MEETING SUMMARY
PRESIDENT'S CANCEL PANEL
TRANSLATING RESEARCH TO REDUCE THE BURDEN OF CANCER

August 30, 2004
San Francisco, CA

OVERVIEW

The purpose of the meeting, the first 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

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

Speakers

Anna Barker, Ph.D., National Cancer Institute, Bethesda, MD
Kenneth Bertram, M.D., Ph.D., Department of Defense, Fort Detrick, MD
Moon Chen, Ph.D., M.P.H., UC–Davis Cancer Center, Sacramento, CA
Peter Corr, Ph.D., Pfizer Inc, New York, NY
James Feusner, M.D., Children's Hospital and Research Center at Oakland, Oakland, CA
Joe Gray, Ph.D., Lawrence Berkeley National Laboratory, Berkeley, CA
Robert Hiatt, M.D., Ph.D., UCSF Comprehensive Cancer Center, San Francisco, CA
Jon Kerner, Ph.D., National Cancer Institute, Rockville, MD
Ronald Levy, M.D., Stanford University Medical Center, Stanford, CA
Robert Lipshutz, Ph.D., Affymetrix, Inc., Santa Clara, CA
Frank McCormick, Ph.D., UCSF Comprehensive Cancer Center, San Francisco, CA
Heather Hay Murren, C.F.A., Nevada Cancer Center, Las Vegas, NV
Craig Nichols, M.D., OHSU Cancer Institute, Portland, OR
Joanne Schottinger, M.D., Kaiser Permanente Southern California, Pasadena, CA
Margaret Tempero, M.D., UCSF Comprehensive Cancer, San Francisco, CA
William Weaver, M.D., F.A.C.S, Morehouse School of Medicine, Atlanta, GA
Janet Woodcock, M.D., US Food and Drug Administration, Rockville, MD
Brad Zebrack, Ph.D., M.S.W., M.P.H., USC School of Social Work/Association of Oncology Social Work, Los Angeles, CA

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

On behalf of the PCP, Dr. Leffall welcomed invited participants and the public. He also 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 clinical practice. Abstracts submitted in advance by the speakers were made available during the meeting.

WELCOME—DR. FRANK McCORMICK

Background

Frank McCormick, Ph.D., is Director of the University of California, San Francisco (UCSF) Comprehensive Cancer Center (CCC). He received his doctorate in Biochemistry from the University of Cambridge in 1975. He worked for Cetus Corporation and Chiron Corporation before founding Onyx Pharmaceuticals in 1992, where he worked until 1996.

Key Points

- The UCSF Comprehensive Cancer Center is the fourth largest Cancer Center in the country in terms of NCI dollars and the only NCI-designated Comprehensive Cancer Center in Northern California. The UCSF CCC has some 350 faculty, all working on different aspects of cancer research and clinical care, including laboratory sciences, clinical sciences, clinical care, population sciences, education, and outreach. The goal of a Cancer Center is to facilitate translational research at all parts of the translational spectrum.
- UCSF is famous for its tradition of brilliant individual scientists working in small laboratories without much overall infrastructure and with almost an aversion to traditional "big science." This is a culture that has led to a tremendous amount of discovery and resulted in a Nobel Prize for Mike Bishop and Harold Varmus in 1989 for their work in shedding light on the molecular basis of cancer. Another Nobel Prize went to UCSF's Stan Prusiner. This extremely competitive but individualized culture of academic science has helped increase cancer knowledge over the past 20 years.
- The culture is definitely changing: today's cancer research discoveries must be translated and applied to the real world. One of the challenges is to maintain the brilliance of individual academic research but, at the same time, integrate this with the more applied aspects of research to get new ideas out into the real world and into the clinic.

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

DR. JANET WOODCOCK

Background

- Janet Woodcock, M.D., is Acting Deputy Commissioner for Operations at the Food and Drug Administration (FDA). She has served as Director of the FDA Center for Drug Evaluation and research, which regulates prescription, over-the-counter, and generic drugs.

Key Points

- Janet Woodcock presented the FDA's views on how to advance the diagnosis, prevention, and cure of cancer, especially the essential but very poorly understood task of developing medical products: diagnostics, imaging technologies, pharmaceuticals, cancer vaccines, and, perhaps, preventatives. Improving the development process will help remove one of the key barriers to translating scientific knowledge into effective treatments for patients.
- Development of medical products is an often arduous task that typically takes many years and consumes tens to hundreds of millions of dollars. Each successful medical product must negotiate the preclinical stage of development, the clinical evaluation stage, and the application stage before being made commercially available to doctors.
- Each of the stages on this path is regulated or heavily influenced by the FDA, and the agency is required to set the scientific standards that serve as hurdles on this path.
- Last spring, FDA issued a report entitled *Innovation or Stagnation: Challenge and Opportunity on the Critical Path to Medical Product Development*. The report states that the development process is falling behind the rapid progress being made in basic sciences. The costs of bringing successful products to market are discouraging the development of drugs that are not blockbuster drugs, products intended for smaller markets, and innovative or risky products.
- Modernizing the development process would lower the barriers between an innovation and its ultimate use in fighting cancer, and improvements in the cancer drug development process would also benefit other diseases, but how can product development be modernized?
- Developers use a variety of tools to characterize and assess the performance of a candidate product. Examples of such tools include animal toxicology, animal efficacy models, various biomarkers, computer modeling, and human safety and efficacy testing. The FDA uses these same tools to establish the scientific standards for approval of a drug, device, or biological product. Some of these tools—for example, animal toxicology—have changed little over the past 50 years. Others, such as clinical trial design and analysis or the development of surrogate endpoints, are pursued in an ad hoc manner and suffer from the lack of an academic base. Given its health and the economic importance of product development, the lack of technological focus on this area is astounding.
- Development of surrogate endpoints that could speed and simplify cancer trials is moving forward slowly, and there are potentially unnecessary barriers to testing pharmaceuticals in early trials in humans. Development of new diagnostic tests that could select which patient will respond to a drug or identify people with a potential for serious side effects will be essential as the new molecularly directed cancer therapies are brought into clinical evaluation. The lack of a clear path forward for development of cancer prevention agents discourages investment and development in the prevention field.
- After issuing the *Innovation or Stagnation* report, the FDA held a series of public meetings and received very robust response to its request for comments, which are currently being analyzed. Another series of public discussions will culminate later this year with the publication of an

"Opportunities" list. This list will describe concrete scientific projects that could help modernize the tools needed to improve product development. FDA is currently working with the NCI on several such projects as part of the Interagency Oncology Task Force.

DR. JOANNE SCHOTTINGER

Background

- Joanne Schottinger, M.D., is a medical oncologist practicing with the Kaiser Permanente (KP) Southern California medical group in Pasadena. She is an Assistant Medical Director in the regional Administration Office, with responsibility for the development and implementation of evidence-based practice guidelines, a new technology assessment unit, and regional cancer programs. Dr. Schottinger is also a member of the cancer research program steering committee.

