MEETING SUMMARY
PRESIDENT'S CANCEL PANEL

TRANSLATING RESEARCH TO REDUCE THE BURDEN OF CANCER

November 1, 2004
Houston, TX

OVERVIEW

The purpose of the meeting, the third of four regional meetings, was to examine barriers to progress in translating cancer research into reductions in suffering and death due to cancer. The President's Cancer Panel (PCP, the Panel) is seeking input to help develop its recommendations to the President of the United States, the U.S. Congress, the Secretary of Health and Human Services (HHS), and the broader community of researchers, policy makers, advocates, and others.

PARTICIPANTS

President's Cancer Panel

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

Margaret Kripke, Ph.D.

Lance Armstrong

National Cancer Institute

Andrew C. von Eschenbach, M.D., Director, NCI

Maureen O. Wilson, Ph.D., Assistant Director, NCI, and Executive Secretary, PCP

Sarah Birckhead, M.S.W., Special Assistant, Office of the Director, NCI

Heather Kapp, M.S.W., M.P.H., Communications Fellow, PCP

Karen Parker, M.S.W., Special Assistant, PCP

David Pugach, J.D., Legislative Analyst, NCI

Abby Sandler, Ph.D., IRO, NCI

Speakers

J. Carl Barrett, Ph.D., Director, Center for Cancer Research, NCI

Robert C. Bast, Jr., M.D., Vice President, Translational Research, The University of Texas M. D. Anderson Cancer Center

Eric Berger, M.P.A., Vice President of Planning and Public Policy, US Oncology

Kevin T. Brady, M.P.H., Acting Director, Division of Cancer Prevention and Control, Centers for Disease Control and Prevention

Otis W. Brawley, M.D., Associate Director for Cancer Control, Winship Cancer Institute, Emory University

Deborah Collyar, B.S., President, PAIR: Patient Advocates in Research

William Dalton, M.D., Ph.D., CEO/Center Director, H. Lee Moffit Cancer Center and Research Institute

Harry R. Gibbs, M.D., Acting Professor and Vice President for Institutional Diversity, The University of Texas M. D. Anderson Cancer Center

Jack Gill, Ph.D., Founder and General Partner, Vanguard Ventures

Martha Gray, Ph.D., Director, Division of Health Sciences and Technology, Massachusetts Institute of Technology

Elmer Emilio Huerta, M.D., M.P.H., Director, Cancer Preventorium, Washington Cancer Institute, Washington Hospital Center

Anthony Infante, M.D., Ph.D., Professor, The University of Texas Health Sciences Center–San Antonio

William M. Jordan, D.O., President/CEO, Texas Cancer Care–The Center for Cancer and Blood Disorders

Paula Kim, President of Scientific and Government Affairs/Cofounder, Pancreatic Cancer Action Network

Lynn Matrisian, Ph.D., Professor and Chair, Department of Cancer Biology, Vanderbilt University School of Medicine

Thomas Mays, Ph.D., J.D., Counsel for Intellectual Property, Bureau of Competition, Office of Policy and Coordination, Federal Trade Commission

John Mendelsohn, M.D., President, The University of Texas M. D. Anderson Cancer Center

Paul Papagni, J.D., Director, Institutional Review Board, UMDNJ–Robert Wood Johnson Medical School

Amelie G. Ramirez, Dr.P.H., M.P.H., Professor, Department of Medicine, and Member, Executive Committee, The Cancer Center, Baylor College of Medicine

Lynn M. Schuchter, M.D., Associate Professor of Medicine, Abramson Cancer Center, University of Pennsylvania

Jonathan Simons, M.D., Director, Winship Cancer Institute, Emory University

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

On behalf of the PCP, Dr. Leffall welcomed invited participants and the public. He provided a brief overview of the history and purpose of the Panel and the aims of the current series of meetings on translating research into practice. Dr. Leffall explained that the meeting would consist of three panel discussions, each addressing a unique aspect of translating research into reductions in the burden of cancer. Abstracts submitted in advance by the speakers were made available during the meeting.

WELCOME—DR. JOHN MENDELSOHN

Background

Dr. Mendelsohn combines experience in clinical and laboratory research with administrative expertise in order to guide The University of Texas M. D. Anderson Cancer Center in the new century. Since becoming president in July 1996, he has recruited a visionary management team and implemented new priorities for integrated programs in care, research, education, and cancer prevention. Dr. Mendelsohn serves as the Founding Editor of *Clinical Cancer Research*, a bimonthly clinical research journal published by the American Association for Cancer Research. He was Founding Director of the Cancer Center at the University of California, San Diego, and served as Chairman of the Department of Medicine at Memorial Sloan-Kettering Cancer Center for 11 years. For almost three decades, Dr. Mendelsohn has been at the forefront in understanding how growth factors regulate the proliferation of cancer cells by activating surface receptors that control key cell-signaling pathways.

Key Points

- The M. D. Anderson Cancer Center has one of the largest clinical research programs in the nation. In 2003, the Center registered 24,000 new patients and enrolled 12,000 patients in therapeutic clinical trials. The Center, which has almost 900 faculty members focusing on the elimination of the burden of cancer through research, teaching, and patient care, receives more NCI grant support than any other university in the United States.

PANEL DISCUSSION I—BARRIERS TO TRANSLATING RESEARCH INTO REDUCTIONS IN THE BURDEN OF CANCER

INTRODUCTION—DR. JOHN MENDELSOHN

Dr. Mendelsohn introduced the panel members.

MR. ERIC BERGER

Background

Mr. Berger is Vice President of Planning and Public Policy at US Oncology. He is responsible for the Federal and state legislative and regulatory affairs of the network, its public outreach and patient advocacy initiatives, and its strategic planning activities. Beginning in April 1995, Mr. Berger was a member of the professional staff of the Commerce Committee of the U.S. House of Representatives. In that capacity, he was responsible for health policy legislation, including Medicare, Medicaid, FDA, NIH, and health insurance reform. Prior to serving as a congressional staffer, Mr. Berger served as the Legislative and Policy Director for Health and Human Resources in the administration of Virginia Governor George Allen.

Key Points

- US Oncology is a nationwide network of community oncology facilities, physician offices, integrated cancer centers, and similar organizations,. It employs almost 1,000 physicians, including approximately 300 clinical researchers who see 500,000 patients a year and participate in nearly 100 NCI-administered clinical trials. More than 83 percent of all cancer treatment encounters take place in community oncology facilities.
- The Centers for Medicare and Medicaid Services (CMS) will soon release a new regulation that will affect Medicare reimbursement for community oncology. This regulation will clarify the implications of the recently enacted Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which significantly reformed the manner in which Medicare provides reimbursement for cancer care services provided in the community setting. The intent of Congress in passing the MMA was to repair a flawed payment system without negatively affecting patient access to care.
- Earlier proposals called for large reductions in spending for community cancer care; after revisions to the legislation, the Congressional Budget Office (CBO) estimated that the final MMA would result in a reduction of only $4.2 billion.
- Analyses of preliminary data provided by CMS suggest that the new regulation will result in a reduction in spending on community cancer care of $5 billion to $7 billion more than the CBO estimate. This would have the kind of negative effect on access to care that the MMA was intended to avoid. The impact of this regulation will not be limited to those covered by Medicare: managed care plans tend to follow the lead of Medicare in setting their reimbursement policies.
- The President's Cancer Panel should closely monitor this new regulation's impact on access to care and participate in the cancer community's dialogue with CMS to ensure that payment system reform and protection of access to community cancer care receive equal emphasis. The new regulation is subject to revision, and the new payment system will not take effect until January 1, 2005.

Discussion: Mr. Berger—Key Points

- In response to passage of the MMA, an alliance of more than 50 organizations involved in community cancer care created a "global access project" to collect data on the impact of changes in the Medicare system. This effort has shown that Medicare beneficiaries without secondary or supplemental insurance who are unable to pay their portion of their health care costs will become an increasing burden upon the hospital delivery system.

MS. DEBORAH COLLYAR

Background

Ms. Collyar, a two-time breast cancer survivor, has been a leader in cancer patient advocacy since 1991. She has paved the way for patient advocate involvement in research for all cancers by applying her considerable business skills and experience, which she developed working in the computer industry. In 1996, she founded a national network of approximately 200 cancer patient advocates called PAIR: Patient Advocates In Research. Recently, Ms. Collyar became the Co-Principal Investigator/Program Director of an NCI-funded Specialized Program of Research Excellence (SPORE): the Patient Advocate/Research Team (PART) program. The PART program helps 56 SPOREs develop local PART teams and helps them surmount major research barriers that thwart the translation of scientific discoveries into care for people with cancer (or those who seek cancer prevention).

Key Points

- The cancer research community is rightfully proud of its many accomplishments, but researchers should not interpret isolated success stories as evidence that the system is moving in the right direction. Most research accomplishments have resulted from individual efforts within a disjointed system that rewards competition rather than cooperation.
- Through events like the recent withdrawal of Vioxx, the public is beginning to understand that the drug development system is broken. The public's perception that the cancer community does not learn from its mistakes leads to a lack of trust in scientists and their research findings.
- Researchers are often reluctant to call attention to problems because they are afraid their careers will be jeopardized. Practical solutions to operational issues are more likely to be found through interaction among all stakeholders, including the advocacy community.
- Building a cancer research system that supports translational research will require substantial, simultaneous changes. The President's Cancer Panel should consider inviting key decision makers to a retreat to develop measurable action steps and a timeline for overhauling the system in strategic areas.
- Reaching the NCI Director's Challenge Goal for 2015 will require a more detailed roadmap than currently exists. Areas that will need increased emphasis include rewards for participating in team science, cross-disciplinary training, and training in communication skills and team leadership. Cancer Centers must be motivated to place greater emphasis on the creation of information networks and implementation of cancer Bioinformatics Grid (caBIG) initiatives.
- The Panel should ask for an accounting of responses to its recommendations.

