

# President's Cancer Panel Meeting

## Meeting Minutes

**December 06, 1999**  
**Bethesda, Maryland**

## Overview

The President's Cancer Panel was chartered to monitor and evaluate the development and execution of the National Cancer Program (NCP) and to report to the President on barriers to Program implementation. The third in a series of meetings to assess the progress of the National Cancer Program since its inception and identify steps to improve Program effectiveness, this meeting brought together five speakers to describe key aspects of the history of the National Cancer Program, provide an overview of the new National Dialogue on Cancer, discuss survivor concerns and research funding activities by cancer advocacy organizations, and review National Cancer Institute initiatives relative to the 1994 report, *Cancer at a Crossroads: A Report to Congress for the Nation*.

## Meeting Participants

### President's Cancer Panel

Harold P. Freeman, M.D., Chairman

Paul Calabresi, M.D.

### National Cancer Institute

Maureen O. Wilson, Ph.D., Assistant Director, NCI, and Executive Secretary, President's Cancer Panel

Otis Brawley, M.D., Director, Office of Special Populations Research

### Speakers

Diane Balma, J.D., Senior Counsel, The Susan G. Komen Foundation

Michael McGeary, Consultant, science and technology policy analysis

Cherie Nichols, Director, Office of Science Planning and Assessment, National Cancer Institute

Elda Railey, The Susan G. Komen Foundation

John Seffrin, Ph.D., Chief Executive Officer, American Cancer Society

## Overview: Evaluating the National Cancer Program

In opening the meeting, Dr. Freeman reviewed the role of the President's Cancer Panel and the process of the Panel's meetings in 1999:

- The National Cancer Program (NCP) formally dates to 1971, when the National Cancer Act was enacted. The President's Cancer Panel was created under the Act, and has a specific statutory mission to monitor the development and execution of the NCP, to report annually to the President, and to bring to the immediate attention of the President any delays or blockages in the rapid execution of the Program.

- This year, after nearly three decades of meetings focusing on specific issues within the National Cancer Program, the Panel felt it was time to review the history of the NCP, evaluate its current status, and consider ideas concerning the future of the Program itself.
- In July 1999, the Panel met in Boston to discuss the Program's genesis and evolution. The questions discussed at that meeting included: What was the original concept of the NCP as envisioned by its creators? Where are we in terms of implementing this vision? Have we varied from the original goals and if so, why? Have changes in the Program been beneficial? What is the NCP currently intended to achieve? Speakers at the July meeting provided historical perspectives on the Program's history and raised a number of issues concerning future goals. The presentations made in July are described in a meeting summary available at today's meeting.
- Two overarching questions arose from the July meeting: How should we reframe the scope and purpose of the NCP for the 21st century? How can we implement such a program and who would be responsible to do so? These and other concerns raised during the July meeting were incorporated into a draft concept paper entitled, "Evaluating the National Cancer Program: Lessons from the Past, Charting Our Future." The concept paper is still evolving, but is based on the proposition that the NCP has from its beginning suffered from both "a lack of coordination and lack of clarity as to its definition and scope."
- As a starting point in developing the concept paper, the Panel turned to the 1994 report entitled, Cancer at a Crossroads: A Report to Congress for the Nation, which is the only evaluation of the NCP to date. It was written by a subcommittee of the National Cancer Advisory Board in response to a Congressional request for a review of the NCP. The report characterized the NCP as involving all individuals and public, private, and voluntary organizations and agencies whose actions affect the cancer problem. It also characterized the Program's scope as including basic, translational, and applied research spanning the cancer continuum from risk assessment to end of life care. If this premise is used as a starting point, then some aspects of the NCP are not working adequately. For example, the Program is weighted heavily in favor of research, with inadequate emphasis on effective delivery of research results to reduce the burden of cancer on the American people.
- We are not applying what we know nearly well enough, quickly enough, or widely enough. The basic problem is not a lack of knowledge about applying research findings, but perhaps, a lack of willingness to pay the cost of doing so. In addition, professional consensus as to what constitutes quality care is lacking, and cost considerations are being allowed to overshadow patient welfare.
- Many Americans with good health insurance are not receiving what is believed to be the best care available. Those with inadequate insurance are receiving less, and an estimated 44.3 million have no health insurance at all. Economic barriers reduce access to treatment and cause financial catastrophe for cancer patients and their families.
- The current healthcare financing environment has reduced the flow of funds traditionally used by academic institutions to train new generations of researchers

