

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

MINUTES of the DIRECTOR'S CONSUMER LIAISON GROUP MEETING

March 27-28, 2008

Members Present

Mr. Doug Ulman, Chair*	Ms. Lourie Campos	Ms. Joyce Wilcox Graff
Dr. Beverly Laird, Vice Chair	Dr. Yvette Colón	Mr. Alan Kaye
Ms. Peggy L. Anthony*	Ms. Kelly Cotter	Ms. Arlene Wahwasuck
Mr. Bill Bro*	Ms. Marie Dahlstrom	Ms. Cece Whitewolf
Dr. Grace Butler	Mr. Everett Dodson	COL James E. Williams, Jr., USA (Ret.)

*Participated by telephone.

Speakers

Dr. Jeff Abrams, Acting Associate Director, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, NCI

Dr. Karen Bell, Director, Office of Health Information Technology Adoption, Office of the National Coordinator for Health Information Technology, U.S. DHHS

Ms. Shannon K. Bell, Director, Office of Advocacy Relations (OAR), NCI

Dr. Ken Buetow, Director, Center for Biomedical Informatics and Information Technology, Associate Director for Bioinformatics and Information Technology, NCI

Ms. Stacy Collins, Project Coordinator, Education Network to Advance Cancer Clinical Trials (ENACCT)

Ms. Kelly Cotter, Member, DCLG

Ms. Susan Erickson, Director, Office of Government and Congressional Relations, NCI

Mr. James Hadley, Advocacy Program Manager, OAR

Ms. Claudia Hardy, Program Director, Deep South Network for Cancer Control, University of Alabama at Birmingham

Dr. Maureen R. Johnson, Project Officer, NCI Community Cancer Centers Program, and Special Assistant to the Director, NCI

Mr. Mike Katz, Cancer Advocate, Former DCLG Member

Mr. Alan Kaye, Member, DCLG

Dr. Beverly Laird, Vice Chair, DCLG

Dr. Wortia McCaskill-Stevens, Program Director, Community Oncology and Prevention Trials Research Group, NCI

Ms. Margo Michaels, Executive Director, ENACCT

Dr. John E. Niederhuber, Director, NCI

Dr. Edward E. Partridge, Director, Comprehensive Cancer Center, University of Alabama at Birmingham

Dr. Lawrence Tabak, Director, National Institute of Dental and Craniofacial Research, National Institutes of Health

COL James E. Williams, Jr., USA (Ret.), Member, DCLG

Ms. Julie Wolf-Rodda, Director of Partnership Development, Foundation for the National Institutes of Health

Office of Advocacy Relations Staff

Ms. Shannon Bell, Director

Ms. Barbara Guest, DCLG Executive Secretary

Ms. Michelle Hathaway, Advocacy Program Fellow

Mr. James Hadley, Advocacy Program Manager

Ms. Linda Ticker, Program Assistant

Ms. Amanda Woodbridge, Presidential Management Fellow

Executive Summary

On March 27-28, 2008, the National Cancer Institute (NCI) Director's Consumer Liaison Group (DCLG) received updates from the NCI Director on the Institute's budget and recent accomplishments and the need for the cancer community to speak with a single voice. Ms. Susan Erickson of NCI's Office of Government and Congressional Relations reported on the status of congressional appropriations for FY2009 and recently enacted legislation. Ms. Shannon Bell, Director of the Office of Advocacy Relations (OAR), described plans for the FY2010 Bypass Budget document. The Theme of the Bypass Budget will be "Modeling Broad-Reaching Research". Ms. Bell and Ms. Kelly Cotter of the DCLG reported on the progress of the DCLG's Advocates in Research Working Group, which will develop for the DCLG recommendations and an implementation plan for involving advocates in NCI activities.

Ms. Julie Wolf-Rodda described the Foundation for the National Institutes of Health (NIH), which creates private/public biomedical partnerships that complement the NIH priorities and enhance NIH activities. Ms. Wolf-Rodda also described the NCI Cancer Project research initiatives.

COL Jim Williams of the DCLG lead the discussion on Clinical Trials and advocacy. He provided an update on the activities of advocates on NCI's Clinical Trials Advisory Committee (CTAC) and its task forces. Dr. Wortz McCaskill-Stevens described NCI's Minority-Based Community Clinical Oncology Program (MBCCOP), which helps decrease cancer health disparities, and Ms. Margo Michaels and Ms. Stacy Collins of the Education Network to Advance Cancer Clinical Trials (ENACCT) described their project to incorporate the principles of community-based participatory research into Phase III cancer treatment trials.

The DCLG heard Dr. Ed Partridge Director of the University of Alabama at Birmingham Cancer Center and his colleague Ms. Claudia Hardy Program Director of the Deep South Network for Cancer Control describe the center's health disparities research and programs to eliminate cancer health disparities. These include training and coordination of community health advisors, who educate their communities about cancer and its prevention.

In additional presentations, Dr. Lawrence Tabak, Director of the National Institute of Dental and Craniofacial Research, described the recommendations of the NIH working group on Peer Review, which could result in additional advocate involvement in the process. The DCLG received an update on the NCI Community Cancer Centers Program (NCCCP) from Dr. Maureen Johnson. DCLG members Dr. Beverly Laird, Ms. Cotter, Dr. Yvette Colón, and Ms. Peggy Anthony reported on the activities of the NCCCP subcommittees.

Introducing the topic of Electronic Health Records (EHR's) Dr. Ken Buetow, Director of NCI's Center for Biomedical Informatics and Information Technology, and Dr. Karen Bell of the DHHS Office of the National Coordinator for Health Information Technology discussed the importance of electronic health records (EHRs) in redefining how research is conducted and health care is provided. Dr. Bell stated that a business case needs to be made for physicians and hospitals to adopt EHRs.

