

**MEETING SUMMARY  
PRESIDENT'S CANCER PANEL  
STRATEGIES FOR MAXIMIZING THE NATION'S  
INVESTMENT IN CANCER**

October 22, 2007  
San Diego, CA

**OVERVIEW**

This meeting was the second in the Panel's 2007/2008 series on strategies for maximizing the nation's investment in cancer. The meeting was designed as an interactive, facilitated working session focused on identifying changes to the current system of cancer research and care that would have the greatest impact on reducing mortality and morbidity from cancer.

**PARTICIPANTS**

***President's Cancer Panel (PCP)***

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

Margaret Kripke, Ph.D.

Lance Armstrong

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

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

***Roundtable Participants***

Moon Chen, Ph.D., M.P.H., Professor and Associate Director, Population Research and Cancer Disparities, University of California Davis Cancer Center

Robert Croyle, Ph.D., Director, Division of Cancer Control and Population Sciences (DCCPS), NCI

Nancy Davidson, M.D., President, American Society for Clinical Oncology; Professor of Oncology and Breast Cancer Research Chair in Oncology, The Johns Hopkins University School of Medicine

Judith Gasson, Ph.D., Director, Jonsson Comprehensive Cancer Center, University of California at Los Angeles

Stephen Albert Johnston, Ph.D., Director, Center for Innovations in Medicine, The Biodesign Institute, Arizona State University

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

Sandra Murdock, FACHE, Dr.P.H., President and Chief Operating Officer, Nevada Cancer Institute

Robert Topel, Ph.D., Professor of Economics, University of Chicago Graduate School of Business

Geoffrey Wahl, Ph.D., Professor, Gene Expression Laboratory, Salk Institute for Biological Studies

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

On behalf of the Panel, Dr. Leffall welcomed invited participants and the public to the meeting. He introduced Panel members, provided a brief overview of the history and purpose of the Panel, and described the aims of the current series of meetings. Dr. Leffall explained that the meeting would employ a roundtable discussion format, facilitated by Mr. Robert Mittman.

## **OPENING REMARKS—ROUNDTABLE PARTICIPANTS**

### ***Mr. Robert Mittman, Facilitator***

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

Mr. Mittman asked participants to briefly introduce themselves and provide an example of one important change with the potential for significant impact on the cancer enterprise. He explained that discussion would then move toward developing an accurate and honest assessment of the current state of the cancer enterprise, noting that one key point raised during the first meeting in this series was that “The cancer research community should tell the public the truth about the complexity and difficulty of the tasks remaining in understanding and eliminating the burden of cancer.” Further discussion would identify specific objectives for changing the cancer enterprise using an analytical, business-like model that incorporates measurement of success and accountability. Finally, the role of the NCI in the process of changing the cancer enterprise would be addressed.

### ***Dr. Stephen Johnston***

- v As Director of the Center for Innovations in Medicine at Arizona State University, Dr. Johnston is currently focusing on development of a universal prophylactic cancer vaccine.
- v The most important change needed in the cancer enterprise is alignment of strategic analysis with financial incentives and developing improved milestones and measures of accountability.

### ***Dr. Sandra Murdock***

- v Dr. Murdock is President and Chief Operating Officer of the Nevada Cancer Institute. She noted that Nevada has some rapidly growing urban areas but is primarily a combination of rural and frontier land.
- v The cancer enterprise should pay more attention to issues regarding access to care. In addition, scientific research infrastructure should be more equitably distributed across the country.

### ***Dr. Moon Chen***

- v Dr. Chen is Associate Director for Population Research and Cancer Disparities at the University of California, Davis.
- v Stakeholders within the cancer enterprise, both public and private, should coordinate their efforts to ensure application of proven beneficial interventions, especially in terms of lifestyle

changes, and balance the research portfolio to address the most important remaining scientific questions.

***Dr. Robert Topel***

- v Dr. Topel is a Professor of Economics at The University of Chicago. He advises the University's President on the economic value of medical research and health improvements.
- v Advances against cancer have been shown to be extremely economically valuable to society.

