaths in this country is attributable to cancer, which is expected to become the country's leading killer in the next century. Recent scientific gains have fueled the first overall reduction in deaths from cancer, but not all groups in the U.S. population have seen an improvement. Poor people and some ethnic minorities are more prone to certain types of cancer, and less likely to survive it, than are the rest of the population.

African-American men, for example, are more likely to be diagnosed with prostate cancer than white men. Asian Americans are more likely to develop stomach and liver cancer. Cervical cancer is higher among Hispanic- and Vietnamese-American women. African-American women, though less likely than others to develop breast cancer, are also less likely to survive it. Further, lower-income whites in rural areas such as Appalachia have some of the highest rates of specific types of cancer in the country. And Native Americans have the lowest cancer survival rates of all.

A key question for researchers and public health officials is why these differences in cancer and survival rates persist.

The 15-member Institute of Medicine committee that I chaired examined these questions, and looked at how the National Institutes of Health (NIH) approaches cancer research among minorities and the medically underserved. We examined how NIH prioritizes minority cancer research and how it applies research findings to prevention and treatment programs. We also looked at the adequacy of procedures related to including minorities in clinical trials, the communication of research results, and other key issues. Today we offer recommendations that we hope not only will help improve the health of minorities and the medically underserved, but everyone in our increasingly diverse society.

A critical first step is being able to pinpoint exactly what differences exist among ethnic groups and others. By legislation, the National Cancer Institute's Surveillance, Epidemiology, and End Results program—or SEER—is assigned the responsibility of assessing the burden of cancer in the population by continuously monitoring cancer incidence, mortality, and survival rates. It is the closest thing the country has to a longitudinal national cancer database, but limitations in the way data are collected have limited its usefulness.

Unfortunately, several key groups, such as many non-Mexican Hispanics, are not adequately covered in the SEER program. In order for this program to be most effective, it should be expanded to include these and other members of the population not now covered. These populations also include lower-income or poverty level whites, especially those living in rural areas. Further, this database should be coordinated with newer state databases to create a national registry with uniform methods of data collection and analysis.

In accordance with the guidelines of the federal Office of Management and Budget, the National Cancer Institute (NCI) classifies the population into one of four racial categories—White, Black, Asian or Pacific Islander, or Native American. This method of classification was not intended for epidemiological research and, in fact, is not consistent with current scientific thinking. There are no known biological boundaries that justify the division into races.

We recommend that NCI place a greater emphasis on the differences in cancer among ethnic groups, with a view to determining the roles that diet, lifestyle, and customs play in varying rates of cancer. We need to take advantage of the ethnic diversity of the American population to explore, for example, why Chinese American men have such low rates of prostate cancer compared with African American men.

Overall, we believe that NIH needs to formulate a blueprint or a coordinated plan for addressing questions related to cancer among minorities and the medically underserved. NIH's Office of Research on Minority Health coordinates studies on ethnic minority health problems, but its impact is limited by the size of its budget and other constraints. That office should more actively coordinate, plan, and facilitate cancer research across NIH centers and institutes. Within the National Cancer Institute, the Office of Special Populations Research lacks the authority and resources to coordinate an extensive program of research on cancer among ethnic minorities. This office should be given greater authority to expand NCI's research in these areas.

NCI also should improve its estimates of the money it spends on the health needs of minorities and the medically underserved. NCI reported spending about \$124 million in fiscal year 1997 for research and training programs addressing cancer in

these populations, but we believe the true figure is closer to \$24 million—or about 1 percent of NCI's budget. NCI's estimate is derived by calculating the percentage of minorities enrolled in research studies. Our estimate is based on the number of funded projects that are focused specifically on minority health issues. We believe that NCI should base its estimate on the research question involved rather than on the percentage of minorities in its studies. When one considers the greater burden of cancer among minorities and the increasing diversity of the U.S. population, NCI's current allocation is too low.

In setting research priorities, NCI places strong emphasis on research that capitalizes on scientific opportunities, and rightly so. However, we believe that NCI should give consideration to the magnitude of the cancer problem in different ethnic groups. The diversity of the American population offers a great opportunity for exploring all of the possible causes of cancer.

Participation in clinical trials among minorities has improved in recent years, to the point where their participation in NCI-sponsored cancer treatment trials is proportionate to the burden of disease in these populations. However, participation in prevention trials remains low. The absence of minorities in some of these trials—for example the recently concluded tests of tamoxifen to prevent breast cancer in women at high risk for the disease—raises questions about how applicable the results are to minority populations.

As NIH and NCI continue to review strategies for communicating with the public, they should give special attention to the needs of ethnically diverse and medically underserved communities. Among the key issues that remain is how to obtain truly informed consent from research subjects who experience language and literacy barriers.

NIH should establish a formal system of reporting to Congress and the public on cancer studies for ethnic minorities and medically underserved groups. Reports should include details on the number and type of research programs specifically targeted to these groups, and the contributions of ethnic minority scientists and community groups to the research priority-setting process. At the same time, NCI should improve efforts to disseminate information about cancer to patients, clinicians, and others in ethnic minority and underserved populations, and create a system to assess effectiveness. Cancer survivors in ethnic minority groups should be tapped as important resources for educating others in their communities about cancer.

We encourage reporting in a variety of styles, including one based on what might happen if all Americans had the same rate of cancer at each site as the lowest rate of any ethnic group. For example, if all Americans had the low rate of lung cancer as Hispanics, and the low rate of cervical cancer as the white population, etc., the mortality from cancer would be reduced by 50 percent. It is a goal worth pursuing as long as there were not promises of quick results.

Throughout our study, the National Cancer Institute was generous in providing the information that we requested, and it is clear to us that NCI is undergoing dynamic change. In fact, some of our suggestions for improvement today have already been suggested internally at NCI and are in the process of being implemented. We commend NCI's plans to increase its commitment to behavioral research, especially if some of that research is specifically targeted toward minorities and the medically underserved.

The National Cancer Institute is a great national resource that is vigorously pursuing the goal of reducing cancer in America. From the beginning of the "War on Cancer" it has been forced to grapple with the continuous demand for quick results. There was even a strong notion that the problem of cancer would be solved by 1976. But we now know that there are no quick fixes in cancer research. A big breakthrough is often the result of years of patient and sometimes unrecognized effort. Cancer is not one but more than 100 diseases. We hope our recommendations will help NCI and all of NIH tackle this difficult health problem in order to further the health of all Americans.

We are happy to answer your questions. Prior to asking a question, please step to an aisle microphone and state your name and affiliation.

SUMMARY STATEMENT OF DR. RICHARD KLAUSNER

Senator SPECTER. We turn now to the very distinguished Director of the National Cancer Institute, Dr. Richard Klausner. Undergraduate degree from Yale, medical degree from Duke, author of some 280 scientific articles and books. We welcome you here again, Dr. Klausner, and look forward to your testimony.

Dr. KLAUSNER. Thank you. Good morning, Senator Specter.

Let me state at the outset that the issue of the unequal burden of cancer is one of great moment for the NIH and the NCI, and to point out that much of what we do know about this question is the result of the work of the NCI. In this, as in all aspects of what we do, there is much we still do not know and much more we can do.

And I want to extend my appreciation to Dr. Haynes and his committee for their report. We will look very carefully at all of their recommendations and discuss them and their implementation within the institute and with our advisory bodies.

While we must digest this report more thoroughly, I do fully agree with many of the critical recommendations. Let me just briefly state those.

We agree with the need to better address the burden of cancer in the underserved. For years the NCI has studied aspects of this question. The report is correct. We need to develop good, but flexible definitions of what it means to be medically underserved and we need to focus more attention on the impact of being underserved on the burden of cancer.

Second, we do utilize the racial and ethnic classifications as mandated by OMB directive 15 for monitoring and reporting. We agree with the committee that these classifications are neither scientifically sound nor reflect the variables important to the cancer burden. NCI has traditionally gone well beyond OMB 15 and we now regularly report the burden of cancer among many macro-ethnic groups. We have linked the SEER database to other databases to look at the relationship between socioeconomic status, educational levels, and the cancer burden, but there's more we need to do.

It should be noted, however, in terms of classification, that the critical importance of linking our databases with other databases, the Census, Medicare, State databases, in order to address the questions that the committee correctly raises, means that the issue of classification cannot be solved by NCI in isolation. We need to work together about this.

We fully agree with the need to expand and enrich our surveillance programs to give a more complete picture of cancer patterns and trends, and this is underway.

Let me just state, because of the limited time, that we appreciate the committee's recognizing that we are a work in progress and there are many things that have been undertaken over the last few years to address many of the issues, and perhaps we can go through that in the question period.

Let me actually get to the point of our disagreement, and that is about planning and accounting principles in the report. This is important, and I am sure Dr. Haynes is right: We need to do a much better job at being clear and articulate in our communication.

The critical issue of different burdens of cancer and different experiences of cancer in minorities and the underserved must be, I believe, pervasive throughout all of our areas of research, and that's a guiding principle we use. We want as many of our studies as possible to include addressing real issues of the impact of social, cultural, linguistic, and economic and genetic factors in cancer.

When a large or multi-faceted study directly addresses the unequal burden of cancer, we code a fraction of the total research

project costs as directed towards minority and underserved research. If, on the other hand, we only counted dollars for projects that solely addressed questions of unequal burden, we would then need a parallel research structure, segregated from the researchers, projects, programs, and infrastructures we support for all cancer. I believe this is impractical. It is inefficient and counterproductive. It would, in fact, result in our failure to answer many of the questions posed by the IOM, and I can illustrate that, if you would like, with an example perhaps afterward.

STRATEGIC PLANNING

Our approach to strategic planning is to address the unequal burden of cancer within our planning for each component of the NCI. Here is one example. Our Office of Cancer Communications plays a vital role in the dissemination of cancer research information and results to minority and underserved populations. The NCI integrates communications to minorities and underserved populations within each overall effort. Printed and audiovisual materials that are easy to read, culturally appropriate, and translated into Spanish are disseminated through the Cancer Information Service, through direct mailings to minority advocacy groups and partners, through minority media outlets, and through national and State regional and community-based health providers.

One of the three goals of the Cancer Information Service is to provide cancer information to those who do not use the telephone to gather information, primarily minorities and underserved audiences. We do this through formal partnerships with over 4,500 organizations. Two-thirds of these focus on reaching minority audiences. In the next year, the Cancer Information Service will require that 80 percent of those contacts initiated will be with partners that work with minority and medically underserved populations.

This is the type of example of incorporating specific strategic plans, not as a global strategic plan as I understand the IOM recommendation. We do this for each of our areas: training, surveillance, general research, clinical trials, et cetera. That is how we do our strategic planning.

There are many other issues raised by the report which I hope we have time to discuss.

And let me just close by thanking you for your interest in what we all agree is an important issues. The NCI has and will continue to address the unequal burden of cancer and will attempt to act on the many excellent recommendations.

PREPARED STATEMENT

It is important to remember, however, that the root of the unequal burden of cancer is in part a reflection of unequal resources, access, power, and opportunities in our society. I say this not to shirk NCI's responsibilities, but to reinforce the committee's position that NCI alone as a research institution will not erase the unequal burden of cancer unless we as a society are committed to addressing the fact that too many of our people have inadequate access to health care.

I thank you for your attention and I look forward to answering questions.

