

**President's Cancer Panel Meeting**  
Meeting Minutes  
Closed Session

*Genesis and Evolution of the National Cancer Program*

July 19, 1999  
Boston, Massachusetts

## **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 first in a series of four meetings to assess the progress of the National Cancer Program since its inception and identify steps to improve the Program's effectiveness, this meeting reviewed the history of the NCP and raised issues for the coming century in the areas of public health; roles of and collaboration among industry, government, and academia; and communication and education. Thirteen speakers described key issues and offered visions for the future and specific recommendations for progress in each of these areas.

## **Meeting Participants**

### **President's Cancer Panel**

Harold P. Freeman, M.D., Chairman

Paul Calabresi, M.D.

Frances M. Visco, J.D.

### **National Cancer Institute**

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

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

### **Speakers**

David Asch, M.D., Executive Director, Leonard Davis Institute of Health  
Economics, University of Pennsylvania

Bruce A. Chabner, M.D., Chief, Hematology Oncology, Clinical Director,  
Massachusetts General Hospital Cancer Center

Dorothy Foellmer, Director, Office of Legislation and Congressional Activities,  
National Cancer Institute

Peter Greenwald, M.D., Director, Division of Cancer Prevention, National Cancer  
Institute

Robert Hiatt, M.D., Ph.D., Deputy Director, Division of Cancer Control and  
Population Sciences, National Cancer Institute

Kurt J. Isselbacher, M.D., Director, Massachusetts General Hospital Cancer Center

Howard Koh, M.D., M.P.H., Commissioner of Public Health, Massachusetts Department of Public Health

Michael McGeary, Consultant, Science and Technology Policy Analysis

James J. Mongan, M.D., President and Chief Operating Officer, Massachusetts General Hospital

Albert G. Mulley, Jr., M.D., Chief, General Medicine Division, Massachusetts General Hospital

Cherie Nichols, M.B.A., Director, Office of Science Policy, National Cancer Institute

Robert I. Tepper, M.D., Chief Scientific Officer, Millennium Pharmaceuticals, Inc.

## **Opening Remarks**

In opening the meeting, Dr. Freeman indicated that:

- The purpose of the meeting was not to answer questions, but to raise them.
- The concept of a coordinated national effort to address the cancer problem - the National Cancer Program (NCP) - was created in 1971 with the enactment of the National Cancer Act. The President's Cancer Panel also was created by this Act, and the Panel was charged to monitor the development and execution of activities of the NCP and to bring any delays or barriers in its rapid execution to the immediate attention of the President.
- The Panel has considered a wide range of issues in monitoring the NCP. Since 1991, when Dr. Freeman became Chair of the Panel, these issues have included the role of poverty as a determinant of disease; training opportunities and challenges in the sciences; a review of research and progress against breast cancer; the interrelated roles of research and technology transfer; characteristics and needs of the underserved that contribute to excess cancer mortality experienced by these populations; and the role of cancer-related voluntary organizations in reaching and serving the public. In addition, the Panel has conducted a special review of basic research, screening, detection, and treatment options in prostate cancer; examined the usefulness of the Specialized Program of Research Excellence model for breast cancer research; and explored the effects of a cancer diagnosis on patients, caregivers, and children.
- In 1993 and 1994, the Panel began a process to evaluate progress against cancer under the NCP. This has included a review of cancer statistics; testimony on

- regions of the Nation with excessive cancer mortality; an examination of coordination, gaps, and duplication in cancer-related research activities of Federal agencies; strategies for transferring knowledge to the public; special challenges related to lung cancer; and other topics.
- The Panel's inquiry later focused on how changes in the health care system affect the conduct and financial support of clinical cancer research, related training, and access to cancer care. Meetings in 1997 focused on concerns of special populations in the NCP, including the meaning of race in science, the usefulness and validity of assigning racial classifications, and whether race is an appropriate predictor of health outcomes. In 1998, the Panel focused on the meaning of quality in the context of cancer care, including how quality is defined, the role that clinical guidelines play in determining our approach to and understanding of quality, and how quality of life concerns should be addressed.
  - Throughout these discussions, the Panel's emphasis has centered on the NCP's success or lack of success in bringing the benefits of research discoveries to the public. Recurrent themes over the years make clear that while we have made progress, more remains to be done.
  - The Panel believes the time now is right to evaluate the NCP as a whole. The NCP has necessarily evolved from what may have been originally intended by its founders 28 years ago. Moreover, it has not been, and is not always, clear what the NCP is - what it is intended to achieve, how it is intended to do it, and who must be involved in executing its initiatives - even to those intimately involved in fighting the war against cancer.
  - In 1993, the Congress expressed concern that while important breakthroughs had been made in molecular biology and other basic cancer research areas, cancer mortality was still rising, particularly among underserved populations. A call was made to assess the NCP's achievements, reinvigorate it, and establish a new plan for the next century; this assessment and the recommendations resulting from it were published in *Cancer at a Crossroads: A Report to Congress for the Nation*. However, work remains to be done in this regard. Key questions include:
    - What was the original concept behind and intent of the NCP, as envisioned by its creators?
    - "Where are we now in terms of implementing that vision?"
    - Have we varied from the Program's original goals and, if so, why?
    - Have changes in the Program been beneficial?
    - "What is the NCP currently intended to achieve?"
    - How would we reframe the scope and purpose of the Program for the 21st century?
  - It is the Panel's belief that the Program extends from basic research to translation and application of research results to the public, to communication and education, and to enhanced cancer care and access to such care for all populations. We need to be honest in asking what it will take as a scientific community and society to fully accomplish the goals of the NCP, either as they exist now or as we perceive they should be.