***Dr. Geoffrey Wahl***

- v Dr. Wahl is a Professor in the Gene Expression Laboratory at the Salk Institute for Biological Studies. His expertise is in molecular biology and much of his research focuses on breast cancer. He is also the son of two parents who died of cancer. One developed lung cancer as a result of smoking, and the other died of colon cancer. Dr. Wahl is the Immediate Past President of the American Association for Cancer Research, through which he has become increasingly aware of the importance of advocacy and survivorship issues.
- v The single largest impact in reducing cancer mortality would be gained from outlawing smoking.
- v There should be a greater sense of urgency among policy makers and the public about increasing funding for research to address biologic pathways that guide cancer's growth, metastasis, and response to therapy.

***Dr. Judith Gasson***

- v Dr. Gasson is a Professor of Medicine and Biological Chemistry at UCLA, Director of UCLA's Jonsson Comprehensive Cancer Center (CCC), and President of the Cancer Center Foundation, the Jonsson CCC's fundraising arm.
- v Cancer morbidity and mortality can be greatly impacted by better educating the public about their risk of developing cancer and the importance of adopting lifestyle changes that have been shown to reduce cancer risk.
- v In the research environment, serious discussion is needed about developing measures of success in translational activities so that the growing wealth of knowledge can be more effectively applied to reduce the burden of cancer.

***Dr. John Mendelsohn***

- v Dr. Mendelsohn is Professor and President of the University of Texas M. D. Anderson Cancer Center.
- v To improve data sharing, the cancer enterprise needs to develop a comprehensive clinical research database that is linked to electronic medical records. Portable medical records would benefit patients as well, making it possible for all health care professionals to have access to patient information that may be critical to planning the care they receive.
- v The public should be educated about the importance of holding themselves and their caregivers accountable for monitoring their health.

***Dr. Nancy Davidson***

- v Dr. Davidson is President of the American Society for Clinical Oncology and a practicing medical oncologist who specializes in breast cancer. She also directs the Johns Hopkins University Breast Cancer Special Program of Research Excellence (SPORE).
- v Cancer could be described as an individualized form of bioterrorism, and as such should be addressed with a sense of urgency.

- v The most urgently needed change in the cancer enterprise is improvement of care delivery to underserved populations and regions, including rural areas and inner cities.

**Dr. Robert Croyle**

- v Dr. Croyle is Director of NCI's Division of Cancer Control and Population Sciences.
- v Actions to reduce cancer morbidity and mortality should "follow the data." It is clear that reducing tobacco use would reduce deaths from multiple causes, including cancer. Effective strategies for reducing tobacco use have been developed and tested but have yet to be implemented on a national basis. In addition, opportunities for early detection that could have significant impact on mortality are being missed, especially with regard to colorectal cancer.
- v Collaborative decision making on priorities for research and implementation of interventions is needed, replacing turf wars pitting basic and clinical research against epidemiology, or tobacco control against basic science.