Key Points

- Kaiser, a not-for-profit HMO with eight million members in eight regions across the United States, is integrated with the Permanente Medical Groups, representing about 12,000 physicians. Their research departments represent some of the largest non-academically-affiliated research programs in the country. Kaiser's Research and Evaluation Department in Southern California oversees approximately 700 research projects each year, and the Cancer Clinical Trials Access Program has at least 50 trials open for enrollment in Southern California at any given time.
- Kaiser has many opportunities to advance research from the benchside, through the clinical trials process, to the bedside. Besides access to a large population that is available for longitudinal follow-up, the Department of Clinical Analysis has a significant data collection and measurement system in place. This will soon be enhanced by investment in KP Health Connect, an electronic medical record system with warehouse capabilities.
- Several barriers can slow the progress of bringing new patients into clinical trials and incorporating new technologies into community clinical practice. Cancer clinical trials require their own infrastructure in addition to the existing operational structure in a medical group. For example, institutional review boards (IRBs), Health Insurance Portability and Accountability Act (HIPAA) specialists, administrators, research assistants, and others must be added to the staff. It is very difficult in a nonacademic environment to recruit and retain medical professionals who are interested in research. Once the infrastructure is in place, busy clinicians need additional support and time to deal with all the paperwork, regulations, and training that are necessary to participate as researchers in clinical trials. Another barrier to conducting clinical research is the exploding cost of medical care in general.
- Patients still have some reservations about clinical trials, including concerns about receiving placebos. Cultural and language barriers also play into the acceptance of participation in research. Patients are often required to make a larger out-of-pocket contribution to the cost of their care when enrolled in clinical trials.
- Patients are often eager to be enrolled in trials using new drugs, and these trials can produce very compelling evidence. However, it is usually more difficult to demonstrate the efficacy of new technologies, devices, and procedures. Even after the FDA has approved a new technology, more studies may be needed to determine whether it will meet its promise in improved outcomes in the real world.
- Technologies sometimes advance and evolve faster than scientists can evaluate them. By the time a trial of a prototype device has been completed, the device has likely been redesigned and improved. Practicing community physicians often need retraining before they are qualified to adopt new technologies. The learning curve for new procedures can be very steep, and the procedures may at first take longer or be associated with more complications.

DR. JOE GRAY

Background

- Joe Gray, Ph.D. is Director of Life Sciences at Lawrence Berkeley National Laboratory and has a joint appointment at UCSF, where he is head of the Breast Oncology Program and the Cancer Genetics Program. He is also a member of the UCSF Cancer Center. He received his doctorate in Nuclear Physics from Kansas State University in 1972.

Key Points

- Academics are well suited to basic science but are not particularly well suited to translational research. The value systems in academia—teaching, community service, and unfettered individual research—do not reward the detailed, time-consuming, process-oriented research that is required for translation. Academic institutions are not competitive with industrial-scale, development-oriented research enterprises.
- The NCI provides much of the support that scientists need to move forward; much of which is well aligned with the basic academic missions, but it is not necessarily so well aligned with translational research. Most R01 discovery study sections do not reward translational research as generously as individual investigator-initiated research.
- Biotechnology and pharmaceutical companies are strongly motivated towards translation, but they are much less open to unfettered research into mechanisms of action and are not strongly motivated to develop products that will tackle small niche markets that need to be addressed to take important steps in cancer.
- The development of regional or thematic translational research centers would increase translational research. The organizational and technical complexity of current translational research is really much higher than most academic institutions can manage or academic investigators want to participate in.
- National laboratories have the workforce and the incentives in place to be able to play an important role through their capacity to manage large-scale technical projects. However, the standards for participation in these laboratories have been set at a very high level by the agencies that fund them.
- Enhanced funding mechanisms would encourage public-private sector collaborations. These could take the form of contracts to develop technologies that fill important gaps in academic research. Matching-fund grants are needed to encourage academic-industrial collaborations and increased translationally oriented R01 grants.
- Mechanisms to insulate private-sector participants from the impact of academic findings on things like FDA approval are needed to encourage the private sector to be enthusiastic about participating in this kind of research.
- A national cancer registry is crucial. This will require consistent IRB policies to allow the collection and use of critical patient samples to develop markers and therapies in concert.
- Managing conflict of interest is an issue. The people best suited to advancing research findings into the clinic are those who participated in their discovery. However, they are often prohibited from doing so because of potential conflict of interest.

DR. ROBERT LIPSHUTZ

Background

- Robert Lipshutz, Ph.D., is Senior Vice President for Emerging Markets and Molecular Diagnostics at Affymetrix, Inc., a biotechnology company developing DNA-chip-based products for the academic, pharmaceutical, Government, clinical, and other emerging markets. He received his Ph.D. in Mathematics from the University of California, Berkeley.

Key Points

- Recent advances in the ability to conduct whole-genome analysis are rapidly accelerating cancer research in the pharmaceutical and academic sectors. Genetic information will someday improve the treatment of cancer and thereby reduce its economic and human burden.
- The Federal Government is the key to realizing this potential as quickly as possible. It provides the majority of research funding and sets policies that affect both public and private research. Energetic and innovative leadership in the public sector is essential to being successful in translating this research into clinical practice. For example, the NCI's goal of eliminating suffering and death due to cancer by 2015, aggressive moves by the FDA to expedite approval of new drugs and diagnostic methods, and efforts by the National Institute of Standards and Technology to establish genomic standards are already benefiting translational research.
- However, there is a great need to accelerate progress at the interface among Government, the research community, and the private sector. The R01 grant process at NIH has become too bureaucratic and cumbersome to keep pace with the rapid development of technology in industry and the academic sector. The research effort can and should be more ambitious. The R01 process is designed for a more conservative approach that favors predictable outcomes.
- The portion of NIH research funding currently dedicated to R01s should be administered through a process that could be managed by Institute Directors, enabling them to invest in areas not being addressed by the current funding process. This new process would require measures to guarantee compliance with applicable laws and regulations, avoid conflicts of interest, and ensure accountability to Congress and the DHHS.
- Some areas still contain paradoxes. In the commercial setting, regulatory standards are higher and are appropriate to ensure safety of these new devices, but there need to be new ways to bring these higher-quality, commercially developed diagnostics to market as quickly as possible.
- Reimbursement policies need to be reexamined, taking into consideration the medium- and long-term cost/benefit ramifications of new drugs, therapies, and diagnostic methods.
- Standards are essential in bioinformatics. The Cancer Bioinformatics Grid (caBIG) project is a significant first step. The patenting of naturally occurring gene sequences can impair socially useful innovation in terms of new drugs and new kinds of diagnostics. The public and private sectors need to move aggressively to ensure the greatest access to this kind of genetic information to allow research to move forward. One alternative approach to handling genetic intellectual property is patent pooling.
- The Senate recently passed Senate Bill 1053, the genetic privacy and nondiscrimination bill. It is currently pending in the House. The Administration is on record as supporting this legislation. The Panel should strongly endorse and publicly support this measure.

