DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE

MINUTES of the DIRECTOR'S CONSUMER LIAISON GROUP Meeting

October 25, 2006

Members Present

Mr. Doug Ulman, Chair
Dr. Beverly Laird, Vice Chair
Ms. Peggy L. Anthony
Ms. Vernal H. Branch
Mr. Bill Bro*
Dr. Grace Butler
Ms. Yvette Colón
Ms. Kelly Cotter
Ms. Nancy Davenport-Ennis
Mr. Alan Kaye
Ms. Mary Jackson Scroggins
Ms. Sue Sumpter
Col. (Ret.) James E. Williams, Jr., USA

*Participated by telephone.

Speakers

Ms. Peggy L. Anthony, Director's Consumer Liaison Group (DCLG)
Dr. Michele Bloch, Medical Officer, Tobacco Control Research Branch, National Cancer Institute (NCI)
Dr. Michael Burke, Research Scientist, RTI International
Mr. James Dickens, Chief, Financial Management Branch, NCI
Ms. Susan Erickson, Director, Office of Policy Analysis and Response, NCI
Dr. Ernest Hawk, Director, Office of Centers, Training, and Resources, NCI
Ms. Lenora Johnson, Acting Director, Office of Liaison Activities, NCI
Dr. Beverly Laird, Vice Chair, DCLG
Ms. Elizabeth Neilson, Consumer Advocates in Research and Related Activities (CARRA) Program Coordinator
Ms. Cherie Nichols, Director, Office of Science Planning and Assessment (OSPA), NCI
Dr. John Niederhuber, Director, NCI
Dr. Sheila Prindiville, Director, Coordinating Center for Clinical Trials, NCI
Dr. Julia Rowland, Director, Office of Cancer Survivorship, NCI
Dr. Abby Sandler, Executive Secretary, President's Cancer Panel, NCI
Ms. Mary Jackson Scroggins, DCLG
Mr. Doug Ulman, Chair, DCLG
Col. (Ret.) James E. Williams, Jr., DCLG

NCI Office of Liaison Activities Staff

Ms. Jennifer Fritz, *NCI Listens and Learns* Coordinator
Ms. Barbara Guest, DCLG Executive Secretary
Mr. James Hadley, Advocacy Program Manager
Ms. Brooke Hamilton, Program Analyst
Ms. Lenora Johnson, Acting Director
Ms. Courtnay McFeters, Advocacy Program Fellow
Ms. Elizabeth Neilson, CARRA Program Coordinator
Ms. Linda Ticker, Program Assistant

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I. Welcome

Mr. Doug Ulman welcomed participants to this meeting of the National Cancer Institute (NCI) Director's Consumer Liaison Group (DCLG). Because the ethics clearance for the four new DCLG members was still pending, they would be able to participate in the day's discussions but could not vote on any motions.

Mr. Ulman reviewed the rules governing confidentiality and conflict of interest, and Ms. Brooke Hamilton determined that a quorum was present.

II. NCI Director's Update

Dr. John Niederhuber, Director of NCI, welcomed the new DCLG members and listed his leadership priorities:

- Strive to maintain the number of competing awards achieved during the NIH doubling
- Fund new investigators
- Find new ways to leverage resources
- Integrate diverse research
- Bring new science to the people

The FY 2007 President's budget request for NCI is $4,753,609, which represents a 0.8% decrease from the Institute's FY 2006 budget. NCI anticipates increases in the funds it is required to contribute to Department of Health and Human Services (DHHS) and National Institutes of Health (NIH) programs, as well as increases in salaries, rent, leases, and utilities. As a result, the actual decrease in NCI's 2007 operating budget is likely to be 2.6%. NCI's division and center directors have identified $175 million worth of phase-outs and reductions in ongoing programs that could potentially be used to cover the budget decrease. This would make approximately $50 million available to support new scientific priorities.

Between 1998 and 2003, the NIH budget doubled and NCI's budget grew by 80%. As a result of the increased funding, universities built new facilities and resources and added new faculty. Thus, at a time of decreased funding, the number of investigators requesting research support has increased.

Dr. Niederhuber described a continuum of three spaces involved in bringing science to patients:

1. Chemical space—Includes libraries of chemical compounds for screening against potential targets
2. Biologic space—Includes research on signal pathways that become abnormal and cancer stem cells
3. Translational space—Includes animal models and first-in-human studies of targets and biomarkers to inform drug development

These three spaces are connected by biomedical informatics, provided at NCI by the cancer Biomedical Informatics Grid (caBIG™), and integrated by new technology, including nanotechnology, genomics, and proteomics.

NCI supports 61 cancer centers across the country. However, most patients with cancer lack access to these centers of excellence and receive their care in the communities in which they live. Dr. Niederhuber has been working with the NCI divisions to develop a new rim of cancer care activity around the cancer centers program. The new Community Cancer Centers Program will provide state-of-the-art multi-specialty care and early-phase clinical trials in community-based locations. The centers will also conduct disparities and community outreach, develop electronic medical records, and collect biospecimens, and offer hospice and palliative care. NCI plans to sponsor several pilot sites for 4 years and then develop a request for applications (RFA).

Discussion

Col. James Williams said that one of the DCLG's biggest challenges is explaining the dynamics of NCI to the lay public. The community needs to understand that as a result of the indirect costs charged by academic institutions, less money is actually going to research than might be thought. Dr. Niederhuber explained that institutions need indirect costs to support the facilities used by investigators to conduct research. NCI and NIH have no control over indirect cost rates, which vary from institution to institution.

Col. Williams stated that DCLG members and other advocates will find it difficult to explain the important role of genetics in the future of medical research. Advocates need to be involved in planning for genetics research from the beginning to prevent backlashes from concerns about privacy and other ethical issues. But advocates will need help in explaining genetics in simple terms that the public can understand.

Ms. Vernal Branch asked about the status of the Community Cancer Centers Program. Dr. Niederhuber replied that a request for information for the program has been issued and responses have been received. In a few weeks, an RFA will be issued for the pilot program, and the six pilot sites will be selected in early February.

Ms. Nancy Davenport-Ennis asked whether the Community Cancer Centers Program could help increase the accrual rate for clinical trials. Dr. Niederhuber said that the accrual problem is due to the lack of exciting therapies to test in trials. More and more exciting new therapies are being developed, and when they start being tested in clinical trials, patients will line up to participate.