Mr. Mike Katz, an advocate and former DCLG member, and Dr. Jeff Abrams of NCI's Cancer Therapy Evaluation Program discussed the issue of NCI's requirement that NCI's central institutional review board (CIRB) review all Phase III clinical trial protocols before they proceed to local sites for local IRB review.

Finally, DCLG members discussed potential recommendations to the NCI Director.

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Welcome

Dr. Beverly Laird welcomed participants to this the 48th meeting of the National Cancer Institute (NCI) Director's Consumer Liaison Group (DCLG). She reviewed the rules governing confidentiality and conflict of interest, and Ms. Barbara Guest determined that a quorum was present.

Dr. Laird regretfully announced that Ms. Kerry Dewey, a founding member of the DCLG, passed away on March 10 after a long struggle with breast cancer, and acknowledged her service to the DCLG.

The DCLG unanimously approved a motion to approve the minutes from the DCLG's January 24, 2007, teleconference.

Dr. Laird reported that the Office of Advocacy Relations (OAR) will accept applications for six new DCLG members. Information on the application process is available on the DCLG website (<http://dclg.cancer.gov/membership/nominations>), and applications must be postmarked by April 15, 2008. (Note: The Application period has been extended to April 30, 2008)

NCI Legislative Affairs Update

Ms. Susan Erickson reported that Congress finalized the FY 2008 appropriations on December 26, 2007. The appropriation for the National Institutes of Health (NIH) was \$29.3 billion, including \$4.8 billion for NCI. The FY 2009 appropriations cycle began on February 4, 2008, with the announcement of the President's budget. This budget calls for virtually the same appropriations for NIH and NCI as in 2008. Because of the presidential campaign, the 2009 appropriation might not be approved until after the election or even after the next Congress takes office in January, 2009.

This year, the NCI Director did not have an opportunity to testify before the House Appropriations Committee. However, Dr. John E. Niederhuber has met with several House and Senate committee members and staff members in recent months.

Recently enacted legislation of potential interest to the DCLG includes the Breast Cancer Stamp Reauthorization (PL110-150) and the National Breast and Cervical Cancer Early Detection Program Reauthorization (PL110-18).

Ms. Erickson invited the DCLG to visit the new website of NCI's Office of Government and Congressional Relations at <http://legislative.cancer.gov>.

Discussion

A DCLG member asked about pending legislation for colorectal cancer screening sponsored by a congressional representative from Texas. Ms. Erickson promised to obtain information on this legislation.

Foundation for the National Institutes of Health

Ms. Julie Wolf-Rodda explained that the Foundation for NIH is the sole entity authorized by Congress to raise private funds to support the NIH mission. The foundation's board of directors includes representatives from the public and private sectors. The foundation creates private/public biomedical partnerships that complement the NIH priorities and enhance NIH activities. The foundation has raised over \$400 million since its inception in 1996 and currently supports at least 50 projects. Ms. Wolf-Rodda also described the NCI Cancer Project research initiatives.

The foundation enables partners to expand the number of funded NIH grants. For example, the foundation facilitated the partnership between the Avon Foundation and NCI that created the Avon-NCI Progress for Patients Awards. In addition, the foundation helps NIH intramural laboratories develop collaborative projects and supports multi-partner consortia for NIH.

Typically, funds are contributed to the foundation, and the foundation distributes the money to NIH. Once transferred to NCI's gift fund, foundation funds are considered to be appropriated funds and are handled according to the NIH rules. The foundation also funds and manages some projects directly in which cases NIH serves in an advisory capacity.

More information on the Foundation for NIH is available at <http://www.fnih.org>.

Discussion

The foundation typically identifies committee members representing the patient and advocacy communities through networking. The foundation is also seeking to reach out to diverse populations by speaking to groups like the DCLG. DCLG members should consider inviting a representative of the foundation to national conferences organized by their constituencies.

The size of donations to the foundation has increased over time. In a few cases, funders have approached the foundation to support a specific project. But in most cases, NIH itself identified the projects for which it would like the foundation to seek funding.

Report on the Office of Advocacy Relations

Ms. Shannon Bell explained that a PowerPoint was contained in the binder that reviewed Office of Advocacy Relations activities over the last 6 months. She welcomed questions on that information.

Ms. Bell then explained the NCI's Bypass Budget report as a tool used by the NCI Director to disseminate his vision and priorities. The 2010 Bypass Budget report's theme will be "Modeling Broad-Reaching Research". An example of how this theme is to be employed by the NCI is that cancer research provides a model for the study of disease and a model for health care in the community. Subthemes include the national economic benefits of cancer research in a time of economic challenges. Ms. Bell asked the DCLG members to provide feedback on a draft of the

2009 Bypass report and a schematic outline of the 2010 Bypass report to the Office of Science Planning and Assessment (OSPA) before the end of the meeting.

Discussion

A member requested a graph showing the decrease in the population of younger investigators in the United States. The audiences for the Bypass Budget report include the President, Congress, and advocates. In the 2009 Bypass Budget report, Dr. Niederhuber discussed the scientific impact of reducing NCI's purchasing power.

Traditionally, the Bypass Budget has served as NCI's wish list, but only one Bypass Budget has been approved since the early 1970s. Dr. Niederhuber views the Bypass Budget as a plan that NCI can share with the community. NCI hopes that sharing this document with the broader cancer community will create a shared vision for future scientific discoveries that will make a difference in patients' lives. NCI depends on its advisory boards to explicate the fact that NCI is ultimate purpose related to improving outcomes for patients. The document underscores this message. Advocacy organizations represented by the DCLG and others could utilize the Bypass Budget in their work and promote it on their websites.