COL. KENNETH BERTRAM

Background

- Col. Kenneth Bertram, M.D., Ph.D., is Director of the Congressionally Directed Medical Research Programs (CDMRP) Office at the Department of Defense (DoD). He administers all facets of the DoD breast cancer, prostate cancer, ovarian cancer, chronic myelogenous leukemia, neurofibromatosis, and other peer-reviewed medical research programs. He earned his Ph.D. from the University of Minnesota.

Key Points

- The CDMRP supports targeted research in the areas of breast, prostate, and ovarian cancers, as well as chronic myelogenous leukemia. The funds for this program are not to be found in the Department of Defense request nor in the President's request of a yearly budget to Congress. Congress

appropriates these funds each year in response to advice from advocacy groups. The CDMRP is the second largest funder of breast, prostate, and ovarian cancer research.

- The CDMRP Integration Panel, composed of clinicians, scientists, and consumer advocates within each of the targeted disease fields, encourages research in high-risk/high-potential-gain areas as well as areas that represent funding gaps. The Program has helped applicants focus not only on high-quality basic science, but also on translational research. The CDMRP has broadened the peer-review process to include a diverse, multidisciplinary group as well as by including clinicians and consumers in the peer-review process. This helps researchers focus on how their projects will impact the delivery of care.
- The CDMRP has established funding mechanisms and administrative support systems designed to assist investigators with innovative lines of investigation in the absence of preliminary data. Special research awards encourage collaboration between academia and industry to facilitate the introduction of new therapeutics into clinical trials. CDMRP has increased support to clinical investigators through clinical trial development awards designed to give researchers the time, money, and administrative support to navigate the hurdles, including IRBs, HIPAA, intellectual material property agreements, multi-institutional agreements, and FDA requirements.
- CDMRP has offered undergraduate training awards to support summer research experience in breast cancer. The Breast Cancer Program has also initiated a multidisciplinary postdoctoral training program to train scientists in two or more closely aligned areas. Two additional CDMRP awards—the Prostate Consortium Award and the Breast Cancer Center of Excellence Award—encourage assemblage of the best multidisciplinary, multi-institutional teams to solve critical issues in the Program's targeted diseases and develop interventions that will have an impact on the delivery end of the continuum.
- The CDMRP, in collaboration with its integration panels, the scientific community, and the advocacy communities, is working to create in synergy with the NCI—not as a duplication of the NCI—new funding mechanisms for investigators to transition along the discovery, development, and delivery continuum with goal-focused research. To accomplish this goal, CDMRP has encouraged innovation, collaborations, and multidisciplinary research, as well as training and recruitment of new scientists into targeted cancer research programs.

DR. PETER CORR

Background

- Peter Corr, Ph.D., is Senior Vice President for Science and Technology at Pfizer Inc. He received his Ph.D. from the Georgetown University School of Medicine and Dentistry and spent over 18 years as a leading researcher in molecular biology and pharmacology at Washington University.

Key Points

- The complexity, cost, and critical importance of basic research demand a new paradigm for biomedical research—a paradigm of partnerships. Pfizer has pioneered effective partnering with academia, NIH, and the biotechnology industry, as well as with other pharmaceutical companies. The company believes that inappropriate barriers to collaboration, including the issue of how conflict of interest is managed, need to be removed.
- There are formidable barriers to translating research and development into approved therapies, but there are also promising new trends founded in themes of partnership and education that provide the opportunity for better treatment and better management of patients with cancer.
- New approaches to the research and development paradigm include combination therapies, earlier intervention with experimental products, and increased efficiencies in the biomedical review process.

- Biomedical companies that once saw each other as major competitors have realized that the knowledge base and resources required for clinical success lie beyond the resources of any single entity. As a result, many joint ventures are being established to address specific therapeutic goals. For example, SU-11248—a promising Pfizer-owned multi-targeted kinase inhibitor—was moved very quickly into Phase III trials for the treatment of gastrointestinal stromal tumors by an international group of collaborators.
- Unfortunately, the challenge is made even greater because the public and some professionals do not really understand the process and how all the components fit together. Researchers need to work much more vigorously to inform the public about the respective roles of basic and applied research in discovering new therapies; the respective roles of public and private institutions in bringing therapy to patients; the enormous complexity, risk, and expense of bringing a single new therapeutic intervention to patients with cancer; and the fact that business demands and rewards scientific integrity.
- There are four specific areas in which changes in the discovery and development processes can be explored. Combinations of agents based on sound scientific evidence will be needed to evaluate their combined effects on patients. The timing of treatment with experimental therapies needs to be evaluated; when a patient fails to respond to established therapies, it is often too late to benefit from experimental treatment. Clear guidelines and innovative clinical trial designs for prevention research will enhance the biomedical research community's interest in investing in this area. Finally, the timing of treatment approval needs to be reevaluated in light of the reality of the costs associated with cancer treatment trials; approval takes years, but patent law usually starts the clock ticking on a given compound well before the compound enters preclinical development or clinical trials.

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

Key Points

- Translational research focuses on moving specific discoveries into application. *Applied science* is a term used to describe advances in the scientific infrastructure needed to support the development and delivery processes. One example is toxicology, which is moving from whole-animal toxicology to molecular-based toxicogenomics. Identification of biomarkers is an applied science that supports the efforts of translational scientists to identify surrogate endpoints for evaluation of new therapies. One way to improve the cancer research infrastructure would be to develop better animal models. Currently, there is no dedicated program providing support or guidance for building the applied science infrastructure.
- A potential source of tension between the academic and private sectors lies in the fact that some cancers do not provide enough cases to make new drugs and treatments profitable. This can create a barrier to the kinds of partnerships the NCI wants to encourage.
- To address the issue of cancers for which treatments may not be commercially viable, the FDA has an Orphan Grants program to support preclinical and early clinical development to help move treatments for "orphan diseases" toward approval. The FDA's Critical Path Initiative is fashioned to support more informative trials with fewer patients. Costs can be lowered through regulatory and scientific endeavors.
- The same issues that apply to development of new drugs and therapies also apply to development of new diagnostic methods. Many very promising opportunities have to languish. Molecular diagnostics will be as important as molecular therapeutics, but there is no business model or regulatory pathway to ensure that these diagnostics are developed along with the therapeutics.