## **Welcome-Massachusetts General Hospital**

### **Dr. Kurt J. Isselbacher, Director, Cancer Center**

Dr. Isselbacher welcomed the President's Cancer Panel and noted that:

- The first cancer clinic was established at the Massachusetts General Hospital (MGH) more than 75 years ago. Currently, MGH has the largest number of inpatient and outpatient visits of any treatment clinic in New England.
- MGH recently established more than 60,000 square feet of new research space for basic research, which houses more than 120 staff. MGH and its affiliate, Brigham and Women's Hospital, together receive approximately \$37 million in research support from the National Cancer Institute (NCI). Thus, though not technically a cancer center, the institution conducts a significant amount of NCI-supported cancer research. Efforts are under way to establish a Harvard Cancer Center, which would involve the schools of medicine and public health, other departments, and affiliated medical centers. These efforts are expected to benefit cancer patients nationwide, not just those in the New England corridor.

### **Dr. James J. Mongan, President**

Dr. Mongan welcomed the Panel and described recent developments at MGH:

- Dr. Bruce Chabner, formerly Director of NCI's Division of Cancer Treatment, was recruited to MGH in 1995. In addition, MGH has established multidisciplinary cancer care centers for all major disease categories. Training opportunities also are available for physicians who want to specialize in oncology/hematology. Staff see approximately 60,000 patients per year. Of these, about 20,000 receive chemotherapy and 40,000 receive radiotherapy.
- MGH is committed to improving clinical trials research; trials available to patients have increased to more than 300. In addition, MGH recognizes that patients' experience with cancer is extremely difficult; the hospital has committed resources to supporting patients and their families throughout the cancer experience from diagnosis through survivorship. Some of the resources available include a multimedia learning laboratory, chaplaincy, peer support, and counseling.
- MGH will be opening a proton beam facility, the second in the U.S., in the spring of 2000.

## **Dr. Bruce A. Chabner, Clinical Director, Cancer CenterR**

- Dr. Chabner commended the Panel for conducting its meetings in varied sites across the country. It is important to visit communities to learn about local issues and initiatives. As described by Dr. Isselbacher, one such initiative in the Boston area is the merger of local institutions to develop a single cancer care entity that will enhance service to the community, improve patient care, and increase multidisciplinary research.
- n Biotechnology companies are extremely important players in the National Cancer Program; this should be recognized. Increasingly, academic medical centers are outlets for industry drug testing.
- Academic medical centers must be able to subsidize government research funding. Centers' ability to supplement Government funding has been seriously compromised under managed care, placing the cancer research system in jeopardy. Dr. Chabner expressed hope that this message would be carried by the Panel back to Washington, DC.

## **NCI Director's Report**

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

- NCI's primary goals are research and education. Important research initiatives under way include the Cancer Gene Annotation Project, the Cancer Genetics Network, and work on molecular markers and targets for prevention and treatment. In addition, NCI is restructuring its cancer communications program and is recompeting and restructuring the Cancer Information Service. Because the issues in science and medicine are complicated, it is important to communicate to the public what is known, what is not known, and what is believed.
- Clinical trials are a particularly important issue. Currently, 2 to 3 percent of adults, and less than 4 percent of all cancer patients participate in clinical trials. We need to increase the number of patients enrolled in trials and the number of physicians who participate in trials, and we must restructure the clinical trials system. A public information campaign is needed to help achieve these objectives. In addition, NCI is renewing agreements with the Department of Defense and the Veterans Administration to expand access to, and coverage for, clinical trials.
- In recent months, the Institute of Medicine (IOM), and its National Cancer Policy Board (NCPB) have released three reports of note; these focus on reducing tobacco use, ensuring quality cancer care, and addressing the unequal burden of cancer among populations.
- In the context of today's meeting, it is important to remember that while NCI certainly is a part of the NCP, the NCP is much larger than just the NCI.

## PRESENTATION HIGHLIGHTS

### HISTORY OF THE NATIONAL CANCER PROGRAM

#### National Cancer Act: Philosophy and Players Who Created the Act

Mr. Michael McGeary

##### Background

The National Cancer Act of 1971 (PL 92-218), Section 407, National Cancer Program, states:

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: 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 first publication calling for national goals concerning cancer, *Cure for Cancer: A National Goal*, by Solomon Garb, was published in 1968. During the 1960s, attitudes toward cancer changed; the disease went from being a personal secret to a national problem. Sentiment was growing that something could and should be done about cancer. Advances in detection and treatment were occurring - chemotherapy and radiotherapy joined surgery in the treatment arsenal and reduced mortality from some cancers.
- However, budget growth at NCI stalled in the late 1960s. Mary Lasker, philanthropist and influential medical research lobbyist, became the primary force behind the effort to launch a crusade to conquer cancer. Lasker and her allies believed that advances in cancer research had produced much knowledge that could be used to attack cancer, but that NCI was not moving research results quickly enough from the test tube to the bedside. Lasker and Dr. Sidney Farber proposed establishing a national panel of consultants (the Yarborough Commission) to address the issues and recommend how to conquer cancer as rapidly as possible. Co-chaired by Farber and Benno Schmidt, the panel membership included Republicans with close ties to Richard Nixon.
- The panel's report, *National Program for the Conquest of Cancer*, was issued 7 months later in November 1970. It concluded that a national program was essential to exploit effectively the opportunities presented as a result of recent advances in knowledge. The panel indicated that the program effort required