Ms. Mary Jackson Scroggins suggested adding "eliminate health disparities" to Dr. Niederhuber's leadership priorities. Dr. Niederhuber explained that this issue is embedded across all NCI programs. He added that NCI recently formed an integration and implementation (I^2) team focused on cancer health disparities to do strategic planning on this issue.

III. The President's Cancer Panel

Dr. Abby Sandler explained that the President's Cancer Panel was established in 1971 by the National Cancer Act as a federally chartered advisory committee. The Panel's three members are Dr. LaSalle D. Leffall, Dr. Margaret L. Kripke, and Mr. Lance Armstrong. The Panel's mission is to monitor the development and execution of the National Cancer Program. It reports directly to the president on its findings.

The Panel typically selects one topic each year on which to focus and then holds four meetings to address the topic. The panel then produces a report summarizing its findings. Recent topics include survivorship and translating research into cancer care.

Last year, the Panel re-visited key recommendations from the previous two reports on cancer survivorship and on translating research to reduce the burden of cancer. The resulting report, *Assessing Progress, Advancing Change*, summarized progress since the original recommendations were made and discussed priorities for advancing change, in order to facilitate implementation of these important recommendations.

This year, the Panel is focusing on promoting healthy lifestyles to reduce the risk of cancer. It plans to hold two meetings on obesity, physical activity, and nutrition and two meetings on tobacco and environmental tobacco smoke.

Discussion

Ms. Branch pointed out that smoking rates in California have decreased significantly and wondered whether the state could serve as a model for others. Dr. Sandler explained that good evidence is already available regarding effective smoking prevention and cessation programs. The greatest challenge lies in how to implement these programs because the tobacco lobby has been very effective in stopping efforts to curb smoking at the national and state levels. The Panel plans to address the implementation issue.

Ms. Sue Sumpter noted that the Panel's report on survivorship included recommendations regarding adolescent and young adult cancer research. She asked about plans to increase support for this research. Mr. Ulman explained that NCI recently organized a Progress Review Group (PRG) roundtable to identify strategies on this issue.

Ms. Scroggins asked whether nutritional genomics will be included in the Panel's work on healthy lifestyles, given the impact of a genetic predisposition toward obesity on an individual's ability to adopt a certain lifestyle. Dr. Sandler said that the Panel will address genetics but plans to focus more on overall healthy lifestyles. Even those with a genetic disposition toward obesity can avoid becoming obese.

Dr. Grace Butler suggested that the panel address the issues faced by older adults with cancer, including the many comorbidities that this population typically experiences. Dr. Sandler noted that older people are often excluded from clinical trials because of comorbidities. She agreed that more research is needed on the comorbidities associated with survival in those over age 60.

Ms. Davenport-Ennis pointed out that the Panel recommended passage of the Patient Navigator, Outreach, and Disease Prevention Act of 2005. She asked that the Panel encourage the provision of funding so that grants can be available for community-based programs.

IV. NCI Budget Update

Mr. James Dickens explained that the President's budget is the traditional budget that NCI and all of the NIH Institutes and Centers (ICs) prepare according to NIH and DHHS guidelines. This budget is submitted by the DHHS Secretary to the President.

The National Cancer Act gave NCI the authority to submit a bypass budget representing the NCI Director's professional judgment. This document is sent by the NCI Director directly to the President. The 2008 bypass budget was released in October and is available at http://plan.cancer.gov. The bypass budget includes a request of $5.8 billion for current services and $820 million for additional resources.

In FY 2006, more than 80% of NCI's budget went to the extramural community for research grants and contracts and training and career development. Of the remaining funding, 9% supported intramural research by scientists employed by NCI, 6% supported services and assessments supplied centrally by NIH, and 4% supported administrative management.

Discussion

Col. Williams asked for clarification on the FY 2006 budget for bench research. Many legislators believe that because of all of the investment in cancer research, the cancer problem has been solved. But in reality, the pump has been primed and much more funding is needed for genomics and other research. To explain why the Institute needs more money, it must show how expensive it is to conduct business in this field. Mr. Dickens explained that although 80% of NCI's budget supports extramural research, an average 30% of grants is used to support indirect costs and does not support bench research.

Mr. Ulman commented that out of NCI's $4.8 billion budget, less than $3 billion actually supports research, so this country is not spending as much as it thinks on cancer research. Mr. Ulman expressed concern about the amount of NCI funding that is attributed to the indirect cost of cancer research, and that indirect cost is such a large part of the NCI research budget.

Ms. Davenport-Ennis suggested that NCI invest more time in building collaborations with nonprofit and private institutions, while reducing administrative costs, to increase the financial health of the cancer research agenda. Mr. Dickens said that NCI receives less than $10 million a year from foundations.

Mr. Alan Kaye asked about royalty payments to NCI for new technologies. Mr. Dickens said that NCI receives about $35–40 million in royalties but the net amount is closer to $25 million after filing costs are deducted. These funds are not included in the NCI budget and are primarily directed to the relevant intramural program for further technology development.

In response to a question from Mr. Kaye about facilities costs in the budget, Mr. Dickens explained that the budget includes approximately $8 million for repairs and improvements at the NCI Frederick campus. NCI also contributes a portion of its budget to NIH for improvements

and repairs of NIH buildings. In the past, NCI has awarded construction grants to extramural institutions, but it no longer includes this funding in its budget.

Ms. Scroggins asked about the NIH taps that NCI pays. Mr. Dickens explained that a large portion of the taps are for program evaluation and rent for the space that NCI occupies on and off campus.

V. NCI Legislative Update

Ms. Susan Erickson explained that the federal budget appropriations process begins each February when the President announces his proposed budget for all government agencies. The House and Senate appropriations committees hold budget hearings in April and May. Before, during, and after the hearings, members of Congress and their staffs meet with constituents and others about their priorities and concerns. Based on this information, members of the appropriations subcommittees propose funding levels for each agency. Ideally, the full House and Senate vote on the appropriations bill in September, although neither the House nor the Senate has considered the appropriations bill yet this year.

The House and Senate appropriations committees issue reports each year with instructions for federal agencies. In these reports, the House and Senate typically commend NCI for several programs, encourage the Institute to address certain types of cancers, and offer recommendations on a range of issues.