- and care providers. Substantial reductions in cancer incidence and mortality cannot be achieved without significant improvements in cancer prevention and control programs and reducing the impact of lifestyle factors such as smoking, sedentary behavior, and poor dietary habits. In addition, some sectors of society that contribute to the cancer problem, such as the food industry and the media, do not see themselves as participants in the NCP.
- These and other problems have been identified by the President's Cancer Panel and others in recent years. The Panel's recommendations on the above issues since 1982 are available upon request.
  - The concept paper suggests that to truly wage a war on cancer, we must, among other things, increase our focus on outcomes related to the discoveries achieved by researchers and increase public and professional awareness of the magnitude and complexity of the cancer problem. The paper concludes with three overarching questions: What do we need to do differently? What must be done to make it happen? Who should be accountable?
  - On November 19, 1999, the Panel met in Salt Lake City to discuss the future of the NCP. The concept paper served as a catalyst for these discussions. It was the Panel's intention to solicit the perspectives of people outside the community of cancer researchers who usually make presentations at Panel meetings. A group of experts in fields including public health policy, economics, health care financing, and oncology nursing were brought together to think "out of the box," going beyond the purely scientific issues to bring new, creative ideas and deeper insights to the evaluation of the NCP. The testimony provided was highly thought provoking and will be extremely useful in preparing recommendations following this series of meetings.
  - The purpose of today's meeting is to continue discussions concerning the nature of the NCP and its future as a coordinated effort to reduce the burden of cancer in our Nation.

### **NCI Director's Report**

Representing Dr. Richard Klausner, Director, NCI, Dr. Brawley indicated that:

- In virtually any endeavor, it is appropriate to stop periodically and examine where we have come from, where we are, and where we are going; the NCP is no exception. *Cancer at a Crossroads*, an important and far-sighted document, provides ongoing guidance to the NCI.
- NCI's fiscal year 2001 bypass budget, *The Nation's Investment in Cancer Research*, is the Institute's strategic plan. It describes a number of extraordinary opportunities for progress in the basic, clinical, and population sciences. One of these opportunities of special relevance for today's meeting is in the area of cancer communications.
- The fruits of cancer research findings have not been distributed equally throughout the population. In two recent reports, *The Unequal Burden of Cancer*

and *Ensuring Quality Cancer Care*, the Institute of Medicine has described these problems and provided recommendations for addressing them.

## **PRESENTATION HIGHLIGHTS**

### **TWENTY-EIGHT YEARS OF THE PRESIDENT'S CANCER PANEL AND THE NATIONAL CANCER PROGRAM**

#### **Mr. Michael McGeary**

The National Cancer Program was created by the National Cancer Act of 1971. Section 3 provides that:

1. The Director of the National Cancer Institute shall coordinate all of the activities of the National Institutes of Health relating to cancer with the National Cancer Program.
2. In carrying out the National Cancer Program, the Director of the National Cancer Institute shall:
  - a. With the advice of the National Cancer Advisory Board, plan and develop an expanded, intensified, and coordinated cancer research program encompassing the programs of the National Cancer Institute, related programs of the other research Institutes and other Federal and non-Federal programs.

#### **Key Points**

- The National Cancer Advisory Board, created by the National Cancer Act, was expanded in size and role from its predecessor, the National Advisory Cancer Council. It was to be the one body with representation from all of the sectors that would be involved in the NCP, and would advise the NCI Director in his role as head of the NCP.
- The President's Cancer Panel was also created by the National Cancer Act, and was charged to report obstacles to NCP implementation directly to the President.
- The National Cancer Act was based heavily on the conclusions of the Yarbrough Commission, chaired by Dr. Benno Schmidt. The Commission concluded that a successful National Cancer Program required a new, independent agency, a comprehensive plan to coordinate the program, and expanded resources. It also was implied that the Program would be broadened to increase research on how to apply basic research findings in the community.
- At the time the National Cancer Act was being formulated, NCI was already a rapidly growing program, doubling in size during the 1960s. However, budget growth had stalled in the late 1960s, and one impetus for the new legislation was to spur additional budget increases. In 1969, NCI reported that 36 percent of its funding was devoted to treatment-related activity, 27 percent to cancer causation, 15 percent to cancer biology research, and nine percent to training. A majority of the budget (52 percent) went to grants in 1970, with the remainder allocated to

direct operations, including contracts, intramural research, other in-house programs, and administration. Several large in-house programs (e.g., chemotherapy, cancer virus, carcinogenesis) combined intramural research and contracts into a directed program. These directed programs were subject to formal program planning techniques because of the degree of coordination and direction involved. The basic allocation of activities did not change much with implementation of the NCP, except for addition of the cancer control program, which had been transferred out of NCI a decade earlier because it was not considered research.