NCI Director's Report

Dr. Niederhuber emphasized that the 2010 Bypass Budget report will focus more on patients in the hope that this will help its audiences better understand NCI's message. The items in the budget reflect resources that the Institute could legitimately use based on what its budget would be if it had received an annual inflationary increase over the past four years. Since Dr. Niederhuber became NCI Director in 2005, he has had to reduce or cut programs by approximately \$600 million to make up for annual budget shortfalls.

Everything that NCI does begins and ends with cancer patients. Dr. Niederhuber related the story of a woman who had tried many treatments for her cutaneous T-cell lymphoma without success. However, an experimental drug she received at the NIH Clinical Center finally made a difference.

Cancer death rates dropped in 2003 and 2004, but they increased slightly in 2005 because the population is increasing and aging rapidly. NCI continues to make progress in its efforts to eliminate tobacco, encourage lifestyle changes, develop new therapies, and increase our screening capacity to find disease at its earliest stage. Spending for cancer health care was \$206.3 billion in 2006. The decreasing mortality rate has led to an increasing number of survivors up to 12 million, who deserve additional study.

NCI's budget has lost 19% of its purchasing power since 2004. To address this need, the Institute has cut or eliminated several programs, reduced inflationary increases for grantees, and reduced the size of grants to fund new and continuing research projects.

Dr. Niederhuber listed many Institute accomplishments in 2006, 2007, and 2008. Most recently, NCI changed the infrastructure of its Small Business Innovation Research (SBIR) program and created a new component to address the “Valley of Death” problem in the gap between Phase I and II studies and private investment. NCI has also made several changes to its Specialized Programs of Research Excellence (SPoREs). For example, SPoRE applicants may now submit an application three times a year, and the SPoRE program has moved to the Division of Cancer Treatment Diagnosis. Finally, NCI recently organized a meeting of theoretical physicists and physical chemists as a first step in developing a theoretical cancer biology field.

Regarding the Research, Condition, and Disease Categorization project, Congress instructed NIH to develop a coding system for all grant activities at all institutes. NCI has argued that the breadth and scope of its work is different from that of the other NIH Institutes and Centers, and a centralized coding system would not give NCI credit for many of its activities. To accommodate NCI’s unique needs, the NIH website will post separate lists of NCI projects and of projects categorized by the Research, Condition, and Disease Categorization project for public view. NCI will develop a plan to explain the differences in reporting between the two systems.

Discussion

In response to a member’s question, Dr. Niederhuber stated that has no plans to discontinue the Community Networks and Patient Navigator Research programs. But NCI will continue to monitor all of its programs to determine whether they represent the best investment to accomplish the Institute’s goals. In response to a member’s question about NCI discontinuing a program co-funded by the NIA, Dr. Niederhuber stated that the specific program was ended, not NCI’s commitment to working with the NIA.

NCI has developed partnerships with some organizations as a way to reduce duplication and to increase collaboration. He encouraged funding that supports research through the NIH Foundation. Centralizing funding is the best way to ensure effective leveraging of funding and resources.

Advocates in Research Working Group

The DCLG’s Advocates in Research Working Group (ARWG) was charged with developing a clear picture of where and how advocates expedite advances in cancer research at NCI. The ARWG will develop recommendations for the DCLG on involving advocates across the spectrum of NCI activities. The group’s members include survivors, caregivers, patients, researchers, and administrators.

Ms. Kelly Cotter reported that to date, the working group has analyzed background information, developed early findings based on a literature review and a survey of researchers and advocates, and has begun to develop an ideal model of advocacy at NCI.

The working group identified four types of advocacy involvement at NCI:

- Review—Peer review, protocol review
- Advise—Advisory committee activities
- Dissemination—Dissemination or infusion of research into the community
- Design—Designing or planning programs and activities

The Working Group divided into four subgroups to focus on each type of advocacy involvement and develop an ideal model of the involvement of advocates in their assigned area around the following activities:

- Selection process
- Training
- Information and resources
- Facilitating involvement
- Communication and feedback
- Evaluation and tracking
- Compensation

Over the next 6 months the ARWG will conduct a preliminary analysis of where and how advocates are involved across NCI, identify challenges and barrier to ideal involvement of advocates in the research enterprise, and develop initiatives to address those challenges and missed opportunities. Ms. Cotter asked DCLG members to contact her or Ms. Bell with suggestions of NCI staff who should be invited to join the ARWG.

Discussion

The discussion centered on the need for training both for advocates and scientists. Scientists need training to understand that advocates play an equally important role in the research process. In addition, NCI needs to include advocates who do wonderful work in their communities but are not engaged with NCI to promote ethnic diversity in the selection of advocates. Finally, NCI needs to enhance its competency in developing partnerships with diverse stakeholders.

Clinical Trials and Advocacy

COL Williams discussed the following challenge: We continue to promote the same programs in the same communities with the same leadership, resulting in the same unsatisfactory results. Advocacy organizations need developmental funds to recruit the numbers of minority participants needed for clinical trials because of the time and effort required to identify community leaders, gain their confidence and support, and work with them to find research volunteers. Only 3-5% of eligible patients participate in clinical trials, and this rate has not improved in recent years.