Discussion: Ms. Collyar—Key Points

- To reward change that produces results, the cancer community must have not only a vision, but also specific, measurable objectives and goals related to that vision. For example, Cooperative Groups should be expected to consolidate operations within a specific timeframe. Each Branch within NCI should have specific objectives related to the overall goal of meeting the 2015 Challenge.
- The NCI culture of management has traditionally been based on a hierarchical, regulatory model. The Institute should look to the business community for models based on distribution of power and facilitation of productivity.
- Since there is no one person directing all Federal efforts against cancer, it would be difficult to convene a retreat of key decision makers representing all stakeholders. This might be feasible if an HHS Departmental mandate required all agencies involved in cancer research and services to participate in a joint cancer translational research initiative.
- Outcomes assessments are rarely conducted because most projects do not plan or budget for them. Institutions conducting clinical trials should be required to develop accrual plans to ensure that a variety of populations and communities are involved, as well as dissemination plans to ensure that findings are communicated.
- Because they are not involved in the business of research, advocacy organizations can play a major role in bringing other stakeholders together to bring the benefits of research to patients in a timely fashion.

DR. WILLIAM DALTON

Background

Dr. Dalton's research interests include biochemical mechanisms of drug resistance and new drug discovery. He is also an expert in the biology and treatment of multiple myeloma. Dr. Dalton was the Founding Director of the Bone Marrow Transplant program at the University of Arizona. From 1997 to 2001, he was Deputy Director of the H. Lee Moffitt Cancer Center and Chairman of the Department of Interdisciplinary Oncology at the University of South Florida. He served as Dean of the College of Medicine at the University of Arizona in Tucson from 2001 to 2002. Dr. Dalton returned to the Moffitt Cancer Center and Research Institute in August 2002 to serve as its Chief Executive Officer and Center Director.

Key Points

- When discussing the continuum of discovery, development, and delivery, it must be remembered that delivery is more than just disseminating information; it is a science unto itself. The delivery enterprise must be a dynamic, real-time system that not only provides information, but also carries information back from the community to inform further discovery and development efforts.
- Communities must be involved from the beginning in the design of trials investigating the application of molecular signatures in cancer screening, diagnosis, and treatment. Early community participation in this process will make it easier to determine whether the use of molecular signatures will have a significant impact on the delivery of interventions.
- Creation of an Internet-based information system will enable real-time linking of patient points of contact throughout the health care research and delivery system. To avoid violating Health Insurance Portability and Accountability Act (HIPAA) regulations, providers will have to ask patients for their consent to follow them over time using shared information. This will create a large database of evidence to determine as efficiently as possible whether new interventions are effective.
- The Moffit Cancer Center in Tampa, Florida, has initiated a 5-year pilot project called Moffit Total Cancer Care. This project involves a network of 15 affiliates that serve almost 20 percent of all cancer patients in Florida. An information system is being developed to coordinate investigator-initiated studies conducted by these affiliates, including trials of molecularly targeted therapies. Patients are being asked for permission to follow them throughout their cancer journeys, including submission of tissues to a central repository and database at the Moffitt Cancer Center.

Discussion: Dr. Dalton—Key Points

- The cancer research community has made some progress in creating interdisciplinary teams and fostering a cross-cultural scientific environment. However, little has been done to involve business specialists in the research enterprise and create an entrepreneurial culture in academia. To take advantage of translational research opportunities, the research culture needs to add a mission-oriented element to its traditional focus on knowledge for its own sake.
- The traditional reward system in academia is based on individual accomplishments, such as grants awarded and papers published. Academic Deans must be persuaded to provide rewards for team participation and contributions to the achievement of mission-oriented goals.
- The affiliates involved in Moffit Total Cancer Care are developing protocols for studies addressed by the pilot project. Every 6 months, the affiliates' principal investigators, along

with representatives of the many physician practices and medical centers involved in the pilot project, meet to discuss the design and implementation of active and proposed protocols.

DR. MARTHA GRAY

Background

Dr. Gray is Director of the Harvard-Massachusetts Institute of Technology (MIT) Division of Health Sciences and Technology (HST) and the Edward Hood Taplin Professor of Medical and Electrical Engineering,. Her research interests center on ways to diagnose and treat cartilage degeneration (arthritis) and include connective tissue physiology, imaging, and microfabrication. She holds key leadership roles in a number of educational projects, including HST's Biomedical Engineering Internship Program, the National Science Foundation's (NSF) Engineering Research Center for Bioengineering Educational Technologies (VaNTH), and Realistic Patient Simulation for Training in Critical Care and Emergency Medicine.

Key Points

- As a metaphor for the challenges intrinsic to translating research accomplishments to advance human health, Dr. Gray quoted cell biologist Ursula Goodenough: "Life can be explained by nothing but its underlying chemistry, just as chemistry can be explained by nothing but its underlying physics, but the life that emerges … is something more than the collection of molecules. Once these molecules came to reside inside cells, they began to interact with one another to generate new processes like motility and metabolism and perception, processes that are unique to living creatures." The "cells" in the development chain from discovery to delivery are diverse, multidisciplinary groups of people. Translational science is accomplished when these groups interact as equals.
- Translational advances are slowed by the dominance of traditionally distinct and nonoverlapping scientific communities that focus on different parts of the process. Changing the scientific and industrial culture would increase the rate of translation. This culture undervalues factors that advance the translational process. Research is disproportionately devoted to basic science.
- There is a vast imbalance between the number of individuals involved in basic research and the number involved in its translation. Much effort has been made to increase the number of M.D.s involved in clinical research, but not enough is being done to encourage Ph.D.s to become involved in addressing unmet medical needs.
- One solution to these problems is establishing a deep and genuine integration of technology and science within each step of the translational process, as well as across the continuum. The research community needs to nurture individuals who are capable of working across disciplinary boundaries to drive this integration.
- HST provides a useful model for integration of engineering and physical sciences with the biological sciences. HST trains physicians, basic scientists, engineers, entrepreneurs, and business leaders. Students and faculty are forced to confront the perspectives of professional and patient communities throughout the translational process. The success of HST graduates over the past 30 years stands as a refutation of the claim that HST has sacrificed depth for breadth.

Discussion: Dr. Gray—Key Points

- The editorial policies of peer-reviewed biomedical research journals contribute to the culture that separates science into nonoverlapping disciplines. Individuals who engage in and support

multidisciplinary research should work together to develop new models for research publications that make translational science more visible.

- Accomplishing a cultural shift in biomedical rsearch will require new educational approaches that expose students to both basic science and patient care. A gradual change should occur as more people with a translational perspective assume positions as Deans and Department Chairs within academic institutions. Federal agencies like NIH can further this cause by supporting broad-based, multidisciplinary research programs. However, efforts should not be limited to students; established investigators can still be trained in new ways of doing things.
- The Panel's recommendations on these issues should be disseminated to leaders of academic institutions. Any ideas that may affect the way the Government allocates resources will be of great interest to that audience.
- The technological advances most likely to produce significant benefits for translational science are bioinformatics and imaging, which are both multidisciplinary areas. They both require deep understanding of both basic science and patient care.

DR. THOMAS MAYS

Background

As Counsel for Intellectual Property in the Federal Trade Commission's Bureau of Competition, Dr. Mays advises on and assists with non-public investigations of mergers and anticompetitive activities. He also assists with litigation involving the Commission that deals with intellectual property issues and comments and advises on draft legislation, policy statements, and reports relating to intellectual property. He has written and spoken on issues relating to intellectual property, technology transfer, and pharmaceutical product development. He is admitted to practice law in the District of Columbia and the states of Maryland and Washington as well as before the U.S. Supreme Court, U.S. Court of Appeals for the Federal Circuit, and the U.S. Patent & Trademark Office.

Key Points

- Dr. Mays began by noting that his comments did not necessarily reflect the views of the Federal Trade Commission.
- The President's Cancer Panel should ask NCI to convene a small working panel of representatives of the research, commercial, and patent law communities to consider and prepare proposals for experimental research exceptions for patent infringement that will promote cancer research while continuing to permit patent owners to protect their commercial interests.
- The United States, unlike Europe and Japan, does not have a statutory research exemption for patent infringement. There has been commentary in the trade press suggesting that pharmaceutical and biotechnology companies should conduct research outside the United States, which would reduce the ability of the United States to compete.
- There have been numerous anecdotal reports of instances in which patents have interfered with research. A report from the Australian Law Reform Commission states that most researchers in Australia are simply ignoring patents, believing that they are exempt; the same thing is happening in this country.
- The National Research Council, which recently issued a report entitled *A Patent System for the 21st Century*, has indicated that the number of letters requesting that a university specifically consider taking a license or cease infringement activities increased between 2002 and 2003.

- Several years ago, a suit was brought against NCI for using a DNA polymerase enzyme; 30 universities became involved in the suit before NCI was able to negotiate a settlement.
- A number of specific exemptions have been proposed. One, which has been promoted by the American Intellectual Property Law Association, addresses use of a patent to learn more about the claimed research findings, but not to use the invention as it was meant to be used in its market.