- NCI's budget quadrupled from fiscal year (FY) 1971 to FY 1980, from \$233 million to \$1 billion. Though NCI requested the full amount authorized each year, the administration would cut the request substantially, leaving it to Congress to restore most of the reduction. The administration also was holding the budgets of the other institutes flat or cutting them; this created a backlash against NCI. Benno Schmidt and the President's Cancer Panel intervened frequently at the White House to counter efforts by the Office of Management and Budget (OMB) and the Department of Health, Education, and Welfare (now the Department of Health and Human Services) to constrain NCI's growth. NCI represented 33 percent of the NIH budget in 1977, and then declined steadily to about 20 percent in the late 1980s (it was 19 percent in 1998).
- Despite fears of the scientific community that the War on Cancer would involve a wholesale shift from grants to contracts, funding for contracts reached its historical peak as a share of the NCI budget in 1971. The allocation of funds among broad areas of research has not changed much over the history of the NCP.
- Cancer control was the term used to refer to efforts to move new treatments and other state-of-the-art technologies and knowledge (e.g., diagnostics, prevention) into general use by health professionals and the public. NCI's cancer control program was among several such activities transferred to the public health programs of the Public Health Service in the 1960s. Many NCI leaders at that time did not believe cancer control belonged at NCI, but in the early years following passage of the National Cancer Act, cancer control was identified as a key new feature of the expanded program. Despite a flurry of activities and budget growth from zero to \$60 million in five years, the cancer control program did not expand to the size originally planned. According to budget projections in the original planning exercises, cancer control was to grow to about 15 percent of NCI's budget in 1980, but was no greater than seven percent. It was 8.5 percent in 1980, and then fell to 4.2 percent by 1990.
- The framers of the National Cancer Act also placed great emphasis on planning and management in implementing a more vigorous attack on cancer; their model was the large-scale program planning and management techniques used by the National Aeronautics and Space Administration and the Atomic Energy Commission. In the initial years, there was a large, fairly elaborate planning effort, however, after the first few rounds, it was dropped. The operational plan was updated annually by NCI staff until 1985, when that too was dropped. Though favored by then-Director Carl Baker, there was little support for the planning process. The scientific community did not believe research could be

planned when there was so little basic knowledge. Although Benno Schmidt chaired the Yarborough Commission, which recommended a comprehensive plan to coordinate the NCP, as chairman of the President's Cancer Panel, he spoke in favor of a major role for undirected basic research, and judged the Program's balance of directed/undirected, basic/applied, and research/cancer control to be about right.

- The National Cancer Act gave the NCI Director the authority but not the power to coordinate the cancer-related programs of the NIH, other Federal agencies, and the many non-Federal agencies and organizations involved in cancer research and control. Accordingly, coordination was described in the strategic plan as voluntary action, including mutual exchange of information and ideas, joint development and execution of programs, joint meetings, interlocking committee memberships, and membership on NCI advisory committees. A number of cooperative efforts were launched, such as mammography clinics co-funded with the American Cancer Society. NCI also counted as coordination funding of the growing network of cancer centers, organ site programs administered by universities and other non-profit institutions, interagency funding agreements, and the new Frederick Cancer Research Center. The NCAB was intended to be a nationally representative board of directors to oversee the NCP, but the Board has focused principally on NCI's own budget and programs.
- The NCI Director only has the power to persuade an array of organizations that have their own agendas and that often are competing for resources, for recognition, to be first to discover new knowledge or applications, and to conduct their own affairs.
- The main source of coordination is the NCI budget, which NCI uses to develop and expand joint efforts with agencies and organizations nationwide. The main change since 1971 has been in the amount of the budget available; most of the mechanisms were already in place.
- An important change since passage of the National Cancer Act has been the vastly increased investment in research by private industry (from two percent of total national spending on cancer research in 1974 to 31 percent today). Much of this private research has been made possible by the results of earlier NCI-funded research that led to the development of the biotechnology and related industries.
- Funding at NCI has been constrained by being one of the NIH institutes, since funding increases tend to be allocated evenly across the institutes; the framers of the National Cancer Act anticipated this problem.
- Cancer control did not become a major part of NCI's overall program because: (1) it was not seen as research and was inconsistent with NCI's culture, (2) it involved working in the public health arena with a different set of constituencies and involved health care delivery and professional and industrial practices, which involved NCI in political controversy, and (3) little was known about how to effect changes in the behavior of health professionals or the public. More recently, the prevention and control programs have grown from five percent to ten percent of NCI's budget, reflecting changing attitudes in the research community toward the importance of such efforts in reducing cancer rates and better understanding

behavior and the role of basic and applied behavioral research in developing and testing cancer control interventions.