- There is concern that patent pooling may appear to discourage investment by large companies. However, pooling would lower barriers to participation in this area of research. Owners of patents would be paid for the use of their property and collaborative research would be expedited.
- The need for a national cancer registry has been recognized, but tissue collection is not conducted uniformly around the country. Tissues collected during early-phase clinical trials would be useful to academic and industrial investigators, but they do not usually make their way into the public domain. The FDA approval process for trials should include requirements and guidelines for tissue collection.
- In addition to tissue repositories, cancer registries need to contain patient information that goes back farther than cancer diagnosis. A complete patient history is needed to conduct population-based cancer control research.
- Strategizing funding to account for future research opportunities is difficult for the Federal Government because appropriations are provided on an annual basis. Some funds must be spent in the current year, while others are committed to multiyear activities, These restrictions reduce flexibility in responding to unexpected opportunities. Private industry also has commitments to multiyear efforts but has greater financial flexibility to respond to new ideas. Better coordination of infrastructure resources will lead to improved flexibility for the whole community.
- Barriers to improved accrual to clinical trials include language barriers resulting from wide cultural diversity in some communities, failure to prioritize trials to avoid overlapping recruitment efforts, and the lack of availability of patients with rare disorders.
- Conflict of interest is a problem for academic as well as private institutions. Academic investigators aggressively promote the development of their ideas, primarily based on their desire to see science advanced. Most institutions do a good job of monitoring the process by fully disclosing the economic interests of all parties.
- The unethical acts of a few researchers have damaged public trust in clinical researchers. NCI is working with advocacy leaders and others to ensure that patients' privacy rights are protected in the building of national tissue banks and cancer registries. Some aspects of HIPAA have a somewhat inhibitory effect on collaborative research, but the Government still has a responsibility to regain and keep public trust.
- Researchers need to educate the public about the discovery and development processes. The need to provide full disclosure should not inhibit collaboration among scientists involved in both the discovery of compounds and the development of their applications against particular targets.

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

INTRODUCTION—DR. ANNA BARKER

Background

- Anna Barker, Ph.D. is Deputy Director of Advanced Technologies and Strategic Partnerships at the National Cancer Institute. She develops and implements programs to accelerate the movement of laboratory discoveries through development into new interventions to prevent, detect, and treat cancer. She earned her doctorate in Immunology and Microbiology from The Ohio State University.

Key Points

- The NCI has undertaken several initiatives to enhance the nation's translational cancer research infrastructure. The Cancer Bioinformatics Grid (caBIG) will connect researchers in real time. NCI is working to bring advanced technologies like nanotechnology and advanced imaging into practice. The Institute is also trying to bring the thousands of investigators it supports into collaborative efforts to address translational issues common to all, such as shared tissue banks and bioinformatics resources.

DR. ROBERT HIATT

Background

- Robert Hiatt, M.D., Ph.D., is the Deputy Director of Population Sciences at the UCSF Comprehensive Cancer Center. He is a Professor of Epidemiology and Biostatistics at UCSF and a Senior Scientist in the national Kaiser Permanente Medical Care Program in Oakland. He studied Medicine at the University of Michigan and Epidemiology at the University of California, Berkeley.

Key Points

- It is critically important for the National Cancer Program to be focused to its full extent on the problem of how to get results into practice. There should not be any competition between discovery and creativity. Basic science must be supported, but at a leadership level, it is important to focus on moving the knowledge that is gained from basic discovery into application.
- Translation occurs not only from bench to bedside, but also from "bench to trench." Translational research needs to be directed towards populations at risk, applying discoveries that enable development of new early detection and prevention methods.
- Knowledge transfer or dissemination is critical to the transition from development to delivery. All of these ideas are critical and require different people. Whereas scientists and funding agencies are primarily responsible for translation from discovery to development, the translation of those discoveries and developments into improved health care delivery is carried out by organizational systems analysts, economists, health services researchers, advocates, and community workers. The task involved in translating research into practice is not sufficiently emphasized, and sufficient infrastructure for this does not exist. There are very few people responsible for this latter part of the paradigm.
- The difference between interdisciplinary and transdisciplinary work is that transdisciplinary research requires that the multiple disciplines focused on a problem use the same theoretical basis and the same understanding about how a process works, while interdisciplinary science brings together people from multiple disciplines to work in proximity. NCI has begun to support research like this in the area of tobacco control, cancer communications, gene-environment interactions, and other areas, and this support needs to be sustained over time. Cancer Centers are excellent places to make this

happen along with their partners in industry and in the public sector. It is also part of the Cancer Centers' mandate to disseminate their discoveries broadly in their communities. This is an additional research mission on which the system has fallen short.

MS. HEATHER HAY MURREN

Background

- Heather Murren is President of the Nevada Cancer Institute (NVCI) and one of its founders. Before that, she was Managing Director, Global Securities Research and Economics, at Merrill Lynch, where she was Group Head for the Global Consumer Products equity research effort and coordinated the efforts of Merrill Lynch's 16-member Global Products team.

Key Points

- The Nevada Cancer Institute, a state-sponsored, nonprofit cancer center, is due to open its doors in 2005; in the interim, faculty are working in temporary space. Because Nevada previously had no academic medical center, its population has had limited opportunity to benefit from the translational research conducted through clinical trials.
- NVCI will focus on translational research, not only because the state lacks the basic infrastructure needed to support basic research, but also because translational research is the best approach to address the needs of a state with high cancer mortality rates and extreme geographic isolation from NCI-designated Cancer Centers. About 25 percent of Nevada's cancer patients leave the state to seek treatment, which is an enormous burden that has obvious implications for the state from both economic and academic perspectives.
- NVCI has been very successful in seeking out partnerships and funding through the private sector. Its structure is a unique corporate-academic hybrid. The Board of Advisors includes veterans of the financial community and members of *FORTUNE 500* companies. The Institute also has a very strong scientific faculty, including director Dr. Nick Vogelstein, who came from the University of Chicago Cancer Research Center, and deputy director Dr. David Ward, a member of the National Academy of Sciences.
- The Hotel Employees and Restaurant Employees International Union made a substantial financial commitment to the establishment of NVCI and is partnering with the Institute to provide health services to its members and their families. The union covers about 120,000 individuals through its health care plan. The Institute is conducting a wellness tracking study with 2,500 union workers. Preventive services, including smoking cessation, are being developed. A Patient Navigator program has been established for union members, and prevention and screening research projects are being planned. The Nevada Cancer Institute is also reaching out to the Hispanic population and other minority groups in the state.

DR. RONALD LEVY

Background

- Dr. Ronald Levy is a Professor of Medicine and the Chief of the Division of Oncology at Stanford. He received his M.D. degree from Stanford. He has spent his entire professional career trying to find better treatments for cancer. His work has led to new ways of marshaling the immune system to treat cancer, especially lymphoma.

