MEETING SUMMARY
PRESIDENT'S CANCER PANEL

STRATEGIES FOR MAXIMIZING THE NATION'S INVESTMENT IN CANCER

September 10, 2007
Atlanta, GA

OVERVIEW

This meeting was the first in the Panel's 2007/2008 series focusing on strategies for maximizing the nation's investment in cancer. The meeting was designed as an interactive, facilitated working session to describe a vision for the future of the National Cancer Program and strategies for achieving that vision.

PARTICIPANTS

President's Cancer Panel (PCP)

LaSalle D. Leffall, Jr., M.D., F.A.C.S., Chair

Margaret Kripke, Ph.D.

National Cancer Institute (NCI), National Institutes of Health (NIH)

John E. Niederhuber, M.D., Director, NCI

Abby Sandler, Ph.D., Executive Secretary, PCP, NCI

Roundtable Participants

Margaret Anthony, R.N., M.H.S., C.N.O.R., Director's Consumer Liaison Group, NCI

Deborah Banker, Ph.D., Vice President, Research Communications, The Leukemia & Lymphoma Society

Edward Benz, Jr., M.D., President and Chief Executive Officer (CEO), Dana-Farber Cancer Institute and CEO, Dana-Farber Partners Cancer Care

Martin Brown, Ph.D., Chief, Health Services and Economics Branch, Applied Research Program, Division of Cancer Control and Population Sciences (DCCPS), NCI

Janet Collins, Ph.D., Director, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC)

Michael Fiore, M.D., M.P.H., Director, Center for Tobacco Research and Intervention, University of Wisconsin and Professor of Medicine, University of Wisconsin School of Medicine and Public Health

William Hait, M.D., Ph.D., President, American Association for Cancer Research; Senior Vice President, Worldwide Head of Hematology and Oncology, Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Clifton Leaf, M.F.A., Journalist; Member, Board of Directors, Susan G. Komen for the Cure; and Author of *Why We're Losing the War on Cancer (And How To Win It)*

Greg Simon, J.D., President, FasterCures/The Center for Accelerating Medical Solutions

Michael Sporn, M.D., Professor in Residence, Pharmacology and Medicine, Dartmouth Medical School

OPENING REMARKS—DR. LaSALLE D. LEFFALL, JR.

On behalf of the PCP, Dr. Leffall welcomed invited participants and the public to the meeting. He introduced Panel members, provided a brief overview of the history and purpose of the Panel, and described the aims of the current series of meetings. Dr. Leffall explained that following an update on NCI activities from NCI Director Dr. John Niederhuber, the meeting would employ a roundtable discussion format facilitated by Mr. Robert Mittman.

NCI UPDATE—DR. JOHN NIEDERHUBER, DIRECTOR, NCI

- The United States is facing a crisis in terms of the rapidly increasing costs associated with health care delivery. This crisis is complicated by changing demographics and limits on the discretionary portion of the Federal budget.
- Cancer is a global concern. Ninety percent of the cancer burden falls upon populations outside the United States. Cancer kills more people each year in the developing world than malaria, tuberculosis, and HIV combined. This is a crisis in itself, but also has a great economic impact on the developed world.
- Access to state-of-the-art cancer care in our country will be the greatest determinant of mortality over the next decade. There will be great progress in science, but current methods for bringing state-of-the-art care to people in the communities where they live are inadequate.
- A new era in medicine is beginning; rapidly advancing genomic and proteomic technologies are beginning to impact the practice of medicine and health care decision making. Within 10 years, medicine will be dramatically transformed, using more targeted and less toxic therapies and individual patients' genetic and molecular information to deliver personalized medicine, including prevention interventions. Groundbreaking research performed and funded by NCI is leading to applications of this paradigm for a number of diseases.
- NCI is establishing a Research Center of Excellence within the NIH Clinical Center to develop the capacity to perform subcellular imaging to identify molecular targets for drugs and evaluate therapeutic outcomes within hours of application. These methods will reduce the cost of drug development by reducing the time required to determine treatment effectiveness.
- NCI is also working to create a "drug discovery platform" that involves communication and collaboration among pharmaceutical companies, biotechnology companies, universities, Comprehensive Cancer Centers, Community Cancer Centers, and the cooperative groups that conduct clinical research. It is clear that the public wants NIH and NCI to place a high priority on finding new ways to more quickly move candidate drugs from the bench to the bedside.
- NCI's current initiative to develop Phase 0 clinical trials for early drug discovery has strong support from Dr. Elias Zerhouni, Director of NIH. Because NCI studies constitute about 40 percent of the research conducted within the Clinical Center, the Institute is called upon to play a leading role in the NIH intramural program. Dr. Jim Doroshow and his team in the NCI Division of Cancer Treatment and Diagnosis deserve a tremendous amount of credit for the development of the Phase 0 clinical trials program.
- The NCI Office of Technology and Industrial Relations is launching a series of Advanced Technology Initiatives in the areas of nanotechnology, proteomics, molecular analysis, and biosensors, which work to accelerate the pace of cancer research and the translation of research results into new therapies, diagnostics, and preventive agents. Industry appears excited to partner on these initiatives with NCI; a significant part of the Institute's role will be developing technologies that can be shared.