## Discussion

### Key Points

- RO1 grants, one of many research project grant mechanisms, are the traditional investigator-initiated grants. Over time, a proliferation of support mechanisms has occurred, including within the research project grants. This occurred in part because many activities that had been supported by contracts were converted to grant mechanisms. Cooperative agreements are classified as grants but are in fact a blend of the contract and grant mechanisms.
- Mary Lasker and her colleagues intended that the National Cancer Act would set in motion activities that would have an impact on cancer incidence and mortality. They believed that a lot of research had already been done and that the problem was that resulting advances (e.g., chemotherapy) were not being applied rapidly enough.
- In its 28 year history, the NCP has recognized that changes in health care delivery are part of what must be done to impact the cancer problem, but the emphasis on the clinical aspects of cancer have been overshadowed by the emphasis on basic research. In addition, while significant effort was being devoted to developing better treatments, relatively little effort was spent figuring out how to disseminate new treatments. Considerable work was done to understand and monitor the cancer burden, particularly through the SEER program, but the major barrier to the cancer control effort was the difficulty of stimulating behavior change in health professionals and the public. In addition, since cancer control was not considered research, cancer control funds initially were put into demonstration projects that were not evaluated systematically.
- The NCAB was envisioned as an opportunity for coordination and bringing diverse agencies with an interest in cancer to the table (however, the CDC and some other equivalent agencies were not among the ex-officio members). It was expected that participation in the NCAB would lead to joint efforts or appropriate division of labor between different agencies. Like the NCI director, however, the NCAB became principally concerned with the operations of the NCI, a large and rapidly growing agency. The NCAB was still reviewing grants at that time, and for this and other reasons did not develop into a national forum and active (albeit advisory) board of directors to the extent originally intended.
- The NCP as envisioned by the Lasker group was larger than the NCI, a dedicated effort equivalent to the national resolve to go to the moon. In fact, except for the addition of the cancer control program, the National Cancer Act served to expand the existing research effort against cancer, but did not radically change its focus. Today, the NCP is still being defined. The National Cancer Policy Board report on quality of care issues has led to a Department of Health and Human Services interagency committee to address these issues; this effort may lead to better

success in defining roles and coordinating activities that will address quality and access issues.

## **THE NATIONAL DIALOGUE ON CANCER-AN UPDATE**

### **Dr. John Seffrin**

The National Dialogue on Cancer started with the notion that we did not have a forum or opportunity for the various players in the cancer community to understand what each was trying to accomplish. The Dialogue is a nationwide, ongoing discussion on the topic of cancer as a public health problem; it is not an organization or governmental entity. It is predicated on two ideas: that coordination of all organizations' efforts is what is needed to have maximum impact on the cancer problem, and that it is crucial to bring all three sectors (public, non-profit, for-profit) at the highest levels to the same table to discuss cancer issues. The first meeting of the Dialogue was hosted by former President George Bush and First Lady Barbara Bush and was attended by 60-70 representatives from all sectors. The mission of the Dialogue is to establish a lasting and ongoing dialogue in support of eradicating cancer as a public health problem at the earliest possible time. Though it took ten months to persuade participants to come to the Dialogue's initial exploratory meeting, three meetings have now been held, and more than 100 partners are collaborating in the effort.

### **Key Points**

- The 1994 report, *Cancer at a Crossroads: A Report to Congress for the Nation* was in part the impetus for formation of the National Dialogue on Cancer. In a manner that may not have been done previously, the report illustrated the multitude of organizations and institutions having a major commitment to the national cancer effort, and placed the individual at the center of all of the activities of these varied entities.
- It has been understood that much of our knowledge about cancer must be gained through research, and that to have an impact on the disease, it is necessary to apply our knowledge through an expanded delivery infrastructure (for prevention, screening, and care). Only in this way can we reduce the gap between what is doable and what gets done.
- Public, voluntary, and private entities, as stewards of tax monies, public contributions, and public investments, respectively, are increasingly being held accountable for the effective use of these funds. We have done a better job in research (reducing the gap between what is known and what is knowable) than we have in leveraging the resources in the public, private, and voluntary sectors to bring maximum benefit of knowledge to people.
- Though newly underway, a number of activities have already been launched, such as an assessment of the Nation's research program related to cancer. This assessment includes all activities in all three sectors; it is estimated that \$5.5

billion per year is being expended on these efforts. The assessment is considering the current balance of the research effort and whether this balance will have the maximum possible impact against cancer. Though the Dialogue does not advocate directly for specific legislative initiatives, it has worked with organizations that encourage full funding of the national public cancer research effort, and has been working with states on acquiring tobacco settlement funds. Spin-off activities from the Dialogue by private sector members include special constituent dialogues with state governors and a Fortune 500 Chief Executive Officer (CEO) roundtable. In addition, a priority team from the Dialogue has been formed to try to build closer linkages between major cancer surveillance systems. Further, the Dialogue is exploring how to disseminate reports such as the recent IOM report on quality of care so that they can be catalysts for change, and has set a target of increasing clinical trials participation from two percent to ten percent of cancer patients. A tobacco control tool kit for use by states seeking funds from the master tobacco settlement has been developed and is in use.