- establishing a new independent agency (a National Cancer Authority), a comprehensive plan to coordinate an expanded and more aggressive national cancer program, and increased financial resources. Further, the panel called for an expanded network of comprehensive cancer centers to accelerate clinical research and training, demonstrate and disseminate information about better methods of detection and treatment, and work with community medical centers in their regions.
- After a year of complex political maneuvering, the National Cancer Act was passed. Funding was expanded, but instead of a new independent agency, NCI was elevated to bureau status, and the Director was made a Presidential appointee and was given authority to submit budget requests directly to the President (bypass budget authority). Section 407 authorized the NCI Director to coordinate the National Cancer Program. The Act also elevated the National Advisory Cancer Council to a Presidentially appointed Cancer Advisory Board; created the President's Cancer Panel to oversee implementation and bring delays or barriers to the attention of the President; established programs to facilitate conversion of research into better prevention, detection, and treatment methods; and provided a separate appropriation for a cancer control program to foster wider use of clinical advances.
  - Enduring issues for NCI and the National Cancer Program as a whole include:
    - What should be the balance among basic research, translational research, and application, and between biomedical and behavioral research?
    - What is NCI's role in cancer control? What is its responsibility to ensure that improved prevention, diagnosis, and treatment methods resulting from research are adopted in the community?
    - Why is coordination (the least successful outcome of the National Cancer Act) so difficult? Contributing factors include: the highly fragmented and decentralized nature of the health care system; the complexity of cancer itself and resulting differences of opinion about desirable policies and approaches; the voluntary nature of the coordination authority granted to the NCI Director; the time and costs of coordination activities, particularly given constraints on the NCI Director's authority; and potential role conflicts of the NCI Director as leader of NCI and of the NCP, of which NCI is a part.

## **Discussion**

**Mr. McGeary**

### Key Points

- Coordination of the NCP was discussed in annually updated 5-year plans produced in the years immediately following passage of the National Cancer Act, and a few interagency committees were established. Within a few years, however, the cancer centers came to be viewed as the locus of program coordination. There



- was no apparent defining moment when this shift occurred. In addition, the NCI Director's energies were largely consumed in running the Institute.
- Though initially, due to Lasker's influence, there was greater emphasis on application of research results and cancer control, over time those favoring emphasis on basic research prevailed. In addition, funding was given to the research community, but its efforts were not connected to access to care. NCI currently is expanding its efforts in cancer control, but its longstanding priority and excellence is in basic research. One speaker suggested that it is difficult to do both. Part of what NCI would need to do to be equally successful in cancer control is not within its mission.
  - Lasker and her allies believed that the only way to get attention for the NCP was to place it at a higher level than the NCI, but many in the cancer community still do not want to resort to a cancer "czar." In addition, there are limits on what can be legislated outside of the Government. Should the National Cancer Act be rewritten, it would need to address not only the scope of activities to be included in the NCP, but the range of agencies and other groups, particularly industry, that should be involved. Industry has benefitted greatly from the knowledge and cadre of highly trained professionals developed by the NCI, and is now a major player in the cancer research enterprise.
  - As the national cancer effort is far more fragmented than it was in the 1960s, so is the Congress far more partitioned than in the years surrounding passage of the National Cancer Act. Currently, relatively autonomous committees deal with different programs (e.g., Medicare) that are important to addressing the cancer problem, and there is little awareness of intersecting issues or coordination of committee activities.
  - At the time of the National Cancer Act, analogies were made between the Apollo (manned moon landing) and Manhattan (atomic bomb) projects and the National Cancer Program. The panel of consultants believed a similar crash program could be mounted against cancer. This notion was disputed by the scientific community, which knew that the requisite knowledge base did not yet exist. Moreover, at the time of the National Cancer Act, some of what was known (notably, concerning the connection between tobacco use and cancer) was not recognized or was denied. By contrast, the Apollo and Manhattan projects were essentially engineering problems; the critical knowledge existed and the challenge was in applying it.

## **Legislative Changes Since 1971**

### **Ms. Dorothy Foellmer**

#### Key Points

- The need to coordinate cancer research was recognized as early as 1937. The National Cancer Institute Act of 1937 (P.L. 244) established the NCI within the Public Health Service and directed the Surgeon General, through the Institute, to

coordinate research conducted by NCI and similar research conducted by other agencies, organizations, and individuals.

- The National Cancer Act of 1971 grew out of the report of the Yarborough Commission. It elevated and expanded certain authorities of the NCI Director, conferred bypass budget authority to the Institute, and established the National Cancer Advisory Board (NCAB) and the President's Cancer Panel. The Act placed responsibility for coordination of the National Cancer Program with the NCI Director (see above, McGeary - Background). The Act also authorized the first cancer centers, and established cancer control programs, an information dissemination program, and the International Cancer Research Data Bank
- The National Cancer Amendments of 1974 (P.L. 93-352) broadened the Institute's authority to collect, analyze, and disseminate information; authorized expanded information dissemination for scientists, health professionals, and the public; and authorized construction grants for new facilities, and alteration and renovation of basic research laboratory facilities.
- In 1978, further amendments were passed as part of the Community Mental Health Center Extension Act of 1978 and Biomedical Research and Research Training Amendments of 1978 (P.L. 95-622). These amendments recodified the 1971 Act, reorganized and consolidated duties and functions of the NCI Director (coordination of the NCP was de-emphasized), called for expanded research for prevention of cancer caused by occupational and environmental exposure to carcinogens, reduced the minimum number of President's Cancer Panel meetings to four annually, expanded the mission of cancer centers to include basic research and prevention, expanded the cancer control mandate, and added several ex-officio members to the NCAB with expertise in environmental carcinogenesis. In these amendments, the language regarding the scope of the NCP that included other Federal and non-Federal programs was dropped.
- The next reauthorization of the National Cancer Act occurred in 1985 as the Health Research Extension Act (P.L. 99-158). It established the position of Associate Director of Prevention, added to NCI's mission and cancer control activities research on continuing care of cancer patients and their families, and consolidated cancer communication activities. It was also the beginning of the President's Cancer Panel requirement for an annual report on the status of the National Cancer Program.
- In 1988, rehabilitation research was added to NCI's mission, and its information dissemination programs were further expanded (Health Omnibus Programs Extension of 1988, P.L. 100-607). The most recent amendments occurred in the NIH Revitalization Amendments of 1993 (P.L. 103-43), mandating set-asides of NCI's appropriation for cancer control activities, and requiring intensified and expanded research programs in breast/women's cancers and prostate cancer. A case-control study of elevated breast cancer rates on Long Island was mandated as a result of pressure from women in that area who believed they suffered excess cancer incidence due to environmental exposures. The study launched a different approach to studying a chronic disease (i.e., using geographic information system technology).