The current continuing resolution expires on November 17. Congress is currently in recess and will return on November 13 for 1 week. Although Congress could pass an appropriations bill that week, it is more likely that the bill will not be considered until after the 110th Congress is sworn in next January.

Ms. Erickson also reported on the status of the NIH reauthorization bill. The NIH Reform Act bill was introduced on September 25 by Congressman Joe Barton and approved by the full House on September 26. The bill provides for a 5% increase for NIH in FY 2007, a permanent funding mechanism to encourage collaboration between NIH ICs, and a new strategic planning office at NIH. When Congress adjourns in November or December, all of the legislation introduced by the 109th Congress will no longer be active. To be considered further, the legislation would need to be reintroduced by the House or Senate when the 110th Congress takes office.

Discussion

Mr. Ulman commented that the House and Senate appropriations committee reports create unrealistic expectations for NCI and confusion among members of Congress and the broader community. Congress needs to understand that if NCI conducts the activities requested in the reports, it will need to cut other important programs. Ms. Erickson explained that NCI addresses each item in the reports in the congressional justification submitted the following year.

In response to a question from Ms. Branch, Ms. Erickson explained that the time between the introduction of a bill and its passage by the House and Senate depends on the level of support for the bill. In some cases, it takes several years for a bill to pass.

Ms. Kelly Cotter asked about feedback from the Senate on the reauthorization bill. Ms. Erickson replied that the Senate has not issued any public statements or expressed any objections to the bill.

Mr. Bill Bro commented that legislators often complain about fragmentation in the cancer community. Too many organizations are visiting members to request support for the "organ of the week" and advocates need to discuss how to speak with one voice to decision makers. Mr. Ulman agreed that the DCLG should address this issue.

Ms. Davenport-Ennis expressed concern about equity in the House and Senate reports, which address certain kinds of cancer and not others. NCI should discuss with the House and Senate where the science is moving and the need for continued latitude to focus on the most important scientific priorities. Ms. Erickson noted that the cancers mentioned in the reports are typically selected based on the number of requests from advocates, constituents, and others. NCI uses every opportunity to meet with members and explain the current state of science.

VI. The Nation's Investment in Cancer Research: A Plan and Budget Proposal for Fiscal Year 2008

Ms. Cherie Nichols presented an overview of the FY 2008 Bypass budget document, *The Nation's Investment in Cancer Research: A Plan and Budget Proposal for Fiscal Year 2008.* The document addresses current patterns shaping the future of research, advances made in 2006, progress in achieving NCI's eight strategic objectives, how NCI works, and NCI's professional judgement budget request for FY 2008.

Ms. Nichols listed several activities that the DCLG could undertake as a partner with NCI:

- Participate in peer review
- Attend conferences to learn about the science and meet investigators
- Attend or view other advisory meetings, such as the National Cancer Advisory Board and the President's Cancer Panel, as well as the NIH Council of Public Representatives (many of these meetings are webcast on http://videocast.nih.gov)
- Review and comment on NCI priority-setting and planning documents

Ms. Nichols encouraged the DCLG to think of the bypass budget as a tool for planning, budgeting, science, education, and collaboration enhancement. This FY 2008 plan and budget proposal is available on the Web at http://plan.cancer.gov. and as an NCI print publication. Copies of the report will be distributed to DCLG members next week

Discussion

Col. Williams wondered whether the DCLG should encourage passage of the bypass budget. In 2006, most cancers are still discovered and treated when the tumor has matured, and the only treatment options continue to be minimal for patients with cancer.

Mr. Ulman asked whether the bypass budget has become more realistic, given the current funding climate. Ms. Nichols explained that this year and in recent years, NCI Directors have issued bypass documents targeted at maintaining current services and highlighting a small number of high priority investment areas..

In response to Nancy Davenport-Ennis' request that NCI create a brief fact sheet about the Bypass budget, Ms. Nichols asked the DCLG to assist her office in preparing a one- or two-page summary of the key issues in the bypass budget document that should be communicated to Congress. The DCLG could use this document to explain to communities and NCI's funders why funding cancer research is so important.

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Mr. Kaye suggested that the DCLG members in their role as members of advocacy organizations could inform their groups that letters in support of the Bypass could have an impact.

Ms. Scroggins asked about the budget for developing the bypass budget. Dr. Lisa Stevens explained that the budget for printing and distributing the bypass budget is $170,000 but this does not include staff time. This year, the budget was developed by four full-time staff members in 4 months.

Ms. Nichols noted that once the President's FY 2008 budget is issued in late January or early February, NCI must support that budget. The Bypass budget can be used to communicate with and educate members of the public and the Congress in a limited timeframe before the President's budget is issued. However, the Bypass is a public document and can be referenced and used by others at any point.

Mr. Bro offered to share with the DCLG members a tool developed by his organization that helps constituents contact members of Congress and federal agencies that they can use in their role as members of advocacy organizations.

VII. Celebrating a Decade of Cancer Survivorship at the NCI: Is the Best Yet to Come?

Dr. Julia Rowland reported that in 1986, a group of survivors established the National Coalition for Cancer Survivorship. At that time, survivors were defined as having been disease-free for 5 years. But the coalition reframed the concept of survivorship to include anyone diagnosed with cancer from the time of diagnosis through the balance of life. The coalition played a seminal role in the establishment of the Office of Cancer Survivorship at NCI in 1996.

The Office of Cancer Survivorship is taking advantage of its 10th anniversary to review the accomplishments in survivorship by the office and many others. For example, the number of grants in this area has increased dramatically since the office's formation. This impressive trend

has occurred despite the relatively modest investment by NCI in set aside dollars (e.g. for RFAs or grant supplements) to support the growing body of science addressing post-treatment issues. In addition, research has advanced dramatically in the past 10 years—many investigators are now conducting multidisciplinary intervention studies at multiple institutions with large samples. Their research is now driven by theory and hypotheses, and their studies include long-term follow-up of study participants.

As a result of the recent research on survivorship, the evidence base provides a better understanding of the prevalence and significance of the late consequences of long-term survivorship in childhood and adult cancer survivors and a growing appreciation that lifestyle changes could have important health benefits following treatment.

Dr. Rowland posed a final challenge to DCLG members to consider how, looking to the future, we might be able to show that the investment in cancer survivorship research and programs is making a difference in peoples' lives? She reviewed several ideas to both benchmark and highlight change that could be considered.