- The Dialogue offers the opportunity to re-energize the country around the notion of overcoming cancer. It also offers the opportunity to leverage resources in ways not previously possible to achieve common goals. The forum also offers a measure of protection against consolidation of influence in that since it is not an organization, it has no legislative authority, cannot garner awards, and operates only through leadership and collegiality.
- To date, we have not gotten full value out of our investment in cancer research and care, largely because efforts have not been coordinated. The Dialogue provides a forum for participants to collaborate toward achieving common goals.
- To bring cancer under control as quickly as possible, we must: (1) redouble the Nation's commitment to cancer and cancer control research, (2) make a success of the National Dialogue on Cancer, and (3) persuade the myriad public, private, and voluntary participants in the cancer effort to modify their mission and activities to achieve the maximum impact against cancer. The last of these three goals will by far be the most difficult.

## Discussion

### Key Points

- The recommendation in *Cancer at a Crossroads* calling for better coordination of the National Cancer Program has been misconstrued as advocating some form of strong central coordination. Though it is too soon to tell, the National Dialogue on Cancer may well be able to provide some of the collaborative coordination that most agree is more appropriate. Initial meetings of Dialogue participants were hampered by some cynicism, skepticism, and territoriality. The discussion during its most recent meeting showed growth and maturity of the group, and a heightened sense of optimism that productive synergy can be achieved. The level of commitment to the effort (including that of former President and Mrs. Bush) appears to be increasing.

- Some of the issues being addressed require the formation of smaller, spin-off groups. For example, Vice Chair of the Dialogue, Senator Diane Feinstein, has formed a subgroup of Dialogue participants (chaired by Dr. Vincent DeVita) to advise her concerning the prospect of developing new cancer legislation. This group could not appropriately include public sector Dialogue participants. The Dialogue is also concerned, however, that the number of subgroups does not become unmanageable.
- The Dialogue also has initiated an advocacy roundtable composed of volunteer participants who feel it is within the mission of their organization or their personal perspective to address advocacy issues. The American Cancer Society, for example, has learned through previous efforts that although it is among the largest not-for-profit organizations, there are limits to what it can accomplish alone. Working with others through the roundtable, however, it is hoped that the combined influence of the participants will yield results in better articulating issues, and in shaping public policy and public opinion concerning cancer.
- Last year, more people were saved from cancer than ever before; at the same time, more people died needlessly from cancer than ever before. This situation reflects the gap between what is and what could be in cancer control at the community level. Through the advocacy roundtable, players that only knew of one another are beginning to work together to address delivery issues, some of which the National Cancer Institute, as a research institution, cannot address. NCI appears to be moving toward a philosophy that recognizes that it cannot address many of the issues related to application of research findings in the population.
- The committee to consider the feasibility, desirability, and potential principles of a new or renewed National Cancer Act has not had its inaugural meeting. However, Dr. Seffrin expressed his belief that a compelling case can be made for a new National Cancer Act that would more fully address screening and treatment access and other cancer control issues. The investment to date in basic research has been a great success that serves the worldwide community, and such investment must continue, but one of the most time-honored principles of public health is that access to the means for attaining and preserving health is a basic human right. As a Nation, we have not been able to implement that principle. A second attempt at a National Cancer Act would be much more enlightened today about what would be necessary to implement that principle such that people would have access to state-of-the-art cancer care.
- The tobacco company settlement funds provide a unique opportunity to impact the cancer problem. This situation-potentially infusing billions of dollars in new, non-tax funds into the effort against cancer-has never before occurred and probably never will occur again. Unfortunately, much of this money will not be used for tobacco control. Many of the organizations that might have helped make the case for using more of the funds for cancer control have not done so; this is a key reason why so large a percentage of the monies are being diverted to fund highway repairs and other projects. Even with this situation, however, there is more money for tobacco and cancer control than there was before the settlement. Two governors associated with the Dialogue have been very active in working with other states to showcase local best practices in tobacco control and advocate

for use of state settlement funds to limit tobacco use. Still, it will be a yearly struggle to keep the opportunities these funds offer from being lost.