- The Act is unlikely to be reauthorized in the near future because of current political issues (e.g., fetal tissue research). Legislative changes may, however, be made as part of stand-alone bills or amendments to unrelated bills.

## Discussion

**Ms. Foellmer**

### Key Points

- In the current political climate, special interest groups tend to use legislative shortcuts for their own needs, rather than going through traditional processes (i.e., reauthorization). NCI is often charged with undertaking initiatives through appropriations and report processes. Some believe the 1971 Act was the result of special interest pressure.
- The bypass budget used to be an unrealistic wish list; as money became tighter, it became more realistic in its requests. The resurgence of interest in the bypass budget is being driven by patient advocates, who are speaking with a more united (and therefore more powerful) voice than in the past.
- Though not the only study to be mandated, the Long Island breast cancer study was the only one in which the study design was part of the legislation; this seems to be an aberration rather than a trend.
- Views vary as to the definition of the National Cancer Program. The lack of clarity is due to the lack of a definition in the legislative history of the Program and a lack of agreement as to what coordination entails. As a result, little consensus exists as to what can or should be done. Viewing the Program's history overall, it appears that the basic intent was to get information out to communities and coordination was the mechanism for achieving this objective.
- There is a disassociation between discovery and application; to have an impact on cancer mortality, application of discoveries must take place in the neighborhoods of the Nation. Legislation could help NCI do this, but the Congress may be unaware of this possibility or unwilling to make changes that could have unanticipated undesirable effects. A global look at the issues is needed. It must also be understood that collaboration cannot be legislated, and non-Government action can be legislated only to a limited degree. The National Dialogue on Cancer is discussing a major revision of the National Cancer Act, but the likelihood of achieving such a change is uncertain.
- To date, we have done a better job of developing the research part of the NCP than developing cancer care and control. An opportunity exists to improve cancer control efforts in States that were parties to the recent tobacco company settlement. Concern was expressed that these funds might be diverted to support other State activities; since the Federal Government was not a party to the settlement, it has little influence on how these funds are used. Moreover, the settlement funds do not address system-wide issues.

## Evaluating the National Cancer Program

Ms. Cherie Nichols

### Key Points

- An evaluation of the National Cancer Program was requested by the Congress in 1993; a three-phase approach was approved. In Phase I, past progress was evaluated; six expert panels were convened to examine progress over the previous 10 years in the following areas: molecular medicine, cancer induction and progression, prevention, early detection and diagnosis, treatment, and cancer control. The evaluation of advances in each area considered scientific significance, current impact, potential implications, the extent of translation of advances to application, barriers, and future directions. The conclusions of these panels were contained in six reports, *Measures of Progress Against Cancer*. In addition, a consolidated report of the panel Chairs highlighted advances having broad, cross-cutting significance in understanding the biology and etiology of cancer, and individual advances having a far-reaching impact.
- In Phase II, the current state of the Program was evaluated. This was accomplished by a review of testimony presented to the President's Cancer Panel from 1991 to 1993, and by reviewing testimony and the final report of the President's Cancer Panel Special Commission on Breast Cancer (1992-1993).
- To recommend future directions for the NCP (Phase III), a 16-member subcommittee of the National Cancer Advisory Board was appointed. Known as the Subcommittee to Evaluate the National Cancer Program, or SENCAP, its membership represented the cancer research, medicine, nursing, industry, communication, and advocacy communities. The Subcommittee was charged to integrate information from Phases I and II; assess progress; define gaps, shortfalls, and opportunities; develop recommendations for future directions of the NCP; solicit and incorporate outside review and comments; and provide a final report to the Congress. The report, *Cancer at a Crossroads: A Report to Congress for the Nation*, was released in 1994.
- The SENCAP report defined the NCP as including:
  - Government at all levels
  - The health care community (e.g., physicians and other health care providers; Federal, State, and local programs; private insurers)
  - Business and industry (e.g., hospitals and other health care facilities; pharmaceutical, biotechnology, and other industries; universities and academic health centers; voluntary organizations; foundations; advocates; mass media)
  - The research community
- SENCAP recommended action in four broad areas: application of research, translational research, basic cancer research, and overarching recommendations. The 37 recommendations were prioritized as immediate (substantial progress toward completion within 1 to 2 years); those to be initiated (major effort to be

- started in 1 to 2 years); and ongoing needs (continued and increased support of current efforts). Parties responsible for implementation were identified.
- First among SENCAP's overarching recommendations was to establish a Presidentially led plan for overall coordination of the NCP that includes, among other provisions, reestablishing the 1971 legislative authority for coordinating cancer-related research activities of Government, industry, and voluntary sectors. Other overarching recommendations called for evaluating cancer research programs and priorities; providing sufficient funding to maintain a balanced portfolio of basic, translational, and applied research; and expanding the number, scope, and geographic distribution of NCI-designated cancer centers.