Discussion

Ms. Branch noted that as a result of NCI's work on survivorship, several cancer survivorship clinics are being opened across the country. Dr. Rowland explained that the Lance Armstrong Foundation has been a major force in this area. She noted that the challenge going forward will be to show that these clinics make a difference and thus justify broader uptake.

Ms. Sumpter asked about incentives for states to provide survivorship clinics, noting that her state, Oregon, has no survivorship clinics for children. Dr. Rowland explained that NCI, the Lance Armstrong Foundation, the American Cancer Society, and the Centers for Disease Control and Prevention are encouraging state planning groups to include survivorship issues as part of their cancer control plans. At present, because there is limited evidence for optimal design of these programs, or their expected impact on survivors' health outcomes or costs, it is difficult to generate support for them.

Mr. Ulman suggested that when cancer centers apply to NCI for continuation funding, NCI should require that the centers offer survivorship services. Dr. Rowland said that NCI could only issue such a mandate if funding were available to support it. In addition, a minimum standard for these types of program or services would need to be established.

Ms. Davenport-Ennis suggested creating a process to ensure that state secretaries of health become aware of the Office of Cancer Survivorship's work so that they address survivorship in their plans and budgets.

Ms. Scroggins stressed the need to stop equating 5-year survival with long-term survival. She also urged Dr. Rowland to establish a goal of eliminating (rather than reducing) disparities in survivors..

Dr. Rowland noted that the NCI *Bulletin* recently devoted an entire issue (October 17, 2006) to survivorship that presented some hard data. A special issue of the *Journal of Clinical Oncology* on survivorship will be published in November 10, 2006 issue). In addition, the American Society for Clinical Oncology (ASCO) offered a patient and survivor track at its annual meeting this past year, 2006.

Col. Williams noted that some definitions of survivors include friends and families, as well as patients. Dr. Rowland explained that this definition was originally developed by the National Coalition for Cancer Survivorship and the Office of Cancer Survivorship has embraced it. As the U.S. population ages, the caregiving burden on friends and family members is likely to be significant and will need to be addressed.

VIII. Interim Report on the Translational Research Working Group

Dr. Ernest Hawk explained that NCI's Translational Research Working Group (TRWG) was established at this time because continuation of NCI's current approach to fostering translational research is untenable in the face of translational systems that cannot keep pace with the many advances in cancer biology that are creating new opportunities and increased expectations from the public, yet flagging resources. Thus the TRWG was charged to evaluate the current status of NCI's investment in translational research and to envision its future in an inclusive, representative, and transparent manner.

The TRWG has 63 members representing a broad array of constituencies and has developed 17 draft initiatives. The TRWG is soliciting public comments on these initiatives until November 3 through the TRWG website: http://www.cancer.gov/trwg. Dr. Hawk reviewed the TRWG's 17 initiatives, which are categorized into coordinated management, tailored funding mechanisms, and operational effectiveness.

The TRWG decided to focus on what the President's Cancer Panel has defined as "early translation," which includes the developmental transition of a discovery into phase 1/2 trials. This approach was taken to complement the prior Clinical Trials Working Group (CTWG) which focused on later translational steps, including phase 3 trials.

The TRWG has developed pathways to five clinical goals or product lines: agent, immune response modifier, interventive device, risk assessment device, and lifestyle alteration. These pathway diagrams outline the steps from discovery to early-phase clinical trials, and suggest the related personnel, resources and decisions that underlie progress.

The TRWG sponsored an analysis of NCI's translational research portfolio, which identified a large number of core services in cancer centers, Specialized Programs of Research Excellence (SPOREs), and P01 awards. The TRWG is considering whether these services could be organized more effectively to improve efficiency and effectiveness, and reduce any redundancies that might exist. The portfolio analysis also showed that NCI's awards are not adequately categorized to provide meaningful and detailed quantitative assessments of their translational content at the current time.

After the TRWG collects feedback on its initiatives from the public and other groups, it plans to submit a report to NCI's National Cancer Advisory Board in February and to other advisory committees thereafter, as needed.

Discussion

Dr. Beverly Laird represented the DCLG at the recent TRWG roundtable meeting and urged DCLG members to submit comments on the TRWG's 17 initiatives. She added that during the roundtable meeting, some NCI staff members were surprised to learn how ready and able advocates are to contribute time and resources to this effort.

Dr. Hawk explained that according to the portfolio analysis, approximately 25% of NCI's portfolio involves translational research. However, a better system is needed to characterize this translational research in terms of various quantitative measures as well as progress.

Col. Williams emphasized the need for the translational endpoint to be the patient. Dr. Hawk explained that the TRWG's ultimate goal is to reach the patient. The committee recognizes that many steps are required to reach this endpoint and these steps are currently vested in many NCI programs.

Col. Williams expressed concern about the TRWG's proposal to create another level of bureaucracy, which might be difficult in the context of NCI's limited budget. He suggested developing a single program that addresses the entire continuum of translational research from the bench to the bedside. Dr. Hawk explained that many steps must be taken to move from discovery to the patient. By its very nature, the process is too complicated to be encompassed within a single program. The TRWG believes that managing the existing process is a critical first step and that the process will be easier to understand and communicate to others if it is simplified.

Ms. Sumpter asked about incentives to ensure that productive failures are comprehensively reported when industry is involved. She also wondered how NCI could ensure that it benefits financially when it collaborates with industry. Dr. Hawk said that NCI could stipulate that productive failures be reported for any research that involves federal funding, whether industry is involved or not. He added that NCI is governed by laws that do not require NIH to profit from research, but its grantees do have rights to profits. The TRWG has not suggested changing these laws, and this might be beyond its purview. If DCLG members think that this is important, they should note this in their comments on the TRWG's initiatives.

Ms. Davenport-Ennis suggested that each DCLG member collect comments on the draft initiatives from the scientific advisory boards of their organizations.

IX. Restructuring the Nation's Cancer Clinical Trials Enterprise: An Update of the CTWG Implementation Plan

Dr. Sheila Prindiville explained that the CTWG has proposed 22 initiatives to support a transparent clinical trials enterprise that integrates the current system's components into a cross-

disciplinary, scientifically driven, cooperative research effort. These initiatives were categorized into five themes: enterprise-wide/integrated management, prioritization/scientific quality, coordination, standardization, and operational efficiency.