Discussion: Dr. Mays—Key Points

- There are other legal issues that impinge on translational research, including delays in the initiation of new clinical trials. In the negotiation of clinical trial agreements, each party tends to focus on its own interests. The Association of American Medical Colleges (AAMC) has produced a pamphlet that addresses a number of issues relevant to this problem, including indemnification and intellectual property. The development of model agreements would enable more efficient negotiations.
- A survey of major U.S. universities is currently being conducted by the AAMC in collaboration with several other groups to determine the extent to which investigators feel that patents infringe upon their ability to conduct research.

MR. PAUL PAPAGNI

Background

Mr. Papagni served as Chief Operating Officer of a for-profit post-acute-care venture at the Cleveland Clinic Foundation prior to moving into the areas of research compliance and institutional review board (IRB) concerns. This included development and implementation of internal audit operations and Federal audit management procedures accomplished through coordination and relationship building in a multi-campus structure. As Administrative Director at the UMDNJ–Robert Wood Johnson Medical School and Columbia University/New York Presbyterian Hospital, and as Executive Director for the IRB for the Cleveland Clinic Healthcare System, Mr. Papagni was responsible for operational reorganization; new system design; audit; regulatory compliance; system validation; HIPAA, Good Clinical Practice, and Research Billing Compliance; and budgetary oversight responsibility for IRBs serving multiple campuses.

Key Points

- When issues related to clinical trials are discussed, participants usually include IRB members and investigators, but patients are seldom represented. Patients are a critical part of the translational research process; while researchers bring their expertise to the table, patients bring their lives. Improving patient education will result in increased participation in clinical studies and improved compliance with protocols.
- IRBs in the past have been blamed for slowing the research process. However, when investigators plan ahead and address potential ethical and regulatory issues, problems can be solved before the research plan is presented to an IRB.
- There is a move towards accreditation of IRBs. One major benefit would be consistency in the review of studies involving human subjects and human subject protection programs. Any accredited institution would be able to accept the review of another accredited institution, which would reduce delay in implementing multicenter studies.
- HIPAA is not as complicated as many people believe it is. There are ways to determine the minimum amount of information necessary to get a trial done, build in needed protections, and get authorization from individuals involved. This will expedite the creation of large databases that will benefit future research.

- The Government should support development of "adverse event" databases on a national level so that academic institutions, researchers, and patients can see what types of adverse events are occurring in real time. Cooperation from industry, the Food and Drug Administration (FDA), and the Office for Human Research Protections (OHRP) would be necessary to make these data available.
- To make collaborations viable, it will be necessary break down some of the competition that occurs between institutions and between investigators. Many states have laws that hinder interstate collaborative research.
- The Cancer Institute of New Jersey is establishing a statewide oncology group in which disciplinary sections are developing their own protocols and making them available to their statewide affiliates. This model includes a centralized IRB. The group is also reaching out to industry to streamline the process of establishing clinical trial agreements.

Discussion: Mr. Papagni—Key Points

- Accreditation of IRBs has the potential to reduce the burden of paperwork associated with conducting clinical trials. The amount of paperwork would not be reduced, but standardization would enable an IRB to work more efficiently. The ability to accept the review of other institutions participating in multicenter studies would allow investigators to spend more time working with the community.
- One purpose of accreditation would be to increase and improve the monitoring of research by IRBs. When establishing audit programs, IRBs must be careful to explain to investigators that the process is intended to assist them in conducting better research. If an appropriate rapport is established, investigators will welcome the IRBs' assistance.

DISCUSSION: PANEL I—BARRIERS TO TRANSLATING RESEARCH INTO REDUCTIONS IN THE BURDEN OF CANCER—KEY POINTS

- A strategy is needed, at the national level, to provide investigators who conduct translational research with recognition that is equal to the recognition given to those who conduct basic research.
- Experimental research exemptions would have to include rules to resolve ownership issues when an investigator invents a secondary use of a patented product.
- NCI has established a training commission to explore how to train future investigators to conduct interdisciplinary research. A conference will be held at NIH June 16–17, 2005, to discuss these issues.
- The Center for Research on Minority Health (CRMH) at the M. D. Anderson Cancer Center is a member of the Asian American Network for Cancer Awareness, Research and Training (AANCART), one of the NCI-supported Special Populations Networks (SPNs). In collaboration with the Asian American Health Coalition of Greater Houston, CRMH is bringing cancer awareness to the Asian community in that city. A survey of Chinese and Vietnamese communities has shown that 20 to 25 percent of this population is uninsured. Over 60 percent of the Vietnamese surveyed did not know where to go to find information on cancer and cancer services. The Health Coalition received a grant to conduct free mammograms for uninsured, low-income Asian women. Among almost 400 women screened, three had positive diagnoses. These women would never have known about their cancer or had the opportunity to receive treatment without this program.
- For many potential participants in clinical trials, their first encounter with the clinical research process, as well as their only orientation to that process, is being handed a 25-page consent form to complete.

- Implementation of the central IRB concept will require improved education about collaborative research for investigators, IRB members, and the community. IRBs should be able to communicate with investigators as studies are being designed, rather than simply being presented with completed applications for review.
- An IRB, like the FDA, has two roles: to promote development of new therapies and to protect the public. However, people with end-stage cancer are often more interested in access to new drugs than in human protection regulations. Participation of well-informed patient representatives on IRBs will help create a balanced analysis of the risks and benefits of new therapies.

NCI DIRECTOR'S REPORT—DR. ANDREW C. von ESCHENBACH

- In 1971, the goal of the National Cancer Act was to conquer cancer, and the means to that end was to commit the nation to an intensive research effort to understand cancer and to begin to apply what was known and what could ultimately be learned to the treatment, prevention, and detection of the disease. The NCI was empowered to oversee, coordinate, integrate, and direct the entire National Cancer Program. The effort clearly needed to focus on the front end of the continuum of discovery, development, and delivery because the fundamental mechanisms of cancer were largely unknown.
- The progress that has been made since the Act was signed has opened up an entirely new portfolio of opportunities to intervene and preempt cancer in ways that were unimaginable in 1971. Tools have become available that rapidly accelerate the pace at which progress can be made across the discovery, development, and delivery continuum. However, one can never lose sight of the fact that the endpoint of all that progress is to conquer cancer for those who are threatened and affected by the disease.
- The NCI is now focused on the full continuum of discovery, development, and delivery and has crystallized the destination for its efforts and assigned a timeline to them. The destination is not the elimination of cancer; the destination that is within reach is the elimination of the outcomes of cancer, the suffering and death that result from the complex process that is understood as cancer.
- Building on the accomplishments of the past three decades, the NCI is focusing enormous infrastructure and intellectual capital on the problem of cancer. There have never been as many investigators across the full continuum of basic, translational, clinical, and population research as there are today.
- These resources must be nurtured and expanded and—more importantly—coordinated, integrated, and applied. NCI is taking the view that its role and responsibility are not only to provide the resources necessary, but also to provide the leadership needed to nurture this effort. This applies both to areas the NCI directly controls and areas in which the Institute has influence, including other Federal agencies, the extramural community, and other outside organizations.
- A number of programs have been launched that are clearly directed towards integrative approaches to the continuum of discovery, development, and delivery. These include initiatives with the Centers for Disease Control and Prevention (CDC), FDA, and CMS. With CMS, for example, NCI is addressing enhancement of the delivery end of the continuum to ensure quality of care and adequate reimbursement so that all patients can receive the fruits of discovery and development.
- Other initiatives include caBIG, which is intended to integrate the infrastructure of Cancer Centers, and the National Advanced Technology Initiative for Cancer (NATIC), which will develop and apply the emerging technologies in genomics and proteomics and information technology and nanotechnology.
- Cancer is being used as a model for the emergence of the Department of Health and Human Services (DHHS) eHealth Initiative, which is designed to put in place an infrastructure of information technologies for management of the delivery of state-of-the-art care throughout the entire community.
- NCI also took the initiative to address the critically important problem of health disparities by serving as a model for DHHS in creating the trans-HHS health care disparities agenda.
- NCI looks forward to providing the essential and appropriate resources necessary to the discovery, development, and delivery continuum as well as providing the leadership and

integrating force that will bring together all the parts and pieces of the National Cancer Program, the purpose of which is the elimination of the suffering and death due to cancer for everyone by 2015.

PANEL DISCUSSION II—THE ROLE OF ACADEMIC MEDICAL CENTERS IN TRANSLATING RESEARCH INTO CLINICAL PRACTICE

INTRODUCTION—DR. J. CARL BARRETT

Background

Dr. Barrett is the Director of the NCI Center for Cancer Research (CCR) and Chief of the Laboratory of Biosystems and Cancer within the CCR. Previously, he was Director of the Division of Basic Sciences at NCI. Prior to coming to NCI, Dr. Barrett was Scientific Director of the National Institute of Environmental Health Sciences in Research Triangle Park, North Carolina. Dr. Barrett's research focuses on the molecular and environmental causes of cancer. As Chief of the Laboratory of Biosystems and Cancer and Head of the Cancer and Aging Section, he studies the molecular genetics of cancer and mechanisms of cancer progression. His laboratory has made several important contributions to the understanding of the mechanisms of aging and senescence of normal cells and the process of immortalization of cancer cells.

Dr. Barrett introduced the panel members.

DR. ROBERT C. BAST, JR.