**ROUNDTABLE DISCUSSION—"TRUTH TELLING"**

- v Regular communication among NCI, the extramural community, and patient advocates is needed to ensure that the limited budget available for cancer research is focused on the most important priorities.
- v Education is needed to help the public understand that there will never be a single "cure" for cancer and that the cancer research community is not withholding discoveries. Cancer is more than one disease, and more than one type of intervention will be needed to reduce its impact. As science progresses, many cures or treatments to reduce the severity of cancer are likely to be discovered; however, some new drugs may lead to the development of drug-resistant tumors, requiring further research. There will be no dramatic end to the fight against cancer. Some new drugs will also be useful for a number of cancers, especially when appropriately combined with other drugs. Thus, drug development must be planned and managed broadly, rather than focused on drugs in isolation.
- v Since the passage of the National Cancer Act in 1971, NCI has not funded research on prophylactic cancer vaccines other than those targeting infectious agents. It was suggested that NCI consider a significant investment in studies to develop a vaccine that could serve as a universal preventive intervention for cancer.
- v Commentary on the "failure" of the cancer research enterprise does not take into consideration the uncertainty of hypothesis-driven scientific investigation. No one can know in advance whether the results of a study will be positive or negative; negative findings can be seen as the result of successfully testing a hypothesis.
- v Cancer patients should not have to rely upon word of mouth or luck to find the best treatment. Collection of outcomes data must be improved to make information on quality of care available to health care consumers.
- v Important gains have been achieved in cancer survivorship, but they have been exaggerated by both researchers and pharmaceutical companies. While some patients have experienced extended survival of 4 to 5 years as a result of participation in clinical trials, average extended survival is measured in months.
- v Statistics provided to the public should be not only truthful but also meaningful on an individual level.
- v When comparing the cost of investment in research with the economic value to be gained from reductions in cancer mortality, the future costs of treatment resulting from research discoveries must be taken into account.

- v The nature of the current health care delivery system biases researchers in favor of developing expensive technologies rather than more efficient methods of treatment. There are no incentives for conducting medical research to develop cost-effective interventions.
- v Public discussion of cancer should move away from site-specific cancers toward a broader discussion about pathway-driven cancers. The scientific community has made this shift, but the concept has not been adequately explained to the public. Advocates could help by emphasizing the broader benefits of advances against individual cancers. It is especially important that third-party payers move beyond the concept of drugs designed to treat specific cancers and accept the concept of mechanism-driven treatment.
- v When confronted with fragmented messages about the funding needs of multiple interest groups (e.g., advocacy groups focused on specific diseases, scientists within various disciplines), policy makers find it difficult to understand the overall impact of cancer and are unable to prioritize needs or make decisions that could move the entire cancer enterprise forward. The cancer research and advocacy communities need to begin speaking with a single voice. Maintaining momentum in the cancer research enterprise requires steady funding and planning, rather than fragmented efforts in response to individual diseases.
- v The rapid availability of information about pathways activated by new drugs is leading to real-time modification of clinical trial designs to apply those drugs to different cancers.
- v Shrinking research budgets are leading investigators to conduct research more efficiently. The sharing of resources (e.g., molecular reagents, mouse strains) and information among scientists has increased.
- v The slow but steady decline in cancer mortality over the past 30 years has been caused less by incremental improvements in treatment than by changes in exposures and lifestyle factors. In the past century, tobacco was the leading factor in cancer mortality. In the coming century, it will likely be replaced by obesity. The cancer enterprise needs to do a better job of linking basic and clinical science to address the factors that drive mortality at the population level. The health care delivery system can be used as a research platform to address this issue by linking surveillance data with biological data.
- v In addition to “talking the talk” of unity, the scientific and health care enterprise must “walk the walk” by integrating the conduct of research and the delivery of health care to eliminate competition for resources.
- v NCI cannot provide the same level of leadership in changing the health care delivery system as it has in the area of scientific research. However, the research community can play an important role in the future of the health care system by providing evidence, including outcomes data and findings concerning the economics of health care, to inform decision making.
- v A key element of strategic planning for cancer research is to examine progress in specific areas (e.g., breast cancer research grants, vaccine development) in comparison with the stated goals of those programs. Additional milestones need to be created so that accountability can be better assessed.
- v The public should be made aware of the cancer risks associated with obesity and lack of physical activity. Personal accountability is an important factor in improving public health. The public underestimates individual cancer risk and overestimates the amount of money being spent on cancer research.
- v The public perception that cancer is a genetic, and therefore inherited, disease has led to fatalism about cancer risk. In fact, most genetic changes associated with cancer are acquired after birth due to behavioral factors or environmental exposures.

- v Further study is needed on how best to communicate cancer-related information to the public. Some messages receive a more positive reception than others. For example, evidence has shown that people are more receptive to the concept of “protection” than to “prevention.”
- v The research community and health care delivery system should take the opportunity to create a research platform for basic, clinical, and population science by better capturing medical data.
- v Clinical trials, including those conducted by NCI-funded cooperative groups, are often unimaginative and poorly designed. Biopsies and molecular biology should be incorporated into trials so that pathways can be studied in humans rather than in animal models.