Key Points

- The Health Insurance Portability and Accountability Act (HIPAA) went into effect in April 2003. Although HIPAA addresses the important problem of privacy of electronic medical records, its

implementation is impeding efforts to improve the diagnosis and treatment of cancer. HIPAA regulations should be amended to address these problems.

- HIPAA regulations are burdensome for those involved in the translation of basic discoveries to patient care. These are the investigators who use electronic databases that contain information on outcomes of treatments and on the associations of those outcomes with patient and tumor characteristics. Accessible and portable medical information empowers efforts to understand disease trends, associations, and outcomes.
- Prior to the passage of HIPAA, safeguards were already in place to protect human subjects. These included strict review of each planned investigation to ensure that potential subjects were properly informed and their privacy protected. HIPAA regulations do not add measurably to privacy protection, but they do add substantially to the administrative and bureaucratic burden of the medical researcher and to the confusion of people being asked to read, understand, and sign lengthy documents at a time of personal stress. HIPAA, in addition to creating redundancy and confusion, elevates privacy to equal priority with critical aspects of safety and side effects of experimental treatments.
- A recent survey of the Association of American Medical Colleges (AAMC) asked about the effects of HIPAA regulations on the research enterprise. Respondents included investigators, IRB personnel, privacy officials, research administrators, deans, and others involved in the conduct and oversight of research. Numerous deleterious effects were cited, including burdens on subjects caused by an additional consent process; impairment of recruitment of subjects into research studies; difficulty in collaboration; burdens on researchers and staff due to additional bureaucracy in the research process; increased costs of research; and conflicting interpretations of HIPAA guidelines by different institutions.
- The President's Cancer Panel should advocate for the adoption of AAMC recommendations for modification of HIPAA privacy provisions, which include modifying the requirement for authorization and waiver of research; harmonizing HIPAA with the Common Rule regarding privacy protections; relaxing the de-identification standard; eliminating accounting for disclosures for research; and shifting from an organizational to a functional focus.

DR. CRAIG NICHOLS

Background

- Dr. Craig Nichols earned his M.D. degree from Oregon Health and Science University (OHSU) in 1978. He received further training in Hematology/Medical Oncology at Indiana University. He serves as the Chairman of Hematology/Medical Oncology and Associate Director for Clinical Research at OHSU.

Key Points

- The direct cost of cancer in the United States has been estimated at over $200 billion, but death and disability caused by cancer lead to additional economic loss. Successful treatment of testicular cancer, for example, returns in excess of $100 million to the economy each year by returning productive citizens to society.
- Primarily through the efforts of basic science discoveries, researchers have the tools to validate targets so that clinical trials are no longer conducted by the "shotgun" approach. Advances in pharmacogenomics are making it possible to understand why drugs work differently in people of different genders, races, and age groups.
- One of the most compelling examples of translational research is the development of Gleevec, which emerged from 40 years of basic science on chromosomal abnormality in chronic myelogenous leukemia (CML). OHSU's Dr. Brian Druker postulated that a compound could be developed that

would inhibit the protein (BCR-abl) that causes CML. Novartis had a candidate compound, STI-571, but did not consider its development worthwhile from a business perspective. Dr. Druker persuaded the company to provide enough of the compound to test in leukemia cell lines and then with patients. With difficulty, 31 patients were entered into a trial, and all obtained complete remission through application of a well-tolerated targeted therapy.

- Academic centers and their patient volunteers have an absolutely critical role in translational research. However, their sources of funding through Government grants, philanthropy, and income generated from patient care are under pressure, from shrinking paylines to community demands for reduced-cost services.
- All cancer patients should be told about clinical trials when confronted with standard therapy that may not meet their needs. Clinical trials result in equal or better outcomes compared with standard therapy across the board, and if providers and patients asked enough questions, accrual to clinical trials would increase enormously.
- The cancer research community should take advantage of the current emphasis on collaborative science. Full funding of the *NIH Roadmap* agenda will go a long way toward supporting large-scale cooperation among institutions, regions, and nations.

ROLE OF ACADEMIC MEDICAL CENTERS FOR MOVING RESEARCH INTO COMMUNITIES—DISCUSSION

Key Points

- The traditional discovery enterprise is very individualized. Academia traditionally does not reward collaborative efforts. Until there is an appreciation of the value of a collaborative transdisciplinary approach and a steady stream of funding, those who are concerned about academic advancement or career advancement (Deans, Chairs of departments, others in academia) will not embrace it.
- The NCI has established several large, collaborative, transdisciplinary research projects, but the question of how to sustain them has not been answered. Because these efforts are expensive, they need to be evaluated to prove their efficacy to justify continued support.
- There are many rewards from working through partnerships outside the traditional academic setting. Communities can be engaged to help simplify the pursuit of research, disseminate its findings, and remove barriers to improved outcomes. Philanthropic support can be obtained that is rewarding to the institution and, often, the investigators themselves.
- Basing traditional academic advancement on collaborative research will require the reeducation of promotion and tenure committees, which are experienced in judging teaching but not in evaluating teamwork. These committees should include clinicians who understand the value of cooperation. It is also important for team leaders to make it clear that they will support team members in terms of promotion and tenure.
- Many investigators would like to do transdisciplinary research but do not have the necessary resources. There is no recognized infrastructure in academic institutions for supporting collaboration and dissemination. In addition, the community needs a voice to express its needs in terms of dissemination and delivery, as well as a channel to make that voice heard by academia. The next generation of scientists should be educated using a new approach that includes service to the community among the rewards and obligations of their profession.
- The implications of HIPAA in the ability to follow cancer survivors and study late effects need to be examined. The only way to validate surrogate endpoints is to measure outcomes. The only way to measure outcomes is to look at medical records. Tissues are almost useless if they are not connected to medical records, both past and future.

- The new Cancer Center guidelines list three terms that have been used during this meeting—*multidisciplinary, interdisciplinary*, and *transdisciplinary*. The distinction between the last two is that transdisciplinary research involves people from multiple disciplines working together on a common problem rather than simply coming together to share what they have learned separately.
- In addition to tissue from cancer patients, repositories should include samples from people who do not have cancer. This would improve the ability to conduct research aimed at identifying people at risk for cancer and developing preventive interventions. However, this would be expensive, and results would not be forthcoming until several years of data have been collected. Funding specifically targeting this effort would be needed.
- At a *Designing for Dissemination* conference sponsored by the NCI and CDC, researchers, practitioners, and a variety of funding agencies came together to discuss the question of who is in charge of dissemination. No individual or institution expressed any interest in being in charge. Dissemination will work only as a partnership in which roles are clearly identified.
- Changes in Nevada have created a more hospitable environment for health promotion. The population is more diverse, but the community is more unified than ever before. Although the gaming industry has objected to tobacco control efforts in the past, many casinos support the Nevada Cancer Institute.
- A national strategy for early detection needs to be built upon advances in molecular diagnostics. A useful collaborative model for this strategy is the development of the Internet, which was based on broad involvement of all stakeholders and standardization of protocols and technology.