As a result of these recommendations, NCI is establishing a Clinical Trials Advisory Committee (CTAC) to make recommendations on the structure and conduct of the Institute's clinical trials program. The committee will be chaired by Dr. Niederhuber and will consist of members of current NCI boards, including the DCLG, and representatives of the extramural clinical trials community. NCI has also established the Clinical Trials Operations Committee, an internal committee to provide strategic oversight of NCI clinical trials programs and infrastructures. This committee includes representatives from all NCI divisions, offices, and centers involved in NCI-supported clinical trials. Dr. Prindiville heads NCI's new Coordinating Center for Clinical Trials, which supports implementation of the CTWG initiatives in conjunction with NCI's divisions, centers, and offices.

Dr. Prindiville described all of the CTWG's initiatives and the progress made to date in each of these areas. She noted that the new clinical trials structure will undergo a structured evaluation.

Discussion

Ms. Branch commented that although the CTWG is analyzing the barriers to use of the central institutional review board (IRB), many local IRBs continue to review protocols that have been approved by the central IRB. Dr. Prindiville explained that not all institutions subscribe to the central IRB, but those that accept the central IRB process need only review protocols for local context. The CTWG plans to ask institutions why they are not using the central IRB.

Dr. Laird reported that Dr. David Dilts (Vanderbilt University) examined the time and steps required to design and activate phase III clinical trials in Cancer and Leukemia Group B, an NCI cooperative group. In response to a question from Mr. Ulman, Dr. Prindiville explained that the study would be extended to another cooperative group and two cancer centers by next summer.

Dr. Butler asked about the association between lack of funding and difficulties in accruing minority participants. Dr. Prindiville replied that the minority accrual problem goes beyond funding. The CTWG formed a trans-NCI committee of NCI directors with divisions, offices, and centers conducting clinical trials to identify successful programs that would benefit from additional funding. Grant identified for supplemental funds were in the Cancer Disparity Research Program and the Minority-Based Community Clinical Oncology Programs, so the funding was provided to these programs. The impact of this funding still needs to be assessed.

Mr. Kaye asked about phase 0 trials to speed up and reduce the costs of development. Dr. Prindiville said that this is a new concept in investigational drug development to potentially speed up the process.. Phase 0 trials are first-in-human studies to examine drug parameters such as pharmacokinetics prior to taking on large-scale studies. The NCI intramural program has a Phase 0 program that is assessing the feasibility of Phase 0 studies.

Ms. Cotter suggested using the success of NCI's pediatric cancer cooperative groups as a model for other cooperative group research.

Ms. Davenport-Ennis asked about incentives for collaboration. Dr. Prindiville said that cooperative group guidelines were recently revised so that they are reviewed positively when they interact with SPOREs and cancer centers. She hoped that the steering or oversight committees would identify additional incentives for collaboration.

Ms. Davenport-Ennis noted that the American Health Information Community has helpful information on informatics systems. Dr. Prindiville explained that the CTWG's standardization initiatives are being implemented in partnership with caBIG.

Dr. Prindiville explained that the disease steering committees will periodically review accrual rates in clinical trials. If a trial is not accruing well, the relevant steering committee can form a focus group to address the issue. In addition, one of the larger committees could address minority recruitment. Ms. Lenora Johnson added that NCI has broader initiatives that are examining accrual, including minority accrual to clinical trials.

X. The U.S. Department of Justice Tobacco Lawsuit: An Update

Dr. Michele Bloch focused her remarks on the U.S. Department of Justice lawsuit filed in 1999 in the U.S. District Court for the District of Columbia against the leading U.S. cigarette manufacturers. The Department of Justice sued under the Racketeer Influenced and Corrupt Organizations (RICO) Act, which was created to prosecute organized crime. The Department of Justice alleged that the cigarette manufacturers coordinated their public relations, research, cigarette design, and marketing efforts to advance their overarching scheme to defraud the public in numerous ways including denying the dangers of smoking and secondhand smoke, misrepresenting the health risks of light and low-tar cigarettes, and marketing to youth.

As a result of an appeal by the defendants, the Court of Appeals ruled that RICO does not permit sanctions aimed at "undoing" past conduct, so only "forward-looking" remedies would be permitted. On August 17, 2006, the judge decided the case for the government, finding the cigarette manufacturers liable for racketeering. The judge noted that she was limited by the Court of Appeals decision in the remedies she could impose, but she did provide for several significant remedies, including a prohibition on misleading brand descriptors, such as "light" and "mild." The judge also issued a powerfully worded decision, detailing the cigarette manufacturers' misconduct.

The tobacco companies plan to appeal the judge's ruling and have asked for a stay of the remedies pending appeal. The public health community has urged the government to appeal the adverse ruling on permitted remedies under the RICO statute to the U.S. Supreme Court. The case will probably remain in litigation for several more years.

Discussion

Col. Williams asked about efforts to enhance smoking cessation programs. Dr. Bloch explained that NCI's Tobacco Control Research Branch funds approximately130 grants each year and many of these are aimed at improving cessation interventions. An evidence base is available on medications and therapies that are effective, but many smokers do not use them. Most people need to try to quit more than once, and they must understand that each unsuccessful effort is a learning experience, not a failure. The trial judge did not impose a cessation remedy perhaps because of the constraints imposed by the Court of Appeals ruling on remedies. Public health advocates would argue that if smoking cessation were a priority, states, localities, and the federal government would use master settlement agreement money and/or tobacco taxes to support implementation efforts.

Ms. Branch asked about the effectiveness of taxes on cigarettes to decrease smoking. Dr. Bloch replied that a large body of evidence shows that increasing the price of cigarettes reduces consumption by adults and children.

In response to a question from Dr. Butler, Dr. Bloch noted that the Surgeon General recently released a report on secondhand smoke. Many cities and states are implementing smoking bans, which not only protect non-smokers from exposure to secondhand smoke, but also reinforce the dangers of smoking to smokers.

Col. Williams noted that many states do not use their master settlement funds for health-related activities. Dr. Bloch said that it has been estimated that just 7.5% of states' combined master settlement and tax monies can fund tobacco prevention and cessation program in every state at the minimum level recommended by the CDC. However, as of November 2005, only four states spend the minimum amount CDC recommends; most use the funds for other priorities. If the Department of Justice lawsuit results in significant payments from the tobacco companies, the court could mandate how those funds are to be spent.