Senator SPECTER. Thank you very much, Dr. Klausner.
[The statement follows:]

PREPARED STATEMENT OF RICHARD KLAUSNER

Good morning, Senator Specter and members of the subcommittee. I am Richard Klausner, Director of the National Cancer Institute (NCI). We are here today to discuss the important issue of the unequal burden of cancer for ethnic minorities and the underserved. Let me state at the outset that this issue is one of great moment to the National Institutes of Health (NIH) and the NCI. Indeed, much of what we know about this problem is the result of the work of the NCI. In this, as in all aspects of our mission, there is much we still do not know and much more we can do. I want to extend my appreciation to Dr. Haynes and his committee for their report. It is a very thoughtful analysis, and we will look very carefully at all of their recommendations and discuss them, and their implementation, with our advisory bodies.

I can say unequivocally that we are making real progress against cancer. We measure progress in two ways: first, the increase in knowledge about cancer, and second, the reduction of the burden of this disease on people. I will tell you about progress in both our fundamental understanding of this disease and in our efforts to prevent it, find it as early as possible, and treat it. But first I want to say that progress made in both areas is already evident in the declining cancer incidence and death rates. Between 1990 and 1995, these rates dropped for all cancers combined and for most of the top 10 cancer sites, reversing a long-time trend of increasing cancer incidence and death rates in the United States.

After increasing 1.2 percent per year from 1973 to 1990, the incidence rate for all cancers combined declined an average of nearly 1 percent per year between 1990 and 1995. The rates declined for most age groups, for both men and women, and for most ethnic groups. The exceptions were black males, where the rates continued to increase, and Asian and Pacific Islander females, where the rates were level. The overall death rate declined an average of 0.5 percent a year from 1990 to 1995, with the declines greater for men than for women. The only ethnic group not included in the downturn was Asian and Pacific Islander females.

These decreases are good evidence of the power of this Nation's investment in cancer research and of the value of carefully conducted basic research, and clinical trials in a broad range of areas, including cancer control. We also realize that these declines, while encouraging, must be accelerated and extended so that all of our population benefits. The trends also show us that while some ethnic groups have higher incidence and mortality rates, others have lower rates, and we seek to better understand all of these variations.

RECENT ADVANCES IN UNDERSTANDING CANCER

As we understand the nature of cancer, we understand that it is a unique set of diseases, and that the answers to cancer are related to the most fundamental mysteries of life itself. We know that cancer is not one disease, but at least 100 different diseases that share certain features. Because of this, it is unlikely that one magic bullet will solve the problem.

The most remarkable progress in the past 25 years has been in our knowledge of cancer biology. We are dramatically extending our understanding of what is required to turn a normal cell into a cancer cell. Cancer arises when a single cell changes so that it divides continuously, released from the controls that constrain the replication of normal cells. This transformation results from changes in the function and activity of genes. Of the approximately 100,000 genes found in the human genome, the altered activities of only a relatively small number of genes are responsible for transforming a normal, well-behaved cell into a cancer cell. Identifying these cancer genes defines the central scientific hunt in cancer biology, and opens an unprecedented window into the nature of cancer. Up until now, our detection tools have lacked the sensitivity and the specificity that we must demand if early detection is to be useful and successful. Our interventions, despite their success, have, by and large, been the result of guesswork. But now, we are at a point where we can transform our approaches to cancer.

No one genetic alteration is enough to make a normal, healthy cell a cancer cell. Rather, an accumulation of changes in a relatively small number of genes during the lifetime of a cell is required. We have learned that some individuals carry a very high lifetime risk of developing cancer. This understanding has allowed us to begin

describing the evolution of specific cancers from predisposition to pre-cancer to cancer. Each cancer is ultimately defined by its particular pattern of altered and normal gene activity. This unique pattern determines the cancer's rate of growth, tendency to spread, responsiveness to hormones and therapies, and also predicts the ability of a person's immune system to recognize and respond to the cancer. Moreover, cataloging these molecular patterns will ultimately tell us how many different cancers exist, and enable us to distinguish the differences between a cancer cell and a normal cell.

We also are learning to understand the causes of cancer. Research on cancer risk—the probability that the disease will occur in a given population—is identifying populations with a significant probability of developing cancer. Because cancer is a multistage process, analysis of risk factors leads to the development of prevention and control strategies, early detection methods, and in some cases more precise treatments. Epidemiologic research has identified many factors that increase cancer risk. Most of these are related to environment and lifestyle, while others are part of a person's genetic makeup. With the exception of a few genetic conditions, however, it is still not possible to predict with any degree of certainty that a person having one or more of these factors will develop cancer. This uncertainty is related to the very nature of cancer and the need for many specific alterations to accumulate in a single cell for that normal cell to be transformed into a cancer cell.

THE INSTITUTE OF MEDICINE REPORT

I take seriously my responsibility as Director of NCI to ensure that the research we carry out in our own laboratories and the research we support in facilities across the country benefits all Americans. Whether this means finding new ways to prevent cancer, improving patient access to clinical trials, or entering into new partnerships to more broadly disseminate information about advances in prevention or diagnosis or treatment, I have personally urged our staff to continuously strive to find new and better ways to accomplish our goals. We have made significant progress in many areas during my tenure as Director of NCI, but clearly this is an area where we need to do more.

NCI has three core responsibilities in addressing the issues raised by the Institute of Medicine (IOM) committee. First and foremost, we must conduct research that answers questions about the burden of cancer for all populations. Second, we must assure that individuals of diverse populations are represented in all aspects of our research enterprise: in population studies, clinical trials, and in the oversight and conduct of research. And third, we must communicate the results of our research and the opportunities to participate to a wide range of audiences, including patients, advocates, physicians, families, health professionals, Members of Congress, scientists, and the general public, in ways that are both valid and effective.

The report developed by the IOM presents a series of findings and recommendations for the NIH and NCI related to cancer in minority and underserved populations. As one might expect, there are some items on which we agree, and there are some areas where I strongly disagree with the recommendations presented. These are not simple problems, and there are no simple solutions. Many of the issues go well beyond the scope of a single Institute at NIH, and in some cases they have at their core some of the major social and public health challenges that face our entire Nation. While we need time to digest this report more fully, let me present three reactions to my initial study of it.

AREAS OF AGREEMENT

I fully agree with many of the recommendations: (1) There is a critical need to improve our ability to address the needs of the underserved. This is true in all aspects of our health care delivery system, in many of our social services, and in research to improve our knowledge of the special needs of these individuals. We have addressed aspects of this question, but the report is correct: we need good, but flexible, definitions; and we need to focus more attention on documenting, understanding and disseminating knowledge gained about this very complex area.

As pointed out in the IOM Report much of "NCI's data collection efforts are shaped by Directive No. 15 of the U.S. OMB." Consistent with this mandate, the NCI has collected and reported data according to four basic "racial" categories (American Indian or Alaska Native, Asian or Pacific Islander, black or African American, or white), along with Hispanic ethnicity. The NCI Surveillance, Epidemiology and End Results (SEER) program collects information on country of origin of the cancer patient, which provides additional data on ethnicity.

The issue of monitoring and reporting on the racial and ethnic classifications, as called for in Office of Management and Budget (OMB) Directive 15, is important.

These classifications are not scientifically sound, and do not reflect the variables important to the cancer burden. NCI has gone well beyond OMB 15 in attempting to monitor the burden of cancer, for example, by linking the SEER databases to other sources of information to evaluate socioeconomic status (SES) and to look at wider sets of macro-ethnic groups. However, the importance of linking data from disparate sources (the Census, Medicare, etc.) means that this issue cannot be solved by NCI in isolation. The NCI agrees that we should strive to develop and implement uniform definitions of ethnic minorities and medically underserved groups, whether it be through the use of 'special populations' or other terms. Clear definitions of underserved populations are useful in categorizing and tracking research in this field and we are initiating more research in this area which extends current work. In particular, internal surveillance activity is focused on linkage of aggregate Census population data to SEER incidence and National Center for Health Statistics (NCHS) mortality data at the county level. Analyses are underway which develop alternative characterizations of geospatial cancer rates based on SES population attributes. Other developmental work is in progress which should lead to research initiatives from extramural investigators on the relationship of SES to cancer, guided in part by the recent publication by the International Agency for Research on Cancer (IARC) on social inequalities and cancer.

Cancer research must go beyond these OMB categories and SEER data, and, as I stated in my presentation to the IOM committee, there is no biologic basis for "race." The NCI has acted on this understanding and for some time sought to collect data on specific ethnic groups beyond the OMB definitions, as evidenced by publications from the SEER program and the research initiatives it has supported. Thus, the task at hand is to develop the best measures of medically underserved to link to cancer outcomes (e.g., risk, incidence, morbidity, mortality, and survival).

The categorization of societally underserved people by their socioeconomic class, insurance status, or cultural background, is itself a subject for research. This is an area being pursued by NCI-sponsored investigator-initiated research, including some of our studies that focus on screening among underserved populations, as well as by initiatives from the Cancer Surveillance Research Program (CSRP) which address the measurement and monitoring of cancer rates based on SES indicators at the level of the individual and that person's neighborhood and community characteristics. In the fall of 1998, the SEER program hired a demographer with expertise in health data regarding racial/ethnic populations to help direct these efforts. Several new initiatives have been funded which enhance NCI's health services and economics research, particularly in regard to various managed care and other provider systems; e.g., the Cancer Research Network, the SEER-Medicare linked data base, and the Breast Cancer Surveillance Consortium.

We fully agree with the need to expand and enrich our surveillance programs and we are doing that, as the body of the IOM report documents. We are now awaiting the recommendation of a Surveillance Implementation Group we asked to address these complex questions.

We need to much more clearly articulate the planning and monitoring of our activities in these areas than we currently do.

I will state again that we will look very carefully at all of the recommendations and discuss their implementation with our advisory bodies.

PROGRESS HAS BEEN MADE

The NCI, as pointed out in the report, has been very active in the past few years in addressing many of the issues raised. Following are examples of some of our efforts in selected areas that were addressed in the report.

SEER

Work is in progress to enhance the NCI CSRP and improve our capacity to measure the National cancer burden and our progress to reduce its impact on all Americans. The scope of the NCI surveillance enterprise covers a broad and complex range of data and data systems to measure the cancer burden. In addition to SEER's coverage of cancer incidence and survival for 14 percent of the U.S. population and significantly larger proportions of most racial/ethnic groups, the NCI utilizes and publishes reports based NCHS data on cancer mortality for the entire U.S. population. Specially-funded NCI surveys, cooperative group consortia, data linkage with national data bases, and supplements to federal health surveys are mechanisms we use to provide information on cancer risk, health behavior and health status, patterns of care and cancer outcomes, cost and quality of cancer care, and quality of life. Every surveillance research and analysis project includes an emphasis on information for different population groups. Selected examples are the recent 1998 SEER monograph on prostate cancer which includes a special chapter devoted to racial/

ethnic patterns (available via the NCI web site), as well as the ongoing longitudinal SEER Prostate Cancer Outcomes Study which over-sampled black and Hispanic men.

The NCI recognizes the need to better explain the cancer burden in several high-risk ethnic minority and medically underserved populations and is concerned with research on the full diversity of the U.S. population. In 1975, 1979, 1983, and 1992, SEER has expanded to include populations critical to explaining the burden of cancer in this country. As noted in the IOM Report (page 40), these have included Hispanics, urban blacks and Asian and Pacific Islanders in Southern California and the South San Francisco Bay Area, rural African-Americans in Georgia, northwestern populations in Seattle, Arizona Indians, and Alaska Native Americans. One of the recommendations of the current Surveillance Implementation Group suggested in the NCI Cancer Control Review Group (again as noted by the IOM Report, page 40) is to further expand coverage to capture additional key populations, such as rural low-income whites, more diverse American Indian populations, rural African-Americans and other Hispanic groups. Beyond the SEER program, the CSRFP is planning a coordinated co-funded effort with the NCHS and other NIH agencies, such as the National Heart, Lung, and Blood Institute to improve data collected on mortality by race/ethnicity.