## **Discussion**

**Ms. Nichols**

### Key Points

- The NCAB set up a committee to monitor implementation of the SENCAP recommendations; however, the committee became defunct. To date, there has been no formalized review of implementation progress. Progress has been made in achieving many of the recommendations, but it is difficult to determine the extent to which this progress has been attributable solely to the influence of the report. The Panel has said that the least progress has been in coordination of the NCP, and inadequate progress has been made in bringing the benefits of research to the people.
- No formal answer to the recommendations has been made by the Congress; however, no such answer was requested by the National Cancer Advisory Board. There is a need to rejuvenate an examination of the recommendations at a higher level. It was suggested that a thorough report card be prepared on what has been accomplished, what is in progress, what remains to be done, and barriers to progress. It is unclear who should undertake such a complex activity, but it should not be NCI. It may be up to the Panel to reignite the Congress' interest in these issues.
- Dr. Freeman indicated that the report deserves more attention; the Panel will use the report as a point of departure for discussions in its meetings this year.

## **THE NATIONAL CANCER PROGRAM: LOOKING TOWARD THE 21ST CENTURY**

**PUBLIC HEALTH PANEL**

## **Distributing Health Effects Across Individuals in a Population**

**Dr. David Asch**

### Key Points

- Several views exist concerning distribution of health care resources relative to cancer and public health. One favors distributing resources for future rather than present benefits; for example, investment in basic research is an investment in the future, while investment in intervention research realizes benefits much sooner. Another view favors distributing resources toward cancer versus other diseases. A third view considers how resources are distributed across individuals; this approach often affects the value that people place on cancer control.
- Population-based studies often miss the point that people care about the distribution of outcomes as well as the central tendency. In a scenario (described by Dr. Asch) in which resources are limited and the probabilities of a disease outcome are known for each of several strategies, cost-effectiveness theory would view all strategies with equal average benefits. Yet, feelings about the strategies are likely to differ, with some being viewed as more "ethical" or "fair" than others. Similarly, when a study population of jurors, ethicists, and decision-making experts were asked which of two colon cancer screening tests should be recommended as policy (Test A, a less expensive test, can be provided to a low-risk population and will prevent 1,000 colon cancer deaths, versus Test B, which is twice as expensive, can be provided to half as many people, but will save 1,100 lives) the preference was for Test A. To overcome these potential biases, published studies could report outcome distributions rather than just central tendencies. The findings demonstrate that people care about the distribution of outcomes and not just the overall population effect. Health policymakers should also care about outcome distributions.

## **Cancer Prevention Research**

**Dr. Peter Greenwald**

### Key Points

- Cancer prevention is taking two directions - toward public health interventions designed to reach all segments of the population (e.g., tobacco use policies, dietary guidance), and toward medical research designed to identify persons at high risk of disease and titrate risks down to lower levels with chemopreventive agents.
- In public health, there has been a shift away from prevention and toward medical care. Part of the reason for this is the need for a vision of excellence in public health in medical schools. This public health focus must be sharpened, and public health and prevention must be partnered.

- Among the future prospects for prevention are public guidance in areas such as tobacco and diet, and research focused on genetic and molecular targets/pathways to assess risk and speed preventive drug discovery. Evidence suggests that addressing overall genetic instability may be more important than targeting single genes.
- Biomarkers and imaging technology improvements are also areas of intensive investigation and promise. Other prevention research is focusing on the development of vaccines (e.g., prophylactic vaccines against human papillomavirus, the cause of nearly all cervical cancers), and biotechnology changes in the food supply (e.g., plant genomics) that may increase production or nutrient value.
- Applying new informatics technologies to the benefit of the average person is a challenge. Many scientists have limited ability to use new technologies.
- It is unclear how environmental changes are related to cancer, but left unchecked, current forces may destroy the environment at increasing rates. Greater sensitivity to the environmental impact of technologies and policies is needed.
- There is a need to build a cancer prevention ethic into the mainstream of cancer research so that investigator-initiated efforts and major institutions become more committed to it.

## **Cancer Control Research**

### **Dr. Robert Hiatt**

#### Background

The concept of cancer control dates to 1913, when surgeons were concerned about invasive cervical cancer and recognized a need to alert the population about early detection, collection of data, and the education of the public. Perspectives on cancer control have changed somewhat over time, as evidenced by changing priorities and opportunities. In 1997, the NCI Cancer Control Program Review Group defined cancer control research as "the conduct of basic and applied research in the behavioral, social, and population sciences that, independently or in combination with biomedical approaches, reduces cancer risk, incidence, morbidity, and mortality and improves the quality of life."

#### Key Points

- Cancer control is at the intersection of cancer research and public health applications. Its areas of concern have expanded over time.
- Cancer control research activities are interdependent; lessons from fundamental research inform intervention research. Once proven, interventions move to application and program delivery. Surveillance research tells us where we are and informs both fundamental and intervention research. Research on dissemination

and message development is essential. Knowledge synthesis and decision-making are central to all aspects of cancer control.

- In developing and applying cancer control programs, we need to recognize major social trends, such as the aging and increased diversification of the population, advances in molecular biology and genetics, the growth of information technologies, and the reorganization of the health care delivery system.
- A number of research infrastructures will help to move cancer control forward in the coming years. These include the Cancer Family Registries; the Cancer Genetics Network; Transdisciplinary Tobacco Use Research Centers; the Surveillance, Epidemiology, and End Results (SEER) program; and the HMO Cancer Research Network. Others are anticipated in the near future in cancer communications and population research.

### Additional Research Needs and Other Recommendations

- Extraordinary opportunities exist in the area of tobacco, which is responsible for 30 percent of all cancer cases and one in five deaths in the United States. The number of tobacco-related deaths continues to rise, especially among women, and smoking among adolescents has increased by 73 percent in the last 10 years. It is estimated that over their lifetimes, the population of current and former smokers will generate \$501 billion in excess health care costs. The challenge is to develop more effective interventions and better strategies for cessation. Research is needed to further explore gene-environment interactions that affect tobacco use, and to prevent cancer in the enormous population of former smokers. There is also a need to expand the national research infrastructure to support these activities.
- We have had the same perspective concerning the translation of research into application for most of the past century, and the task of bringing research results to the benefit of the public is still with us. Moving us forward in this area is a collaborative responsibility of the NCI and its partners currently active in cancer control, but greater coordination is needed in these efforts.