PANEL DISCUSSION—BEST MECHANISMS FOR MOVING RESEARCH INTO COMMUNITIES

INTRODUCTION—DR. MARGARET TEMPERO

Background

- Margaret Tempero, M.D., is Deputy Director of Clinical Sciences and Chief of Medical Oncology at UCSF Comprehensive Cancer Center. She is best known for her work in pancreatic cancer and the potentially therapeutic role of radiolabeled antibodies.

Key Points

- America has the best cancer care system in the world, but that system is not accessible by all. Millions of Americans are uninsured, and even those with insurance are not satisfied with the care they receive.
- The reimbursement system for cancer care services is flawed because it lacks incentives to keep people well. Physicians are paid for treating illness but are not paid for prevention services. Most doctors try to provide the best care possible, but there are no systems to track quality of care.

DR. JON KERNER

Background

- Dr. Jon Kerner is Deputy Director for Research Dissemination and Diffusion in the Division of Cancer Control and Population Sciences at the National Cancer Institute. He received his Ph.D. in Community Psychology from New York University and postdoctoral training in cancer epidemiology, biostatistics, and clinical trials design at the Johns Hopkins University School of Public Health.

Key Points

- It has been suggested that community-based organizations need to take the lead in dissemination rather than Cancer Centers because Centers lack the necessary infrastructure. However, Cancer Centers receive NCI grant dollars, and part of their mandate is to serve the community in addition to conducting outstanding research. Most Cancer Centers are good at describing their research accomplishments, but they are less active in informing their communities about the benefits of the research conducted at their facilities. An exception is The University of Texas M. D. Anderson Cancer Center, which maintains a Web site with guidelines and recommendations for practitioners and practical information for patients.
- Many people in the cancer community wonder why only 5 percent of cancer patients are enrolled in clinical trials, based on an assumption that all cancer patients would benefit from participation. In fact, high-quality conventional care is the best option for many cancers detected at an early stage. Clinical trial accrual efforts should target cancer sites for which conventional care is not successful, such as pancreatic, non-small-cell lung, and esophageal cancers. Meanwhile, Centers should work with communities to improve care delivery for cancers that are shown to respond well to conventional treatment.
- Communication amongst the various sectors—public, private and voluntary—should be improved to facilitate more rapid movement from development to delivery. Science has developed many new ideas that are ready to be adopted in community health care settings. Not enough is being done to help community organizations learn about new ideas and adapt them to their particular situations.

- Many scientists assume that once a paper has been delivered at a major annual conference, the entire field immediately adopts the latest findings and techniques. Health services research data show that this is not the case. Dissemination barriers are as important as reimbursement barriers and infrastructure barriers in creating the existing disparities in cancer care. NCI and other Government agencies also need to learn from their own dissemination research and "practice what they preach."
- Models of innovative approaches from business and statewide coalitions should be examined and used to inform cancer care delivery. Businesses operate through distribution networks. The distribution networks available to cancer researchers are health departments, primary care practices, oncology organizations, and HMOs. Government and voluntary organizations have been establishing statewide cancer control coalitions designed to train the next generation of leaders in putting research into practice.

DR. MOON S. CHEN

Background

- Moon Chen, Ph.D., M.P.H., is a Professor in Public Health Sciences at the University of California–Davis Cancer Center and Program Leader of Cancer Etiology, Prevention, and Control. He previously served as Chair of the Division of Health Behavior and Health Promotion at the School of Public Health at The Ohio State University's College of Medicine and Public Health.

Key Points

- One example of a useful mechanism for moving research into the community is the report called *Making Cancer Health Disparities History*, a product of the NCI's Progress Review Group (PRG) process. While previous PRGs have focused on specific cancers, this group addressed disparities not only across all cancers, but across all DHHS programs. More than 80 researchers, advocates, and practitioners developed a time-scaled set of 14 priority recommendations. This effort, led by NCI, will be used as a model for future trans-HHS Progress Review Groups.
- A second example is the NCI's Special Populations Networks (SPNs). This program, which is an outgrowth of the National Black Leadership Initiative and similar initiatives focusing on minority and underserved populations, funded 18 projects serving 30 states and 150 communities. SPNs sponsored more than 1,000 cancer awareness activities, 250 pilot studies conducted by junior minority investigators, publication of many peer-reviewed articles, and leverage of over $20 million in non-Federal supplementary support. The 5-year SPN program is now being supplanted by a new Community Networks Program that will build upon the success of the SPNs.

DR. JAMES H. FEUSNER

Background

- Dr. Jim Feusner is Director of Oncology at the Children's Hospital and Research Center at Oakland, Chair of the Multidisciplinary Tumor Board, Professor of Pediatrics (adjunct) at UCSF, Senior Scientist at the Children's Hospital Oakland Research Institute, and Principal Investigator (PI)/Co-PI of the Bay Area CCOP grant since 1989. He obtained his M.D. degree from the University of Washington–Seattle.

Key Points

- The more rapid transmission of research is hampered by four specific problems: (1) lack of sufficiently innovative trials covering the most important cancer sites; (2) ancillary studies that make it more difficult to treat cancer patients—adult cancer patients in particular—in an office practice setting; (3) the complexity of the informed consent process; and (4) the need for translation and interpretation skills and services in diverse communities.

- The most significant barrier faced by investigators, especially medical oncologists, to enrolling patients in clinical trials is the absence of trials for some of the specific disease categories. In addition, few office-based medical oncologists have the time to enroll patients in clinical trials.
- Another factor that would increase accrual would be a decision by HMOs and insurance companies to insist upon clinical research as a therapeutic option when there is not good evidence-based medicine to dictate otherwise.
- Unlike investigators affiliated with university hospitals or Cancer Centers, the average community oncologist lacks the facilities and other resources necessary for participating in ancillary studies. There should be some consideration given to allowing exemptions for medical oncologists to enroll patients in trials without having to comply with biologic specimen requirements.
- Informed consent forms for pediatric trials range from 8 to 33 pages. Recently, there has been a decline in the number of newly diagnosed children entering trials, and the consent process appears to be one of the reasons for this decline.
- Language barriers also inhibit accrual to clinical trials. This makes the consent process more difficult and requires patients to wait for services until translators are available.
- The Panel should consider the following recommendations: (1) adult and pediatric cooperative groups must find a way to offer community physicians and their patients more interesting and important trials for all the major cancer sites and, perhaps, emphasize earlier-stage patients, for whom there is a better chance of meaningful increase in survival; (2) ancillary studies that impede participation by community physicians should be made optional; (3) there should be careful and thorough examination of HIPAA and patient consent requirements to reduce their burden on physicians and patients; and (4) NCI should consider creating and maintaining a translation service that would provide, at no cost, accurately translated consents in all major languages for all patients of all ages.