## **ROUNDTABLE DISCUSSION—THE CANCER RESEARCH ENTERPRISE**

- v The cancer research enterprise can be described metaphorically as a symphony orchestra comprising individual musicians, as well as musicians functioning as sections within the orchestra, and requiring a conductor to guide the ensemble as it performs a coherent piece of music.
- v In addition to a conductor guiding the cancer research enterprise, an overall health coordinator may be needed to harmonize the efforts of cancer researchers with those of researchers in other fields (e.g., diabetes, heart disease), regulatory agencies, and the public health enterprise.
- v Guidance in overall direction for the cancer research enterprise should not preclude opportunities for independent innovation and competition between ideas.
- v One objective of basic research is to create a fertile environment in which innovative applied research can take place. However, bidirectional communication is needed so that applied researchers can ask basic scientists for answers to questions that they encounter. Applied researchers can also ask for strategic shifts, such as development of low-cost, moderately effective interventions instead of high-cost, highly effective interventions in order to make better use of society’s resources.
- v The New American University at Arizona State University is combining basic and applied research by conducting bench science that is goal-oriented. Experiments are intended to extend basic knowledge in a direction that has potential utility. The alignment of personnel and other resources required by this approach is similar to the Apollo Project, which brought together a team of engineers and scientists to solve the problems associated with putting a manned spacecraft on the moon.
- v A strategic plan for cancer research must have some flexibility because it is not possible to know in advance which basic science discoveries will be important. Investment should be focused on areas that show promise, but priorities should be reexamined on a regular basis in order to quickly capitalize on opportunities that become available as a result of hypothesis-driven research.
- v Due to funding limitations, NIH study sections are reluctant to fund good ideas unless the investigator has already done similar research and proven that usable results can be obtained. Many universities must resort to raising philanthropic funds to support early work in high-risk areas (a concept referred to as “venture philanthropy”) so that investigators can build a track record that can lead to successful R01 applications.
- v A key characteristic of the traditional investigator-initiated research paradigm is risk avoidance. Projects with great potential benefit but high risk of failure are unlikely to obtain funding. The Defense Advanced Research Projects Agency (DARPA) is a model for a milestone-driven approach to basic and applied research that mobilizes resources to meet

challenging goals. DARPA project managers are not penalized for failures. Such strategies, which anticipate more failures than successes, are similar to the concept of venture capitalism in the business world.

- v The DARPA model is most appropriate for technology development, in which prototypes can be rapidly tested, modified, and retested. In biomedical and clinical research, the first question in a sequence of questions can take 10 years to answer. Funding methods for research should be selected in context with the scientific questions being addressed. A generic model cannot be applied to all scientific problems.
- v In the Federal biomedical research community, numerous trans-agency coordinating committees and working groups have been formed with high-level leadership, but they are often ineffective due to a lack of incentives. The centralized priority-setting model has not worked well because even when consensus on priorities is achieved, there are no resources to address them. Since most financial resources in biomedical research are managed at lower levels within Federal agencies, a business model is needed to facilitate horizontal collaboration through which partners can pool resources to address agreed-upon priorities.
- v The current training and incentive systems make it difficult for physician scientists to plan careers in population-based clinical research.
- v The Federal Government provides approximately 47 percent of the funds spent on cancer research in the United States. The remainder comes from philanthropic and for-profit organizations. No organization or agency keeps track of where and how these non-government funds are spent.
- v The Department of Defense Breast Cancer Research Program has experimented with a new funding mechanism called the Impact Award, which is designed to support programs that are expected to make an impact on cancer and do not require preliminary data. The program is flexible in allocating funds to the most promising ideas. This program should be evaluated to learn whether it could be replicated by other agencies.
- v The first step in improving the cancer research enterprise is gaining a better understanding of the current research portfolio. This issue has been addressed in portfolio analyses conducted by NCI-convened Progress Review Groups (PRGs) focusing on specific cancers; these groups have struggled with the process of defining cancer research and determining to what extent individual research projects focus on the topic under discussion (e.g., breast cancer).
- v Sharing information about the cancer research portfolio is not enough to foster change. Each institution represented in the portfolio seeks to maintain its own funding stream; defense of the status quo is a significant barrier to redirecting funds to address new priorities.
- v An evaluation of the entire extramural cancer research portfolio is needed to determine whether the needs of cancer patients are being met. The review panel should include business and economics experts, as well as scientists and physicians.
- v An alternative to evaluating the existing research portfolio would be to begin with a description of an ideal portfolio, based on prioritized goals and objectives, and then to compare the status quo with this ideal.
- v Given a finite budget, new research initiatives should not be proposed unless a proposal is also offered to identify current activities that should be suspended so funds will be available for the new effort.
- v To adequately inspire the public and the cancer enterprise, the goal of reducing suffering due to cancer must be expressed in terms that demonstrate feasibility and measurability. It must be made clear that reaching the goal is worth the anticipated cost.