Formulating new plans for training and career development

Several activities promote the availability of research training and career development opportunities at NCI. The NCI/Minority Access to Research Careers (MARC) Summer Training Program is designed to increase research training opportunities for underrepresented minority MARC scholars entering into cancer-related research careers. Through the Comprehensive Minority Biomedical Program of NCI, the American Association for Cancer Research (AACR) provides travel fellowships for minority students to attend annual meetings of the AACR; increases the attendance of minority scientists at the annual AACR meeting; and stimulates participation of predoctoral and postdoctoral minority students in cancer research. NCI invites academic health centers and other health professional schools that employ, educate, or serve a preponderance of minority faculty, staff, trainees, and communities to submit applications for support of activities directed at the development of faculty investigators at minority schools in areas relevant to cancer. National Research Service Awards, Individual Predoctoral Fellowships for Oncology Nurses, and Minority Students and Students with Disabilities Awards encourage nursing students, students with disabilities, and students from minority groups that are underrepresented in the biomedical and behavioral sciences to seek graduate degrees.

The Continuing Umbrella of Research Experience for Underrepresented Minorities Program (CURE) is a new strategy being implemented by the National Cancer Institute to expose minorities to cancer research at the high school and undergraduate levels. The program is being initiated nationwide and provides a "continuum of competitive opportunities" through the successful established independent cancer investigator. As part of the CURE initiative, NCI is collaborating with the National Science Foundation, the Office of Research on Minority Health, the National Center for Research Resources, the National Institute of General Medical Sciences, the National Institutes of Environmental Health Sciences and the Department of Defense on a nationwide minority training and career development program known as "The Bridge to the CURE." "The Bridge to the CURE" focuses on working with Minority Serving Institutions (historically Black Colleges and Universities, Hispanic-serving Institutions, and Tribal Colleges serving native Americans) to encourage minority participation in biomedical research. These institutions, while providing high quality education for minorities, typically lack the infrastructure and institutional commitment needed to conduct high quality biomedical research. This program aims to work with the institutions on developing the infrastructure and commitment to research and become full partners in the cancer research enterprise. The IOM committee was provided with information about this new, innovative program.

Setting goals for minority participation in clinical trials

The appropriate participation of ethnic/racial minority patients in clinical trials has been a specific goal of NCI. Indeed, there has been a considerable effort to provide wide access to clinical trials. Participation of diverse populations is desired out of a sense of social equity and because it may provide more valid and more generalizable results. All NCI-supported clinical trials are reviewed to ensure that access to research protocols is equitable and that no arbitrary age-specific criteria are included in any of these studies. Older patients are generally eligible for all protocols unless specific medical contraindications exist. While accrual of minority pa-

tients is proportional to the population with cancer, accrual of the elderly has been lower than desired.

Behavior

Lifestyle and attitudes towards the health care system itself can directly and indirectly affect one's risk for cancer. Therefore, strategies to encourage change in behavior or attitudes in favor of healthier habits is an area currently under study by NCI, especially in regard to intervention research on tobacco use. NCI is conducting and sponsoring a number of programs and projects aimed at testing interventions that will motivate individuals to change their behavior with regard to smoking. Many of the studies target a specific culture or ethnic group, while others target youth with the idea that healthy habits should begin early and that children will teach their parents these healthy habits.

Survivorship

In agreement with the IOM Report we have recognized the need to enhance the collection and reporting of data on survival among ethnic minorities and medically underserved. SEER investigators and NCI staff are currently developing a new monograph on Cancer Survivorship for publication early next year. In addition, methodological and data quality issues related to estimating cancer survival for racial/ethnic groups are being addressed by NCI surveillance research staff. Publication of these data is in progress, which involves staff from the Office of Special Populations Research and a senior scientist from the extramural community. Furthermore, this topic has also been identified by the Surveillance Implementation Group as a priority and is one of the recognized aspects of expanding SEER to include additional populations. Non-SEER National Program of Cancer Registries (NPCR) states currently are required only to collect cancer incidence data. One mechanism to expand SEER would be to work with National American Association of Central Cancer Registries (NAACCR) non-SEER states that include high-risk populations of interest and who have demonstrated their ability to adhere to NAACCR's quality standards and to support the addition of survival data. Other approaches, such as facilitating data linkage of the non-SEER registry states with the NCHS National Death Index, are possible.

In the recent reorganization of the NCI, the Office of Cancer Survivorship (OCS) was formed within the Division Cancer Control and Population Science (DCCPS). The Office of Cancer Survivorship was established in 1996 to provide support and a focus for research and other activities dealing with cancer survivors. OCS workshops were held in 1996 and 1997 to define priorities for research, which included the prevalence of physical effects from cancer treatment, the prevalence of second cancers in survivors, quality of life, and quality and cost of follow-up care for survivors. In addition, this Office sponsored a national meeting last year on long-term survivors and will sponsor another this March 8-9, 1999 on Research Challenges and Opportunities for the New Millennium. A formal strategic plan for this Office awaits the imminent appointment of its Director in the next month or so.

Targeted Funding

NCI has several initiatives geared to specific groups in the community. These initiatives are intended to lead to more positive results in reducing the disproportionate burden of cancer that is apparent among various ethnic/racial groups. They include:

- Through Cancer Therapy Evaluation Program's (CTEP) Minority Initiative Program, five of the Cooperative Groups received a total of \$1.1 million earmarked to foster minority accrual in Fiscal Year 1997. These funds have paid for focus groups and educational opportunities for minority professionals, advertising to increase minority awareness of clinical trials, as well as data management, translators, and community outreach in institutions with high minority patient populations.
- The National Institute on Aging (NIA) and CTEP have co-sponsored two studies, one in ovarian cancer and one in breast cancer, to determine factors that present the greatest barrier to the participation of older patients in clinical trials.
- Minority Biomedical Research Support (MBRS) grants co-funded by the National Institute of General Medical Sciences and NCI provide expanded opportunities for ethnic minority faculty and students at minority institutions to participate in biomedical research through institutional grants.
- The Leadership Initiatives on Cancer (Black, Hispanic, Appalachia region targeting the underserved) address the cancer-related needs within these communities through the establishment of coalitions; stimulate the involvement of

community leaders; and develop and support intervention and outreach activities in these communities throughout the United States and Puerto Rico.

- Through its 19 regional offices, covering all 50 states and Puerto Rico, the Cancer Information Service (CIS) supports programs according to the specific needs of each region's special populations. The successful CIS collaboration with outreach partners to reach minorities and underserved populations has focused on program planning assistance, increasing breast and cervical cancer screening for women 50 and over, and assuring community access to the latest, most accurate cancer information.

AREAS OF DISAGREEMENT

Although we agree in many areas, the NCI and the IOM differ in our views of the best and most appropriate way to attain very similar goals for research into the unequal burden of cancer. We have clearly stated and written in our planning documents that the pervasive issue of different burdens and different experiences of cancer in minorities and the underserved must likewise be pervasive throughout all areas of our research. We have acted to assure that we ask questions about unequal cancer burden for surveillance, epidemiology, prevention, detection, treatment, survivorship, training, and communication.

We want as many of our studies as possible to address real questions of the impact of social, cultural, linguistic, economic, and genetic factors in cancer. When a large or multifaceted study directly addresses the unequal burden of cancer, we code a fraction of the total research project costs as directed at minority and underserved research. If we only count dollars for projects that solely address questions of unequal burden, we will need to create a parallel research structure, segregated from the researchers, projects, programs and infrastructures we support for all cancer research. This is impractical and inefficient and will fail to answer many of the questions posed by the IOM report. Let me illustrate: The Prostate Cancer Outcome Study is a large community-based effort to provide new information about the reasons for variations in prostate cancer diagnostic and treatment practice patterns among varying populations. It is allowing us to ask many important questions about the detection, diagnosis, and treatment of prostate cancer. Some of these questions include whether various racial and ethnic minorities experience systematic differences. This is an example of a project that we code as including 10–20 percent of the funds directed towards answering questions about the unequal burden of cancer. It is the coding of such clearly relevant research that the IOM committee rejects.

The IOM committee reasonably raises concerns about coding fractions of studies and issues such as minority participation in clinical trials and other studies. We will re-examine our coding, but I do not agree that we should only code dollars for projects that only address issues of the unequal burden of cancer regardless of whether the larger projects are utilizing funds to directly, but not solely, address the issues outlined in the report. This would, in fact, exclude many of the studies that have given rise to publications that specifically address minority and underserved populations. In data provided to the IOM committee, we compiled a list of over 740 publications over the past 10 years specifically addressing minority populations arising from NCI funded research. Of those, 81 percent were from studies that were not focused solely on minorities.

SEGREGATION VS. INTEGRATION

NCI firmly believes that research on the cancer burden of ethnic minorities and medically underserved populations must to the extent possible be woven into the full fabric of our research. There are times when studies should be and are within subgroups. But to segregate research this way would isolate the data we obtain; limit our ability to compare with the full population; and restrict our discovery of trends within subgroups that may only be discerned across the general population. There are very real statistical difficulties when study participation is small, so general population studies greatly improve our ability to decipher results across the various groups, so that all groups benefit from the knowledge we gain. In these large investigations, questions relevant to minority and other subgroup populations are encouraged and supported. Finally, integrated research provides efficient use of resources and higher quality of study design, as compared with conducting the same study for each subgroup. Larger, integrated research studies also have the benefit that compliance problems, which can be crippling in some studies, are not as critical to the study's outcome.

PRIORITY SETTING

Setting NCI's funding priorities is a complex and dynamic process driven by several principles. We recognize that we must support the full range of research activities necessary to confront cancer; therefore, we strive for a "balanced" portfolio of research. This balance must include attention to all of the distinct diseases we collectively refer to as cancer, and to all of the various populations that experience these diseases differently. NCI places a high value on the incorporation of scientific questions relevant to ethnic minority and medically underserved populations in the full spectrum of our research.

RESOURCE ALLOCATION

In 1997, NCI spent an estimated \$124,399,000 on minority research programs. Estimation of funding varies between clinical trials and investigator initiated research projects. Minority groups are proportionally represented in clinical trials and funding is estimated according to the accrual of the study population by racial/ethnic groups. This method may not always equate to a proportional benefit for the larger minority population from which the trial participants were drawn but has the benefit of being consistent across time periods and provides a measure that is comparable with other per capita measures of clinical trials. Investigator initiated research projects estimate funding according to each individual project's relevancy to minority health as determined by the project director and the Office of Special Populations Research. Although this method is highly susceptible to variability, it is felt to be a conservative measurement of NCI funding for minority health research because minority populations participate in many projects that are not considered minority research but require minority participation due to NIH requirements for racial/ethnic diversity.