## **The End of the "Tobacco and Cancer" Century**

### **Dr. Howard Koh**

#### Key Points

- In the past decade, we have begun to see reductions in cancer incidence and mortality; the investment in cancer research is beginning to pay off. We now need to increase emphasis on public health, prevention, and cancer control.
- Future medical historians undoubtedly will recall the 1900s as the "tobacco and cancer century." Lung cancer and tobacco represent the greatest public health disaster of our time. Tobacco use is a drug addiction and should be recognized as such.



- At the State level, the question is how to control tobacco addiction without additional public health funding. Four States (California, Massachusetts, Arizona, and Oregon) have imposed new tobacco taxes. Massachusetts has used dedicated tobacco tax revenues to fund Statewide tobacco control programs. In the past six years, these efforts have included developing counter-advertising and media campaigns, providing public education in schools, establishing a 1-800-TRY TO STOP hotline service, and funding local boards of health. The goal in Massachusetts is to "denormalize" tobacco use. The public has become more mobilized around tobacco use issues due to greater awareness of secondhand smoke. The State has achieved a 30 percent decrease in adult per capita cigarette consumption.
- Tobacco also is a major international issue. In many Asian countries, for example, 70 percent of men smoke. With diversity in the United States increasing, tobacco issues must be addressed creatively to reach the many segments of the population. Factors affecting the design and implementation of public health and cancer control programs include race/ethnicity, culture, language, socioeconomic status, length of residence in this country, sexual orientation, disability, age, and gender.
- Diversity issues are also important in breast cancer prevention and control. If the Asian population is viewed as a whole, breast cancer rates appear to be lower than in the U.S. Caucasian population; however, some subpopulations (e.g., Native Hawaiian women) have breast cancer rates almost as high as those of the white population.
- Melanoma is one of the few cancers that is increasing steadily in incidence. Public health and prevention efforts in the United States have been initiated only in the last decade. In a 1995 study, half of 1,000 American adults surveyed did not know what the term "melanoma" meant. We are beginning to see changes in attitudes about sun exposure, but behavior change is slow. Similar challenges exist with other cancers (e.g., prostate); basic education of both the public and health professionals is needed. In this regard, the State of Massachusetts has implemented an outreach and education program for men of color that emphasizes colorectal cancer, diabetes, heart disease, substance abuse, and violence prevention, as well as prostate cancer.
- Massachusetts is one of the few States with a health department comprehensively addressing cancer and genetics in terms of testing, ethical and policy issues, and professional and consumer education.
- The future of cancer control will involve caring for the whole person, reaching youth with health-promoting education and programs, supporting cancer control in the community (e.g., prevention centers, health networks, local health departments), and fostering collaborative efforts that, for example, give employees paid time off to obtain cancer screening.
- In Massachusetts, the mission of public health in the 21st century is to help people lead healthy lives in healthy communities, emphasize prevention, dedicate special efforts to the health concerns of those most in need, and work to help all people reach their full potential for health.
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## Additional Research Needs and Other Recommendations

- In the 20th century, the focus has been on cancer research and treatment in specialized medical centers; the populations with access to these services have been limited. In the 21st century, we need to shift the focus to promoting health and prevention, and develop a cancer control community that reaches everyone.

## **Discussion**

### **Drs. Asch, Greenwald, Hiatt, and Koh**

#### Key Points

- Resources for cancer control tend to be allocated where NCI perceives that there is a large cancer burden; consequently, a major portion of funding is for tobacco-related efforts.
- Basic research in cancer control recognizes the role of human behavior in cancer prevention and control; this understanding is important to the development of effective interventions (e.g., it is necessary to understand how people respond to messages).
- There is some tension between public health goals (e.g., saving the most lives possible) and individual values (e.g., ensuring that each person gets the best/most care possible). Currently, health care resources in this country are poorly distributed, a difficult political as well as social issue. We have leaned toward the medical model over the public health model, but the medical model is not attractive to the more than 40 million in the United States who have no health insurance. Universal health care was proposed and soundly defeated in 1994. Proposed solutions to this problem are generally stymied by the "iron triangle" of low cost, high quality, and broad access; it is possible to provide two of these parameters, but very difficult to provide all three.

## Additional Research Needs and Other Recommendations

- In the area of tobacco, greater emphasis is needed both in targeting young people and pursuing chemoprevention for the high-risk population of former smokers. In this and other areas of cancer control, centers are needed to bring together multiple disciplines. New types of centers with a different focus (e.g., early detection, population-based studies) would be useful.
- A coordinated national plan for cancer control, with measurable goals and milestones, is needed that encompasses public, private, and voluntary organizations and the individual. All individuals have a role in protecting their own health, the health of their families, and the health of the community. Cancer councils have been established in some States, but continued strong leadership of these organizations is essential to their success.

- Creative use of resources is needed to expand and coordinate cancer-related efforts. For example, States might be induced to use tobacco settlement funds for cancer control efforts if CDC or NIH matching or challenge funds were available. Cancer control training could be enhanced if, for example, students training at cancer centers were required to rotate through the State or other public health department.
- Some points on the cancer control continuum are not being adequately addressed. For example, the benefits of colorectal cancer screening are well known, but screening is being underutilized in the community. Research activity is needed to learn how to use incentives for clinicians and health care payers to induce them to include screening in routine care. We also need to increase access for people, regardless of reimbursement, and educate the public to demand screening and access to treatment if an abnormality is detected.
- A better understanding is needed as to what constitutes quality care; benchmarks and surveillance are necessary once credible measures have been established. People will try to meet such measures and they will become the goals that help us move forward. Establishing these measures should be a part of the research agenda.
- The Long Island breast cancer study has provided new tools (e.g., geographic information systems) for assessing links between environmental risks and medical outcomes. More tools like these are needed. NCI is also funding studies to compare the risks of women with breast cancer in different regions of the country and the reasons for disparities.