- v Overall cancer mortality could likely be easily reduced by 50 percent or more by eliminating tobacco use, expanding screening, and implementing lifestyle changes. However, this would not represent a new challenge for science, but a political and social challenge to apply knowledge that science has already generated.
- v A 20-year plan should be proposed to reduce cancer mortality by 50 percent. During the first 10 years, reductions can be achieved by applying what we know about prevention (especially elimination of smoking) and early detection, and during the subsequent 10 years those reductions can be supplemented through development and adoption of new therapeutic approaches. The cost of expanded cancer research would be paid for through a drastic increase in the price of tobacco. It was suggested that one cigarette should cost at least as much as a cup of gourmet coffee.
- v Setting specific goals might be more compelling to the public. Models are available to estimate the amount of reduction that would be possible over time in breast, colon, lung, and prostate cancers if universal screening could be achieved. An urgent message that specific changes in health care or in behavior will result in specific risk reduction should be disseminated.
- v In holding the research enterprise accountable, “activity” should not be confused with “achievement.” Most existing measures of success are based on quantifying activities (e.g., papers published, grants awarded, tenure).
- v One way to evaluate the impact of research programs is to measure the frequency of nonlinear events, or unexpected results. These are milestones that represent the extent to which research is making a difference.
- v Another measure of success in experimental therapeutics is the extent to which one-size-fits-all toxic therapies are being replaced with less harmful and more personalized therapies.
- v Accountability might be improved if grant applicants were required to include in their research plans an estimate of the impact of the project if successful.
- v The cancer research community is beginning to accept the idea that improved metrics and evaluation, using a business model, are needed to bring accountability into the research enterprise. New initiatives (e.g., NIH Roadmap projects) now routinely include built-in evaluations and measures of progress.

## **PUBLIC COMMENT**

- v Patient advocates should play a greater role in meetings of the Panel and other forums discussing similar issues. This is especially important when discussion includes application of business models to the research enterprise, since many advocates are involved in the business world.
- v Leadership in the cancer enterprise includes providing a vision that can help bring the cancer community together with a common cause. Without a clear vision, accountability is not measurable.
- v A strategic plan for the National Cancer Program was created in 2006. The plan is available on the NCI Web site at <http://planning.cancer.gov>. The two main components of the plan focus on “preempting cancer at every opportunity” and “ensuring the best outcomes for all.” Aspects of the plan are being incorporated into each annual NCI budget request. The plan itself, however, is designed as a model for other organizations involved in reducing the burden of cancer.
- v Based on the work of the PRGs, NCI developed a Common Scientific Outline (CSO), a classification system organized around seven broad areas of scientific interest in cancer



research. The CSO has been adopted by the International Cancer Research Partnership (ICRP), whose members include 8 organizations in the United States, 12 in the United Kingdom, and 12 in Canada. The ICRP maintains a database of research funded by cancer research organizations throughout the world; access to the database is available at <http://www.cancerportfolio.org/index.jsp>.