COL Williams represents the DCLG on the Clinical Trials Advisory Committee (CTAC), which advises NCI's Coordinating Center for Clinical Trials (CCCT). The CCCT has several disease-specific committees and task forces. The task forces develop concepts for future research and report to the relevant disease-specific steering committees. All steering committees and task forces include advocates, and these advocates are part of the Patient Advocate Steering Committee (PASC).

CTAC needs to recruit additional advocates for the steering committees and task forces. COL Williams asked the DCLG members to recommend advocates who might be interested in joining these groups.

Taking NCI Clinical Trials to Minority Communities

Dr. Wortz McCaskill-Stevens discussed NCI's efforts to recruit minorities to its clinical trials.

The 1993 NIH Revitalization Act called for the inclusion of women and minorities in all human subjects' research. Reports from the Institute of Medicine, the Trans-Department of Health and Human Services (HHS) Progress Review Group, and an NCI-wide workshop all called for increased accrual of minorities to clinical trials. In particular, the 2005 NCI-wide workshop, *Enhancing Interaction to Reduce Cancer Health Disparities*, called for elevating health disparities as a discipline; providing resources to enhance individual, investigator, and community participation in clinical trials with health disparities outcomes as the primary or secondary objective; providing supplements to existing clinical trials programs to address health disparity interventions; conducting trials to evaluate health disparities interventions; and annotating population registries and biospecimens for health disparities (by race and socioeconomic status).

To enhance the recruitment of minorities to clinical trials, NCI created the Minority-Based Community Clinical Oncology Program (MBCCOP) program. The MBCCOP supports clinical research in communities with large minority populations, increases the involvement of primary health care providers and relevant specialists, and helps decrease health disparities in cancer treatment, prevention, and control. NCI currently funds 14 MBCCOPs.

The MBCCOP is training oncologists and physicians in related disciplines in oncologic practices in minority communities. The program also serves as a laboratory for identifying preclinical, clinical, and behavioral issues related to health disparities.

Increasing minority recruitment to clinical trials will require:

- A multidisciplinary approach to understanding why different populations make their decisions.
- Upfront funding for recruitment and compliance.
- Sustained support for key outreach staff.
- An increased pool of minority investigators.
- Community representation throughout the development, implementation, and information dissemination of clinical trials.

Communities as Partners in Cancer Clinical Trials

Ms. Margo Michaels described the project entitled: *Communities as Partners in Clinical Trials: Changing Research, Practice and Policy*. The project conveners, The Education Network to Advance Cancer Clinical Trials (ENACCT) and the Community-Campus Partnerships for Health (CCPH) with support from NCI and others, are assembling recommendations to incorporate the principles of community-based participatory research (CBPR) into Phase III cancer treatment

trials. In CBPR, community members are full participants in all phases of the research, including study design, implementation, interpretation of results, and dissemination of findings.

Among its objectives, the project seeks to improve the low accrual rates in therapeutic cancer clinical trials particularly among minority populations and other underserved groups. The project focuses on Phase III trials because these studies have the broadest reach

Ms. Stacy Collins explained that the project began in early 2007. Project outcomes to date include a background paper, which presents a vision and a model for community engagement in cancer clinical research. In addition, two invitational meetings – which included members of community-based organizations, patient advocacy groups, cancer centers, health professional schools, the pharmaceutical industry, Federal health agencies and local oncology practices – have been convened to develop recommendations for research, practice and policy. The first set of draft recommendations was distributed for public comment, and the final draft report is now in preparation.

The project leaders seek comment and feedback from DCLG members on the final draft recommendations, due to be released in June 2008. The project team also hopes to leverage the recommendations of other groups, including the DCLG's ARWG.

Ms. Michaels and Ms. Collins asked the DCLG for suggestions on:

- Ways to collaborate to promote the report
- The draft recommendations from ENACCT
- Ways to synergize the work of the DCLG and the CBPR project.

Discussion

NCI's Cancer Health Disparities Integration and Implementation (I²) team is developing recommendations for the NCI Executive Committee that address the 2005 NCI-wide workshop's priorities. Other workshop recommendations have already been implemented.

The MBCCOP does everything possible to support collaborations between CCOPs and Native American communities. Challenges include the distance between funded sites and the communities. CCOPs determine the best ways to communicate with different groups depending on their relationships. For example, for one CCOP in Tulsa OK, the Cherokee agreed to participate and to become increasingly involved in clinical trials.

The DCLG would like a presentation on the interactions between NCI and the Indian Health Service and become more familiar with ways in which the DCLG could enhance this recommendation.

Several activities are ongoing in the MBCCOPs to encourage more oncologists and primary care providers to discuss clinical trial participation with their patients. However, much more needs to be done.

DCLG members offered the following recommendations for the MBCCOP:

- The MBCCOP could consider collaborating with the National Association of Community Health Centers.
- It is critical to have a standard to for collecting information to identify a patient's ethnicity accurately.

The CBPR report will be distributed to all stakeholders in clinical research, including clinical trial sponsors. It was suggested that the investigators should invite CARRA members to speak to their group about the CARRA program.

Mr. James Hadley announced that COL Williams and Ms. Susan Leigh of CTAC will lead an Understanding NCI teleconference in May. He also noted that the NIH Director's Council of Public Representatives (COPR) had a work group on clinical trials that stressed the importance of communicating the results of clinical trials to the communities that participated in them.

Eliminating Cancer Health Disparities and Advocacy

Research Leading to Elimination of Cancer Health Disparities

Dr. Ed Partridge described the development of the cancer health disparities program at the University of Alabama at Birmingham (UAB). He began by describing the disconnect that exists between (i) the discovery and development stages that are the focus of NIH and NCI research and (ii) the delivery of these findings to cancer patients. This disconnect is the major cause of cancer deaths today and is a key determinant of the unequal burden of cancer. Based on past discovery and development efforts, the knowledge exists today to prevent up to 70% of all cancer deaths in the United States.