STRATEGIC PLANNING

Contrary to the implication in the IOM report that NCI does not engage in strategic planning, I can state unequivocally that we have a very active, dynamic, and visionary planning process. The IOM committee was provided with copies of a document entitled "Priority Setting at the National Cancer Institute: A Summary Report Updated February 1998" which contains a detailed description of NCI's strategic planning process, as well as with copies of other documents relevant to planning such as reports from various groups reviewing NCI's major programs. We involve a very broad constituency of advisors, advocates, researchers, and practitioners in developing our plans. Further, the Bypass Budget serves as a two-year strategic plan, describing the areas of scientific advancement we believe merit funding to enhance research, training, and communications programs. It serves as our central planning document, laying out clearly our funding priorities. It represents the investment needed to take the next crucial steps toward the day when cancer is no longer a burden. We also do in-depth strategic planning in specific areas. For example, we recently completed development of our Tobacco Research Implementation Plan and the development of a Surveillance Implementation Plan is in progress.

NCI has a long history of making frequent use of extramural experts and advisors to determine its forward motion. There have, in fact, been three comprehensive reviews in the last two years that have recommended strategic initiatives relevant to research among ethnic minority and medically underserved populations. Recommendations from these groups have generated the creation of strategic implementation groups at NCI which have outlined strategies that are being followed in all of our programs.

Thus we have a different approach to strategic planning than envisioned by the IOM committee. Contrary to its assertion that because we explicitly plan for the issues of the unequal burden of cancer within the context of our overall planning, there is therefore no planning, we believe that our approach is a valid, honest and effective alternative to the approach it is calling for.

THE ROLE OF THE NCI OFFICE OF SPECIAL POPULATIONS RESEARCH

The Office of Special Populations Research advises the Director of NCI and serves as a focal point to provide leadership and coordination on research related to America's special populations. The Office coordinates NCI programs addressing scientific questions pertinent to minority and ethnic populations as well as the elderly, the medically underserved, rural and low-income groups. The Office works closely with other NIH Offices interested in the health and welfare of special populations. The expertise of individuals, scientific and lay, from the community is also being sought through the establishment of an NCI Special Populations Liaison Working Group.

This Office has also recently completed a summary report on research and program activities related to minorities and the underserved titled "NCI Initiatives for Special Populations 1998" which will be available the week of January 25, 1999 on the NCI website.

EVALUATION OF INFORMATION DISSEMINATION

The NCI plays a vital role in the dissemination of cancer research information/results to minority and underserved populations. Communications are carefully and strategically planned to achieve the following goals: dissemination of new research information for cancer prevention, screening, detection, and treatment to minority and medically underserved populations, health care providers, federal agencies, and the general public; and coordination of cross programmatic areas with other agencies (i.e., Centers for Disease Control and Prevention), while addressing concerns such as targeting low-literacy populations.

NCI achieves these goals through strategic communications planning, and integrates communications to minority and underserved populations within each of its overall efforts. NCI targets its audiences, uses appropriate dissemination channels for each audience, develops and disseminates appropriate messages and materials through mass media campaigns, and through partnerships with other federal and non-governmental agencies and organizations that have special access to the target audiences.

The NCI develops media and print materials designed for distribution to a variety of audiences to achieve objectives/goals set forth in the strategic plan. Some of these collateral materials are designed specially for minorities and the medically underserved and are often implemented as part of national campaigns. These materials support the main message of a campaign (for example, women over age 40 should have regular mammograms) but are designed to be used by community leaders to target populations including African Americans, Hispanics, Asians, and Native Americans.

Other collateral materials for minority populations include posters in English for African-American, Asian, and Native American women, and in Spanish, Vietnamese, Chinese, and Korean that encourage women to have mammograms. In addition, NCI developed a Pap test video for Native Americans, radio and television public service announcements encouraging African-American women to have mammograms, English and Spanish print public service announcements promoting good nutrition. NCI also contributed to a nationally syndicated Spanish radio show, hosted by Elmer Huerta, promoting breast and cervical cancer prevention and detection.

Printed and audiovisual materials that are easy-to-read, culturally appropriate or in Spanish are disseminated through the Cancer Information Service outreach program, through direct mailings to minority advocacy groups and partners, through minority media, and through national, state, and regional community-based health providers, cancer prevention experts, and health care professionals. Special media promotions are also conducted. One example is the effort to increase awareness about clinical trials by placing stories in the minority media. More recently, we have funded a number of investigators who are developing tailored health communications. Some of these investigators have designed materials tailored to specific variables, including ethnicity, income, and gender. Research shows that tailored materials used in a community health center dramatically increased smoking cessation among poor African Americans; decreased fat intake in a diverse population; increased mammography among African American women with incomes below \$26,000; and increased fruit and vegetable consumption among rural African Americans who participated in a church-based project.

CANCER INFORMATION SERVICE (CIS)

The CIS program has three interrelated components: (1) telephone service; (2) outreach aimed at providing cancer information to those who do not use the telephone to gather information (primarily minorities and other underserved audiences); and (3) cancer control research.

The CIS Outreach Program develops partnerships with nonprofit, private, and Government agencies, mostly at the local and regional levels. These local and regional partners have an established presence in their regions, are trusted within their communities, and are dedicated to serving minority and underserved populations.

Outreach staff respond to 100,000 requests by 4,500 organizations annually. Two-thirds of these CIS partners focus on reaching minority audiences.

More than three-quarters of CIS partners strive to reach medically underserved audiences.

In a 1996 survey of CIS partner organizations, over 90 percent rated the service provided by CIS to be important to meeting the goals of their projects.

In the next year, CIS will require that 80 percent of all contacts initiated by Outreach staff be with partners that work with minority and medically underserved populations.

The CIS is in the process of developing a comprehensive outreach evaluation plan which will better measure the impact of our efforts with partners serving diverse communities.

Through the CIS, we have tested new ways to encourage African Americans to call the CIS for help to quit smoking. These methods have included targeted radio outreach and have been effective.

PHYSICIAN DATA QUERY (PDQ)

Patients and health care professionals want and need access to accurate, up to date, comprehensive information about ongoing clinical trials. Through PDQ, NCI provides information about NCI-sponsored trials. PDQ presents information in both English and Spanish. It can be reached via a computer or fax machine. Information about clinical trials is also available through the CIS.

We are in the process of expanding the database, with the cooperation of patient advocates, the Food and Drug Administration (FDA), and the pharmaceutical industry, to include all cancer clinical trials approved by the FDA and to revamp the way information is presented. This system has served as a model for other institutes at the National Institutes of Health, and we want to ensure that it continues to be responsive to the needs of all of the communities we serve.

PATIENT EDUCATION ACTIVITIES

The National Cancer Institute's patient education programs are designed to enable cancer patients to make informed decisions about cancer care, deal effectively with cancer treatment, side effects, and recurrence, and adjust to a life with cancer. Because the medically underserved and minority populations must overcome both socioeconomic and cultural barriers to cancer information and treatment, as well as higher incidence rates, and often have more advanced disease at the time of diagnosis, special efforts have been made to ensure that the educational and informational needs of these groups are addressed by NCI's patient education programs.

Examples include:

Development of print and electronic informational resources for non-English speaking audiences, as well as groups with low literacy ability. Several of NCI's core patient education resources are available in Spanish, and plans are in development to produce Chemotherapy and You and Radiation Therapy and You in ten languages.

Testing and conduct of training for health professionals. A new NCI training program for health professionals, The Cancer Clinical Trials Education Program, was pilot tested with numerous minority audiences, and their input and feedback ensured that the program would meet the varied cultural, economic, and educational needs of diverse groups, including the suggestion and execution of slides for Asian-American, Hispanic, and African-American audiences. Involvement of these partners in the development of the program has resulted in programs that support the NCI's interest in increasing population diversity in clinical trials participation.

The Cancer Journey: Issues for Survivors, a training program for health professionals, includes a thirty-minute videotape of cancer survivors discussing the range of issues they faced from the time of their diagnosis through treatment and follow-up care. The videotape includes an ethnically diverse group of patients to assure that the program can be used by educators with multiple audiences. Initial feedback confirms that the program is being well-received.

CONSUMER RESEARCH AND EVALUATION

NCI always includes an evaluation component in its strategic communication planning efforts. Formative and process evaluation techniques, including focus groups, omnibus surveys, in-depth telephone interviews, and bounce-back card analysis allow NCI to gauge the knowledge, attitudes, and behaviors of minority and underserved audiences in order to focus program efforts and develop effective messages.

SEEKING INPUT FOR NCI ACTIVITIES

NCI actively reaches out to receive input on research programs and its overall research agenda from affected minority and medically underserved communities, their health providers, and advocates.

For example, the NCI Director's Consumer Liaison Group (DCLG), multicultural in its membership, helps NCI involve advocates from minority organizations and representatives of underserved populations in a variety of NCI activities. One of the DCLG's activities was to involve such advocates and representatives in a number of advisory and working groups at NCI. These included the Clinical Trials Implementation Group and the Progress Review Groups, which assist in defining and prioritizing the national research agenda for particular cancer sites, including breast, prostate and lung cancers.

CONCLUSION

The NCI must, as I have said, written and acted on, address the questions of the unequal burden of cancer. To act on the many excellent recommendations will require additional resources. It is important to remember that the root of the unequal burden of cancer is, in part, a reflection of unequal resources, access, power and opportunities in our society. Ultimately, this unequal burden will only be readdressed by taking responsibility to correct both historic and persistent inequities. I say this not to shirk responsibility, but to reinforce the IOM committee's position that NCI alone will not solve the question. We have been and are committed to better addressing our responsibilities, as outlined earlier in my remarks, relevant to reducing the unequal burden of cancer.

I will be happy to answer any questions.

SUMMARY STATEMENT OF DR. OTIS BRAWLEY

Senator SPECTER. We turn now to Dr. Otis Brawley, Assistant Director of the Office of Special Populations Research at the National Cancer Institute, a commissioned officer of the U.S. Public Health Service, and a member of the American Prostate Cancer Committee. He received his medical degree from the University of Chicago.

Welcome, Dr. Brawley, and the floor is yours.

Dr. BRAWLEY. Thank you. I will try to be very brief.

I just want to point out that there are issues here of what is relevant research to minorities and the underserved and what is research that is specific to minorities and the underserved, and that is an issue that perhaps we can talk about a little bit more.

I would contend that the most relevant research to a Hispanic or a black woman who may get cancer in the next 10 or 15 years is for the National Cancer Institute to do the research which is going to lead to the best treatment, best diagnosis, and perhaps best prevention of that cancer. And indeed, the best research for that Hispanic or black individual is the same as the best research for a white individual who might be in the same circumstances.

One of the things that we worry about when we look at budget issues that are very specific or very relevant is we are very concerned that we are segregating minority research into one particular area of the institute. We work very hard to integrate minority research into every program within the Cancer Institute.

And I will close by pointing out that there is an element of the IOM document which was very important to me and I think needs to have shed a little bit more light on. Some of the most important research that we at the Cancer Institute have conducted is research that shows that equal treatment yields equal outcome and race is not a factor in that outcome. Some of the most important

research we have also done are patterns of care studies to show that there is not equal treatment in the United States.

PREPARED STATEMENT

There is a substantial number of minority individuals, be they black, Hispanic, or poor white, who do not get adequate treatment. And as the IOM report pointed out, that is, a social question to be addressed beyond the purview of the National Cancer Institute, and that is how we ultimately will bring decreases in cancer mortality amongst minorities as we have seen dramatic decreases in the last 5 years in the majority population.

I will stop at that point.

Senator SPECTER. Thank you very much, Dr. Brawley.

[The statement follows:]

PREPARED STATEMENT OF OTIS W. BRAWLEY, M.D.