## **RESEARCH AND MEDICINE-INDUSTRY, ACADEMIA, AND THE GOVERNMENT PANEL**

### **Clinical Research in Academic Health Centers**

**Dr. Bruce Chabner**

#### Key Points

- Despite unprecedented national prosperity, the health care system is in chaos and we are experiencing an erosion of institutional support for clinical research. This means an erosion of the translation of research to the public. National debate is needed concerning new investment in medical research. For example, we must look at what will replace institutional subsidies (the infrastructures supporting salaries for clinicians, diagnostic research, and prevention interventions research) in the wake of Medicare and other cutbacks. At the Dana Farber/Partners Cancer Care System, the cancer clinical trials system infrastructure costs \$6 million annually; approximately one-third of this comes from the institution, another third from industry, and the remaining third from NIH and foundations. At this time, there is no obvious source of support to replace these dollars.

- Important opportunities exist - rapidly expanding investment in the biotechnology industry, and unprecedented scientific opportunity for progress in cancer prevention, diagnosis, and treatment. MGH has initiated steps to take advantage of opportunities for conducting clinical research with the expanding biotechnology industry. In 1996, a joint venture for cancer care was established with the Dana Farber Cancer Institute and Brigham and Women's Hospital, and ties to industry were strengthened. This has resulted in increased testing of new products, increased support for innovative basic and translational research, and more input on trials design and implementation. In 3 years, accrual to clinical trials increased threefold; accrual to industry-supported trials increased 10-fold.
- Industry pays for the full cost of its trials; the institution recovers only one-half to three-fourths of the cost of NIH-sponsored trials. Investigator-initiated trials at MGH are supported by the institution. Thus, institutional support is critical to make possible investigator-initiated research and participation in NIH-sponsored trials.

## **Cancer Drug Development**

### **Dr. Robert Tepper**

#### Key Points

- Our understanding of genetics and the building blocks of human life is growing exponentially. In the next 3 to 5 years, we will identify all human genes and will thereby have the tools for understanding human physiology. This can be likened to the discovery of the periodic table, before which there was no pharmaceutical industry because there was no real understanding of chemistry. The human genome will provide the building blocks of biomedical research of the future and a new understanding of human disease. Genomics will not replace individual investigation, but will enable us to look at disease in a new way.
- Industry has also been developing software needed to understand the genome and developing ways of storing the information so that it can be used repeatedly. This information must now be applied to understanding disease. Molecular markers will help to define disease.

#### Additional Research Needs and Other Recommendations

- A key question is: How can the human genome be used optimally for novel cancer diagnosis, prognosis, and therapy? Industry-academic collaborations must be fostered to take advantage of the strengths of each. Industry has been the driver in building tools and using the genome; academics have the models of cancer biology and tissue repositories.
- The most promising approach to applying genomic information to the cancer problem is through Government, industry, and academic collaboration. Such collaborations should result in a resurgence of clinical researchers, since they

- know the patients best. Consortia are forming, but a more focused effort with positive sanctions is needed.
- Ethical issues associated with using patient genetic information must be addressed now.

## **Discussion**

### **Drs. Chabner and Tepper**

#### Key Points

- Biomedical research is endangered and threatens to become the missing link to clinical application if we do not address the crisis occurring in academic medical centers. The clinical research issue is part of a broader question of what will happen to academic centers in the next several years. Key issues are: (1) the Federal Government is cutting back on Medicare; this is being done abruptly and is creating an imbalance in the system; and (2) the growth of managed care is increasing conflicts with insurers concerning reimbursements. A great amount of the care provided at academic medical centers is not reimbursed.
- Academic centers still want to do NIH research because of the associated prestige and other reasons. They are willing to do the research at a loss, but research progress is not only about winning grants and writing publications. In the real world, bills must be paid and the community must be reached. These realities are also part of research, and they are difficult.
- Funding for research must be restored, but fee-for-service is not the answer. The public (through taxes) and insurers must contribute more. Industry is paying its way for clinical trials, but NCI clinical trials are not. To enable institutions to pursue their own research agendas and support their own trials, reasonable operating margins must be restored. To date, managed care organizations have been unwilling to accept this view.

#### Additional Research Needs and Other Recommendations

- Currently, the health care system is stressed. Health professionals are working hard, but those who feel it the most are the sick, who experience directly the waiting, the delays, and the red tape. A comprehensive evaluation of the health care delivery system is needed.

## Communication and Education

### Dr. Robert Hiatt

#### Key Points

- Major segments of the population have limited or no access to cancer information and support resources. More cancer communications choices are needed for all audiences.
- We are witnessing tremendous growth in the population's ability to access information using new technology. In 1998, 22.3 million adults searched online for health and medical information. In the same year, 1.3 million pieces of e-mail were processed each week by cancer-related listservs. In 1997, 41 percent of U.S. households had at least one personal computer. Though not evenly distributed, these technologies offer great opportunities for reaching the population with cancer information.
- The Science Panel on Interactive Communications and Health suggests that "few other health-related interventions have the potential that interactive health communication does to simultaneously improve health outcomes, decrease health care costs, and enhance consumer satisfaction" (Eng, 1998).
- The NCI has established a new branch in its Division of Cancer Control and Population Science to address cancer communication issues. A Request for Applications (RFA) was issued to explore cancer communication issues in cancer control. Six grants were funded for a total of \$2.5 million. Awards were made in May 1999 and will run through April 2004. Among the objectives are to study optimal communications strategies for underserved populations, conduct studies of risk communication and message development, explore how to better use the NCI Cancer Information Service as a communication tool, and assess the effectiveness of the World Wide Web as a tool for cancer communications.
- In addition, NCI has identified extraordinary opportunities in cancer communications. Goals in this area are to reduce the cancer burden through improved communications, make communications an accepted component of quality care, increase public demand for cancer information and communication, speed the dissemination of "best practices," and develop the cancer communications infrastructure.