NIH research focuses on biology, but many other factors affect mortality, including individual risk factors, social relationships, living conditions, neighborhoods and communities, institutions, and social and economic policies. Arguably, these factors have a more significant impact on cancer death rates than pathophysiological pathways and genetic or constitutional factors.

The discovery that colon cancer screening could reduce mortality led to a decrease in colorectal cancer deaths in whites but not in blacks. This disparity did not exist prior to the discovery. Similar trends have occurred in breast and prostate cancer. Even when stage of disease is held constant, cancer mortality differs by insurance status, suggesting a difference in the delivery of treatment.

In 1993, the UAB cancer center decided to focus on eliminating cancer health disparities in its local region, whose population is at least 50% African American. The first health disparities program involved the recruitment and training of community health advisors. The cancer center also helped pilot test the Alabama Breast and Cervical Cancer Early Detection program in "Alabama's Black Belt".

In 1996-2000, the cancer center obtained two large infrastructure grants to support the Deep South Network for Cancer Control (funded by NCI) and Racial and Ethnic Approaches to Community Health Across the U.S. (REACH) 2010 (funded by the Centers for Disease Control and Prevention [CDC]). The center also used NCI funding to create a partnership with Morehouse School of Medicine (in Georgia) and Tuskegee University (in Alabama) to develop research programs at these minority-serving institutions and enhance cancer health disparities research at UAB.

Once the infrastructure was in place, UAB investigators began conducting hypothesis-driven research on cancer health disparities. The program became so successful that researchers studying other diseases at UAB also began to work with minority populations. As a result, UAB created the university-wide Minority Health and Research Center for research, training, and community outreach to eliminate health disparities in all diseases.

Deep South Network for Cancer Control

Ms. Claudia Hardy described the NCI-supported Deep South Network for Cancer Control, which serves a region that is approximately two-thirds African American and has a median annual income of \$13,000. The program goals are to promote cancer awareness, encourage clinical trial recruitment, and assist with community-based research. The program has trained 883 community health advisors, who promote cancer awareness at a broad range of community events. As a result of their efforts, the disparity between the percentage of whites and African Americans who receive a mammogram has decreased dramatically.

UAB received a grant from NCI for a Community Network Partnership that will improve access to and use of proven beneficial cancer interventions and develop a cadre of well-trained investigators who will address the elimination of cancer health disparities. The program targets breast, cervical, and colorectal cancer using CBPR principles. Program activities include a walk campaign, a healthy-eating program, and advocacy to restore funding for the state breast cancer early detection program.

Discussion

In answer to a member's question, Dr. Partridge described the need to balance the NCI portfolio between basic and behavioral factors. NCI's research portfolio focuses heavily on basic science and clinical trials. Very little funding goes to support research on modes of preventing cancer prevention discovery and the impact of policy, behavior, social structures, and other issues on cancer mortality. These issues are critical for eliminating the disconnect in NIH/NCI activities and the delivery of services to patients. There are program efforts to reach out with funded cancer education programs, but the disconnect in the university community between research and the community still exists. For example, 40% of all women of different races are not obtaining a mammogram, and many people are still uninsured. While UAB programs collect information on patients with cancers, they do not have information on cancer family histories.

In the area of clinical trials research, pharmaceutical companies have expressed an interest in clinical trials using the populations connected to the Deep South Network. UAB has a

recruitment-and-retention facility that helps investigators develop a recruitment plan and budget. In addition, navigators are now promoting participation in therapeutic trials and helping patients overcome any barriers to participation. As a result, more African Americans and white populations are enrolling in UAB's therapeutic trials.

In answer to a question about treatment follow-up after colorectal cancer screening, Dr. Partridge stated that some patients screened by the UAB program are eligible for treatment under Medicare, and people aged 45-65 with incomes under 200% of the federal poverty limit can receive treatment under a state program. Susan G. Komen for the Cure helps pay for screening and diagnoses for breast cancer, and those with a cancer diagnosis can sometimes receive treatment through Medicaid. But treatment for colorectal cancer patients is more challenging, and Dr. Partridge hopes to develop agreements with local surgeons to treat these patients at no charge.

NIH Working Group on Peer Review

Dr. Lawrence Tabak reported that NIH has conducted a self-study of its peer review system in partnership with the scientific community. A large proportion of NIH research is investigator-initiated. The Center for Scientific Review accepts the proposals and refers them to the study section (group of scientific experts) that reviews proposals to assess scientific merit. The results of the reviews are shared with a program officer in the relevant Institute or Center (IC), who discusses the results of the review to the researcher. The IC's national advisory council uses the peer review results to determine how well the application fits the IC's mission and whether the proposed research would fill a critical gap in the science. Dr. Tabak emphasized that although scientific peer review panels play an important role in reviewing proposals, they do not make funding decisions. IC directors make these decisions in conjunction with their national advisory council.

Between July 2007 and February 2008, the NIH working group on peer review identified a series of challenges and recommended actions in the following areas:

1. Reduce administrative burden of applicants, reviewers, and staff
2. Enhance the rating system
3. Enhance review and reviewer quality
4. Optimize support at different career stages
5. Optimize support for different types of science and approaches to conducting science.
6. Reduce stress on the support system of science
7. Meet the need for continuous review of peer review.