I thank you for the opportunity to appear here. I wish to briefly add just a few things after Dr. Klausner's opening statement. It is my belief that the most relevant research to a Black or Hispanic person who might develop cancer in the future is research aimed at developing optimal prevention, detection, and treatment of the disease. We all need to appreciate that the same research, most relevant to that Black or Hispanic person, is also the most relevant research to a white or majority person. I wish to note some of the most important research that the National Cancer Institute has sponsored shows that equal treatment yields equal outcome regardless of race. That is to say that race is not a factor in outcome when optimal treatment is given. Indeed, Congress said this was a question relevant to minority health in the NIH Revitalization of 1993. Other very important NCI sponsored patterns of care studies show that there is not equal treatment. Blacks, Hispanics and primarily the poor are more likely to get less optimal therapy. This body of data has been developed by the NCI over the past ten years. Half of the mortality difference between Black and White women in breast cancer is directly related to a larger proportion of Black women receiving less than optimal medical care. The IOM study clearly states that the decline in mortality that has recently been seen in some American populations is due to improvements in screening, diagnosis, and treatment. Improvements developed in research that the NCI has largely sponsored. An important fact that I hope is not overshadowed is that a large proportion of the problem in minority health is people not getting this optimal care. This is not an issue just for the NCI, it is a societal issue. In coding research, there are a number of projects that include people of all races and ethnicities with cancer but have particular relevance to an ethnic minority that is disproportionately affected by that cancer. The Cancer institute reported that it spent 124 million dollars in supporting minority participation in projects relevant to minority health. I want to point out there is a difference in research relevant to minority health versus research targeted to minority health. There are specific projects that are targeted to a specific question pertinent to a minority population. The NCI calculated its spending on projects targeted to minority health as 43.9 million dollars among 127 projects. I am amazed that the IOM developed an estimate of 24 million dollars and that they chose to compare it to the 124 million dollars in relevant funding. Again I thank you for the opportunity to appear and discuss this study on this important topic.

ETHNIC MINORITIES PRONE TO CERTAIN CANCERS

Senator SPECTER. I began with a threshold question and that is the question as to why some ethnic minorities are more prone to certain cancers. The explanation given here about the consequences of a finding less likely to survive those cancers is understandable in terms of access to medical care, to diagnosis, and to treatment. But starting at the very base, what is the explanation, if one is available, as to why ethnic minorities are more prone in the first place to have certain kinds of cancers. Dr. Haynes, would you care to respond to that?

Dr. HAYNES. Yes; I will be happy to respond to that.

We do not know all of the answers. In fact, this is the reason why this research is so important.

What we do know, however—and this is not confined to minorities—is that cancer is strongly related to a lifestyle, diet, and these factors are most likely the important factors. And this is one of the main reasons why the committee emphasizes emphasis on ethnic groups' behavior, lifestyle, rather than on race.

Senator SPECTER. The study discloses that African American men, illustratively, had unusually high rates of prostate cancer. Dr. Haynes would that be related to diet, lifestyle? Or tell me how it might be.

Dr. HAYNES. It could be. If indeed there are things in our diet, which we do not always understand—in fact, we know very little about nutrition and its role in cancer. We know about diet in general but not about the nutrients in the diet. It is entirely possible, and that is the reason why we should be studying why is the rate so low in the Chinese Americans and so high in the African Americans.

Senator SPECTER. Will you repeat that last statement please?

Dr. HAYNES. Why is the mortality from prostate cancer so low in Chinese Americans and so high in African Americans. These kinds of studies we think will throw a great deal of light to answer questions which we cannot now fully answer. I believe that the institute agrees with that.

Senator SPECTER. And another finding of a similar generalized nature, people of Asian descent are more likely to develop stomach and liver cancer than whites. Dr. Klausner, let me direct the question to you as to an explanation. Anything beyond what Dr. Haynes has said?

Dr. KLAUSNER. Well, yes. Probably for liver cancer and also nasopharyngeal cancer, which is another relatively common cancer in the Asian population, relatively rare in the American Caucasian population, relates to exposure to viruses, hepatitis B, other hepatitis viruses and Epstein-Barr virus for the nasopharyngeal cancer.

So, the issue, of course, is as Dr. Haynes said. Exposures, lifestyle, diet, and all of its complexity, which is the target of much of our research, is illustrated by these very different patterns of cancer—not only overall cancer but each individual cancer. The patterns of cancer are different and much of this can be related, for example, to geographic origin or different ethnic groups because of the association of behaviors, diet, et cetera, and often occupational exposures that are differentially distributed among different groups. All of these things are being looked at.

For some we have answers. For others we do not.

Senator SPECTER. Could you amplify why the geographic factor would be relevant?

Dr. KLAUSNER. Well, again, especially for geographic factors, countries of origin are important because there are different patterns of exposure to infectious agents which we do not talk about that much in terms of cancer but worldwide have a significant impact on the incidence of specific cancers, such as liver cancer, head and neck cancer, cancers of the immune system, and others. So, that is one aspect.

Another, of course, is that different geographic areas are associated with different dietary habits, different exposures, et cetera. And that is why our epidemiologic research often looks at exposures in the broad sense across different areas of the world to try to get at those variables.

Dr. BRAWLEY. If I might add to that, sir. I do primarily prostate cancer work. One of the theories that is currently being investigated looking at why people in Scandinavia have high rates of prostate cancer versus people in the lower regions of Europe, is looking at vitamin D metabolism which is directly related to sun exposure or lack of sun exposure during long winters. And vitamin D metabolism and calcium metabolism may have something to do with prostate cancer.

Now, that research is being done in Scandinavians, but it also has tremendous relevance to blacks who get prostate cancer in the United States in terms of eliciting mechanisms of carcinogenesis.

Senator SPECTER. What about the genetic factor? Perhaps that is implicit if not explicit in what you have already testified to here, gentlemen. I note from time to time that Ashkenazi Jews, for example, have certain kinds of ailments that seem to pass down generation to generation. To what extent is that a factor, Dr. Brawley?

Dr. BRAWLEY. Well, it clearly is a factor. In the instance of prostate cancer, we do not know exactly how much yet. We have been looking at that.

I prefer to think of these things as more familial as opposed to more racial. I would think of them as things that occur in families that tend to be Ashkenazi Jewish in your example or families that tend to be black because, especially as we get more interracial and intercultural, the genes that cause these diseases are not necessarily going to be correlated with skin color.

Senator SPECTER. Well, Ashkenazi Jews, for example, are much broader than a family, as are African Americans, a whole race.

Dr. Klausner, I see you straining at the bit. [Laughter.]

Dr. KLAUSNER. Well, we do know something about that that would be interesting, and that is, while Ashkenazi Jews represent people that come from a broad area of Europe, it appears that about 1,000 years ago all of the Ashkenazi Jews currently in the world could trace their descent from a very limited number of people, perhaps about 1,000 or a few thousand. That type of historical bottleneck—

Senator SPECTER. Where did they start from? Ukraine?

Dr. KLAUSNER. No; I think this was actually more in western Europe. Then they moved to Germany, which is where the name Ashkenazi comes from, and later moved further east into Ukraine, Lithuania, Poland, and those areas.

Senator SPECTER. Someone would leave Germany to go to Ukraine? [Laughter.]

Dr. KLAUSNER. It was a lot different then.

Senator SPECTER. My father came from Ukraine. I do not think he had any options. [Laughter.]

Let me go to a very tender point, having started with lesser tender points, and that is the amount of money devoted here. My briefing materials tell me that NCI reports \$124 million allocated to research and training for ethnic minorities and underserved

groups in fiscal year 1997 while the IOM believes the actual figure is only \$24 million. Let us start with you, Dr. Haynes.

Dr. HAYNES. Yes; that is the issue which I mentioned on which there was only partial agreement.

Senator SPECTER. Where is the partial agreement? On the \$24 million? [Laughter.]

There is disagreement on the \$100 million? I would not call that partial agreement, but go ahead.

Dr. HAYNES. NCI accounts for research on minorities in two categories. In category one is the research that is specifically directed toward minorities. In category two, it is general research in which minorities may be included, and in that case they allocate on the basis of the percentage of the population in those studies.

We state that allocation on that basis is not the best way to approach the problem. A better way to approach the problem would be on the research question that is involved. Then the allocation can be made on that basis. If indeed there is a research study of a general population and minorities are involved, why not be able to say that as a result of that study, the way it is designed, you should be able to answer questions about minority populations. And I believe we agree on that.

Dr. KLAUSNER. Yes.

Dr. HAYNES. But somehow when we make that statement, it gets confused with the idea of segregating research. We are not recommending that research be segregated. We are recommending that research be done across and within ethnic groups; that is, you compare various ethnic groups, but then within a large macro-ethnic group, you look at subgroups. And there are times when you would do one kind of research, there are other times when you do both. And we are not trying to segregate the research. So, that is the confusion that has arisen about our criticism.

Senator SPECTER. Well, I did not follow all of your answer, but let me focus back in on \$124 million versus \$24 million. Do you stand by that kind of divergence, that you think NCI has only spent \$24 million on this particular line?

Dr. HAYNES. What we are saying is it is clear about the \$24 million. The rest of it is not clear if it is based merely on the proportion of people in the study. We want to know was the study designed in such a way that it can, indeed, give you an answer to questions about minority populations.

Senator SPECTER. Dr. Klausner, so what is your evidence that you spent \$124 million for ethnic research and underserved people?

Dr. KLAUSNER. Well, we provided all of that data. Let me give an example of what we code in terms of partial—

Senator SPECTER. You say you supplied all that data?

Dr. KLAUSNER. Yes; to the IOM committee, and obviously there is a difference of agreement.

Let me give you an example of a study that we code as partial, not 100 percent. There is something called the prostate cancer outcome study. It is a large community-based study that is trying to understand the differences in detection, diagnosis, and treatment patterns across different groups, different populations. Within that, we are asking explicit questions about the difference in treatment among whites, Hispanic men, and African American men.

We calculate that about 10 to 20 percent of the total cost of the project is aimed at directly answering questions about the different burden of cancer. That is an example of partial funding which would not be allowed in the accounting of the IOM and so is above the \$24 million. The majority of the difference between the \$24 million and the \$124 million—not all of it—is exactly these projects where pieces of the projects are aimed specifically at addressing the questions, we think, relevant to the unequal burden of cancer.

Senator SPECTER. How much of the balance of \$100 million could be accounted for in that way?

Dr. KLAUSNER. Well, in terms of the issue of just counting based upon the fraction of minorities that participate, for example, in clinical trials, that total amount would be \$18 million, which would then be a difference of the \$124 million. But even there, of the \$18 million from our clinical trials, only about half of that would come from accounting based upon looking at proportional representation within treatment trials. A lot of that is specifically within our clinical trials aimed at efforts to increase the accrual of minorities and underserved and efforts to ask specific questions.

So, my understanding in looking at our portfolio and our analysis is that the majority of that difference does represent direct investments aimed at the issues raised by the IOM report.

Perhaps Dr. Brawley can—

Dr. BRAWLEY. Yes; we are answering two questions here. One is research relevant to minorities, which is what the \$124 million is, and the second is research directed specifically at research questions related to minorities.

Now, we answered to the relevancy with the \$124 million. Actually I have here a copy of a document that we provided to the IOM senior staff, and if you would like to look in the boxes of data provided to the IOM, you will find it. In 1997, we said that we had \$43.9 million through 127 projects and we provided a synopsis of each one of the 127 projects that was directed specifically at minorities. So, indeed, I think the question is why we said \$43.9 million and they said \$24 million, and not why we said \$124 million and they said \$24 million.

Senator SPECTER. Dr. Haynes, what is your evaluation of that explanation?