## **THE SURVIVORS' PERSPECTIVE FOR THE FUTURE**

### **Ms. Diane Balma and Ms. Elda Railey**

Survivors and their loved ones want an all-out war against cancer, both to cure and prevent it. Since 1982, the Susan G. Komen Breast Cancer Foundation has been actively engaged in this war. The Foundation was established by Nancy Brinker to honor the memory of her sister, who died from breast cancer at age 36. The Foundation now has an affiliate network of 116 national and international organizations with 35,000 volunteers. This year, one million participants are expected in the Foundation's annual Race for the Cure, a 50 percent increase over last years' participation level. The Race is held on the same date in many cities throughout the country. Seventy-five percent of funds raised locally remain in the local community. To date, the Foundation and its affiliate network have raised more than \$200 million in furtherance of the mission to eradicate breast cancer as a life threatening disease by advancing research, education, screening, and treatment. This year, the Foundation expects to raise \$100 million to fund innovative, non-duplicative outreach programs, including education, screening, and treatment programs for the medically underserved in local communities. The funds raised also will support the Foundation's national grants program for basic, translational, and clinical research. The Foundation also funds three-year post-doctoral fellowships to help recruit young scientists to the breast cancer field. The Komen Foundation is committed to being good stewards of the funds raised; administrative costs remain under ten percent of annual revenues.

### **Key Points**

- When the Komen Foundation was established in 1982, advocates were not generally involved in the scientific domain. That has changed; advocates now are at the scientific table, and are direct funders of research. The Foundation is one of the few breast cancer organizations that both sets its research agenda and administers its grants. In 1999, the Foundation announced \$17 million in research grants evaluated primarily on a peer review process recognized by the NCI in 1992. This recognition has helped leverage the usefulness of Komen's funding for the development of new, seed ideas to the point that they merit larger and longer-term Federal funding. To date, the Foundation has funded more than 450 research grants totaling over \$55 million.
- At the local level, over 850 grants totaling \$16 million were directed to projects targeting underserved populations. These grants were chosen based on a community needs assessment that is conducted in each affiliate network city.
- The Foundation is committed to funding research that takes basic science discoveries to the clinic. In the mid-1990s, a blind review process was instituted to promote grants for innovative, non-duplicative, high impact ideas. In this

process, the merits of the science are reviewed independent of the qualifications of the investigator.

- The Foundation worked with the NCI Office of Cancer Survivorship to fund three grants directed toward breast cancer survivors, reproductive health, and academia. A new fellowship with the NCI Division of Clinical Research is being initiated this year. The Foundation also has partnered with the American Association for Cancer Research to sponsor training grants.
- To increase access and accrual to clinical trials, the Foundation this year is beginning Project CRAFT-Critical Research Affiliate Spending Trials. Through this mechanism, affiliates can directly fund institutional needs such as research nurses, data managers, and outreach personnel.
- The Foundation has established a toll-free help line which is expected to answer over 70,000 calls this year in both English and Spanish. In addition, the Foundation's award-winning web site provides cutting edge information to the people who need it the most.
- Through these activities and collaborations, the Foundation hopes to be some of the "arms and legs" working against the cancer problem until it is no longer a problem for anyone.

## Discussion

### Key Points

- Participation by the advocacy community in addressing cancer issues spans the public, private, and not-for-profit sectors, since advocates (representing the patient) now participate at all of these levels.
- Since passage of the National Cancer Act, significant environmental changes have occurred in the cancer community. Private entities, not the government, now sponsor the majority of cancer research. In addition, the nature of advocacy has evolved into a much different and more potent force. The individual with an interest in cancer is not just the cancer patient, but survivors, their families, and all people at risk for cancer. Currently, 40 percent of Americans will experience cancer at some point in their lives.
- The Komen Foundation involves patients/survivors and families in the grant review process. Scientists present research proposals to outreach workers and consumers in lay language so that there can be dialogue about the research; in addition, gaining knowledge about the science is empowering to the consumers.
- An informal network now exists among funders of breast cancer research; communication through this network is expected to help ensure that scarce resources are most efficiently used to help advance the state of knowledge about the disease. The Komen Foundation also is participating in the National Dialogue on Cancer.
- The Komen Foundation has broadened its philosophy and activities to include cancers other than breast cancer (particularly reproductive system cancers) and women's health issues more generally.