Background

Dr. Bast is best known for developing the OC125 monoclonal antibody that led to the production of the CA125 radioimmunoassay. Serum CA125 levels have provided the first generally useful marker for monitoring the course of patients with epithelial ovarian cancer. CA125 is currently being evaluated as one component of a screening strategy for ovarian cancer. Dr. Bast's early studies focused on the use of immunostimulants and monoclonal antibodies for cancer therapy. Over the last 15 years, his group has pioneered definition of the molecular alterations in ovarian and breast cancers that might serve as targets for therapy as well as diagnosis. Dr. Bast's most recent studies have focused on the identification of ARHI, a novel *ras*-related tumor-suppressor gene that may prove useful for gene therapy.

Key Points

- One critical role for the academic medical center is to devise effective strategies for the prevention, detection, and treatment of cancer. Over the last two decades, the increasing understanding of cancer at the level of molecules and cells has permitted the development of targeted therapies and the promise of individualized therapy and management of cancer. Individualized management of cancer will require not only drugs, but also more novel and accurate diagnostic techniques to assess risk, detect early-stage disease, estimate prognosis, monitor tumor burden, and predict response to particular agents. Diagnostics have been a traditional strength of academia, and the academic medical center is where molecular diagnostics, molecular imaging, and molecular therapeutics can be brought together to eliminate suffering from cancer.
- There is a disconnect within medical centers between progress in the laboratory and progress in the clinic. The challenge for medical centers is to make progress in the clinic look more like progress in the laboratory by building a stronger, wider bridge between the laboratory and the clinic for "two-way traffic." The traffic on this bridge includes patients and investigators, but there are other, equally important players outside the academic medical center, including the pharmaceutical industry, FDA, and NCI.
- Traditionally, the pharmaceutical industry has come to the academic medical center relatively late in the process of drug development to conduct Phase I/II trials and, possibly,

pharmacokinetics and pharmacodynamic monitoring. With the development of targeted therapies, however, there are opportunities for new collaborations to identify relevant pathways in validating targets and developing biomarkers that predict and monitor response. NCI could support these efforts by recognizing the importance of and rewarding cancer center-industry collaborations in the context of Cancer Center Support Grant (CCSG) renewals and by facilitating the evaluation of drugs in combination, either preclinically or clinically. Most targeted therapies do not have a profound, long-term impact on human cancers; combinations of new, targeted therapies, either with each other or with more conventional drugs, will be needed to prevent and treat malignancies.

- NCI could provide a clearinghouse to facilitate the exchange of drugs across company boundaries to permit evaluation of targeted and conventional agents in combination. NCI could also provide RFAs for studies on the clinical evaluation and validation of predicted preclinical models for early clinical trials.
- FDA has placed increased emphasis on expedited review of promising antineoplastic agents. NCI should continue to encourage FDA to accept novel trial designs, particularly for Phase II studies; permit the simultaneous evaluation of drugs in combinations; and permit the use of surrogate biomarkers.
- NCI has substantially strengthened translational research in academic medical centers with training grants, SPOREs, and other funding mechanisms. Despite fiscal constraints, expansion of these programs is needed. The potential of SPORE grants to promote translational research is only now being realized; this program should be expanded to less common tumors.
- NCI can help advance molecular diagnostics and imaging by bringing together academia, diagnostic companies, NCI, and FDA to identify needs for biomarkers in the clinic and to define a paradigm for molecular biomarker development that might include novel methods of support, such as the Rapid Access to Intervention Development (RAID) program, for diagnostics. Also, diagnostic companies and academic investigators could be brought together to present novel markers developed by NCI-sponsored investigators and educate investigators regarding new approaches and platforms developed in the private sector.

Discussion: Dr. Bast—Key Points

- The primary criterion for renewal of CCSGs is the conduct of investigator-initiated, hypothesis-driven clinical trials. NCI should add collaborative work with industry to the criteria for grant renewal.
- While the SPORE program is designed to focus on cancer sites, targeted therapies may be useful for a small percentage of cancers across different cancer sites. In the future, it may be desirable to orient SPOREs around targets rather than around particular diseases. Another possibility would be to create working groups across SPOREs. M. D. Anderson has nine different SPOREs and is conducting PI3 kinase studies across several SPOREs within the institution. NCI could help by developing a matrix of SPOREs and facilitating collaboration among investigators who are working on particular targets.

DR. JACK GILL

Background

Dr. Gill is a founder and general partner of Vanguard Ventures, a venture capital firm specializing in high-technology startups, with offices in Palo Alto, California, and Houston, Texas. Vanguard manages over $500 million in capital and has been the lead investor in numerous highly successful companies, such as Aldus, Digital Microwave, Pyramid Technology,

EndoSonics, Mycogen, EndoTherapeutics, Macromedia, Network Appliance, Indigo Medical, CardioGenesis, Advanced Fibre Communications, Ciena, LightSpeed (CISCO), Tut Systems, and Digital Island. Vanguard Ventures specializes in startup investments in the computer, communications, and life sciences industries. Dr. Gill is a member of the Harvard Medical School faculty and serves on the boards of the M. D. Anderson Cancer Center, Horatio Alger Association of Distinguished Americans, Project Hope, and the Presidents' Circle of the National Academies.

Key Points

- Translating research into commercially viable and useful products is expensive and time-consuming. Bringing a medical or diagnostic device to market requires $30 to $50 million annually and 4 to 6 years. A biotechnological drug usually requires over $100 million and 4 to 8 years.
- Most funding for academic biomedical research comes from Government agencies, whereas commercialization research and development typically takes place in the private sector and in small rather than large companies. This private-sector effort creates products that go to market, improve health care, and generate jobs, exports, and taxes.
- Most intellectual property is generated by academic researchers and independent inventors who have no business experience. Venture capitalists and other investors are needed to help them develop ideas into practical products. They often have trouble working with people they perceive as having inflexible egos and naïve or unrealistic expectations. The typical process of matching a technical team with a business interest, determining the viability of a product concept, and developing a business plan takes about $1 million and about 12 months. This process is worthwhile to venture capitalists because the worldwide market for drugs is about $400 billion, and for devices and diagnostics, about $200 billion.
- Academic medical centers need to develop better-organized processes for starting commercial enterprises. Academic institutions should be establishing technology transfer departments and developing policies and procedures related to intellectual property issues. Scientists and engineers who also have business experience must be involved in this process. The final step is to provide "gap funding" to support development of ideas that are not yet ready for the involvement of venture capitalists.

Discussion: Dr. Gill—Key Points

- The Harvard-MIT Center for the Integration of Medicine and Innovative Technology (CIMIT) makes funds available for collaborative projects in interventional medicine. In its 6 years of existence, the program has raised about $100 million.
- Foundations that raise money for cancer research should be encouraged to become involved in providing the gap funding needed to bring ideas to the point at which they are ready for business plan development.

DR. ANTHONY INFANTE

Background

Dr. Anthony Infante, M.D., Ph.D., is Professor of Pediatrics and Microbiology and Immunology and Associate Dean for Research at the Medical School of the University of Texas Health Sciences Center at San Antonio. He served as Head of the Division of Pediatric Hematology/Oncology/Immunology from 1994 to 2001 and as interim Director of the Children's Cancer Research Institute from 1999 to 2002. He became the Medical School's first Associate Dean for Research in 2000. Dr. Infante's current research focuses on the expression, development, and function of T-cell receptors in the immune systems of children with immune

deficiency disorders. He practices medicine as Director of the Children's Immunology Clinic at CHRISTUS Santa Rosa Children's Hospital in San Antonio.

Key Points

- Minority-Based Community Clinical Oncology Programs (MBCCOPs) enroll patients into NCI-supported clinical trials as an important means of providing patients with access to state-of-the-art therapies. There is a vast cultural difference between academic physicians and private-practice physicians, and it takes a long time to build the communication and mutual trust on both sides needed to bring private practitioners into MBCCOPs. Reaching the goals of the program requires listening to both the participating physicians and patients.
- The South Texas Pediatric MBCCOP has built continuous quality improvement into its program. One example of this grew out of frustration at the typical inability of Cooperative Groups to provide "cancer control credits" for pediatric patients. By looking at the incidence of obesity and diabetes in childhood cancer survivors, it was noticed that childhood leukemia survivors have higher-than-normal rates of obesity; this may have something to do with exposure to glucocorticoids during treatment. The South Texas Pediatric MBCCOP is working with local diabetes experts to address this problem.
- Other problems faced by programs working with minority patients are cultural differences that affect health-related behavior and create problems with the informed consent process. Academic medical centers need to improve their efforts to provide patients with the information they need to understand clinical protocols.

Discussion: Dr. Infante—Key Points

- The MBCCOP grant primarily pays for clerical support and the work of research nurses. Most of the cost of data management is covered by funding for other research projects.
- The field of pediatrics has a strong tradition of supporting clinical research. This has made the task of establishing trust between researchers and private physicians somewhat less difficult than in other disciplines.

DR. LYNN MATRISIAN

Background

Dr. Matrisian is Professor and Chair of the Department of Cancer Biology and Ingram Professor of Cancer Research at Vanderbilt University School of Medicine. She is the Program Leader of the Host-Tumor Interaction Program at the Vanderbilt-Ingram Cancer Center, a member of the Board of Scientific Advisors of the National Cancer Institute, and President of the American Association for Cancer Research. Dr. Matrisian has served as a member of the NCI Pathology B Study Section, NIH, and associate editor of several cancer journals. She has organized several national and international scientific conferences and is a cofounder of the Protease Consortium. Her research interests revolve around the molecular mechanisms underlying tumor progression and metastasis, with emphasis on the biology of matrix-degrading proteinases.