Dr. HAYNES. Our evaluation is that it would be better for NCI—incidentally, this is not only the National Cancer Institute. It is our understanding that NIH does this all the time. It is an easy way of giving an answer to the question, and I am not sure whether it is a question you want answered, but it is an easy way of addressing the question.

We think it would be better to do what Dr. Klausner just did, to analyze the design of the study to determine whether it was specifically determined by that study that you could answer some questions about minorities.

Senator SPECTER. Well, this is a very fundamental question as to resource allocation, and the Congress has been very generous with the National Institutes of Health in recent years, adding some \$2 billion last year. And I want to get to the bottom of it. I want your evaluation specifically, and we will follow up with staff, as to what resources are being allocated because on our oversight function, we

want to be sure that minorities and underserved are fairly treated, and there is a big gap between \$24 million having been expended and \$124 million.

Now, Dr. Klausner is contending essentially that the money is under a different umbrella but it is being directed to minorities and underserved. But I would like to examine that, and it may be that it could be directed more specifically to those groups. You have made a very detailed study, and let us really find out what the facts are.

Senator Harkin, the ranking member, is in a party caucus himself at this time. He otherwise would have been here.

We have been joined by our very distinguished chairman of the full appropriations committee, Senator Stevens. Senator Stevens, would you care to make a statement or ask a question?

Senator STEVENS. Well, I am sorry to be late. I had some meetings also.

But I am delighted you are having this oversight, and I think that we should have more oversight before we get around to allocating funds this year. I am really very interested in the recommendations of the Institute of Medicine, but I am also looking forward to meeting with Dr. Klausner about just the overall allocations of NCI.

It does seem to me, as a cancer survivor, there is little information out there for survivors. Those people who really need the help more than any are those that are uninsured and those in the lower income brackets because they just do not have the networks that are out there to assist the others.

We have a network around here. Bob Dole heads it. If Dole gets any information, he shares it with everybody. I am literally congratulating him for that, not making a pun.

I believe there are not enough systems that think about the survivors. I will be very interested in the comments that you receive from the Institute of Medicine.

I also think that we have to find some way to coordinate this research. As I travel around, Mr. Chairman, I find there is a great deal of redundancy in the research that is being done in the cancer area. I believe there ought to be a better way to allocate those funds to target what appears to be areas of potential breakthrough in terms of the research patterns.

I congratulate you for holding this hearing. I represent, as you know, a State that is made up of minorities. Most people do not realize that. We really do not have a majority population in Alaska. We have a series of minorities, Alaska natives and blacks, and a great many of the families from the Pacific Rim, the Asian groups, have come to Alaska. So, we have a series of minorities. We have a series of very distinct problems in a small population base with an enormous area to deal with.

I look forward to working with you and appreciate your having this hearing, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Stevens.

Well, thank you very much, gentlemen. We will be pursuing the many questions and I know the National Cancer Institute will be replying in some greater detail to the findings that you have made, Dr. Haynes. I think it is a very, very significant step forward, and

we ought to be devoting substantial resources to minorities and underserved people because they do have less access, and if there is going to be an imbalance here, we ought to err a little bit on the side of serving people who are unable to serve themselves with their own resources. So, thank you very much.

SUMMARY STATEMENT OF DR. LOUIS SULLIVAN

Senator SPECTER. We will now turn to the second panel, Dr. Louis Sullivan and Dr. Armin Weinberg.

Dr. Sullivan comes to the subcommittee, having been here on many, many occasions in his capacity as Secretary of Health and Human Services where he performed great assistance to the Bush administration. He is President of the Morehouse School of Medicine in Atlanta since January 1993, a member of numerous medical organizations, and the founding President of the Association of Minority Health Professionals Schools. Welcome again, Dr. Sullivan, and we look forward to your testimony.

Dr. SULLIVAN. Thank you very much, Senator Specter, Senator Stevens. It is a pleasure to be here before you this morning and I certainly had a great experience during my time here in Washington. Certainly I am pleased with your continued interest and support for improving the health of the American people.

I want to comment on the report from the Institute of Medicine that is under discussion today. I want to begin by congratulating Dr. Haynes and the members of the committee that is looking at the issue of cancer among minorities and the medically underserved. I believe they have done a tremendous service to our Nation through this landmark report.

Mr. Chairman, as President of the Morehouse School of Medicine and as principal investigator of the National Black Leadership Initiative on Cancer and as former Secretary of Health and Human Services, I have spent a great deal of time addressing the issue of cancer in ethnic minorities and in medically underserved populations.

It is my hope that the findings of the IOM study will prompt NIH officials, researchers, and policymakers to strengthen NIH's biomedical research and surveillance programs focused not only on cancer but on other diseases as well which disproportionately impact our Nation's minority communities.

All of us recognize NIH as the premier biomedical research organization in the world. Indeed, the NIH is at the forefront of unprecedented breakthroughs in the fight against disease and disability as we approach the next millennium. But as the report from the Institute of Medicine shows, NIH needs to reevaluate its cancer research portfolio in order to adequately address the higher death rates from cancer in our Nation's minority and underserved populations.

Several of the study's findings reinforce what many of us have known for many years, and that is the culture, the structure, and the programs of the National Cancer Institute and NIH as a whole serve the white population well, but fall far short in addressing the needs of the Nation's ethnic minorities. This is frustrating, Mr. Chairman, because ethnic minorities represent the fastest growing

segment of our population, and as you are already aware, they suffer a disproportionate burden of disease and disability.

As you have already been discussing, one of the findings of particular importance is that only 1 percent of the Cancer Institute's budget is allocated for research and training programs focused on the Nation's ethnic minorities and medically underserved groups.

Now, this finding from IOM is consistent with an article published 6 years ago in the Chronicle of Higher Education in 1993 that demonstrated that less than 1 percent of the funding at NIH was dedicated either to African American researchers or African American institutions. And although that number may be subject to some debate—and there is always disagreement, as you have already heard earlier this morning. I will be pleased to comment on that—it clearly demonstrates that much more needs to be done to address the needs of the Nation's minority citizens.

I am also concerned that targeted programs which have been put into place to reverse this trend such as NCI's Office of Special Populations Research that Dr. Brawley serves, as well as the NIH-wide Office of Research on Minority Health in the Director's Office, these offices have not been given the resources nor the authority they need to have a significant impact on the research direction of NCI or NIH overall.

For example, the Office of Research on Minority Health was established during my tenure as U.S. Secretary of Health and Human Services. This was done in part to leverage NCI and the other institutes' resources to expand the focus on minority health research. That was almost 10 years ago, and as we look back, it appears that funding of this office has been used to supplant the modest resources available from the individual institutes at NIH for research focused on areas of particular need for the Nation's minority citizens. That was not the intent when these programs and this office was established.

Mr. Chairman, what is needed is an exponential leap forward in the orientation of NIH officials with respect to their approach to ethnic minorities and underserved communities. To that end, the IOM study recommends the establishment and the implementation of a strategic plan to address the cancer survivorship needs of ethnic minority and underserved groups. I agree with that recommendation and strongly believe that this effort should be led by the Office of Research on Minority Health.

To facilitate this undertaking, I believe that this office should be elevated to center status, the same way that a year ago the Office of Alternative Medicine was elevated to the Center for Complementary and Alternative Medicine.

It is also important that the new center's budget be significantly increased. This would provide the Office for Research on Minority Health with the necessary organization and resources to assume a leadership role in developing a strategic plan for minority health research across NIH. It would also enable this office to make grants on its own budget for important minority health research projects without having to go through existing research institutes which in my view have not demonstrated sufficient leadership in this area.

PREPARED STATEMENT

Mr. Chairman, the NCI Office of Special Populations can also play an important role in expanding cancer research, surveillance, and awareness among ethnic minorities and underserved populations if it is given the authority to coordinate and leverage program activity at NCI. Without the authority to help set priorities, to fund programs of special benefit to minorities, and to hold other NCI divisions accountable for supporting minority research activities, I am not convinced that much will change. Simply stated, if we are to see meaningful change from what exists today rather than continued benign neglect, bold steps are necessary.

Thank you for the opportunity to present my views on this issue, and I look forward to your questions.

Senator SPECTER. Thank you very much, Dr. Sullivan.
[The statement follows:]

PREPARED STATEMENT OF DR. LOUIS W. SULLIVAN

Mr. Chairman and members of the subcommittee, please allow me to thank you for this opportunity to present my views on the Institute of Medicine's report, *The Unequal Burden of Cancer: an Assessment of NIH Research and Programs for Ethnic Minorities and the Medically Underserved*.

I would first like to congratulate Dr. Alfred Haynes for his leadership in chairing the Committee on Cancer Research Among Minorities and the Medically Underserved. Dr. Haynes and his colleagues have done a tremendous service to our nation through their work on this landmark report.

Mr. Chairman, as president of the Morehouse School of Medicine in Atlanta, principal investigator for the National Black Leadership Initiative on Cancer (NBLIC), and former secretary of the U.S. Department of Health and Human Services, I have spent a great deal of time addressing the issue of cancer in ethnic minorities and medically-underserved populations. It is my hope that the findings of the IOM study will prompt NIH officials, researchers, and policymakers to strengthen NIH's biomedical research and surveillance programs focused not only on cancer but other diseases as well which disproportionately impact minorities.

I believe that all of us recognize NIH as the premier biomedical research organization in the world today. Indeed, NIH is at the forefront of unprecedented breakthroughs in the fight against disease and disability as we enter the new millennium. However, as the IOM report shows, NIH needs to re-evaluate its cancer research portfolio in order to adequately address the higher death rates from cancer in minority and underserved populations.

Several of the study's findings reinforce what many of us have known for years—that the culture, structure and programs of the National Cancer Institute (NCI) and NIH as a whole serve the white population well, but fall short in addressing the needs of ethnic minorities. This is frustrating, Mr. Chairman, because ethnic minorities represent the fastest growing segment of the U.S. population and suffer a disproportionately high burden of disease and disability.

One of the study's findings of particular concern is that only about 1 percent of the National Cancer Institute's budget is allocated for research and training programs focused on the nation's ethnic minorities and medically underserved groups. This finding is consistent with an article published in the *Chronicle of Higher Education* in 1993, which demonstrated that less than 1 percent of NIH funding was dedicated to African American researchers or African American institutions. Although that number may be subject to some debate, it clearly demonstrates that much more needs to be done to address the needs of the nation's minority citizens.

I am also concerned that targeted programs which have been put in place to reverse this trend, such as NCI's Office of Special Populations Research and the NIH-wide Office of Research on Minority Health (ORMH), have not been given the resources nor the authority they need to have a significant impact on the research direction of NCI or NIH overall. For example, ORMH was established during my tenure as secretary of the Department of Health and Human Services, in part to leverage NCI and other institutes' resources to expand the focus on minority health research. Instead, it appears that ORMH funding has been used to supplant the modest resources available from individual institutes for research focused on areas

of particular need for the nation's minority citizens. Clearly, that was not the intent when these programs were established.

Mr. Chairman, what is needed is an exponential leap forward in the orientation of NIH officials with respect to their approach to ethnic populations and underserved communities. To that end, the IOM study recommends the establishment and implementation of a strategic plan to address the cancer survivorship needs of ethnic minority and underserved groups. I agree with this recommendation and strongly believe that this effort should be led by the Office of Research on Minority Health.