Addressing all of these areas would have a positive impact on the DCLG's three priority areas (minority recruitment and patient outreach, cancer care delivery, and eliminating cancer health disparities). However, enhancing review and reviewer quality could have a direct impact on minority recruitment and patient outreach. For example, if more ICs include consumers or advocates in their review processes, these individuals could provide important insights into recruitment and outreach. Optimizing support for different types and approaches to science

would help eliminate cancer health disparities by, for example, encouraging culturally competent research in community settings.

The final draft report was submitted to NIH Director Dr. Elias Zerhouni in February. Although the formal comment period has ended, Dr. Tabak encouraged DCLG members to review the report (available at <http://enhancing-peer-review.nih.gov/meetings/NIHPeerReviewReportFINALDRAFT.pdf>) and submit comments. A working group is now determining how to implement the draft recommendations if Dr. Zerhouni approves them. The committee is holding meetings with scientific review and program officers and plans to provide a set of final recommendations to Dr. Zerhouni in mid-April.

All of the implementation strategies will be pilot tested and evaluated. The results will inform the development of new NIH policies.

Discussion

Many proposals do much better when they are resubmitted after the investigator receives the first round of peer review comments. One recommendation would permit investigators to resubmit their proposals much more rapidly after the initial review.

According to the committee, the single most important change is to refocus the review so that it increases the emphasis on impact on the field and decreases the emphasis on methodological details.

Changing the culture is difficult, and this will take time. Scientific review officers will need formal training on committee management. Study section chairs will need formal training on keeping the discussion focused on important issues and paying less attention to minor details. Some ICs have begun to provide training for advocate and scientist reviewers. For example, the National Institute on Mental Health is pilot testing training for advocates on peer review and for study section chairs to ensure that advocates participate in the discussions. Experience from other agencies shows that the overall proposal scores of advocates are very similar to those of scientists.

DCLG Discussion of Day 1 Events and Wrap-up

Dr. Laird led a discussion of the first day's presentations and discussions.

Dr. Butler requested more information on the impact of NCI's efforts to eliminate cancer health disparities. Mr. Kaye requested data on the percentage of NCI grants that address health disparities. COL Williams asked for clarification on targets for recruitment of minorities. Dr. Laird explained that investigators are required to establish minority recruitment and accrual goals based on the population of the geographic area in which the study takes place. Perhaps the requirement should be to recruit minorities based on the incidence of cancer in these populations.

Ms. Geoghegan emphasized the need to establish accrual goals that are enforceable. Dr. Laird explained that investigators typically say that they will recruit a certain number of minorities based on Census data, but they rarely include a detailed recruitment plan. Advocates often point

this out during peer review discussions, and Dr. Laird believes that many proposals receive lower scores and may go unfunded because they lack a strong minority recruitment plan.

Ms. Graff commented that investigators should demonstrate a reasonable level of effort in executing a recruitment plan. Ms. Dahlstrom argued that accountability is more important than effort.

Dr. Laird reported that Dr. Isabel Scarinci of UAB, who conducts research in the Latino community, requested a year off from an NCI grant to build trust in the community. During this period, Dr. Scarinci attended four different churches each Sunday. Her efforts to establish trust in the community have enabled her outreach efforts to raise the screening rates for breast and cervical cancer substantially.

COL Williams pointed out that this type of research involves behavioral science, which is not a focus for NIH. In addition, it is difficult to build trust in a limited grant period. Multiyear developmental funds are required to establish relationships with communities.

Dr. Butler wondered whether any NCI office provides local population data (such as screening rates by zip code) for researchers, who need this information to conduct research at the grassroots level. Ms. Bell replied that NCI does not have this type of data by zip code. Ms. Guest stated that NCI's Division of Cancer Control and Population Sciences conducted a portfolio analysis of grants that address cancer health disparities. However, this list is not complete because of the way in which grants are coded. Ms. Graff noted that no good source of local data exists in the United States. UAB, for example, collected data from Medicare records but does not have comparable data on patients not covered by Medicare. Ms. Amanda Woodfield commented that NCI's Cancer Control PLANET has cancer data at the state and county levels.

Cancer Health Services and Advocacy

NCI Community Cancer Centers Program (NCCCP) Pilot Update

Dr. Maureen Johnson reported that the 10 NCCCP pilot sites have co-invested at least \$47 million to support the program's goals. An advisory committee oversees the pilot, and it has subcommittees focused on the four program areas: information technology (IT), clinical trials, cancer health disparities, and biospecimens. Other subcommittees address survivorship/palliative care, quality of care, communications, and advocacy. The Pilot Executive Subcommittee provides overall oversight.

All of the pilot sites have completed their baseline assessments. Each site is examining its gaps and developing site-specific plans to address these gaps. In addition, the subcommittees have identified projects in which all 10 sites will participate.

The NCCCP sites are trying to develop relationships with NCI-designated cancer centers but have encountered some resistance. NCI will continue to educate its comprehensive cancer centers about the value of complementing the NCCCP programs.