Key Points

- Academic medical centers provide an opportunity for real transformational advances in translational research, not only because they bring together basic science and patient care, but also because of their educational mission, which is sometimes undervalued in looking at this problem. Encouraging translational science in the academic setting will make it easier to train the next generation to become effective translational researchers. This can be accomplished by realigning the reward system to promote multidisciplinary research.

- The missions of academic units should be broadened. Vanderbilt University, for example, has established a multidisciplinary Cancer Biology department. Translational research is part of the mission of this department.
- The leaders of academic institutions will have to revise their criteria for tenure and create ways to give individuals credit for their contributions to team efforts. Changes are also required in the way space and resources are allocated within academic institutions.
- NCI can help promote translational research in academic medical centers by acknowledging the contributions of multiple principal investigators to NCI-funded research projects. Another concept that should be explored is the idea of shared senior authorship of journal articles.
- Another problem that needs to be addressed is inadequate basic science input into the design of clinical trials. A possible solution is an NCI-supported, Web-based system through which investigators working on specific pathways could be contacted when a clinical trial related to that pathway is being designed in order to solicit input and, perhaps, even invite them to participate in the trial's design. NCI could also provide supplements to basic science grants to support participation in clinical trial design.

Discussion: Dr. Matrisian—Key Points

- Traditional study sections, over which NCI has no control, focus on research-oriented rather than mission-oriented goals. The constitution of special study sections to address multidisciplinary initiatives might be effective in moving beyond the traditional mindset.
- Multidisciplinary academic departments must be creative in piecing together traditional research-oriented funding mechanisms to support their mission-oriented work. At Vanderbilt, faculty in the Cancer Biology department maintain their investigator-initiated research in addition to participating in multidisciplinary work.
- Involving basic scientists in clinical trial design is primarily a matter of creating opportunity. When basic scientists interested in specific pathways are informed that trials related to those pathways are being developed, they usually want to become involved.

DR. LYNN M. SCHUCHTER

Background

Dr. Schuchter is Associate Professor of Medicine at the Abramson Cancer Center of the University of Pennsylvania, where she also serves as Program Leader of the Clinical Investigations Program and Director of the Clinical Research Unit in the Cancer Center. Her clinical interests focus on patients with melanoma and breast cancer, with an emphasis on novel treatments. She is a Project Leader in the newly awarded Skin Cancer SPORE at the University of Pennsylvania/Wistar Institute. Her project is directed towards evaluating molecularly targeted therapies in patients with melanoma. Dr. Schuchter initiated the Data and Safety Monitoring Committee for the Cancer Center. She currently serves on the University of Pennsylvania's IRB, is Vice-Chair of the General Clinical Research Center, and sits on the faculty advisory committee for the Office of Human Research.

Key Points

- Clinical trials have helped establish standards of care and have improved overall cancer care, yet only 3 to 5 percent of adult patients enroll in trials. One reason for this is negative publicity concerning trials and a lack of public understanding of the benefits of clinical research.

- Barriers to physician participation in clinical trials may be a significant problem. Many physicians fail to refer patients to trials because they view the clinical research process as burdensome.
- Cost is an important issue. Inconsistent and inadequate insurance coverage for patient care associated with clinical research affects the ability to enroll patients in trials.
- The infrastructure required to support clinical research is expensive and inadequately supported. This is especially true for translational research, which often requires tissue collection and the engagement of radiologists and pathologists.
- The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) will dramatically change how cancer care costs are provided, and close attention must be given to the effect MMA will have on the ability to conduct clinical research. Many researchers are concerned that changes mandated by the MMA will dramatically affect access to cancer care and cancer clinical trials.
- OHRP and FDA should initiate directives encouraging institutions to consider centralized IRB review, which could improve the efficiency and reduce some of the costs of clinical research.
- Conflict-of-interest policies are extremely important in protecting patients' understanding of the research process and maintaining public trust. However, excessively strict conflict-of-interest policies sometimes prevent the person who makes a basic science discovery from translating that discovery into practice.

Discussion: Dr. Schuchter—Key Points

- The lack of infrastructure support for trials might be addressed in part by redesigning the clinical research enterprise to reduce duplication of effort.
- Improved education for researchers concerning conflict of interest could enhance their ability to move forward with their research while avoiding public perceptions of conflict. Full disclosure of potential conflict of interest may allow limited involvement of inventors in early-phase trials, but at the Phase III level, a separation between the inventor and the application should be made clear.

DR. JONATHAN SIMONS

Background

Dr. Simons is widely recognized as a leader in the molecular oncology and genetic therapy of prostate cancer. He came to Emory University from the Johns Hopkins University School of Medicine, where he was Director of the Molecular Pharmacology Program and the Cancer Gene Therapy Laboratory. With his February 2000 appointment as Director of Emory's Winship Cancer Institute, Dr. Simons began strategic planning to receive a National Cancer Institute Comprehensive Cancer Center designation, recruited several internationally recognized clinical investigators to Emory, and guided the ongoing construction of a new Translational Research building. Sixty percent of the building's space is devoted to supporting outpatient cancer care, and 40 percent is devoted to basic molecular cancer research. The new building was designed as a pavilion in which patients with cancer and their families, doctors, and nurses, as well as researchers, are all brought together under one roof.

Key Points

- The cost of a medical school education has soared astronomically. Current graduates average well over $100,000 in student loan indebtedness. Because of financial considerations, careers

in translational research are not attractive to these graduates as compared with private practice. NCI-supported Cancer Centers are finding it more difficult to recruit investigators.

- An intensive NCI program to "buy back" student loans in exchange for a time-limited commitment to mentored cancer research service could double the number of young investigators participating in clinical research. This human capital investment would benefit not only the academic clinical research enterprise, but also research conducted by the private sector.
- Physicians and scientists engaged in cancer research should be recognized and validated by the President of the United States. The Jeffersonian ideal that sent Lewis and Clark on a journey of discovery 200 years ago should be applied to reducing the cancer burden today. The repayment of student indebtedness could be a new "Louisiana Purchase" that creates a new Corps of Discovery in cancer research.

Discussion, Dr. Simons—Key Points

- The cancer research enterprise needs both physician-scientists and scientist-physicians participating as partners in conducting clinical trials. Creative funding, such as corporate sponsorships similar to those that support Olympic teams, should be used to make it financially feasible for young graduates of schools of medicine, nursing, and public health to engage in clinical research.
- Teams conducting translational science may need to include specialized members who dedicate their efforts to marketing, fundraising, and project management. These types of activities should not infringe on the ability of investigators to conduct their experiments.
- The effort to create interest in cancer research should begin at the high-school level.

DISCUSSION: PANEL II—THE ROLE OF ACADEMIC MEDICAL CENTERS IN TRANSLATING RESEARCH INTO CLINICAL PRACTICE—KEY POINTS

- Young investigators need to be exposed to private practice and community oncology so that they can learn how to conduct translational research in those settings.
- It is difficult to implement complex protocols in community settings that lack the necessary resources for data management, diagnostic imaging, and molecular profiling. Testing hypotheses may not be possible if a protocol must be made compatible with the resources of every medical center and community. In addition to limited infrastructure resources, community medical facilities are faced with constraints within the managed care system on the amount of time physicians and nurse practitioners can devote to research.
- As Phase I trials become more pharmacodynamic and require more detailed laboratory backup, they become less appropriate for community settings. However, in Phase III and IV trials, after a drug is approved for a specific use, community oncologists could explore off-label applications using simple protocols.
- Translational research requires extensive support from radiologists and pathologists. Creative ways must be found not only to pay for this support, but also to give these contributors appropriate recognition for their work.
- Informed consent forms should be shortened and made easier to read, but no document can substitute for personal interaction between the physician and the patient to ensure understanding of the risks and benefits of research participation. Investigators should receive training in obtaining meaningful informed consent.
- Patient advocates can play an important role in helping researchers improve the informed consent process based on the patient's experience of cancer diagnosis and treatment.

- Conflict of interest arises from normal human endeavor and cannot be entirely eliminated. Potential conflicts must be acknowledged, and rational rules of ethical conduct must be crafted to deal with these issues.

PANEL DISCUSSION III—BEST MECHANISMS FOR MOVING RESEARCH INTO COMMUNITIES

INTRODUCTION—DR. AMELIE G. RAMIREZ

Background

As a behavioral science and health communications investigator, Dr. Ramirez directs and participates in several research projects involving Latinos in relation to such issues as cancer risk factors and genetics, smoking prevention and cessation, substance abuse, and the effects of breast cancer on families. In addition to her positions at Baylor College of Medicine, her academic appointments include positions as Clinical Associate Professor in the Department of Pediatrics at the University of Texas Health Sciences Center at San Antonio and Associate Director for Community Research and Program Leader for the Cancer Prevention and Health Promotion Program of the San Antonio Cancer Institute. She is Principal Investigator of *Redes En Acción*, the National Hispanic/Latino Cancer Network, an NCI-funded Special Populations Network initiative. Dr. Ramirez has received presidential acknowledgment for her work, with appointments to the National Cancer Advisory Board and the Behavior Change Expert Panel for the Office of National Drug Control Policy's National Youth Anti-Drug Media Campaign.

Dr. Ramirez introduced the panel members.