- Many are unaware that NCI is a tremendous resource to the extramural community and also to the rest of NIH. The Institute provides research support services to 26 of the 27 NIH Institutes and Centers, primarily through the resources available at NCI-Frederick.

ROUNDTABLE DISCUSSION

Opening Remarks—Mr. Robert Mittman, Facilitator

Mr. Mittman explained that the first objective of the roundtable discussion was to identify changes in the cancer enterprise system most likely to have a positive impact on cancer mortality and morbidity. These changes could occur in the conduct and translation of research, development of interventions, clinical practice in the field, or economics and reimbursement for cancer care. The cancer enterprise, for the purpose of this discussion, was defined as encompassing every facet of cancer research and care delivery, from research on the causes of cancer, to treatment, to palliation in the final stages of the disease. The second objective was to develop recommendations on how to achieve needed changes.

In the opening session, participants were asked to briefly introduce themselves and provide an example of one important change within the cancer enterprise that could make the greatest impact. The second session focused on developing a vision for the future of cancer research and care for the next 5 years. A final session focused on identifying barriers to reaching that vision. Lastly, participants were asked to summarize the most important opportunities for immediate action.

Dr. Martin Brown

- Dr. Brown's 20-year career at NCI has included helping establish the Surveillance Research Program, which includes the Surveillance, Epidemiology, and End Results (SEER) Program and the Statistics Research and Applications Branch. His current research focuses on analysis of factors that impact cancer incidence and mortality, with a special interest in patient-centered outcomes and economics.
- Establishment of a long-term surveillance and feedback system for the entire cancer health care delivery system would help us to understand and solve the problems of cancer patients throughout their life cycles. The health care system, from prevention and screening to treatment and survivorship, can be viewed as a research environment in which performance can be monitored and information can be collected to identify new areas of research focused on problems encountered by patients.

Dr. Deborah Banker

- Dr. Banker has 25 years of experience in basic cancer research and translation of clinical research, but attended this meeting as a representative of the Leukemia & Lymphoma Society and as an advocate for patients the Society represents.
- The educational system that prepares scientists to conduct cancer research needs to adopt a patient-centered focus. Most scientists rarely interact with patients and few understand the collaboration and coordination that are necessary between the research and care delivery worlds to meet patients' wide range of needs.

Dr. Michael Sporn

- Prior to joining Dartmouth Medical School, Dr. Sporn served at NCI for many years, first as Chief of the Lung Cancer Branch and later as Chief of the Laboratory of Chemoprevention.
- The public must recognize and accept the fact that many cancers are preventable, not only through lifestyle changes but also through pharmacological interventions. Such interventions

have proven extremely successful in reducing the impact of cardiovascular disease; resistant attitudes must change to achieve similar success in cancer prevention.

Dr. Janet Collins

- The National Center for Chronic Disease Prevention and Health Promotion houses the CDC Division of Cancer Prevention and Control, Office on Smoking and Health, and Division of Nutrition, Physical Activity and Obesity. Dr. Collins' research focuses on the effects of lifestyle decision making on health in a community context.
- Research is needed on how the translation of new knowledge into evidence-based interventions happens and how the process can be improved and expedited. Much of the valuable information already established has not resulted in improved health because it has not been applied in the community.