To facilitate this undertaking, I believe that ORMH should be elevated to "center status", in the same way that the Office of Alternative Medicine was recently elevated to the Center for Complementary and Alternative Medicine. It is also important that the new center's budget be significantly increased. This would provide ORMH with the necessary organization and resources to assume a leadership role in developing a strategic plan for minority health research across NIH. It would also enable ORMH to make grants from its own budget for important minority health research projects without having to go through the existing institutes, which have not demonstrated sufficient leadership in this area.

Mr. Chairman, the NCI Office of Special Populations can also play an important role in expanding cancer research, surveillance, and awareness among ethnic minorities and underserved populations if it is given the authority to coordinate and leverage program activity at NCI. Without the authority to help set priorities, to fund programs of special benefit to minorities, and to hold other NCI divisions accountable for supporting minority research activities, I am not convinced that much will change. Simply stated, if we are to see meaningful change, rather than continued benign neglect, bold steps are necessary.

Mr. Chairman, thank you for the opportunity to present my views on this important issue. Again, I offer my congratulations to Dr. Haynes and his colleagues. I will be pleased to respond to any questions that you may have.

SUMMARY STATEMENT OF DR. ARMIN WEINBERG

Senator SPECTER. We turn now to Dr. Armin Weinberg, cochair of the—

Senator STEVENS. Sorry, Dr. Weinberg. I have got to go.

Senator SPECTER. Dr. Armin Weinberg is cochair of the Intercultural Cancer Council; Director of the Center for Cancer Control Research at Baylor College of Medicine. He received his Ph.D. in anatomy at Ohio State University and is a member of a special review committee on breast cancer education initiatives at NIH.

Thank you for joining us, Dr. Weinberg, and we look forward to your testimony.

Dr. WEINBERG. Thank you very much, Senator.

With your permission, I will ask that my entire statement be submitted for the hearing record, and in the interest of time, I will try and—

Senator SPECTER. The full statement will be part of the record, and we look forward to your summary.

Dr. WEINBERG. OK.

I would like to say that I am presenting this report on behalf of the Intercultural Cancer Council and my cochair, Dr. Lovell Jones, who is also here with me, from the M.D. Anderson Cancer Center. We appreciate the opportunity to be here today.

The ICC, the Intercultural Cancer Council, is the Nation's largest cancer coalition addressing the tragic disparities in the incidence and mortality rates in the ethnic minority and medically underserved communities, which, by the way, includes respective survivors from each of those communities.

The ICC commends your leadership. Your directive launching the IOM report required for the first time the NIH's accountability in how it establishes and measures its ethnic minority and medically

underserved research commitment. We urge the report be used as a springboard to launch a more constructive and focused national effort.

The IOM deserves many thanks for the fine work led by Dr. Alfred Haynes, the committee, and the IOM study staff. While the report acknowledges the triumphs and commitments of the NIH and the NCI, it also correctly identifies current areas of deficiency which must be addressed. The study, we believe, creates a wonderful opportunity for the interested cancer community, including the NIH, as well as the Centers of Disease Control and Prevention, and other public and private sector organizations, to look for better solutions as we approach the millennium.

The ICC's No. 1 recommendation today to the appropriations committee is to ensure that NIH and NCI undertake the necessary steps to implement the IOM recommendations without delay. Expeditiously, the agency must develop an implementation plan that addresses these recommendations. It must, I think, commit itself to be accountable for achieving the outcomes and results envisioned in the recommendations. It must develop and adhere to a reasonable but expeditious timetable for genuine systemic and cultural change, and secure adequate funding resources necessary to address priority areas such as research training, cancer surveillance, and database enhancements.

The changes called for in the study require substantial dollars and a significant retooling of the agency culture and priorities. We urge Congress to require the General Accounting Office to undertake periodic independent and objective assessments of the progress in this area. In fact, the Congress must hold all of us accountable to solving the problems and eliminating the inadequacies identified in this benchmark report. It is an investment we cannot afford to postpone. These groups are the fastest growing population in the United States and will represent the majority in the millennium. Ignoring these demographics is myopic and injurious to our long-term and national domestic interests.

While all the IOM findings are significant, we specifically call the committee's particular attention to the box summary committee findings found on pages 3 to 5 in the IOM summary report. We would like to focus immediate concern on a couple of things.

The first is the issue of NCI and the parent organization having no blueprint or strategic plan to direct or coordinate research among these minority and underserved populations. This does need to be addressed.

The second point is that even though the budget that was discussed by you so aptly and Dr. Klausner and Dr. Haynes was well founded. Either way, whether it is \$124 million or \$24 million, it is still too small. It is too little given the amount of money that we have available to spend in this area.

With regard to the discrepancies, I will be happy to comment, if we have time, further.

Another factor which we would like to mention is that we were disappointed to see that the Minority Health Initiative funding, under the Office of Minority Research mentioned by Dr. Sullivan, appears to have been supplanted rather than leveraged in its use in many instances.

Regarding the necessary database to monitor these activities, SEER is a fine database for giving us a national snapshot, but it has a blind spot that does not address the people of our constituencies. While we support the IOM recommendations, we must clarify for the record today that the Centers for Disease Control and Prevention is responsible by statute for establishing population-based registries. We urge the CDC to accelerate its efforts to improve the quality of this program. We recognize that this is a relatively new program that remains sorely underfunded. And just as we urge you in the Congress to increase SEER funding, we urge Congress to increase funding substantially for the Centers for Disease Control's registry effort.

Regarding defining race and ethnicity, although we agree that there is no longer a biological basis for race, it should not be misunderstood to suggest the absence of a need for targeted studies. In fact, quite the opposite. It represents a substantial need to do it.

Regarding research training, all I can say is that long-term stable funding for research must receive highest priority. Clearly, no 21st century solutions to this problem can be achieved without adequate involvement of minority researchers and health care providers at all levels.

Mr. Chairman, we support the NCI and NIH research missions and the substantial increases that are proposed from the Federal Government's renewed war on cancer. But any such funding increases must place a priority on addressing the disparate burden cancer presents to ethnic minority and medically underserved populations.

In closing, we would confirm that the ICC agree that the war on cancer must be fought and won across Federal Departments and agency lines. Your committee and the Senate Cancer Coalition recognize the challenges here. We believe that it is time to designate a highly visible, national coordinating entity.

PREPARED STATEMENT

In closing, we cannot allow this study to be shelved—

Senator SPECTER. Is this your final closing, Dr. Weinberg?

Dr. WEINBERG. It is. It is. Thank you. I am sorry for that too.

We cannot allow the study to be shelved. Instead of burying any bad news it contains, it must be utilized as a baseline framework against which we measure future progress and enhance accountability.

[The statement follows:]

PREPARED STATEMENT OF DR. ARMIN D. WEINBERG

Good morning. I am Dr. Armin D. Weinberg, Co-Chair of the Intercultural Cancer Council and Director of the Center for Cancer Control Research at Baylor College of Medicine. I also want to introduce the ICC Co-Chair, Dr. Lovell A. Jones, Professor and Director, Experimental Gynecology-Endocrinology at the University of Texas M.D. Anderson Cancer Center in Houston, Texas. We appreciate the opportunity to be here today on behalf of the Intercultural Cancer Council (ICC). The ICC is the nation's largest cancer coalition addressing the tragic disparities in incidence and mortality rates in the ethnic minority and the medically underserved communities.

Mr. Chairman, the ICC commends your leadership in initiating the Institute of Medicine (IOM) Study to assess the programs of research at the National Institutes

of Health (NIH) relevant to ethnic minority and medically underserved populations. Chairman Specter, you and your staff recognized several years ago that ethnic minorities and medically underserved populations frequently experience a disproportionately greater burden of cancer. Your directive launching the IOM report required, for the first time, the NIH's accountability in how it establishes and measures its ethnic minority and medically underserved research commitment.

We applaud you and your staff for immediately focusing on the IOM's findings with today's timely hearing. We urge the Congress and the Clinton Administration to use the IOM report as a springboard to launch a more constructive and focused national effort to address the disparate impact of cancer on ethnic minorities and the medically underserved.

The IOM deserves kudos for the one work of Dr. Alfred Haynes' Committee on Cancer Research Among Minorities and the Medically Underserved (IOM Committee) and the IOM's study staff. What this group produced is a long needed, independent assessment and baseline report from which future progress can be measured in a number of significant areas. The IOM Committee's challenging task has cut across institute and agency lines. While the report acknowledges the triumphs and commitment of the NIH and National Cancer Institute (NCI), it also correctly identifies current areas of deficiency—in the cancer program generally and minority cancer research arena specifically—which must be addressed to tackle effectively the cancer burden among ethnic minorities and the medically underserved.

The IOM Study creates a wonderful opportunity for the interested cancer community—including the NIH and NCI, as well as the Centers for Disease Control and Prevention and other public and private sector organizations—to look for better solutions as we approach the millennium. In testifying here today, Mr. Chairman, the ICC pledges to do everything we can to work with you, the NIH and NCI, and our private sector partners to assist in tackling the challenges ahead. The ICC's number one recommendation is that the Appropriations Committees ensure that NIH and NCI undertake the necessary steps to implement the IOM recommendations without delay. The agency must:

- Expediently develop an implementation plan to address the specific IOM recommendations;
- Commit itself to be accountable for achieving the outcomes and results envisioned in the IOM recommendations;
- Develop and adhere to a reasonable but expeditious timetable for genuine systemic and cultural change; and
- Secure adequate resources necessary to address priorities identified by the IOM, such as research training, cancer surveillance and database enhancements.

Everyone must recognize that the changes called for in this study require substantial dollars and a significant retooling of agency culture and priorities. In fact, the Congress must hold all of us accountable for solving the problems and eliminating inadequacies identified in this benchmark report.

While implementation of many IOM recommendations will require a significant investment of federal dollars, this is an investment that we cannot afford to postpone. Ethnic minority and medically underserved groups are the fastest growing populations in the United States. These populations will represent the majority in the millennium. We owe it to our nation and to these population groups to reverse the disastrous trends and cancer burdens in these communities. Ignoring these demographics is myopic and injurious to our long-term and national domestic interests.

While all the IOM findings are significant, we specifically call the Committee's particular attention to the "Box" Summary of Committee Findings found on pages 3–5 of the IOM "Summary" of its report entitled "The Unequal Burden of Cancer." We would like to focus on three areas of immediate concern:

- NCI and its organization, The National Institute of Health, have "no blueprint or strategic plan to direct or coordinate" research on cancer among ethnic minority and underserved populations.
- NCI actually spent only about 1 percent of its budget—about \$24 million—on research concerning ethnic minorities and underserved populations, while NCI had claimed to have spent \$124 million in 1997. Even if its claims were correct, that would represent only 5 percent of NCI's budget, obviously not nearly enough to effectively address the research needs of these groups.
- The NCI "lacks the necessary database concerning the disproportionate cancer incidence, mortality and survival rates among ethnic minorities and the medically underserved that would permit it to develop and evaluate effective cancer control strategies for these populations."

LACK OF STRATEGIC PLAN

No blueprint or strategic plan to direct or coordinate NIH's and NCI's ethnic minority and medically underserved cancer research activity appears to exist. Furthermore, overall funding to address the needs of ethnic minority and medically underserved populations is woefully inadequate. The agency must develop a game plan to address and measure its progress in the ethnic minority and medically underserved cancer arena.