Dr. Johnson summarized the pilot's accomplishments:

- Disparities: The program has completed a survey of breast cancer and colorectal cancer screening activities and established baseline metrics for outreach and patient navigation activities. A draft breast screening tracking tool is in development, and the American Cancer Society has agreed to train patient navigators at each site.
- Clinical trials: The program has surveyed clinical trial activity and use of patient navigators at each site. The co chairs identified a set of Phase III trials, and plans are being developed to increase accrual in these trials.
- Information technology: The sites have completed baseline assessments of their IT infrastructure and interfaces of existing health IT systems. The sites are developing IT plans and learning about the cancer Biomedical Informatics Grid (caBIG™) work spaces. The sites facilitated an NCI meeting with several major health IT vendors, which have agreed to incorporate caBIG compatibility in their software packages.
- Biospecimens: The sites are creating standardized specimen collection and processing procedures and finalizing their baseline assessment reports. Several sites are interested in contributing specimens to The Cancer Genome Atlas (TCGA).
- Quality of care: A workgroup will identify site barriers and facilitators of multidisciplinary program planning. The Commission on Cancer is establishing procedures for sharing patient-level quality-of-care data within and across pilot sites. Site physicians have agreed to participate in EQUIP, which monitors quality of care.
- Survivorship and palliative care: An informal survey has collected data on care plans, survivorship and palliative care services, and education programs. The NCCCP is using American Society of Clinical Oncology (ASCO) templates to create treatment summary and care plan models.
- Communications: NCI developed news releases, fact sheets, a website (ncccp.cancer.gov), a logo, brochures, and letters to congressional offices prior to the program launch in June 2007. The program is developing custom electronic toolkits for pilot sites. All sites now have access to a private program intranet.
- Advocacy: DCLG members contributed to the development of the request for proposals (RFP) for the pilot program. One DCLG member serves on the NCCCP Program Advisory Committee (NPAC) and she and others serve on the subcommittees. They also provide ongoing input and educational resources across major pilot focus areas. Mr. Bill Bro of the DCLG is making informal visits to NCCCP sites.

Reports on the NCCCP Program Advisory Committee (NPAC) and Subcommittees

Dr. Laird shared Mr. Bro's report on his site visits. Mr. Bro will visit as many sites as he is able.. He is producing a video log of his visits for the DCLG.

As a member of the NPAC, Dr. Laird reported that the DCLG was successful in including a question in the baseline survey about sites' use of free resources from national and local organizations. Most of the sites were familiar with the resources offered by major organizations, such as the American Cancer Society and the Lance Armstrong Foundation, but they were less familiar with other organizational resources. Several sites requested additional information on

some of these organizations, and these requests have been forwarded. In addition, the NCCCP website will post links to these organizations.

Dr. Laird invited the DCLG to attend the annual meeting of the NCCCP sites in Arlington, Virginia, on June 26-27. All 10 sites will send several representatives to this meeting.

The DCLG has members on all subcommittees except for the IT and biospecimens subcommittees. If either of these two groups raises issues that are relevant to advocates, the groups will inform the DCLG so that it can make an advocate available.

Ms. Cotter serves on the Survivorship Subcommittee, which is developing an electronic template that will include treatment and survivorship care plans. The subcommittee is focusing on breast cancer initially and is modifying an ASCO template to incorporate recommendations from the Institute of Medicine. The subcommittee is working with the Lance Armstrong Foundation to pilot test its Web-based treatment summary form for breast cancer. The sites are finding it challenging to identify people who have the time and access needed to fill out the forms, so they are trying to find ways to complete the forms using existing data from other electronic systems. Ms. Cotter asked DCLG members to share with her other models that might be useful for this purpose.

Dr. Yvette Colón, who serves on the Health Disparities Subcommittee, reported that this subcommittee is trying to standardize processes that will be effective for all sites. The group is also discussing patient navigation and the training to be provided by the American Cancer Society. One exciting aspect of this project is its inclusion of communities that are rarely involved in NCI activities.

Ms. Peggy Anthony reported that the Clinical Trials Subcommittee is trying to standardize the patient navigator role and is planning a clinical trials webinar for investigators. The group has also addressed institutional review board (IRB) and minority accrual issues.

Dr. Laird reported that the Quality of Care Subcommittee is developing a definition of multidisciplinary care and has noted that if sites offer genetic testing, they need to provide appropriate counseling as well.

Discussion

In answer to questions posed by members of the DCLG, the following points were made:

- ✚ Because the NCCCP sites have contracts with NCI through SAIC and each site is writing its own program plan within the guidelines of the contracts.. The contract calls for 40% of funding to be allocated to reducing cancer health disparities. The NCCCP sites provide detailed reports on how they spend their NCI funds. The sites are spending most of their awards on personnel to implement programs. NCI does not mandate how the programs spend their funding, because the goal is to show how they address their gaps. Once the infrastructure is in place, the sites will probably focus more of their efforts on programmatic activities.

✚ A breast screening tracking tool will be used to track and provide services to underserved women who have an abnormal screening result and do not have a relationship with the community center. The tool will help decrease the time between the screening and the first appointment for treatment. The program will post all of the best practices developed by the sites on its public website.

✚ The NCI Office of Communications will present marketing tools for the sites at the June annual meeting. One goal of the NCCCCP is to expand the program beyond the 10 sites. The pilot is establishing minimal requirements for an NCI-designated community cancer center and will share best practices through its website so that other sites can use this model.

✚ NCI's Center for Bioinformatics is working with the sites to formally assess their information technology (IT) capabilities. NCI is also helping the sites use caBIG's open-source, open-access tools. The sites are already negotiating with large-scale vendors of hospital-based management information systems about interoperability so that they can share data across sites.

✚ The communications representatives from all of the sites belong to the Communications Subcommittee and meet monthly by teleconference. One of their goals is to use NCI expertise to help them better communicate with the communities they are trying to reach.

✚ The sites need to develop culturally competent infrastructure. For example, when the sites develop plans for reaching Native Americans and other underserved populations, they must involve survivors who understand what it means not to have a voice. The sites must also use a broad array of communications vehicles because many communities do not have access to the Internet. Efforts will be made to determine if Native Americans are being recruited to the patient navigator program. The DCLG asked to receive regular updates on the way the NCCCCP reaches underserved populations.