DR. BRAD ZEBRACK

Background

- Brad Zebrack, Ph.D., M.S.W., M.P.H., is an Assistant Professor at the University of Southern California (USC) and Chair of the Research Group of the Association of Oncology Social Work, where he studies the impact of cancer on patients, survivors, and their families. As a social scientist and oncology social worker, patient advocate, and cancer survivor, Dr. Zebrack's primary concern has to do with patients' and families' experiences when they are told that they or a loved one has cancer.

Key Points

- Translating research into clinical practice and moving research into communities involves examining the interface where health care practitioners and institutions meet individual patients and families.
- The lack of information about certain subsets of the United States population serves as a barrier to translating research into practice, particularly with regard to psychosocial and behavioral research. Overcoming barriers to translating research so that it improves the lives of cancer patients and their families requires acknowledging social and cultural differences and understanding what happens when people of varying economic, ethnic, and cultural characteristics attempt to access the health care system in the United States.
- There is a disproportionate allocation of resources in the United States. Many programs feature the application of research and theory into practice, but the actual outcomes and benefits resulting from participation in these programs are rarely evaluated. Translational research requires assessment of measurable outcomes to justify funds to keep the programs going.

- There is an apparent disconnect between individuals involved in the research industry and those involved in the implementation of new knowledge at the clinical and community levels. Many social and behavioral scientists, including those who set research priorities within NIH and other large funding agencies, do not have enough direct contact with patients; their research objectives, agendas, or specific aims may or may not directly address patient and family needs. Researchers need to be exposed to the clinical setting through rotations in hospitals or community health care centers, and clinicians need better training for participating in research projects.
- Clinical social workers are especially positioned to play an important role in addressing real-world problems of patients that serve as barriers to participation in research; they have a skill set that includes not only case management, but also community organizing and linking agencies with individuals. However, there is no structural support to encourage or enable them to participate. Funding agencies such as the NCI and the American Cancer Society should consider providing infrastructure for clinicians and social workers to participate in research projects when writing RFAs and Program Announcements.
- There is often a power imbalance at the interface between health care practitioners and patients and their families. Rules and norms from an institutional point of view may or may not be consistent with the beliefs and values that the patient brings to this exchange.
- Perceiving cancer as a community problem, as opposed to an individual problem, may be helpful in overcoming barriers to translating research into practice. The notion of cancer as a community problem suggests the need for community-based approaches to translating research into practice. Involving communities in research means ensuring that they have access to the same resources that independent academic investigators enjoy.

DR. WILLIAM LYNN WEAVER

Background

- William Lynn Weaver, M.D., F.A.C.S., is a Professor in and Chair of the Department of Surgery at Morehouse School of Medicine in Atlanta. He attended Meharry Medical College as a U.S. Army Health Profession Scholar and completed his surgery residency in the Army.

Key Points

- Dr. Weaver spoke as a practitioner and as the father of a boy who had recently died of cancer. His son was diagnosed at age 15 with glioblastoma and survived 2 years due to participation in a clinical trial, which not only prolonged his life, but made those years comfortable. As a parent, Dr. Weaver spoke from the perspective of someone who has endured the burdensome consent process and economic difficulties faced by families affected by cancer.
- The Morehouse School of Medicine is a historically black institution established to recruit and train minority and other students as physicians, biomedical scientists, and public health practitioners committed to the primary health care needs of the underserved.
- The Morehouse School of Medicine has developed three strategies to address disparities in cancer through clinical research training and community partnerships. These methods have a direct impact on translation of research. First, minority scientists and clinicians are trained to become independent investigators and clinical trialists through the Clinical Research Education and Career Development Program, which leads to a Master of Science in Clinical Research degree. One requirement of the program is development of a competitive grant application.
- Second, the Community Practice Network promotes participation of African-American physicians and successful recruitment of African Americans and other minority patients into clinical research protocols that specifically target health disparities. The Network has partnered with more than 60 community practices.

- Third, participant recruitment and retention are at the core of the Participant Recruitment and Retention Core of the Center for Research Studies. This program has screened almost 2,800 individuals and enrolled 872 into various research protocols, including prostate cancer, hypertension, and breast screening.
- The importance of establishing trust within the community cannot be overemphasized. Everyone knows about the Tuskegee study and what that means to black Americans. The majority of care is provided not in academic centers or Cancer Centers but in the community; to involve community physicians in clinical research, a community of trust and a network of concern must be established.

BEST MECHANISMS FOR MOVING RESEARCH INTO COMMUNITIES—DISCUSSION

Key Points

- Dissemination of screening guidelines may not improve outcomes if people cannot pay for screening and insurers are not willing to cover it. The availability of screening programs funded by the CDC and local programs with Government grants partially bridges this gap, but many people are unable to follow the guidelines due to lack of resources.
- NCI-designated Cancer Centers are expected to address the needs of the community, but often their outreach programs are not connected to the research they conduct. NCI is actively encouraging Cancer Centers to make sure that their research activities inform the practices of the community organizations the Centers become involved with. Centers should also encourage their investigators to submit dissemination-related proposals to NIH Study Sections. The peer-review process is conservative, but Study Sections can be educated over time. NCI also plans to modify guidelines and resource sharing to remove the "unfunded mandate" stigma from the requirement that Centers engage in community outreach. Cancer Centers should become leaders in long-term dissemination research.
- One barrier to involving social workers in clinical research is that they are not revenue-generating professionals because they cannot charge their services to the cost center. The Panel should consider a recommendation that support for the involvement of social workers be included in the budgets for clinical research projects.
- Like M. D. Anderson, UCSF is involved with a national group, the National Comprehensive Cancer Network (NCCN), in developing guidelines for cancer care. The problem is that researchers cannot make people read or follow these guidelines, and there is no mechanism for learning whether Centers are adhering to them. The Centers for Medicare and Medicaid Services (CMS) must be a partner in this effort, since any new care or management strategy has an impact on the health care budget.
- The NCI is working collaboratively with CMS to speed the process of Medicare reimbursement for new strategies and to address cancer-related health disparities. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act, MMA) includes funds for health disparity demonstration projects, and NCI is working with CMS to ensure adequate scientific review of those projects.
- No training programs in cultural oncology are available. There is a need to develop culturally, linguistically, and literacy-specific evidence-based strategies for eliminating cancer health disparities.
- Although Web sites are an excellent means of information dissemination and sharing, they will not solve the problem of applying the knowledge developed by Cancer Centers in the communities where they are embedded. Centers need capacity-building resources so that they can provide technical assistance to community organizations on an ongoing basis.
- Because of budget constraints, NCI is not in a position to greatly increase funding for Cancer Centers to perform community outreach, but it will continue to help Centers form partnerships and bring in resources from various organizations. To further examine this perspective, the Panel should involve

representatives of C-Change in its meetings; this organization of organizations is fostering partnerships in this area.