Dr. William Hait

- Prior to joining Johnson & Johnson, Dr. Hait was Founding Director and Professor of Medicine and Pharmacology at the Cancer Institute of New Jersey. Before that, he served as Chief of Medical Oncology at Yale University.
- The cancer enterprise should place a greater emphasis on addressing those causes of cancer that are correctable. These include inflammation, infection, addiction, and hormonal factors. Reducing the effects of these causes would have an impact on a number of cancers similar to what will likely be seen in cervical cancer as a result of reducing HPV infection.

Dr. John E. Niederhuber

- Before coming to NCI, Dr. Niederhuber was a cancer surgeon and conducted both basic and clinical research at Stanford University and the University of Wisconsin. In addition, he served as Director of the University of Wisconsin Comprehensive Cancer Center.
- Although NCI is charged with conducting research rather than delivering services, efforts are needed to ensure that every cancer patient is part of the research continuum. New communications and bioinformatics technologies can contribute to fostering patient involvement in research.

Ms. Peggy Anthony

- Ms. Anthony has 25 years of experience as a nurse in a variety of settings, including surgical oncology. She attended this meeting as a representative of the NCI Director's Consumer Liaison Group. In addition, her husband is an 8-year lung cancer survivor.
- The needed change most often cited by cancer patients is improved access to care, especially cutting-edge treatments being studied in clinical trials. The problem of limited reimbursement for clinical trial participation and other constraints associated with health care coverage for screening and diagnostic procedures is a serious barrier to this access.

Dr. Michael Fiore

- At the University of Wisconsin, Dr. Fiore directs a program called the Center for Tobacco Research and Intervention, which is dedicated to understanding and treating tobacco addiction.
- Significant reductions in tobacco addiction and resulting disease could be achieved by taking advantage of the fact that 70 percent of all smokers see their primary care physicians at least once a year. Currently, few of these encounters result in delivery of evidence-based smoking cessation interventions. Barriers include lack of insurance coverage for and provider awareness of these interventions.

Mr. Greg Simon

- FasterCures is part of the Milken Institute, a nonprofit organization located in Washington, DC. The mission of FasterCures is to save lives by accelerating research, discovery, and development of cures for diseases of all kinds. The group does not accept funding from drug companies, biotech companies, or device companies.
- The concept of patient-centered medicine encompasses many aspects of health care, including electronic health records to coordinate care, improved communication to help patients understand the value of participating in research, and creation of a national cancer care system in which information and resources are shared so that patients can get the care they need regardless of where they live.

Dr. Edward Benz, Jr.

- Dr. Benz is President of the Dana-Farber Cancer Institute. He was trained as an internist and a hematologist and conducted research on the molecular biology of human disease. Dr. Benz is also the only member of his family who has never been diagnosed with cancer.
- Between one-third and two-thirds of all cancer deaths could be prevented by improving the application of current knowledge across the cancer care continuum.
- The ability to understand cancer by using non-human models is limited. Accelerated research in human pathobiology is necessary to make progress in reducing the burden of cancer. The time involved in the process of initiation and growth of cancer in humans exceeds the lifespan of a mouse.

Mr. Clifton Leaf

- Mr. Leaf is a journalist and a cancer survivor. He was first treated on an NCI clinical trial in 1979.
- The cancer research community should tell the public the truth about the complexity and difficulty of the tasks remaining in understanding and eliminating the burden of cancer, as well as about the enormous cost that will be involved in delivering the drugs and technology needed to reach this goal.

DEVELOPING A VISION FOR THE FUTURE OF CANCER RESEARCH

- Traditional thinking about the care continuum begins with basic science, proceeds to development and testing of new therapeutics, and finally addresses delivery of care to the patient. In this discussion, participants were asked to place the patient at the center of the cancer care model and describe: (1) what the patient should experience within an ideal cancer care delivery system, (2) how the clinical care and public health systems would need to be redesigned to create that experience, and (3) the research strategies, public policies, and infrastructure that would be needed to support that model system.

Patient-Centered Cancer Care

- Public education will be crucial in establishing a patient-centered system. Patients must understand their treatment options and likely outcomes. The consent process should be designed to help patients understand why biospecimens and personal data are needed and how privacy will be protected. Without public trust, the system will fail.
- Public education should focus not only on disease prevention but also on wellness. Insurance providers, as well as health care professionals, need to better understand the benefits of activities designed to maintain health.