NCI ACCOUNTING AND SPENDING DISCREPANCIES

The IOM study found some disturbing discrepancies in how NCI accounts for its commitment to research efforts affecting ethnic minorities and the medically underserved. While NIH says it spent \$124 million on research relevant to these populations in 1997, the study documents the real number at less than one-fifth of that amount—or about \$24 million—barely 1 percent of the NCI budget. One reason is that NCI included research involving ethnic minorities and the medically underserved, but which was not actually targeted to these populations. We were chagrined to learn this and urge that NCI abandon its current accounting methods and adopt the modifications set forth in the IOM report.

Another factor that further skews NCI's accounting estimate is the lack of a clear and consistent definition of "special populations," as pointed out in the IOM report. Without clear definition of what constitutes and who comprises a special population, accurate accounting and understanding of the complex research allocation and funding process are impossible. Semantics is not the issue. The actual impact of these definitions will be far-reaching, particularly as we move forward into the new millennium and witness the changing demographic trends I alluded to earlier. The ICC stands ready to help NIH develop more precise language to clarify critical terminology and put an end to the confusion that now abounds.

INSUFFICIENT NCI SPENDING

Even if one were to acknowledge the NIH numbers as accurate, clearly the paltry amount dedicated to focused ethnic minority and medically underserved concerns contrasts starkly with dedicated NIH research priorities such as women's health research. In addition to inaccurate accounting, we were also alarmed to learn from the IOM report that the Minority Health Initiative funding that is administered by the NIH Office of Research on Minority Health (ORMH) appears to have supplanted rather than leveraged NCI resources for important research and program activities in many instances. Therefore, the \$24 million figure given in the IOM Study in reality is even less because it may include other ORMH research funding. For example, \$1.75 million of the \$6 million listed as dedicated to ORMH research actually includes funding for an adolescent minority HIV treatment project. In light of these findings, the ICC urges the Senate Appropriations Subcommittee to ensure the integrity of these dollars by directing that ORMH funding is not, in fact, utilized inappropriately.

NCI LACKS NECESSARY DATABASE

The federal government is the most important single player in cancer research, not only because it is a major provider of funding, but also because the statistical data it compiles on cancer serves as a guide for how research resources are to be allocated. NCI's Surveillance, Epidemiology and End Results (SEER) program builds the statistical database that serves as the means of measuring cancer rates in the United States. This is done by gathering data from selected geographic areas around the country to represent the nation as a whole. This is fine for giving us a national snapshot, but the SEER program has blind spots that obscure many of the populations we serve.

Therefore, we agree with the IOM recommendations to enhance the SEER program and respectfully request that Congress provide requisite funding. The ICC applauds the Committee for recognizing the need to strengthen the U.S. Cancer Surveillance system.

While we support the IOM recommendations, we must clarify for the record today that the Centers for Disease Control and Prevention (CDC) is responsible by statute for establishing population-based cancer registries through the National Program of Cancer Registries (NPCR). CDC's mission, with the passage of the Cancer Registries Amendment Act of 1992, is to collect data for analyzing the cancer burden in the U.S. as well as to enhance the ability of states to use local data for program planning, evaluation and resource allocation. Further, this data will strengthen our capacity to identify important applied research questions.

While we urge the CDC to accelerate its efforts to improve the quality of its program, we recognize that this relatively new program remains sorely underfunded. Additionally, the ICC urges the NCI to strengthen its collaborative efforts with the CDC, NPCR and other cancer registries through the National Coordinating Council for Cancer Registries. Just as we urge Congress to increase SEER funding, we urge Congress to increase funding substantially for CDC's national cancer registry program.

The ICC also urges Congress to focus attention on the IOM's concerns relating to several additional areas.

DEFINING ETHNICITY AND RACE

The ICC is grateful to the IOM for their thoughtful discussion and recommendations relating to the definition of ethnicity and race. The ICC agrees with the conclusions stated in the IOM report. However, even though we agree there is no biological basis for race, this should not be misunderstood to suggest the absence of a need for targeted studies on cancer outcomes in ethnic minority and medically underserved populations. In fact, the IOM report substantiates that far more needs to be done in this area.

As noted numerous times in the report by the IOM Committee, we can still benefit from understanding differences in health status between the original four racial definitions. The ICC welcomes the opportunity to participate in helping to formulate these definitions. Furthermore, while the ethnic definitions are in development, as the IOM report points out, there still are numerous benefits to be derived from current studies directed at groups as they are currently defined.

CHANGING THE NIH CULTURE: RESEARCH TRAINING

The IOM report clearly documents the dearth of ethnic minority research investigators. One major concern identified by the ICC since its inception relates to the need for an institutional and cultural commitment on the part of NIH which will permit and stimulate a substantial increase in the number of trained minority investigators. The ICC endorses immediate implementation of the IOM's research training recommendations and inclusion of this priority in a strategic plan. Long-term, stable funding for research training must receive highest priority—clearly, no 21st century solutions to the problems cited by IOM can be achieved without adequate involvement of minority researchers and providers at all levels.

Mr. Chairman, the ICC strongly supports the NIH and NCI research missions and substantial increases in the amount of federal funds dedicated to a renewed war on cancer. But any such funding increases must place priority on addressing problems identified in the IOM study and redressing the research inadequacies in dealing with cancer in ethnic minority and medically underserved populations.

The agency must focus on and expand its commitment to behavioral and epidemiological research specifically, and translational research overall. Addressing the disparate burden cancer presents to ethnic minority and medically underserved populations must become a national priority. This requires the commitment of all involved federal agencies, including the Centers for Disease Control and Prevention, the Department of Defense, the Environmental Protection Agency and other HHS programs. The IOM's report confirms an earlier ICC recommendation that the time has come to designate a highly visible national cancer coordinating entity. The war against cancer must be fought and won across federal department and agency lines. Your Committee and the Senate Cancer Coalition recognize the challenges inherent in addressing the necessary federal agency systemic and cultural changes. We applaud your leadership and pledge our support and commitment toward making substantial progress as we move into the next century.

In closing, we hope the IOM Report serves as a "call to action." This hearing today can provide a fruitful beginning of a new national commitment to address the disparate burden of cancer on minority and medically underserved populations in America today. We cannot allow this study to be shelved. Instead of burying any bad news it contains, it must be utilized as the baseline framework against which we measure future progress and enhance accountability in the expenditures of precious federal dollars devoted to the war on cancer. If the agency takes this report seriously, we are confident agency culture will change and a refocused and expanded priority on cancer among ethnic minorities and the medically underserved will emerge. We urge Congress to require the General Accounting Office (GAO) to undertake periodic, independent, and objective assessments of NIH and NCI progress. On its part, the ICC pledges its strong support and cooperation both to Congress, the National Institutes of Health, and the National Cancer Institute.

ADEQUATE FUNDING

Senator SPECTER. Thank you very much, Dr. Weinberg.

Dr. Sullivan, starting with you—and regrettably we do not have much time for questions—when you posed the issue of having the leveraging come out of the Office of Research on Minority Health, that is a pattern which occurs from time to time. Something in HHS is going to look into NCI and see to it that their particular group is accorded adequate funding. It touches on what Dr. Weinberg says perhaps on a blueprint which he is looking for.

As the former Secretary of the whole Department, Dr. Sullivan, how realistic is it to have somebody who is a subset in HHS—that that director move over and try to exert some real influence on NCI, Dr. Klausner—I am going to give you a chance to answer this question, Dr. Klausner—in NCI? What are the realities of it? Your long arm comes from this building a block away all the way out to Bethesda. Is it realistic? Will Klausner pay any attention to the subordinate of the Secretary?

Dr. SULLIVAN. I think so if that person has, indeed, reporting authority and dollars to implement the program. Certainly having the interest and support and the leadership of the Secretary helps significantly, but you clearly must have an organization that is responsive to these concerns.

Senator SPECTER. How effective can the Secretary be in affecting Dr. Varmus, Dr. Sullivan?

Who was the NIH Director when you were there?

Dr. SULLIVAN. Dr. Healy, Bernadine Healy.

Senator SPECTER. How effective were you in affecting Dr. Healy?

Dr. SULLIVAN. Very effective. Dr. Healy and I worked very well together, and she was the individual who implemented the Office of Research and Minority Health and helped to establish the budget for that office.

Senator SPECTER. She just made one mistake in her career: She was not elected to the Senate. [Laughter.]

Dr. SULLIVAN. Right.

Senator SPECTER. So far.

Dr. SULLIVAN. So far.

Senator SPECTER. How about it, Dr. Klausner? Will you pay attention to the subordinate in HHS who puts a long arm across all those miles out there and says—

Dr. KLAUSNER. Yes, we do very much. We actually do not feel that they are very long arms. They seem to be right there.

Senator SPECTER. And spend more money on minorities?

Dr. KLAUSNER. I feel that that office has been working. It is not really for me to defend Dr. Ruffin's office.

But my sense is what has clearly happened—and it is not hard to demonstrate and I think the committee saw it—is that there has been a change of culture at the NIH over the last 10 years. There certainly has been a change of culture at NCI.

Senator SPECTER. Dr. Sullivan, a two-part question. Has there been a change of culture, and if so, for the better?

Dr. SULLIVAN. There has been a change of culture for the better, but not enough change. These issues, Mr. Chairman, we are talking about today and from the IOM report are not new. These were

issues that, before I came to Washington, we were discussing with officials at NIH.

And I would agree with Dr. Weinberg. I think the question as to whether or not it is \$24 million or \$124 million—it is not enough, even the \$124 million, being generous using NIH's own figures.

Senator SPECTER. Dr. Weinberg, how much is enough? How high is up?

Dr. WEINBERG. Well, I think the way I would answer that is within the context of what has been proposed, for the institute to address the issues on cancer, we believe there is room in the budget that has been proposed to address the issue. It is an allocation issue, and much of it is dependent upon how we define special populations as we talked about before.

Dr. Klausner showed me an abstract before this session that I would agree has relevance to the issues that we are talking about today that was excluded from the count. On the other hand, there are many things which are probably in the account—for example, from the Office of Minority Health and Research, there is \$1.7 million of their total \$6 million that was counted in the \$24 million, if I have got the numbers correct, that went to a pediatric HIV treatment program, which does not necessarily fit the bill.

Senator SPECTER. How much, Dr. Weinberg? I have got my pen poised. How much? [Laughter.]

We have to write figures down.

Dr. WEINBERG. I am sorry. I frankly was not prepared to come with an actual number because I do not think we have the data to describe the answer to that question. That is why this dialogue between us is very important.

Senator SPECTER. Well, if you do not know, how am I supposed to know?

Dr. WEINBERG. You are supposed to know, I guess, by helping us direct the agency to take this question and work with the community to answer the question of how do you define special populations and the issues, how do you then identify what is relevant research. Include us in that.

Senator SPECTER. It is now 10:30 and we are going to have to conclude, but would you give this further study?

Dr. WEINBERG. Yes, I would.

Senator SPECTER. Would you focus on the materials you need and give me a figure?

Dr. Sullivan, would you give me a brief memorandum that I can take up with Secretary Shalala? This is a matter really of internal oversight so you have somebody who is really focusing on minority issues. Dr. Klausner is very much concerned about it, and I am confident of that, but he has got a lot of other fish to fry and a lot of other directions.

Dr. SULLIVAN. I would be happy, Mr. Chairman.

Senator SPECTER. So, perhaps we can put something in our bill or in our report which would be specific standards as to what you think ought to be done because you have had the experience both in Government and out of Government.

Dr. Weinberg, you questioned the figure. Tell me what you think the figure ought to be and why.

Dr. Klausner will be back a lot of times.

CONCLUSION OF HEARING

Thank you all very much for being here, that concludes our hearing. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 10:30 a.m., Thursday, January 21, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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