DR. OTIS W. BRAWLEY

Dr. Brawley is Professor of Hematology and Oncology and Professor of Medicine at the Emory University School of Medicine; Professor of Epidemiology at the Rollins School of Public Health; Associate Director of the Winship Cancer Institute; and Chief of Hematology and Oncology Services and Medical Director of the Georgia Cancer Center for Excellence at Grady Health Systems. From 1995 to April 2001, Dr. Brawley served as an Assistant Director of the National Cancer Institute (NCI) in the Office of Special Populations Research. His research interests include the screening, epidemiology, diagnosis, prevention, and treatment of hormonal cancers. He has additional interests in the design of clinical trials, inclusion of minorities in trials, and the availability of state-of-the-art health care for the socioeconomically disadvantaged. His work concerning racial differences in patterns of medical care and the similarity of outcomes among racial and ethnic groups when there is equal treatment is widely cited in the medical and lay literature.

Key Points

- One of the most important research questions that needs to be addressed is how high-quality cancer care can be delivered to the many Americans who are affected by health disparities. While basic and translational research continues, a large number of people simply are not receiving the fruits of discoveries that are already well established. In Atlanta, SEER data suggest that nearly 5 percent of women with a localized breast cancer diagnosed through screening in the late 1990s did not have the tumor surgically removed.
- Racial minorities are known to be affected by health disparities, but the people most vulnerable to disparities are those who are socioeconomically disadvantaged regardless of race. A black woman in Atlanta is far more likely to die from breast cancer than a black woman in Detroit or San Francisco, and those women in Detroit and San Francisco are more likely to die than a woman who has access to Department of Defense hospitals.
- Efforts to move cancer research out into the community should be applauded, and it should be acknowledged that doctors who participate in clinical trials take better care of all their

patients than those who do not. However, an intense focus must still be placed on how to deliver high-quality care to all Americans.

Discussion: Dr. Brawley—Key Points

- A number of studies using data collected in the 1980s and 1990s by the NCI-supported clinical oncology program showed that doctors who participated in clinical trials were more likely to change their practices and adopt new therapies, including those proven in trials in which they did not participate. Participation in and awareness of trials should be promoted as a means of continuing education for physicians.
- In spite of the best efforts of the Panel, the Institute of Medicine, and others, the level of awareness of cancer-related health disparities among those who deliver and pay for health care is inadequate.

MR. KEVIN T. BRADY

Background

Mr. Brady is the Acting Director, Division of Cancer Prevention and Control (DCPC) at the Centers for Disease Control and Prevention (CDC). The Division is responsible for the development and management of cancer prevention; early detection and control initiatives in the areas of breast, cervical, prostate, colorectal, skin, and ovarian cancers; and cancer survivorship. In addition to conducting surveillance, research, and communications activities, the DCPC administers the National Breast and Cervical Cancer Early Detection Program, the National Program of Cancer Registries, and the National Comprehensive Cancer Control Program. Previously, Mr. Brady was Assistant Director for Research Administration and Professional Education at the Epilepsy Foundation of America.

Key Points

- CDC supports three initiatives to help translate research into public health programs, practices, and services and to convert research gains into public health benefits for all: the *Guide to Community Preventive Services* (known as the *Community Guide*), the Cancer Prevention and Control Research Network (CPCRN), and the National Comprehensive Cancer Control Program (NCCCP).
- The task force that publishes the *Community Guide* is an independent, nongovernmental group that provides leadership in evaluating community, population, and health care system strategies to improve health. Its mission is to develop and publish recommendations based on the best available scientific evidence regarding essential community interventions. The task force recently completed recommendations for increasing informed decision making regarding cancer screening and plans to complete its review of interventions to increase cancer screening in 2005.
- In collaboration with NCI, the CDC Division of Cancer Prevention and Control supports the CPCRN to move research into practice and reduce the nation's cancer burden, especially among disproportionately affected populations. The CPCRN conducts community-based cancer prevention and control intervention and dissemination research, translates effective interventions into practice, and evaluates community-based cancer control programs. The geographic diversity of funded CPCRN centers enhances opportunities to develop community partnerships and conduct community-based assessments, evaluations, and research with populations that represent nearly all racial/ethnic minority groups and medically underserved populations in the United States.

- Finally, the CDC has a ready dissemination outlet for proven intervention studies through the NCCCP. The CDC defines *comprehensive cancer control* as "an integrated and coordinated approach to reducing cancer incidence, morbidity, and mortality through prevention, early detection, treatment, rehabilitation, survivorship, and palliation." This approach is achieved through broad partnership of public- and private-sector stakeholders whose common mission is to reduce the overall burden of cancer. The comprehensive cancer control approach provides a structured means for coordinating activities, tracking progress over time, monitoring emerging developments in cancer and related fields, and periodically reassessing its priorities.
- Since 1998, the number of cancer programs participating in CDC's comprehensive cancer control effort has grown from 6 to 61 programs in 49 states, the District of Columbia, 5 tribes and tribal organizations, and 6 U.S.-associated Pacific Islands and territories. It provides a model for assessing and addressing the cancer burden with a state, territorial, or tribal focus.

Discussion: Mr. Brady—Key Points

- CDC is building bridges to the academic community in several ways. The CDC comprehensive cancer control program invites cancer centers to become active participants in the prioritization and goal-setting process and in developing state cancer plans. Many of CDC's dissemination efforts are conducted through support to schools of public health.
- The Panel can play a significant role in encouraging partnerships among cancer centers, state health departments, and CDC-supported cancer prevention and control programs.

DR. HARRY R. GIBBS

Background

Dr. Gibbs is an Associate Professor of Medicine and Cardiovascular Disease and Vice President for Institutional Diversity at The University of Texas M. D. Anderson Cancer Center. Dr. Gibbs has designed, developed, and produced workshops and seminars, both internal and multicenter, focused on minority faculty and staff development. His work includes diversity initiatives for organizational advancement, mentoring, and cross-cultural communication. In his role as Vice President for Institutional Diversity, he directs the Workforce Diversity, Outcome Measures and Compliance, Recruitment and Representation, and Cancer Disparities programs. He also serves on the Board of Advisors for the University of Houston's International Institute for Diversity and Cross-Cultural Management.

Key Points

- Cancer centers, academic medical centers, and the community are usually discussed as separate entities when, in fact, they are all part of the same family. Unfortunately, they are like siblings who have lost trust in each other because of badly negotiated agreements, broken promises, and geographic isolation.
- Within the M. D. Anderson Cancer Center, the Office of Institutional Diversity is developing programs to reconnect the institution with its community roots, remind its researchers and clinicians about their mission, and create an environment as comfortable for the people receiving health care as it is for those who are delivering it.
- According to a 2002 Harris poll, trust is one of the most important elements associated with success in enrolling patients into clinical trials. Medical centers and the community must demonstrate to each other that there are no hidden agendas. Research objectives must be clear to everyone, and funding mechanisms must be open and transparent.

- Trust depends on the belief that researchers and care providers are competent and are able to deliver what they promise. Cancer researchers must be given the resources necessary to accomplish the objectives expected by the communities in which they work. Moreover, community organizations and advocacy groups must make sure that they truly represent their constituencies and communicate very clearly about both their capacities and their limitations.
- Trust also depends on the belief that programs are reliable over time. Too often, community-targeted programs are the first to be eliminated or reduced when funding becomes scarce, organizations are restructured, or administrations change.
- Building trust will require a shift in thinking about allocation of research resources: a change of focus from short-term spending to long-term investment. In addition to the credentials of principal investigators, attention must be paid to the talents and skills of institutional stakeholders. Power must be shared among all the participating organizations.

Discussion: Dr. Gibbs—Key Points

- To start the process of building trust, cancer centers and academic medical centers must reach out to underserved communities and invite representatives of those communities to participate in decision making and research design.
- Academic institutions, which often operate on narrow margins of financial viability, will have to find creative ways of making long-term investments in activities that build trust in the community. Like money spent on imaging equipment or other resources, money spent on working with the community will pay off in improved research results.
- Every health care organization has a relationship with the community in which it is located. If the organization does not have a reputation for competence and reliability within that community, it is imperative that it reach out to the community and ask for its help in building trust in the future.

DR. ELMER EMILIO HUERTA

Background

Dr. Huerta is the founder and current Director of the Cancer Preventorium at the Washington Cancer Institute at the Washington Hospital Center in Washington, DC. The Preventorium uses culturally appropriate social marketing approaches to promote health and prevent cancer, diabetes, hypertension, and heart disease among members of the Latino community. In addition to his clinical duties, Dr. Huerta continues to pursue his research and educational work with the Hispanic community. He is also the President and Founder of *Prevención*, Inc., a nonprofit company dedicated to the production and dissemination of educational materials for the Latino community in the United States. Dr. Huerta was appointed by President Clinton to the National Cancer Advisory Board and is a member of the National Board of Directors of the American Cancer Society, the Cancer Research and Prevention Foundation, and the American Legacy Foundation.

Key Points

- Science and research can be seen as interrelated products that need to be marketed in the community. Neither has been adequately introduced or disseminated in most communities, especially in minority and underserved communities.
- Given the fact that the public does not have a good understanding of science in general and clinical trials in particular, researchers need to do a more effective job of reaching out to and educating their communities. Responsibility for this educational task goes beyond academic

medical centers and cancer centers—the Federal Government, nonprofit organizations, and the private sector also have responsibilities for educating the public about science.