- A shift from payment to physicians for individual procedures to system-level incentives for improved health outcomes is needed. A new kind of feedback loop would be required to create a care system that rewards everyone for being healthy.
- Different kinds of patients need different forms of care. Elderly populations often require disease management; middle-aged populations have a greater need for screening and late-stage prevention; the primary focus for younger generations should be on prevention. The cancer care system must be designed to guide and support people throughout their transitions from one set of needs to another.
- The vision for the future of cancer care must include improved ways to communicate genetic information to patients in an understandable and useful form. The development of methods for using genetic information to design personalized health promotion will also be required. It will be challenging to use the findings from large epidemiological studies of genetic factors to develop population-based interventions.
- In an ideal future, things that cause cancer will be costly and difficult to obtain, while things that prevent cancer will be inexpensive and readily available.
- Consistent approaches to follow-up care based on best practices are needed to improve end-of-life and palliative care.
- In addition to developing instruments and communication channels for risk assessment, professionals within the cancer enterprise will have to learn how to motivate people to learn about and modify personal risk. So far, the tobacco control community has yet to find the solution to this problem. Other procedures known to be beneficial to public health but not universally accepted include colon cancer screening, cervical cancer screening, and HPV vaccination.

Redesigning the Cancer Care Delivery System

- The United States has long placed an emphasis on universal access to education. A similar commitment is needed to ensure universal access to health care.
- Ideally, many cancers will be treated as a chronic condition requiring long-term care. This will require adjustments in how treatment is planned, delivered, and reimbursed. Lifelong care will be designed to compress morbidity and extend healthy life.
- Assessments of the health care delivery system in the United States have repeatedly shown that availability of high-quality care is not an issue, but our health care system fares poorly in evaluations of coordination and communication. The most problematic phase of the coordination of cancer care occurs between the initial suspicion of cancer and a confirming diagnosis.
- To best accomplish cancer prevention, a risk scorecard based on a wide variety of risk factors, from lifestyle factors, genetics, family history, and biomarkers, could be developed. Decisions about whether to deliver specific interventions could be made based on an individual's risk score. The scorecard could combine guidelines developed by different organizations for different cancers into a comprehensive assessment; this information about relative risk would need to be effectively communicated to the public.
- The future vision of the cancer care system will depend on creating a highly trained health care workforce with expertise not only in delivering care but also in effectively maintaining communication with patients. This work force would be incentivized to work collaboratively with multiple specialists and with physician-scientists and other health professionals trained in translating basic science into practice. This is not a part of the current medical culture. The wisdom of patients, many of whom are expert navigators for themselves and others, must also be incorporated into the cancer care system.

- The electronic health record is a system-level innovation that will improve clinical decision making. Asking the right questions and recording the right information makes it more likely that patients will leave the doctor's office having received the health care they need.