- v A new report called *An Unhealthy America: The Economic Burden of Chronic Disease* is available at <http://www.milkeninstitute.org/index.taf>. This report examines how cancer, hypertension, heart disease, lung disease, and mental disorders are affecting the nation's public health.

## **ROUNDTABLE DISCUSSION—THE CANCER CARE ENTERPRISE**

- v The U.S. health care delivery system is not functioning optimally. More than 45 million Americans do not have health insurance. On a macro level, care is not delivered efficiently or equitably. On a micro level, practitioners struggle to break even financially.
- v There are no existing business models that appear to be appropriate for designing a system to deliver preventive care such as prophylactic vaccines. Consumer demand for treatment when people are ill is very high, but demand for prevention is very low. Even if evidence-based, cost-effective preventive interventions were covered by insurance, public acceptance would remain low. A business model is needed to create a demand for preventive medicine based on its value (the ratio of cost to benefit). Prevention would also be more readily accepted by the public if understandable measures of risk for cancer (similar to cholesterol levels for cardiovascular disease) were available.
- v The lack of an open database of shared information on cancer care acts as a significant barrier to identifying themes related to cancer risk and cancer care outcomes. However, ongoing NCI projects, such as the Cancer Care Outcomes Research and Surveillance (CanCORS) study, are providing proof of principle that large databases maintained by health maintenance organizations can be pooled with data from the Surveillance, Epidemiology, and End Results (SEER) Program, Medicare, the Cancer Research Network, and other sources for analysis using statistical modeling techniques.
- v The NCI Cancer Bioinformatics Grid (caBIG) is developing an open-source platform for integrating basic science informatics. If this system is expanded to encompass health care delivery and public health informatics, the ability to analyze the clinical impact of new interventions will be significantly enhanced. This would provide feedback for prioritization of basic and clinical research, drug development, symptom management, and long-term care.
- v Cancer patients, survivors, and advocates should be enlisted as an informal source of information on how optimal cancer care could be achieved. The anecdotal evidence of their experiences can help indicate where shortcomings exist.
- v In Los Angeles, a patient navigation program funded by the Avon Foundation and the Lance Armstrong Foundation has benefited cancer patients by reducing time between diagnosis and surgery and lowering the number of patients lost to follow-up.
- v The question of how to optimize outcomes of cancer care may have different answers depending on whose perception of outcomes is being considered. Cancer patients place a much higher priority than physicians on the quality of communication and the availability of psychosocial support. Patient-reported outcomes should be included in the evaluation of clinical trials.
- v Much of the variation in the quality of health care in the United States is the result of system-level problems in areas such as the transition from primary care to specialized care (e.g., oncology, radiology, surgery). Interventions that have the potential to improve the quality of

care across specialties must incorporate data collection and feedback that are independent of the actions of individual physicians. Patient navigation addresses this issue because it helps bridge the disconnect among fragmented systems of care.