## AN UPDATE OF NCI'S PROGRESS IMPLEMENTING THE OVERARCHING RECOMMENDATIONS IN *CANCER AT A CROSSROADS*

**Ms. Cheri Nichols**

### **Key Points**

- The evaluation by the National Cancer Advisory Board (NCAB) Subcommittee to Evaluate the National Cancer Program (SENCAP) that culminated in *Cancer at a Crossroads: A Report to Congress for the Nation* was a three-phased effort. Phase I examined past progress, Phase II reviewed the current status of the Program, and Phase III developed recommendations for the Program's future.
- *Cancer at a Crossroads* provided four overarching recommendations for strengthening the National Cancer Program: (1) better coordinate the National Cancer Program through a Presidentially-led plan; (2) evaluate cancer research programs and priorities; (3) provide sufficient funding for a balanced research portfolio; and (4) expand the number and breadth of the Cancer Centers and Community Clinical Oncology Programs.
- With regard to NCP coordination, SENCAP indicated that the Presidentially-led plan and its implementation should include Cabinet-level representation, criteria for broad participation in program planning and activities, and should re-establish legislative authority for national coordination of NCP cancer-related research activities. Better coordination of the NCP was deemed desirable to facilitate information exchange, avoid unnecessary duplication, and support expertise necessary to recognize and stimulate research areas leading to better cancer understanding of cancer biology, improve cancer prevention, treatment, and control, and ultimately, to overcome cancer.
- The NCP is broad and diverse. It would be inappropriate and impossible for the NCI as a research organization to attempt "top down" management of the Program. More than 12 agencies within the Department of Health and Human Services are involved in cancer research and over 11 Federal departments have some involvement in cancer research, care, or regulation. Though not through a Presidentially-led plan, the Administration is strongly committed to coordination and actively supports the funding not only of NCI, but NIH, DOD, CDC, and other Federal components.
- NCI, within the limits of its mission, can stimulate thought, research, and response to scientific needs and opportunities. Its strategy is to emphasize inclusion of all major stakeholders; one important way it has done this is through involvement of consumers as members of NCI's boards, peer review panels, and *ad hoc* groups.
- The Institute's involvement in coordination of the NCP has grown markedly in the past five years. Among NCI's activities and initiatives are its role in formation of the National Cancer Policy Board (NCPB), which addresses and provides advice on national questions related to public policy, societal changes, and individual lifestyles affecting the cancer problem.

- NCI's Bypass Budget provides the research community with a common vision of the priorities and strategies that NCI intends to pursue in working toward its goals. This document is developed with actively solicited input from many different constituencies and communities, including the advocacy community.
- The Common Scientific Outline (CSO) has been developed out of a need, identified in the NCI's Progress Review Groups, to be able to catalogue and evaluate the cancer research portfolio in a consistent way across disease-specific cancer research. The CSO has the potential to be the platform on which we can communicate with many other agencies; it already is being pilot tested by the DOD, and the American Cancer Society also has expressed great interest in it. A second pilot test will include a state or local government, an NIH institute, a foundation, and a volunteer or advocacy group to determine if the common outline is useful for this variety of data contributors and users. The potential of the CSO to help ensure that cancer research resources are used most efficiently is exciting.
- NCI also has initiated a quality cancer care initiative, a working model for quality in cancer care. A DHHS transagency task force has been established with two subcommittees created to address research issues and health care delivery issues. The community also will participate in this effort, the goals of which are to establish consistency between the scientific evidence and the Federal resources spent in delivery of care, and to ensure that the best evidence available is used in the delivery of health care.
- Other NCI efforts in the area of coordination include industrial relations, liaison activities, specific initiatives with other agencies, training programs, advisory boards and groups, the development of consortia and partnerships, and participation in the National Dialogue on Cancer.
- The second overarching recommendation from Cancer at a Crossroads called for a detailed evaluation of cancer research programs and priorities, including questions of value, purpose, function, and duplication. NCI has performed a number of detailed evaluations of this type in the past five years. These have had a dramatic impact, strengthening infrastructures, overhauling the clinical trials program, updating cancer center guidelines, and restructuring the former Division of Cancer Control and Prevention into two new divisions. Implementation groups take the recommendations from the program reviews and implement them for the NCI; those to date include groups implementing recommendations on tobacco research, surveillance, chemoprevention, and early detection. In addition, Program Reviews have been conducted for centers, clinical trials, cancer control, prevention, and developmental therapeutics. Progress Review Groups (PRGs) have been held for breast and prostate cancer; a PRG on colorectal cancer is underway, and PRGs are planned for brain tumors, pancreatic, lymphoma, leukemia, and lung, myeloma, gynecological, and kidney/bladder cancers. Evaluations also are conducted by outside groups; among the recent reports were the Institute of Medicine's report on the unequal burden of cancer and the General Accounting Office report on clinical trials.
- The third overarching recommendation from Crossroads called for sufficient funding to maintain a balanced research portfolio and to eliminate excessive

"earmarking" of funds. With the 60 percent increase in the NIH budget during the period 1994-2000, single investigator grant pay lines have risen from the 15th percentile in 1994 to the 24th percentile in 1999. The Congress has not earmarked for several years. It is notable that current funding levels approach those recommended by SENCAP. NCI's Extraordinary Opportunities for Research, discussed in the Bypass Budget, describe the Institute's many innovative programs and initiatives to accelerate basic science discoveries, translate these findings into interventions for patients and people at risk for cancer, and test those interventions in the clinic. In addition, NCI is strengthening the infrastructure that supports progress in all of these areas.