Research Strategies, Public Policy, and Infrastructure

- Patients should be equally important to scientific study as basic biological phenomena—laboratory data must be merged with clinical data to understand how cancer affects populations.
- Future Federal spending on health should focus less on keeping people alive in the last stages of illness and more on keeping them healthy throughout their lives.
- Most data collected by the current health care system relates not to patient-centered, biologically relevant factors but to procedures and other cost-related factors.
- In spite of the intellectual property and privacy concerns that will have to be resolved, a national biospecimen repository, or a network of repositories using standardized methods for data collection, storage, and retrieval, is needed. The ability to annotate biospecimens and share that information in a common format is underdeveloped.
- A national biospecimen system, with feedback provided through integrated surveillance, would promote discovery of prognostic biomarkers for determining which cancer patients should receive aggressive treatment and intensive follow-up based on likelihood of recurrence and risk of secondary cancers.
- The pilot National Community Cancer Centers Program (NCCCP) was launched in June 2007. The NCI investment is kept at a minimum through leveraging of funds. In the past, NCI has studied access to care, health education, patient navigation, and behavioral aspects of cancer in separate, isolated programs. The NCCCP is designed to address all of these issues through coordinated research in the community environment. The program will focus on questions such as how multispecialty care can be delivered in communities, how practitioners can incorporate electronic health records into their practices, and whether biospecimens can be collected using standarized methods so that they can be pooled and shared. The NCCCP also provides an opportunity for small hospitals and previously isolated oncologists to become part of the NCI cancer center system. These centers will greatly expand the infrastructure for conducting behavioral and population-based studies.
- The pharmaceutical industry needs to be more aggressive in the development of cancer drug interventions. At the same time, companies need help in addressing legal and liability issues. Incentives will be needed to increase industry interest in small-market cancers. A shift may be needed from histological or site classifications to genetic classifications of drugs.
- An integrated clinical infrastructure should be enhanced by a supportive social, physical, and policy environment that addresses issues like nutrition, physical activity, tobacco use, and accessibility. All of these factors affect health outcomes but cannot be fully addressed by providers.
- It is difficult to study complex questions about biology in large populations. This requires idealizing a population almost to the point of nonapplicability. New statistical methods and study designs are needed for conducting observational science in areas like genetics, genomics, and proteomics.
- NCI's Translational Tobacco Use Research Centers (TTURCs) provide a model for multidisciplinary translational research and the bundling of interventions using a holistic rather than a fragmented approach to problems. Another model is the NCI Centers for Clinical and Epidemiological Research (CCER) program.

- Research would benefit from more sophisticated search tools. The worlds of PUBMED and Google should be brought together to enhance the strengths of each approach and improve the ability of scientists to find the information they need.
- The critical need to implement what is already known through translational work should not lead the cancer enterprise to neglect gaps in knowledge. A balanced portfolio must be maintained to continue progress in basic science.
- Future Federal budgets could separate infrastructure and educational support to universities from support for scientific studies. Currently, these funding streams are blended in the grantmaking process.
- Regulations such as the Health Insurance Portability and Accountability Act (HIPAA) should be modified to reduce disincentives that impede research. The concept of privacy itself may need to be reconsidered. People use credit cards because they accept the minimal risk that a merchant might misuse their private data, but they are reluctant to share personal medical information or biospecimens even when protections are in place.
- Better coordination and communication of information about research funding will enhance a scientist's ability to network and collaborate with other scientists.
- Development of an adequate research workforce will require changes in the doctoral and postdoctoral education system, as well as in the Federal grantmaking system, to speed the progress of students entering the research field. It will also require new approaches to motivate young people to pursue careers in biomedical research.
- The "human disease network" described by Barabasi, et al., which explores the relationships between classes of disorders associated with genetic mutations, takes advantage of advances in computer science and represents a new way of conceptualizing medicine.

BARRIERS TO ACHIEVING THE VISION FOR THE FUTURE OF CANCER RESEARCH

- Incentives are misaligned in both the health care and research fields. Physicians are rewarded for treating disease but not for helping their patients stay healthy or improve their quality of life. Citizens are not rewarded for living healthy lives. Scientists are rewarded for obtaining grants and publishing papers rather than for making discoveries that demonstrably improve health outcomes.
- Intellectual property issues present a disincentive for some types of research. Private ownership of drug patents reduces the number of scientists who can study those drugs. If a drug has promise in combination with another drug and both drugs have different owners, research is unlikely to take place. Scientists are also unlikely to study new applications of drugs for which patents have expired because of the lack of profitability.
- Fragmentation of the health care system results in higher costs and poorer outcomes than necessary. For example, Medicare could save money on cancer treatment for eligible Americans (age 65 and older) if they had been screened earlier in life. However, private insurers are often reluctant to pay for screening for younger Americans because the financial benefits of screening (reduced treatment costs later in life) occur after people have left private plans and enrolled in Medicare.
- The current academic reward system discourages collaboration. Young scientists who work with other researchers are penalized for not conducting "independent" research.
- The reliance of NIH and the extramural community on the independent, investigator-initiated R01 funding mechanism is a barrier to achieving the vision being discussed. Only 7 to 8 percent of NCI awards are made based on responses to requests for applications. The pursuit

of individually selected questions in basic science should not be abandoned, but it should be balanced with innovative approaches to supporting research, particularly as technology advances.