- Education is a process that starts early in life and is maintained throughout the lifespan. If high school students are poorly educated in science and research, we cannot expect adults to be well informed. Among the many consequences of this lack of knowledge are superstition, fatalism, and high rates of morbidity and mortality from preventable and treatable diseases.
- When he started his career in medical oncology, Dr. Huerta saw that most of his patients came to him with advanced and incurable conditions. These patients were well informed about popular culture but not about life-saving medical and scientific knowledge. The idea occurred to him that the mass media could be used to promote science and health education in the hopes that an educated public would seek routine medical care before the appearance of the symptoms of disease.
- Dr. Huerta launched three radio programs, a television program, and a Web site and began writing newspaper and magazine articles. Through these channels, he encouraged community members to visit their doctors for regular checkups. He also explained the importance of clinical trials in improving scientific knowledge.
- After 18 years in this effort, Dr. Huerta has found that the media present an effective channel for disseminating messages about health and educating the community about science. When people understand the science that demonstrates the benefits of cancer prevention and screening, they are more likely to participate in those activities.
- In 1994, the Washington Hospital Center's Washington Cancer Institute established the Cancer Preventorium. Over the past 10 years, this program has served about 154,000 patients. The use of daily mass-media messages has helped thousands of people change the way they interact with the health care system.
- The Panel should support the creation of a federally supported, media-based national cancer education program to provide cancer prevention and screening messages on a daily basis. This program should promote the understanding of a broad range of health and science concepts, utilize a multimedia approach, target its messages to many ethnic and cultural groups, and build trust by remaining free of commercialism.

Discussion: Dr. Huerta—Key Points

- The Cancer Preventorium is a fee-for-service operation. Even patients who have insurance pay the standard fee. The program has found that if people understand its value, they will pay to participate.
- The Federal Department of Education, as well as state and local education departments and school boards, should be partners in this effort.
- The Washington Hospital Center benefits financially from the work of the Cancer Preventorium. Many of the people who are screened and diagnosed at early stages would not be able to pay for the expensive care that would be necessary if they presented with advanced conditions; those costs would fall upon the hospital.

MS. PAULA KIM

Background

Ms. Kim is a cofounder of the Pancreatic Cancer Action Network (PanCAN). She recently assumed the role of President of Scientific and Government Affairs to lead the organization's scientific and Government strategic and programmatic involvement with the research, medical, cancer/health, and Government communities. Founded in 1999, PanCAN is the first and only

national nonprofit, patient-based advocacy organization for the pancreatic cancer research and patient communities; it focuses national attention on the need to find a cure for pancreatic cancer. Under Ms. Kim's leadership, PanCAN public policy efforts have resulted in a nearly 150 percent increase in Federal Government investments in pancreatic cancer research in the last 5 years. This unprecedented increase in research funding, combined with the PanCAN Patient and Liaison Services (PALS) Program and PanCAN Team Hope Grassroots Awareness and Education Program, provides unparalleled progress and hope for the pancreatic cancer community.

Key Points

- A comprehensive, national plan is needed to improve the timeliness and coordination of incorporating research advances into clinical practice. The best mechanisms for moving research into the community are those that build strong links among multiple groups; information management and outreach skills are needed to build these links.
- Cancer centers, academic medical centers, and public and private health organizations underutilize the patient advocacy community as a partner in moving research into the community. There is no one more interested in moving research into practice than patient advocacy organizations and the patients and families they represent.
- In 1999, following her father's death from pancreatic cancer, Ms. Kim and two cofounders established PanCAN, the first national advocacy group focusing on this disease. This organization strives to be the community's best resource for moving research into practice. Its advocacy work has contributed to a 150 percent increase in Federal funding for research in pancreatic cancer.
- PanCAN's Patient and Liaison Services (PALS) program uses a unique, comprehensive approach to link together all of the communities involved in dealing with the patient, including academia, industry, patients themselves, and Government agencies. PALS provides one-on-one services to help patients navigate the health care system and understand their options. Clinical trials are integrated into this process. The program has created the largest single database of pancreatic cancer clinical trials.
- The PanCAN Pancreatic Cancer Research Map, developed in partnership with NCI, is a comprehensive Web-based database for researchers, patients, and advocates that provides detailed information about ongoing public and private pancreatic cancer research projects and programs. PanCAN is involved in the development of HUBCaPs™, a concept that builds upon the power of the Pancreatic Cancer Research Map and other available health information to create a Web-based resource in which disease-specific information "spokes" make up a "wheel" of comprehensive information. These tools are intended to help bring evidence-based science into practice as quickly as possible. This is especially important for lethal diseases like pancreatic cancer.
- Advocacy groups must be included as partners in translational efforts rather than being asked to "bring up the rear." Research centers will require financial incentives to build linkages with advocates and community organizations. The intersection of scientific knowledge with the skills advocates have developed in information management, communication, and outreach—combined with national leadership and long-term committed resources—has the potential to achieve the goal of moving science into the community.

Discussion: Ms. Kim—Key Points

- PanCAN has created an outreach mechanism called Team Hope, using grassroots volunteers to develop links between pancreatic cancer patients and researchers in both academic and community settings. In 3 years, 80 Team Hope groups have been formed, and a mailing list of more than 40,000 has been created. PanCAN receives about 300 contacts from patients per

month. The organization has a reputation among both patients and providers for providing reliable information and representing their interests.

- Patients often bring their doctors information about clinical trials obtained from the Internet, but frequently this information is not relevant to their situations or they are not eligible to participate in the trials they have identified. PanCAN uses the Coalition of National Cancer Cooperative Groups' TrialCheck^{SM} system to assist patients in locating clinical trials that are appropriate.

DR. WILLIAM M. JORDAN

Background

Dr. Jordan is a Clinical Associate Professor of Medicine at the University of North Texas Health Science Center in Fort Worth, where he is Director of the Institute for Cancer Research. He is also Director of Education for the Cancer Education and Research Foundation of Texas; President and Chairman of Texas Cancer Care, a network of community cancer centers in the North Texas region; President and CEO of The Center for Cancer and Blood Disorders; and founder and General Partner of Oncology Metrics. His experience includes over 25 years in medical oncology, including clinical research, as well as in-depth involvement in public and professional education and information system development.

Key Points

- The United States maintains high standards of scientific integrity in clinical research. Those high standards have been made possible through the creation of a research infrastructure within any given institution or organization that is compulsive in attention to detail and redundant in oversight. However, the process of clinical trial management is labor-intensive, cumbersome, tedious, and expensive.
- Traditional clinical trial design is either explanatory or pragmatic in nature. Academic centers emphasize the explanatory model, which looks for scientific breakthroughs, whereas the pragmatic model looks at how those breakthroughs apply to the everyday world of decision makers in the field.
- A third, hybrid option utilizes the explanatory research approach, but with a built-in practical intent to address clinical issues within the context of real-life situations. Those situations include patients' specific needs, costs-versus-benefits concerns, and overall societal benefits.
- Data must be understood and contextualized to create information that results in action. A successful community-focused research program requires a sophisticated electronic infrastructure that codifies data at the point of care, screens for clinical trial eligibility, manages information along the way, and measures outcomes in a manner consistent with applicable case-reporting formats. Information from clinical trials must be blended with other data, including economic and patient-specific factors, so that a full picture emerges that contextualizes the outcomes and impacts of the trials. This is the process that turns data into knowledge.
- Economic aspects of moving research into the community are a sensitive issue. Pharmaceutical and biotechnology companies need to market their products. Payers, including Government insurers, stand to gain from eliminating waste and inefficiencies and identifying approaches to care that create real value for their customers. Providers should realize an economic benefit from robust clinical trial participation.
- A phased approach is desirable to demonstrate a proof of concept for this new paradigm. Community practices staffed by individuals who are committed to the concept should be the

first to become involved. A pilot program should combine the best academic centers and the best community oncology practices.

Discussion: Dr. Jordan—Key Points

- Automating current, fragmented systems of paper-based recordkeeping is not enough—an electronic information management system that coordinates the entire clinical research process from recruitment through follow-up is needed. The patient's electronic health record should be an essential part of this system.
- Community oncology practices that have a well-defined and dominant leader, sound business management, good communication among clinicians, and sophisticated information systems tend to produce the highest-quality service delivery and clinical research.

DISCUSSION: PANEL III—BEST MECHANISMS FOR MOVING RESEARCH INTO COMMUNITIES—KEY POINTS

- Research on how best to disseminate knowledge may not be as important as making the community understand that knowledge is not being applied. One question leads to another, and the point at which action is taken never seems to arrive. Eliminating disparities by ensuring equal delivery of care is essentially a logistical problem.
- The people best qualified to disseminate messages about cancer survivorship are cancer survivors.

REPORT BACK—DIALOGUE ON KEY BARRIERS AND AVENUES FOR CHANGE: INNOVATION, AFFORDABILITY, AND PRACTICABILITY

INTRODUCTION—DR. LaSALLE D. LEFFALL, JR.

The discussion panel leaders were asked to summarize what was said in their panels and add anything they would like to express based on their experience and expertise.