- v The NCI Community Cancer Centers Program is a pilot project that has a broad mandate to increase accrual to clinical trials, promote adoption of electronic medical records, and reduce cancer health disparities. The project is very new, but the community cancer centers have already had remarkable success in leveraging limited NCI funds by obtaining supplemental funds from other sources. These Centers are engaged in finding innovative ways to deliver high-quality but low-cost care to populations that cannot afford to pay medical bills.
- v It will be very difficult to design methods to evaluate the impact on quality of cancer care of the Community Cancer Centers because of the large number and complexity of the activities the centers have initiated.
- v The American Society for Clinical Oncology (ASCO) is developing physician-oriented quality improvement initiatives that evaluate individual practices in comparison with standards and guidelines, keeping in mind that variations in individual patients' situations require considerable flexibility in the practice of oncology.
- v The cancer enterprise should emulate the field of cardiology, in which 70 percent of practitioners adhere to practice guidelines, by developing evidence-based practice guidelines for oncology. This will be a difficult task, since oncology is much more complex than cardiology and the state of the art changes rapidly.
- v NCI is actively engaged in research to develop consensus on metrics to evaluate the quality of cancer care; significant progress, for example, has been made in measures of quality in colorectal cancer care. The level of evidence related to effectiveness of care for other diagnoses is highly variable and in most cases inadequate. There is some resistance among physicians to development of quality standards because the penalties for noncompliance have not been clarified. Another barrier to improving the quality of cancer care is the lack of research-based evidence to inform strategies for implementing and disseminating clinical guidelines after they are developed.
- v Translational research will be an essential element of the effort to improve cancer care, but will be difficult to incorporate into a business model because it is not a "money-making" endeavor. As with basic research, it will be necessary to accept the fact that some expensive clinical trials will not provide positive results. The costs of trials could be reduced by eliminating some of the bureaucratic barriers to launching and participating in clinical research.
- v Current clinical trials are often designed to look for incremental changes in clinical outcomes. This approach requires very large numbers of participants in order to generate meaningful results, which is often challenging. It may be more beneficial to conduct trials that are expected to have a larger impact, possibly in earlier-stage patients. This would enable conduct of more trials with fewer patients. An approach that is being pursued by some clinical researchers is to conduct smaller clinical trials in subsets of patients with very specific types of cancer (e.g., defined by presence of a biomarker or activity of a signaling pathway). These trials generally involve extensive collection of biospecimens, in part to allow assessment of whether the desired molecular targets were affected by the treatment. Extensive collaboration among different investigators and institutions is often necessary to identify sufficient numbers of eligible patients for these focused trials. One drawback to conducting clinical trials in smaller sets of patients is that it may be difficult to obtain an accurate estimate of the potential adverse effects of a drug.

- v Finding a way to pay for treatment with experimental drugs in clinical trials is a crucial issue. It is becoming difficult to recruit later-stage patients into trials involving off-label use of drugs because they are likely to be required to pay for expensive treatments.

## **ROUNDTABLE DISCUSSION—THE ROLE OF NCI IN OPTIMIZING CANCER CARE**

- v The elected leaders of organizations who represent physicians, scientists, and advocates should meet regularly with NCI leadership to focus on issues related to optimizing cancer care. The purpose would be not only to discuss broad conceptual topics but also to advise NCI on practical matters, such as management of the clinical trials enterprise. Support from this group would provide NCI leadership with credibility in saying “no” to some projects when there is a consensus that limited funds should be spent on other priorities.
- v Many of the scientific challenges facing cancer researchers are also faced by scientists addressing other diseases. The NIH, which was created in the middle of the 20th century with a focus on disease-specific research, may need to be restructured to better support interdisciplinary biomedical research. The NIH Roadmap for Medical Research is a first step in the process of committing more resources to activities that bridge the boundaries between Institutes. A new structure might combine resources for addressing questions that transcend diseases, such as basic science, diagnostic methodology, and clinical trials design, while setting aside resources for more disease-specific research.
- v NCI plays a leadership role within NIH, and in partnership with the broader biomedical research community, because it has unparalleled resources in terms of infrastructure, staffing, registries, Centers of Excellence, and clinical trials networks. Restructuring NIH to emphasize cross-Institute activities could result in a lessening of NCI’s autonomy.
- v A larger pool of discretionary funds should be made available to the NCI Director to enable quick responses to unanticipated opportunities that promise to improve cancer outcomes.
- v The NCI Director plays a leadership role in the broader cancer research community that is separate from the role of NCI as an organization. As a Presidential appointee, the NCI Director has a unique opportunity to present visionary challenges to the research community.
- v Directors of other NIH Institutes are selected through a traditional process in which a search committee identifies qualified candidates. A search committee should be created to advise the U.S. President on selecting new NCI Directors. This committee should comprise representatives of important scientific organizations, such as the National Academy of Sciences, National Science Foundation, ASCO, and American Association for Cancer Research, as well as patient advocacy organizations.