- The billions of dollars spent by the tobacco industry on advertising and marketing incentives create barriers to reducing lung cancer deaths.
- The current broad definition of conflict of interest is an impediment to the formation of high-quality peer-review groups.
- Low levels of participation in clinical trials are a barrier to the future vision that has been described. There are numerous barriers to participation in clinical trials for both physicians and patients. Physicians are reluctant to spend the time and money that may be involved in conducting a clinical trial. Patients are not well educated about why trials exist and why randomization is necessary; they prefer to find a doctor who will tell them which treatment is best. People might also be more interested in participating in clinical trials if such participation were recognized. Most investigators do not send clinical trial participants thank-you letters or even inform them of study results.
- The lack of a standardized electronic health record is a barrier to coordinated care.
- The model of private health care delivery and the linking of health care coverage to employment are barriers that prevent universal access to health care.

PUBLIC COMMENT

There was no comment from members of the public.

RECOMMENDATIONS

Based on the discussion of the vision for the future of cancer research and barriers to achievement of that vision, four topics were selected for discussion of potential recommendations:

- Regulatory issues
- Intellectual property
- Electronic health records
- Clinical trial participation

In the time available, roundtable participants were only able to discuss recommendations related to the first two topics—regulatory issues and intellectual property.

Regulatory Issues

- Tobacco should be placed under the strong regulatory control of the Food and Drug Administration (FDA). Legislation currently being considered in Congress is flawed but represents a good beginning.
- Regulations governing the conduct of clinical trials should be modified to enable a 30-percent reduction in time and costs associated with activating a clinical trial, such as deploying new drugs, obtaining research data (including biospecimens and clinical data), and entering into contracts with research partners such as pharmaceutical companies.
- Health services research should be expedited by streamlining IRB review for multicenter studies.
- The percentage of institutional budgets spent on indirect costs should be reduced.
- HIPAA should be amended to reduce restrictions on research in communities, particularly survivorship research. Research data should be treated differently than data used for billing.

A "safe harbor" should be created for data sharing in support of research, such as reporting of Veterans Administration data into cancer registries.

- Legislation is needed that would make it illegal for insurance companies to use risk-related information to deny coverage. The protection currently given to the Agency for Healthcare Quality and Research (AHRQ) and to the health care organizations AHRQ collaborates with on health services research is a model for the safe harbor concept.
- The FDA should reevaluate standards for approval of oncology drugs. Currently, the standards for approval of oncology drugs are higher than those for drugs designed to treat other diseases; oncology drugs are required to be proven superior to a standard-of-care treatment, a criterion not applied in other fields. This is, in part, a legacy of the high toxicity of early anticancer drugs. Today, drugs with much lower toxicity are available.
- NIH rules concerning informed consent should be revised and standardized to enable IRBs to more efficiently comply with these rules and reduce the bureaucratic burden on investigators. The review of multisite studies by multiple IRBs should be simplified, using either a single IRB or a single lead IRB. Patients who consent for a study should not have to reconsent if their biospecimens or data are compiled with other data for subsequent studies.
- Regulatory reform will be easier to achieve if turnover among regulatory agency directors is kept to a minimum.
- The FDA should provide more guidance and be more receptive to questions asked by investigators. However, given the risk of conflict, a separate organization may be needed to facilitate assisting applicants for approval.
- NIH, NCI, the Public Health Service, and other interested parties (e.g., the American Cancer Society, professional organizations, universities) should become partners in standardizing conflict-of-interest guidelines.
- Educating advocates and engaging them in discussions about the impact of regulations on the quality of research could help achieve a balance between privacy and research-related concerns. Since researchers stand to benefit from changes in regulatory policies, enlisting advocates to speak in favor of changes would bring additional credibility to the message.

Intellectual Property

- Pharmaceutical companies should be allowed to collaborate to create a "precompetitive space" for new drugs within which early studies could be conducted without patent/ownership concerns.
- An alternative approach is patent pooling, in which each participant owns a share of intellectual property and specific terms governing the relationship are agreed upon by all parties. A similar concept called cross-licensing is used widely in the information technology field; so many different properties are involved in the operation of computer systems that sharing is a necessity. However, cross-licensing is a clearly defined agreement concerning the roles played by partners, whereas patent pooling is an agreement in the developmental stage in which partners do not know in advance how the property may be used.
- The Panel should support pending patent reform legislation that makes it more difficult to patent upstream tools.
- Technology transfer in the academic setting can be promoted by focusing on speed of distribution rather than maximization of revenue. Standarized licensing agreements should be required for all university research supported by NIH. The NCI Translational Research Working Group addressed this issue.