XI. DCLG Working Group Reports and Member Activities

NCI Listens and Learns Working Group

Col. Williams explained that *NCI Listens and Learns* is a web-based pilot program designed to facilitate a dialog between NCI, cancer advocacy organizations, and members of the public. Currently, 137 cancer advocacy organizations and 664 members of the public have registered to participate in the dialog. Fifteen discussion topics and 343 comments have been posted to date.

The NCI *Listens and Learns* Working Group recently posted a question on the site to collect feedback from the cancer advocacy community on the content of the DCLG meeting. The other question that is open on the site addresses NCI's State Cancer Legislation Database.

Dr. Michael Burke explained that the purpose of the *NCI Listens and Learns* evaluation is to enhance collaboration between NCI and the communities it serves by providing an easily accessible, online forum for both the cancer advocacy community and the public to comment on

topics related to NCI's research mission. The process evaluation component is addressing the conditions under which *Listen and Learns* is operating, whether the website is operating as planned, and how cancer advocacy organizations are being reached. The outcome evaluation component focuses on whether cancer advocacy organizations and the interested public are accessing the site, able to use it, and posting comments. Other issues addressed are whether NCI is obtaining the desired input from the cancer advocacy organizations and the public and how useful the site is compared to similar websites.

Dr. Burke plans to review some statistics and documentation on the website, conduct in-depth interviews with stakeholders, and conduct usability testing and web site benchmarking. A report on the evaluation results will be presented to the DCLG at its March 2007 meeting. The DCLG can then use the evaluation results to make recommendations to the NCI Director about next steps for *NCI Listens and Learns.*

Ms. Sumpter asked about the cost of maintaining the *NCI Listens and Learns* site compared to the costs of other ways to communicate with the public. Dr. Burke explained that after the startup costs, the main cost of maintaining the site is the staff time spent to oversee the site. The evaluation could collect data on the costs of maintaining the site if appropriate.

Mr. Kaye asked how the site is promoted. Col. Williams explained that OLA has promoted the site to all of the advocacy organizations on OLA's email list and other organizations known to DCLG members. OLA continues to encourage members of these organizations to participate in the dialog through regular e-mails.

Ms. Sumpter expressed concern that large organizations, such as the American Cancer Society, are permitted to appoint only one individual to post comments on the site. This representative has an equal voice to that of small local organizations.

Consumer Advocates in Research and Related Activities (CARRA) in caBIG™

Ms. Peggy Anthony serves as liaison to the Consumer Advocates in Research and Related Activities (CARRA) members who are involved in caBIG™. CARRA members have developed several recommendations for caBIG regarding the upcoming caBIG™ annual meeting, including the suggestion that cancer centers invite users to the annual meeting. The caBIG™ tissue workspace has gathered some input from users, and this might serve as a model for other workspaces at the annual meeting. Local focus groups could be used to gather input from those who do not have the time or resources to attend the annual meeting. CARRA advocates have also given feedback to the clinical trials workspace group on its protocol life cycle tracking. In addition, they developed a poster on caBIG™ that was displayed at the DCLG's advocacy summit. Additionally, the poster was displayed at the recent meeting so that new DCLG members could become more familiar with the role of advocates within the caBIG™ project.

The advocates are currently discussing the possibility of linking patient treatment summaries with the caBIG™ clinical trials workspace. This would allow patients and providers greater, immediate access to treatment information wherever the patient is within the caBIG™ network.

Summit Working Group II

Ms. Scroggins explained that the original Summit Working Group spent 18 months planning the summit that took place this past June. After this group formally presented the summit's final report and evaluation report, the group was disbanded.

A new Summit Working Group was recently formed to respond to the comments and questions received during the summit's town hall session. Dr. Laird has categorized all of the comments from the town hall, and each working group member will draft responses to some of the issues by November 3. Mr. James Hadley and Ms. Scroggins will combine all of the responses into a single document by November 8 and send the document to the working group members for feedback. After the working group comments are integrated into the document, the full DCLG will have the opportunity to comment on the response.

The working group intends to send the response to everyone who attended the summit and everyone on the OLA listserv and in its database by Thanksgiving. This e-mail will include information on the summit website, where the final report and evaluation report will be available. The e-mail will also ask all summit scholarship recipients to submit details of their dissemination activities following the summit.

Ms. Davenport-Ennis suggested that the responses for summit participants be copied onto CDs for distribution to the organizations that participated in the summit for distribution to others. Col. Williams suggested using these CDs to promote *NCI Listens and Learns* and OLA's teleconferences as well.

The DCLG carried a motion unanimously to allow the Summit Working Group II to continue its activities.

Ms. Scroggins noted that numerous summit participants suggested that NCI organize additional summits for advocates.. Perhaps the DCLG could organize a summit every 2 or 3 years. Mr. Ulman suggested sending a letter to the NCI Director summarizing the event and proposing that NCI organize advocacy summits on a regular basis.

Ms. Hamilton explained that the summit cost more than $400,000 in addition to funds donated to the Summit from the Foundation of the National Institutes of Health Ms. Davenport-Ennis suggested that if the DCLG proposes an additional summit, it form a working group to raise funds from nonprofits and others to underwrite the activity. Perhaps some of the summit activities could be added to large national meetings to save money.

XII. NCI Report on Health Disparities—Integration and Implementation (I^2) Team

Ms. Johnson explained that overcoming cancer health disparities is one of NCI's strategic priorities. To help address this priority, NCI held a workshop that was open to all NCI staff. During the workshop, participants reviewed the results of an NCI portfolio analysis to identify research grants and contracts related to the reduction of cancer health disparities. This analysis

showed that 5.6% of NCI's budget was devoted to cancer health disparities research in 2004 based on current coding criteria.

The proceedings from the workshop address the vision that emerged from the workshop: NCI will lead the nation's effort to eliminate cancer health disparities. The report lays out several goals to achieve the vision and a set of action plans that addresses several areas of focus, including: genetic and biological differences, narrowing the gap between research and practice, clinical trials, sociocultural and behavioral influences, cancer care delivery, education and training, and communications research. The workshop report identified three major next steps: elevate health disparities research across the Institute, maintain momentum and continue communicating, and create an integration and implementation (I^2) team for health disparities.