## **CLOSING REMARKS—ROUNDTABLE PARTICIPANTS**

- v The mention of issues related to making an impact on cancer mortality remains unwelcome at meetings of scientists gathered to discuss research strategies. Scientists prefer to discuss science and leave outcomes-related topics to policy makers and public health specialists.
- v Scientists and advocates should work together with a single voice to remove intellectual and financial barriers to translational research.
- v The most important priority for improving the quality of cancer care and reducing the cost of care is creation of a comprehensive electronic database with uniform reporting of data from clinical trials and integration with standardized, portable patient medical records.

- v The war against cancer will not be won quickly. Adequate, predictable, sustainable funding must be available to support the continuation of this war by the next generation of scientists and advocates.
- v The NCI Cancer Centers program should be sustained and expanded as an effective means of bringing translational research into local communities.
- v A visionary message about the need for improving cancer care and reducing cancer mortality must be presented to the public in the form of a mission similar to the Apollo program of the 1960s. The message should stress the importance of both personal and public accountability.

## **PUBLIC COMMENT**

- v The peer-review process for funding research is too slow and cumbersome, especially in the area of translational research. For many new types of studies, it is difficult to find qualified experts to conduct peer review.
- v The wide range of indirect costs in research grant budgets (from 40 percent to more than 90 percent) is a serious problem that must be addressed by NIH.
- v There is a gap between the knowledge being created in cancer centers and the information that reaches community oncologists. The inability of cancer centers to disseminate new information to community oncologists and bring them into the clinical trials enterprise compromises the quality of care that community oncologists are able to deliver.
- v The role of NCI in creating a vision for the cancer enterprise and in implementing that vision should be clearly defined. The Institute's multiple roles may be too broad and lead to confusion within the cancer community.
- v NCI receives frequent queries and directives from the U.S. Congress that require the Institute to play a greater role in dissemination and public education than other research organizations are asked to play. NCI also interacts frequently with the leaders of other government agencies (e.g., the Food and Drug Administration [FDA], Centers for Medicare and Medicaid Services [CMS], Veterans Administration, Health Resources and Services Administration, Centers for Disease Control and Prevention) whose interests include cancer-related issues. NCI needs input from the cancer community on the most appropriate approach the Institute should follow in maintaining relationships with those other agencies.
- v NCI's mandate is to lead the federally funded National Cancer Program; its charter does not limit its activities to the conduct of hypothesis-driven research. The key question in that context is to determine what powers and authority are needed for the NCI and its Director to optimally spend the Institute's budget. Former NCI Directors may be the most appropriate people to provide insight on that question.
- v NCI's flexibility in addressing its broad mandate is limited by the fact that evaluation of how the Institute's budget is spent is primarily conducted by the academic community.
- v NCI needs a strong working relationship with the FDA and CMS because the approval and reimbursement decisions made by these agencies have a significant impact on the planning of NCI research programs.
- v Ideally, universities that rely on NIH grants to pay for most of the salaries of faculty should increase their salary support to at least 50 percent so that more Federal dollars can be spent on research. This would be a challenge, however, for freestanding research institutions that receive no tuition fees from students.

## **CLOSING REMARKS—PRESIDENT’S CANCER PANEL**

Mr. Armstrong noted that improving cancer outcomes and quality of cancer care is not a race with a clear finish line but a long-term process with sometimes unclear goals. The process will require strong leadership from the top down. There are many questions that the country’s new Commander-in-Chief will need to address in terms of setting priorities for the cancer enterprise.

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

## **CERTIFICATION OF MEETING SUMMARY**

I certify that this summary of the President's Cancer Panel meeting, *Strategies for Maximizing the Nation's Investment in Cancer*, held October 22, 2007, is accurate and complete.

Certified by: \_\_\_\_\_

Date: February 6, 2008

\_\_\_\_\_  
LaSalle D. Leffall, Jr., M.D., F.A.C.S.  
Chair  
President's Cancer Panel