- Revenue streams should be identified, including public-private partnerships, to fund research on potential treatments for which no intellectual property is involved.
- Patent law could be revised so that rights are less exclusive at the beginning of a patent period and loss of rights less restrictive at the end. Mechanisms for reestablishing expired intellectual property to meet perceived needs of the public should be considered.
- Patent life for prevention drugs should be extended because of the long time frame that is necessary for prevention trials. Currently, patents expire before trials are completed, which serves as a disincentive to developing drugs. Surrogate endpoints could provide an alternate strategy for prevention trials, but this would have to be coupled with stringent after-market surveillance to address FDA concerns about long-term adverse effects.
- Prevention drugs could be classified as orphan drugs because they target specific populations. Patents for orphan drugs are extended by several years, based on the development time involved. The fact that drugs initially developed as therapeutic agents often are repositioned as prevention agents would have to be taken into consideration.
- Unpatented treatments could be made profitable by designating them as standards of care, which are reimbursable. However, the ability of multiple companies to compete in producing the drug would limit profits and thus reduce incentives.

General Recommendations

- To achieve the greatest possible reduction in cancer mortality, increased emphasis should be placed on studying the earliest preinvasive stages of disease. Concerted effort is needed to increase interest among young investigators and pharmaceutical companies in research on early-stage detection and prevention.
- A $2-per-pack increase in the cigarette tax would likely result in a 10-percent reduction in smoking and generate $30 billion per year. This money should be dedicated to smoking cessation programs.
- Measures of success in cancer research should focus less on prolonging the life of a cancer patient and more on preventing the incidence of invasive cancer. This will require increased investment in different types of research than those currently considered the highest priority. Addiction, infection, inflammation, and other causative factors would require greater attention.
- A large, multidisciplinary group of experts in all aspects of cancer research and care should be convened to develop a comprehensive cancer risk index. A large, national organization like NCI or the American Association for Cancer Research (AACR) should provide leadership for this effort. A large validation trial would be required to test the predictive value of the index, regardless of how many experts are involved in its development.
- The National Changing Diabetes Program is a model for evaluating Federal agencies' success in applying what is already known about a disease to reduce its overall burden. This project reviewed all of the Federal agencies that were involved with diabetes in any way to evaluate the impact of their programs.
- Existing longitudinal data on cancer could be analyzed to create a virtual cancer risk study based on the model provided by the Framingham Heart Study.
- An analytical framework is needed to develop models for predicting whether specific changes in screening rates, achieved using evidence-based interventions, will actually reduce cancer incidence and whether timeframes for reductions can be predicted.

CLOSING REMARKS—ROUNDTABLE PARTICIPANTS

- Congress should consider the establishment of a single national-level point of contact for coordination of cancer-related research priorities, access to care, insurance coverage, and similar issues.
- In addition to individual risk assessment tools, population-based assessment tools are needed to enable communities to measure success in terms of access to care, quality of care, and environmental factors that affect cancer risk and prevention.
- A national marketing program advocating participation in clinical trials that is as aggressive as tobacco and alcohol advertising might sharply increase participation in cutting-edge clinical research.
- Routine clinical visits provide an often neglected opportunity to deliver patient education about cancer risk and prevention. Clinical practice guidelines should stress this opportunity.
- The President should be reminded that cancer kills far more people than terrorists. Part of the President's job is to protect the health and financial well-being of the American people. The health benefits of eliminating the burden of cancer are obvious, and studies have shown that the economic benefits would be equally significant. Presidential leadership is essential to elevate the importance of this task to a national level.

PUBLIC COMMENT

There was no comment from members of the public in attendance.

CLOSING REMARKS—DR. LEFFALL

Dr. Leffall thanked the attendees and panelists for making valuable contributions and assured them that the Panel would carefully consider the information collected at the meeting.

CERTIFICATION OF MEETING SUMMARY

I certify that this summary of the President's Cancer Panel meeting, *Strategies for Maximizing the Nation's Investment in Cancer*, held September 10, 2007, is accurate and complete.