The proposed cancer health disparities I^2 team was formed in September and is chaired by Dr. Sanya Springfield. The team includes representatives from across the Institute, with technical support from the Office of Science Planning and Assessment. The team began its work by reviewing the recommendations and action steps proposed by the NCI workshop and other recent meetings on cancer health disparities. The team plans to refine and categorize the recommendations and select a small set on which to focus. The team will develop a business plan for the Executive Committee with recommendations for investment across NCI.

Discussion

Ms. Sumpter noted that the elimination of cancer health disparities will require changes in legislation to provide health care to all who are uninsured or underinsured. Ms. Johnson replied that the NCI recognizes that accomplishment of the vision can not be done in isolation and that NCI must foster partnerships and create dialog to ensure progress.

Ms. Davenport-Ennis suggested that NCI collaborate strategically with the Centers for Medicare and Medicaid Services (CMS) so that cancer becomes an immediate qualifying event for members of disadvantaged populations; cancer patients in need would then have immediate access to treatment through Medicaid.

XIII. CARRA Program Update

Ms. Elizabeth Neilson explained that the CARRA program, which was initiated through the efforts of the DCLG, currently has 185 members from across the country. CARRA members participate in a wide range of NCI activities and provide critical insights and analysis that help translate research advances more quickly and safely to patients and the broader public.

NCI staff members may request CARRA participation from OLA when an NCI program could benefit from the input of a member of the public. The CARRA coordinator searches the CARRA member database to identify CARRA members with the requested skills and interests. The NCI staff member selects and contacts the CARRA member(s).

NCI recently changed its peer review policies, and peer review meetings are now clustered together. As a result, fewer peer review meetings are held and the number of requests for peer

review participation of CARRA members has decreased. The number of CARRA members requested for site visits has also decreased.

Although the number of requests for peer review participation has decreased, the CARRA program's outreach has resulted in an increased number of requests for CARRA participation in non–peer review activities. Recent examples of such activities include serving as an external consultant panel member for The Cancer Genome Atlas (TCGA), reviewing a Spanish fact sheet on radiation therapy, and participating in the Adolescent and Young Adult Progress Review Group roundtable meeting.

To increase the CARRA program's flexibility, OLA has proposed a new recruitment process:

- Applications will be accepted year-round and will be reviewed biannually.
- Assessments will be conducted twice a year to determine the Institute's consumer needs.
- Recruitment announcements will be updated biannually to reflect changing research focus areas and corresponding qualifications desired in applicants.
- Applications will be submitted through an in-house online process.
- Competitive applicants will participate in a telephone interview.
- Membership will be for an unlimited period of time.

Although the plan removes time limits for CARRA membership, CARRA members will be required to update their online membership profiles and submit a statement of assurance each year. Those who do not update their profiles and statements of assurance within 14 months and who have not contacted the CARRA program will relinquish their membership.

Discussion

Recruitment

Dr. Laird supported the plan to recruit CARRA members with specific skill sets. However, many current CARRA members feel underused. Perhaps the CARRA program could ask current members if they have expertise they might not have reported in the areas needed for NCI's new initiatives.

Ms. Neilson explained that OLA is shifting its emphasis from recruiting consumers with experience in specific cancer sites; to recruiting advocates with expertise in cross-cutting areas in such as nanotechnology, proteomics, and genomics. If OLA receives a request for a program requiring expertise that current CARRA members do not have, OLA will issue a recruitment notice and attempt to recruit a new member for that activity.

Ms. Davenport-Ennis suggested that OLA conduct a needs assessment to determine how many additional CARRA members are required. Ms. Neilson explained that OLA has been working on this with a contractor since 2005. The assessment will be completed by spring 2007. Ms. Scroggins cautioned against starting the new recruitment plan until the needs assessment is complete. Although active CARRA participants enjoy their activities, those who have not participated feel frustrated, and this feeling should not be increased.

Ms. Scroggins asked whether OLA could find expertise within the advocacy community for emerging scientific areas. Ms. Neilson said that with some novel research areas, it is unlikely that advocates will have much expertise. However, if a CARRA member voices a strong interest in an emerging scientific area, OLA can recommend them to NCI staff, and the advocate might become an expert through their participation.

Promoting the Use of CARRA Members

Mr. Ulman supported the plan to advertise broadly for CARRA members but stressed the importance of establishing appropriate expectations. The DCLG has proposed that the NCI Director require NCI staff to use CARRA members whenever they need public participation, but it is not clear if this will happen.

Dr. Laird suggested that whenever DCLG members participate in an NCI advisory group, they remind the other group members of CARRA's existence.

Ms. Branch suggested that OLA send information to all NCI-supported cancer centers about CARRA members living in their communities. Ms. Neilson approved of the suggestion to develop a stronger relationship with the cancer centers.

CARRA Members in Peer Review

Dr. Laird reported that CARRA members are responsible for reading all of the applications at peer review meetings and steps should be taken to avoid overburdening them. In some cases, additional CARRA members should be to be brought in even if this is more expensive. OLA needs to remind NCI staff who submits requests to be considerate of CARRA members. Ms. Neilson said that if an NCI staff member requests one CARRA members for peer review, she will recommend that they consider inviting additional CARRA members (two or three) in proportion to the volume of applications.

Keeping CARRA Members Engaged

In response to a question from Mr. Ulman, Ms. Neilson stressed the importance of making sure that CARRA members' expectations are realistic. Members need to understand that they might not be called on to participate in an activity at NCI but will have plenty of opportunities to participate in NCI activities online, such as reviewing educational materials.

Dr. Butler, who is a CARRA member, wondered about ways to strengthen ties between CARRA and the scientific community. Ms. Neilson has heard many stories from CARRA members about the appreciation expressed by scientists for their participation.

Ms. Scroggins asked how OLA keeps CARRA members engaged. Ms. Neilson explained that OLA holds quarterly teleconferences for CARRA members and invites them to participate in OLA's monthly teleconferences on cancer topics. Members also receive regular reports on activities in which CARRA members have participated.

Col. Williams asked about certificates or other ways to recognize CARRA members. Ms. Neilson said that OLA provides certificates of completion for peer review training but no other incentives.

Ms. Neilson asked the DCLG members to identify ways to keep members of a group engaged. Col. Williams suggested gift certificates and letters. Ms. Scroggins suggested hand-written thank-you notes listing the activities in which the CARRA member has participated or noting that although the CARRA member has not participated in an activity yet, they are appreciated. Ms. Davenport-Ennis suggested press releases in the CARRA member's home community when someone is named to CARRA. Ms. Neilson explained that press releases are distributed when people join CARRA.