## Interactive Health Communications

### Dr. Albert Mulley

Background The Science Panel on Interactive Communication and Health (SciPICH) was convened by the Office of Disease Prevention and Health Promotion of the U.S. Department of Health and Human Services. This 14-member panel of non-Federal experts in many aspects of health and technology met 10 times over more than 2-1/2 years. The Panel's work was reviewed by liaisons from more than 50 Federal agencies

and offices and non-Federal and private-sector organizations. The Panel's report, *Wired for Health and Well-Being*, can be accessed at [www.scipich.org](http://www.scipich.org).

### Key Points

- Interactive health communications (IHC) is defined as the interaction of an individual - consumer, patient, caregiver, or professional - with or through an electronic device or communication technology to access or transmit health information or to receive or provide guidance and support on a health-related issue. Such two-way communication mechanisms include health-related Web sites and other technology-mediated applications.
- IHC applications relay information, enable informed health-related and clinical decision-making, promote healthy behaviors by individuals and populations, promote peer information exchange and emotional support, promote self-care, and manage demand for health services (i.e., increase utilization of effective services and reduce unnecessary services).
- Advantages of "new media" for health communication and education include: the ability to tailor communications and learning (the user can select medium, style, and pace); improved access (any time, anywhere) and dissemination; reduced language, geographic, and disability-related barriers; and, possibly, reduced costs.
- IHC has potential for harm; for example: (1) minimal research is available on the risks associated with the widespread use of IHC; (2) the ultimate effects on health care quality, the clinician-patient relationship, and the organization of medical systems are unknown; (3) the use of poor- quality or inappropriate applications can result in inappropriate treatment or delays in seeking appropriate medical care, reduced trust in health care providers and prescribed treatments, wasted resources, and privacy and confidentiality violations.
- The phenomenon of "supplier induced demand" is an important consideration in health care. One example in the United States is the overabundance of physicians with the ability to perform certain procedures, which contributes to the likelihood that these procedures are performed. Such phenomena suggest that the care a person gets depends on where he or she lives and what doctor he/she sees as much or more than on who he/she is and what he/she values. Variations in care can be striking.
- The way messages are communicated affects patient understanding, stress levels, choices, and outcomes. Most patients want to know the probability of outcomes for a given medical intervention; better data are needed from health care providers to support such shared decision- making.
- A patient's decision will depend on that person's individual value judgements as well as the probability of outcomes. We need to give patients a sense of what the future will be like if the outcome may be one not previously experienced by the individual. Peer interaction is especially helpful in communicating such information.
- Providers need to discuss feelings with patients (e.g., How do you feel about losing a breast?) to help the patient connect feelings and values to the treatment

- selected. The general principle is to give people the care they want based on what they value and care about, rather than offering the same care to everyone.
- In a study of shared decision-making, patients reported that they found the process valuable, and participants elected surgery up to 40 percent less than the average for selected procedures. Similarly, men who were provided full information about PSA screening risks (e.g., the possibility of unneeded intervention with side effects following detection of an abnormality) elected to forego screening.

### Additional Research Needs and Other Recommendations

- New partnerships are the keys to implementing shared decision-making to: help patients understand the critical nature of their role in the process; help providers realize efficiencies and increased market share; reduce risk barriers for purchasers; and achieve system integration. Public-private partnerships are needed for applications development and distribution. Business models are needed that realize the economic value of support to sustain ongoing development, evaluation, and maintenance.
- Major policy issues in IHC include: privacy and confidentiality concerns; oversight, regulation, and liability; accreditation and certification; integration of IHC with clinical practice, public health, and the workplace; payment and reimbursement issues; access to IHC, and public and private investment in development and research.
- Developers of IHC applications should publicly disclose information about their applications (e.g., identify developers, sponsors, source of content, advertisers, purpose of application, and privacy protections). Users and purchasers need this essential information to make informed decisions.
- More research is needed on the use of the Internet; specifically, how people are induced to buy or use a product or service, and how they can be protected from inappropriate supplier-induced demand.

## **Discussion**

### **Drs. Hiatt and Mulley**

#### Key Points

- Policymakers and the media seem to want health communications in simple messages or sound bites, while the public and the scientific and medical communities want detailed information. For those who want sound bites, a detailed explanation of what is known, what is not known, and what is believed may not be acceptable.
- Medical decisions probably rely more on values than on medical probabilities and risk. Information often does not provide the answer to the decision the patient



must make. Science provides the probabilities, not the answers; we need to be careful about overselling what science can do.

- Half of cancer patients are over age 70; they are the least likely to use the Internet, but have the highest risk for cancer. Research is ongoing to explore how to use youth (who are comfortable with technology) to teach parents or other adults, including elderly and low literacy populations. Less complex media may be needed to reach some populations.
- Patients are becoming more informed and empowered by health information obtained on the Internet. If the physician uses technology to work with the patient, he/she is likewise empowered. Many physicians, however, lack the time to conduct Internet searches for information.

#### Additional Research Needs and Other Recommendations

- Patients may perceive information obtained on the Internet as authoritative when, in fact, it is not. Tools are needed to help consumers navigate and evaluate the quality of Internet health information.
- IHC is becoming an integral part of the health care system. We need to determine how best to incorporate these technologies into this system.

#### **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 three 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 July 19, 1999, is accurate and complete.

Certified by:

Harold P. Freeman, M.D.  
Chairperson  
President's Cancer Panel  
Date: July 19, 1999