- The best way to ensure dissemination of research results is to encourage collaborating community organizations to take ownership of new ideas and play an active role in the scientific testing of those ideas.
- The definition of the term *translational research* should be broadened to include "from bench to bedside by way of the community." When researchers partner with the community, dissemination is not a problem.
- The NIH is adopting a Community-Based Participatory Research (CBPR) model and will soon release a trans-NIH program announcement in this area. The resistance of the Center for Scientific Review to including nonscientists in the peer-review process is a barrier to this kind of research; however, the CBPR will be reviewed by a Special Emphasis Panel that will probably be more open to an expanded review process.

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 give a summary of what was said in their panels and anything else they would like to add based on their experience and expertise.

DISCUSSION PANEL 1—DR. FRANK McCORMICK

Key Points

- The major topics of this panel were legal and legislative issues, the need for infrastructure for applied sciences and translational research, and leadership and cooperation issues.
- Some patent law creates barriers, such as difficulties in constructing genome arrays that will be essential in identifying people at risk and monitoring response to different therapies. There are also barriers to establishing facilities for developing new diagnostic tests that are compliant with requirements of the Clinical Laboratory Improvement Act (CLIA).
- Short patent lifetimes create barriers to development of cancer prevention agents. By the time a prevention trial has been completed and an agent is approved, the patent has expired, removing the financial incentive for the developer. Patent life of therapeutic agents is also becoming shorter.
- Researchers need better mouse models for developing cancer drugs. This will be particularly relevant when combination therapies need to be tested in the future.
- Among legislative issues discussed, a major issue is the need for restructuring HIPAA regulations.
- Material transfer agreements (MTAs) present significant barriers to transferring materials between pharmaceutical companies and academic research laboratories so that laboratories can become more involved in testing and developing new agents. The MTAs pose barriers to many interactions between the biotechnology and pharmaceutical industries and the academic community.
- Academic institutions need to better manage conflicts of interest so that scientists can stay focused on discovery and development activities.
- Increased investments in infrastructure are needed to support translational research, which requires new diagnostic and related products, imaging tools, and analytical tools. This new industry requires investment in specialized training of scientists, technicians, nurses, and others. Centralized databases and tissue repositories are also part of the needed infrastructure for translational research.
- There is also a need to overcome language and cultural barriers to clinical trials and other kinds of translational research. It is very difficult to find the resources to solve these problems in the current system, but it is necessary if new agents are going to be disseminated effectively into the entire community.
- Leadership issues center on the question of who should make decisions about centralizing registries, databases, and protocols. A federation of groups involving the NCI, FDA, the pharmaceutical industry, the academic community, DoD, and others should be convened to define leadership roles.
- Communication and education need to be improved, as the public has very little understanding of what scientists do or what is involved in drug development and clinical trials.
- The challenge in promoting cooperation is in learning how to motivate and reward team players in a culture—not only the medical research culture, but the culture as a whole—that glorifies individual achievement.

DISCUSSION PANEL 2—DR. ANNA BARKER

Key Points

- There is no generally accepted definition of *translational research*. There are two gaps in the research and development process. The first is in translation from the basic science laboratory to the clinic. The second is in translating developed interventions into public health.
- Cancer Centers have a responsibility to play a major role in discovery, development, and delivery, including dissemination. This message will be received by NCI.
- The Nevada Cancer Institute has made a commendable effort in putting together a public-private partnership focusing on community needs in an area without a major academic medical center. This is an interesting model that other Cancer Centers could learn from as they build their community constituencies.
- The cancer research community has a responsibility to meet the challenges posed by HIPAA, and this must be done in partnership with patients.
- The system that supports and guides cancer research is not limited to the public and private sectors. It is a three-part system, and the third partner is the public.
- The system of translation is a continuum that consists of discovery, development, commercialization, delivery, and public health. There are feedback loops at every step in that continuum. The fact that all the steps will always be connected means that conflict of interest issues must be addressed and solved.
- Barriers to translational research include the lack of a seamless system for developing therapeutics, diagnostics, and behavioral interventions. Creation of such a system requires cooperation among the NIH, other Federal agencies, and the private sector, as well as better connection with the community. It also requires shared resources and increased incentives for transdisciplinary science.

DISCUSSION PANEL 3—DR. MARGARET TEMPERO

Key Points

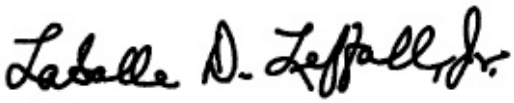
- Some of the key points made during the meeting focused on the power of networks, the need to bring concept of cultural oncology into translational research, the need for translation services to address language barriers, and the importance of Progress Review Groups in bringing multiple disciplines together to lay out agendas for action on specific questions.
- One issue that was not directly addressed is outcomes research, which, the field is beginning to learn, is very difficult to accomplish. There are several possibilities for partnership to facilitate this type of research. CMS has the capability of looking at trends in care, drugs used, site of care, and other variables through Medicare reimbursement data.
- The delivery system must be incorporated into the planning process for cancer research. There are not enough qualified and experienced community practitioners who are fully engaged collaborators in the research process.
- The research community must make legislators understand the implications when mandates are handed down without sufficient funds to meet them and when well-meaning regulations like HIPAA unintentionally hinder research and care delivery.
- Part of the infrastructure problem is that too many homegrown systems have been created that are not mutually compatible. The same issue applies to standard operating procedures, sample processing, and technology applications.

CLOSING REMARKS

- Mr. Armstrong pointed out that the issue of trust is important because delivery of cancer care is a matter of life and death. Mistrust is based on fear and confusion and can be eliminated through education and communication.
- Ms. Cathy Coleman, a cancer nurse, stressed the importance of continued support for the toll-free service provided regionally by the Cancer Information Service. She also asked the Panel to speak in support of the CMS pilot project called the Doctors' Office Quality Information Technology (DOQ-IT) project, which promotes the adoption of electronic health record (EHR) systems and information technology (IT) in physician offices.
- Ms. Emilia Jankowski of the American Cancer Society mentioned that because many physicians misinterpret HIPAA, they hesitate to refer patients to the ACS and other organizations that have much to offer cancer patients. She also noted that dialog between doctors and patients about clinical trials must be culturally appropriate.
- Ms. Jenesse Miller, a Media Coordinator with the ACS, stressed the importance of working with the media as strategic partners in translational research. It is especially important to work with ethnic media, which are active advocates for their communities.
- Dr. Leffall thanked everyone who participated in the meeting. He announced that upcoming meetings in this series will be held in Columbus, Ohio; Houston, Texas; and New York City.

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 August 30, 2004, is accurate and complete.

Certified by:  Date: 12/15/2004

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Chair
President's Cancer Panel