- The fourth overarching recommendation stated that NCI Cancer Centers and the Community Clinical Oncology Programs (CCOPs) should be expanded in number, broadened in scope and both geographic and demographic distribution, and strengthened in the areas of research dissemination and outreach. Since 1994, four new Cancer Centers have been designated (total now 59), and the program is changing. Centers traditionally were based in a single institution; now, consortia of institutions link freestanding clinical and academic centers with community hospitals and networks. Some of these are focused on scientific concepts, population studies, or translational capabilities within a scientific discipline such as immunology. These changes will increase scientific versatility, the translation of research capabilities, and geographic distribution. The Cooperative Groups are a network of 12 consortia that seek to define key unanswered questions in cancer research and conduct clinical trials to try to answer them. The CCOPs have 49 central offices in 31 sites with 2500 community cancer care specialists participating. Research Centers of Excellence are multidisciplinary research teams focused in a specific disease, modality, biological process, or scientific area of significance. The Specialized Programs of Research Excellence (SPOREs) are expanding; and Regional Enhancement Centers are strengthening the Cancer Centers program by expanding the base of patients and populations available for early detection, prevention, and early therapeutic studies.
- In addition, NCI has just established Special Populations Networks to fund diverse projects aimed at improving cancer prevention and control in minority and other special populations. NCI also has just approved an initiative to establish partnerships between its Cancer Centers and minority and minority-serving institutions. These partnerships will enhance the Cancer Centers' approaches to outreach and education for underserved communities as well as the institutions' approach to conducting cancer research and training future cancer specialists.

## **Discussion**

### **Key Points**

- Issues of access, healthcare reform, and the uninsured in the NCP are largely outside the purview of the NCI, and for that reason were not specifically addressed in the report provided to the Panel by Ms. Nichols, who suggested that evaluation of national progress overall, in these areas might best be undertaken by

- an independent group with broad representation from the scientific, clinical, and consumer communities. Dr. Freeman concurred with this suggestion, since *Cancer at a Crossroads* report focused on more than research progress and an assessment is needed as to where we stand on improving patient outcomes and cancer incidence, morbidity, survival, and mortality.
- Lack of funds has been a barrier to implementing cancer prevention and control interventions at the state level. The tobacco settlement funds provide an opportunity to significantly enhance available resources and improve care. A mechanism is needed in every state (such as Cancer Councils that exist in some states) to help advocate for funding and coordinate cancer interventions. Such Councils provide a bridge between information coming out of the NCI or the local cancer center and the health department.
  - It was suggested by Dr. Calabresi that the National Dialogue on Cancer may be a key mechanism for addressing the coordination issue in the NCP.
  - Comprehensive cancer centers are required to have an outreach component but are not funded for these activities. It was suggested that relative to the Crossroads recommendation concerning cancer centers, that progress has been only moderate in terms of the number of new centers and the scope of cancer center activities. Ms. Nichols indicated that the new models for cancer centers, involving linkages and partnerships with smaller academic institutions, are designed to bring cancer center expertise to communities and populations in which the academic institution may not have the core resources to qualify independently as a cancer center. Similarly, the new centers of excellence and NCI's behavioral research activities are designed to provide information on communication strategies and message development to help move research findings into the community. The NCI Director actively seeks novel, flexible mechanisms for addressing these kinds of problems.
  - From the inception of the National Cancer Act, there has been little acknowledgment of the need to connect the research enterprise with the delivery system; this problem was identified clearly in *Cancer at a Crossroads*, but still exists today. Policymakers have a deep responsibility to correct the problem, because it is in part a political issue and in other respects a health care delivery system issue. At this time, health care is quite good for some, but nonexistent for others. Though recent efforts at health care reform were unsuccessful, this complex problem still must be addressed.

### **Closing Remarks**

In his closing remarks, Dr. Freeman highlighted aspects of the day's presentations and indicated that the Panel will use the testimony provided at the meeting to inform the planning process for the next several meetings as well as in its report to the President.

I certify that this summary of the President's Cancer Panel meeting on the Genesis and Evolution of the National Cancer Program, held on December 6, 1999, is accurate and complete.