Dr. Butler commented that if the DCLG organizes a second summit, the summit would provide an ideal opportunity for involving CARRA members. Ms. Neilson noted that several CARRA members participated in the summit and found it very energizing.

CARRA Member Participation in NCI Listens and Learns

In response to a question from Ms. Yvette Colón, Ms. Neilson explained that CARRA members now receive e-mails encouraging them to participate in the *NCI Listens and Learns* website discussions.

Mr. Ulman wondered about the possibility of requiring that CARRA members participate in the *NCI Listens and Learns* web discussions. Ms. Neilson replied that some of the topics that are posted might not be of interest to CARRA members.

XIV. Public Comment

Mr. John Schneider

Mr. John Schneider reported that when he developed skin cancer several years ago, his dermatologist removed the lesions surgically and left a scar. When Mr. Schneider developed another lesion, he created a medication that cured his lesion without leaving a scar or killing healthy cells. Mr. Schneider has since developed several lesions and has treated all of them successfully with his medication.

Mr. Schneider believes that his medication kills internal cancers as well as skin cancers without harming healthy cells. Mr. Schneider stated that in 1990, NCI did some preliminary tests with the medication and found that it killed all types of cancer. However, NCI was only seeking medications for specific types of cancer and chose not to pursue Mr. Schneider's medication.

Mr. Schneider asked the DCLG for assistance in ensuring that his medication is clinically tested.

Ms. Branch asked whether Mr. Schneider has discussed his medication with industry. Mr. Schneider explained that he has approached several pharmaceutical companies but none expressed an interest. Similarly, he has been unable to find support in the academic community.

Mr. Kaye praised Mr. Schneider's long-time advocacy for a cancer cure and suggested that Mr. Schneider seek venture capital or funding from a bank. He might also identify a young researcher in his community who is willing to pursue research on the medication.

Ms. Davenport-Ennis suggested that Mr. Schneider present his medication to researchers at the Roswell Park Cancer Center near Mr. Schneider's home. Perhaps some melanoma researchers at that institution might be interested in a collaborative project.

Col. Williams suggested that Mr. Schneider seek support from the NIH National Center for Complementary and Alternative Medicine, which tests many compounds.

Mr. Ulman commended Mr. Schneider for his advocacy over the years. He explained that the DCLG is charged with providing strategic recommendations and guidance to the NCI Director and responding to NCI priorities and strategies from the Director. DCLG members will review the material provided by Mr. Schneider but Mr. Ulman could not promise that they would take any specific action at this point. However, he did offer to provide Mr. Schneider with a written record of the suggestions made at this meeting by DCLG members.

Mr. Jay Bitkower

Mr. Jay Bitkower of Action to Cure Kidney Cancer is concerned about the disparities in funding for research on different types of cancer. For example, NCI spends much more money on breast cancer research than on urinary or pancreatic cancer research. He asked if the DCLG could address this issue in its response to the questions posed during the summit town hall session. Mr. Ulman offered to continue to explore disparities in funding that do not appear to be based on the amount of burden associated with each type of cancer.

Ms. Paula Kim

Ms. Paula Kim, Founder and President of Translating Research Across Communities, urged DCLG members to review and provide feedback on the first-generation guidelines posted on the Office of Biorepositories and Biospecimen Research website (http://biospecimens.cancer.gov/resources/nci_biospecimen_resources.asp). When the office solicited feedback on the guidelines through the *Federal Register*, the advocacy community did not weigh in, and Ms. Kim would like to see more activity in this area.

Ms. Kim asked DCLG members to offer feedback on how advocates should be involved in the disease-specific steering committees proposed by the CTWG. She hoped that the DCLG would encourage NCI's leadership to review the role of advocacy at NCI.

Ms. Kim closed her remarks by acknowledging Ms. Hamilton for her leadership as acting director of OLA. Mr. Ulman added his congratulations to Ms. Hamilton for all of her hard work. He also thanked all of the OLA staff who make the DCLG's work go so smoothly.

Certification

I hereby certify that the foregoing minutes are accurate and complete.

_____	_____
Date	Doug Ulman, Chair Director's Consumer Liaison Group
_____	_____
Date	Executive Secretary Director's Consumer Liaison Group

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
DIRECTOR'S CONSUMER LIAISON GROUP
October 25, 2006

Action Items

- Members of the DCLG's Summit Working Group will prepare responses to the questions raised during the town hall portion of the recent advocacy summit by Thanksgiving.
- The DCLG will provide Mr. John Schneider with a written summary of the recommendations provided to him during the public comment session of the meeting.

Suggested DCLG Activities

During the meeting, presenters and DCLG members offered suggestions for DCLG action. The DCLG has not yet decided whether to undertake these activities:

- Address the need for advocacy organizations to speak with a single voice to decision makers.
- Participate in peer review.
- Attend conferences to learn about the science and meet investigators.
- Attend or view meetings of other advisory groups, such as the National Cancer Advisory Board and the President's Cancer Panel, as well as the NIH Council of Public Representatives.
- Review and comment on NCI priority setting and planning documents.
- Use the bypass budget to explain to communities and NCI's funders why it is so important to fund cancer research.
- Send a cover letter to the President expressing support for the bypass budget and ask other advocacy agencies to do the same thing.
- Collect comments on the draft TRWG initiatives from the scientific advisory boards of DCLG members' organizations for submission to Dr. Ernest Hawk's office.
- Create CDs with the DCLG's responses to summit town hall questions, as well as promotional information on *NCI Listens and Learns* and OLA's teleconferences, and ask the organizations that participated in the summit to distribute these CDs to others.
- Send a letter to the NCI Director summarizing the summit and suggesting that NCI organize advocacy summits on a regular basis.
- When participating in an NCI advisory group, remind other group members of CARRA's existence.
- Explore disparities in NCI funding for different types of cancer.
- Review and provide feedback on the first-generation guidelines posted on the Office of Biorepositories and Biospecimen Research website (http://biospecimens.cancer.gov/resources/nci_biospecimen_resources.asp).
- Provide feedback on how advocates should be involved in the disease-specific steering committees proposed by the CTWG.
- Encourage NCI's leadership to review the role of advocacy at NCI.