REPORT BACK ON DISCUSSION PANEL I: BARRIERS TO TRANSLATING RESEARCH INTO REDUCTIONS IN THE BURDEN OF CANCER—DR. JOHN MENDELSOHN

Key Points

- CMS must take the lead in ensuring that community physicians are reimbursed for both their services and the drugs they administer. These physicians must be brought into the clinical research structure in a much more meaningful way, probably at the Phase III and IV levels, since they take care of 83 percent of all cancer patients.
- Patients should be educated about clinical research early in the course of disease, not when their disease has progressed and is incurable. The process of obtaining informed consent needs to be improved to better inform patients about the balance of risks and benefits in clinical research. Consent forms should include permission for long-term follow-up and the use of tissues and data to support broad research aims.
- The reward system in academic research needs to be changed, including criteria for promotion and tenure, which tend to stress grants and first-author or last-author publications. Academic medical centers need to devise mechanisms that give credit for collaborative teamwork and the kind of research that clinical trials entail. Clinical investigators who are clinicians should receive the same protected time, infrastructure, and resources that laboratory investigators who are clinicians receive.
- NCI should take the lead in creating a focused roadmap for its 2015 goal. This roadmap should delineate specific, targeted goals and measures that can be apportioned among the various Institute internal units and the external units they support through grant mechanisms.
- NCI should increase support for grants to conduct collaborative clinical research with multiple principal investigators. Training programs should be established for basic scientists who decide late in their careers that they want to collaborate across disciplines in translational research. This could extend to engineers and physicists as well as molecular biologists.
- NCI should convene a large conference of researchers and representatives of the commercial and legal worlds to propose and draft patent law providing statutory exemptions for use of certain inventions in certain kinds of research.
- A single IRB mechanism is needed that uses uniform methodologies in order to permit transferability and trust so that one IRB can trust another because they are following the same ground rules. This would help eliminate the tremendous duplication that occurs in multi-institutional trials.
- FDA must play an essential role in encouraging innovative and adoptive clinical trial mechanisms that can accelerate clinical research as well as encouraging the study of treatments in combination.
- Researchers are required to expend a great deal of effort in documenting medical records, informed consent, and conflict of interest. About one-fifth of a clinical researcher's time is

spent on paperwork designed to avoid liability. Some of this work needs to be delegated to administrative staff to provide more time for researchers to conduct research.

- Pharmaceutical companies and other private-sector organizations should be encouraged to share their intellectual property, serve as participants in team science, and help develop information technologies. Contracts between academic institutions and private-sector companies should be standardized.
- Insurance coverage is needed for clinical trials based on off-label drug use and for trials that aim to discover and validate molecular markers.

REMARKS—U.S. REPRESENTATIVE GENE GREEN

- As a member of the Health Subcommittee of the U.S. House of Representatives Energy and Commerce Committee, Rep. Green expressed his pride in the accomplishments and reputation of the M. D. Anderson Cancer Center and the Texas Medical Center. He thanked Dr. von Eschenbach, an M. D. Anderson alumnus, for his leadership of the National Cancer Institute. He added that, as a Congressman, he is committed to ensuring access to quality health care for all Americans.

REPORT BACK ON DISCUSSION PANEL II: THE ROLE OF ACADEMIC MEDICAL CENTERS IN TRANSLATING RESEARCH INTO CLINICAL PRACTICE—DR. J. CARL BARRETT

Key Points

- Current barriers to increasing translational and multidisciplinary research include: the persistence of a culture that emphasizes research for its own sake; lack of mechanisms for rewarding participation in team science; the high cost of infrastructure improvements, especially in terms of advanced technology and tools for molecular diagnostics; access to drugs; difficulties in enrolling patients; issues related to IRB review; and concerns about liability.
- Possible solutions to some of these problems include: building bridges between investigators and patients and between laboratory and clinical researchers, as well as improved links with pharmaceutical companies, FDA, community oncologists, and the advocacy community; creation of centralized IRBs; new approaches to acknowledgment and regulation of conflict of interest; NCI support for a clearinghouse to improve access to drugs; new working groups to help SPOREs address critical molecular targets across multiple disease sites; and new funding mechanisms that support studies with multiple principal investigators.
- To stimulate progress in translational research similar to the exponential progress in basic science, it will be necessary to find ways to reward physician-scientists for doing this important work.
- Novel approaches to molecular targets are more likely to come from academic centers than the private sector. Gap funding is needed to move new ideas through the translational research process until they are mature enough to be of interest to pharmaceutical and biotechnology companies.
- NCI and other cancer research organizations need to think about the tools that will be needed for the future of translational research and whether the necessary preparations have been made to ensure their availability. This is especially important in the area of advanced technologies like imaging, proteomics, nanotechnology, and information technology. Tumor specimens that represent different types of cancers from different types of populations will be

needed. New tools are needed to monitor Phase IV clinical trials for off-label use of drugs for new adverse effects.

- It will be critical to identify pathways for patients to gain access to clinical trials. More and more elderly cancer patients will be involved in cancer trials in the future, and strategies to address their special needs must be developed.
- Cancer research needs to move from the reductionist approach of taking cancer cells apart toward an integrative approach that applies what we know about cancer cells to the development and testing of biomarkers, targeted therapies, and combinations of therapies. This approach will require a deeper understanding of systems biology.
- Cancer needs to be understood in the context of the individual. Many clues about links between risk factors, such as obesity, and certain diseases have been uncovered. Interdisciplinary, inter-disease studies can take advantage of knowledge about one disease to better understand another.

REPORT BACK ON DISCUSSION PANEL III: BEST MECHANISMS FOR MOVING RESEARCH INTO COMMUNITIES—DR. AMELIE G. RAMIREZ

Key Points

- Strategies for moving research into communities include: designing pragmatic trials to address "real-world" issues; maximizing the role of advocates in the design and evaluation of cancer research; disseminating research gains through mechanisms like the *Guide to Community Preventive Services*; developing interventions that are fully participatory, engaging all forces in society and building trust and respect between the community and researchers; ensuring that the same high-quality cancer care is available to all Americans; and using innovative, media-based tools to disseminate messages about science, cancer control research, and cancer prevention. In the past, many of these issues have been identified as high-priority concerns but given low budgetary priority.
- Researchers should endeavor to educate the community about clinical research by: disseminating the practical outcomes of clinical trials to community decision makers; accelerating dissemination of effective community-based interventions; capitalizing on communications technology to improve access to clinical trial information; and developing long-term, mutually beneficial, and culturally relevant partnerships between underserved communities and cancer centers. Academic medical centers and collaborative programs like CCOPs should develop links with community physicians to provide continuing medical education and improve the standard of care in communities.
- Funding for clinical trial recruitment and retention has not kept pace with the pressure to increase participation in clinical research.
- Data sharing and communication among academic medical centers, cancer centers, and community physicians should be enhanced.
- Cancer centers and academic institutions need to encourage the activities of "champions" and early adopters of innovations who translate vision into reality within organizations.
- Innovations sometimes challenge existing paradigms and structures. Traditional academic pathways, such as peer-reviewed publications, may not be the best way to disseminate such new ideas.
- Mentoring of junior investigators, especially those representing minority populations, is essential within research organizations.

- High priority should be placed on engaging the public in all aspects of community-based research, including study design. Research subjects must be considered full partners with scientists in translational studies.
- In addition to describing and analyzing cancer-related health disparities, NCI should support research on ways to encourage policy changes to reduce those disparities and to increase funding for delivery of services to disadvantaged populations.

DISCUSSION: REPORT BACK—KEY POINTS

- Clinical investigators must be treated by NCI and academic institutions as the equals of basic science investigators in terms of rewards, professional recognition, and availability of resources. Steps should also be taken to increase the representation of ethnic and cultural minorities among clinical investigators.
- Many institutions spend almost as much time negotiating issues connected with intellectual property as they do in conducting related research. Templates or standard operating procedures for working with intellectual property would facilitate and accelerate the process of translational research.
- Although interdisciplinary research is part of the NIH *Roadmap Initiative*, progress in this area has been slow. NCI is in a position to take a leadership role in promoting interdisciplinary science because cancer has been addressed through translational research to a greater degree than other diseases. The best starting point for improving interdisciplinary research is developing a robust capacity for data sharing using interoperable systems and common standards.
- New strategies and policies are needed to communicate with the public and with community health care providers about translational research.
- Peer review for translational research should be modeled on the Department of Defense practice of reviewing proposed research on two levels—first, according to scientific merit, and then, according to relevance to the goals and objectives of the research program. Review by the National Cancer Advisory Board might be the appropriate mechanism through which NCI could evaluate the relevance of proposed research.
- The translational research community needs to develop clear criteria for scientific merit in order to inform the peer-review process and improve the success rate for proposed translational research projects. Study sections for review of translational research should include patient advocates and community representatives in addition to scientists.
- Documentation is essential to developing evidence-based interventions and disseminating innovation, but much of the burdensome documentation currently required of clinicians is generated for the use, convenience, and legal protection of organizations that deliver or pay for medical care rather than for scientific purposes.
- Creative mechanisms are needed to provide gap funding for therapies and diagnostics that are not ready for commercialization. Philanthropic or foundation support may be necessary to meet this need.
- PanCAN is an excellent model for providing information about clinical trials to families of cancer patients. This model should be applied to other cancers.
- There is increasing interest in the proposition that articles reporting on research supported by Government grants should be made available to researchers, clinicians, and the public at no cost. Journal publishers have a financial interest in resisting this idea. NIH has proposed that all articles written by its grantees be made available at no cost 6 months after publication.

CLOSING REMARKS—DR. LEFFALL

- Everything discussed emphasizes that it is not just that one lives, it is how one lives. Quality of life is important, and that is why translating research to reduce the burden of cancer is so important. Ultimate delivery of research to help real people will improve the quality of life and reduce the burden of cancer for all.

CERTIFICATION OF MEETING SUMMARY

I certify that this summary of the President's Cancer Panel meeting, *Translating Research to Reduce the Burden of Cancer*, held November 1, 2004, is accurate and complete.

Certified by: LaSalle D. Leffall, Jr. Date: 5/3/05

LaSalle D. Leffall, Jr., M.D.
Chair
President's Cancer Panel