✚ The evaluation will compare patient satisfaction and quality of care before and after program implementation to measure effects. The control group will consist of people who were exposed to the sites prior to the program. It was requested that the evaluation collect data on people who are not reached by the NCCCCP sites.

Electronic Health Records (EHRs)

caBIG™ and EHRs

Dr. Buetow explained that NCI wants to enable a molecular revolution throughout biomedicine. Through this revolution, scientists will direct their therapeutic efforts based on the individual characteristics of the patient and his or her disease. This requires bringing together a diverse collection of information and technologies.

Biomedical informatics enables the seamless flow of data from bench to bedside and back. A basic infrastructure is required to support this activity, and NCI constructed caBIG™ to respond to this need. caBIG™ is a virtual web of interconnected data, individuals, and organizations that redefines how research is conducted, care is provided, and patients and participants interact with the biomedical research enterprise.

caBIG™ connects the cancer community through a common interoperable infrastructure based on international standards. It offers tools for analyzing, integrating, and disseminating information across the entire research-and-care spectrum. caBIG™ connects patient care systems to clinical research systems. The information is accessible as needed with appropriate controls and consent for access to the information.

caBIG™ is working with ASCO to develop electronic health record (EHR) standards that incorporate caBIG™ interoperability for oncology practice software. caBIG™ is also creating patient health record systems for facilitating the discovery of clinical trials. In addition, it is bridging research and care delivery through the NCCCP by creating clinical data warehouses to support evidence-based medical decision making and facilitate clinical research.

Health IT: Better Health and Care

Dr. Karen Bell reported that President Bush has called for widespread adoption of EHRs by 2014. The Office of the National Coordinator for Health Information Technology (ONCHIT) identifies barriers and enablers of widespread national adoption of health IT (HIT) and coordinates federal activities that address these barriers and enablers. The American Health Information Community is moving into the private sector, and the Brookings Institute is studying how this will be accomplished.

Providers create EHRs to store information for patient care, while patients create their own personal health records (PHRs) with information from EHRs or other sources. The National Health Information Network develops standards and specifications that allow information to be shared securely and reliably among multiple authorized parties and entities.

The American Health Information Community (AHIC) helps move the EHR process forward. ONCHIT has issued several contracts to implement AHIC recommendations. These contracts address interoperability standards, certification processes for EHRs and PHRs, state variance in privacy and other HIT-related issues, adoption measurement, and Regional Health Information Organization support.

Adoption of EHRs among U.S. physicians has been slow, with only 7% of physicians in solo practices using EHRs. Although 68% of hospitals have at least partially adopted EHRs, only 11% have fully implemented an EHR system.

The barriers to adopting the EHR are the high cost of the software, and no reimbursement for physician time. Another major barrier to adoption of EHRs consists of privacy and security concerns. People are concerned about the consequences of security breaches. ONCHIT is

developing policies to address these concerns. To move EHRs forward, a business case needs to be developed, because these technologies are expensive. The Stark amendment and anti-kickback relief will permit hospital donations to physicians for up to 85% of the cost of EHR software. The Health Resources and Services Administration (HRSA) offer grants to rural and community-based federally qualified health centers. A Centers for Medicare and Medicaid Services (CMS) demonstration project provides a large incentive to physicians who implement a certified EHR system. ONCHIT is working with payers to pilot test secure messaging systems to demonstrate that these are at least budget neutral and can improve care.

The Certification Commission for HIT is a multi-stakeholder public/private partnership that has developed criteria for EHR functionality, security, and interoperability. The first products were certified in 2006. In 2008, three specialty modules will be issued for pediatrics, behavioral health, and cardiology. An electronic PHR certification process is in development. One major barrier to this vision consists of privacy and security concerns. People are concerned about the consequences of security breaches. ONCHIT is developing policies to address these concerns.

Dr. Bell invited DCLG members to learn more about ONCHIT at www.hss.gov/healthit.

Discussion

A member stated that after 9/11 and Hurricane Katrina, many companies began to understand the need for off-site backup health information systems. This interest could be used to increase the adoption of EHRs and build the business case for EHRs. In addition, EHRs can be used to obtain a second opinion from experts in other parts of the country. But many people are afraid of electronic health data because of incidents in which personal records are exposed. The Health Insurance Portability and Accountability Act (HIPAA) needs to provide enforcement mechanisms. In addition, the purchase of hardware and software needs to be less risky and costly.

Federal reimbursement is important for moving the EHR agenda forward. For example, Medicare policies that define the conditions for reimbursement for telemedicine need to be expanded. ONCHIT is working with the Secretary's office to recommend ways to address the need for enforcement of HIPAA violations.

The American Health Information Community (AHIC) is seeking representatives from many stakeholder groups, but consumers are difficult to recruit. Dr. Bell asked DCLG members to contact her if they might be interested in joining or EHR's to address health disparities, Dr. Bell stated that when providers have access to information that can benefit all of their patients, this can decrease disparities. The Office of Minority Health is about to recommend to AHIC that every contract and grant used to support HIT include populations experiencing health disparities.

A member asked about the potential for personal health records (PHRs), and the response was that PHR's are still in development, and very few people are using them, so their benefits are not yet clear. Although the PHR data are electronic, applications will be available to translate the information into terms that are understandable to different people and to present the information in ways that are accessible to patients.

NCI Central Institutional Review Board (CIRB)

The NCI Central IRB: Consumer Feedback from the Eastern Cooperative Oncology Group (ECOG) Patient Representative Committee

Mr. Mike Katz co-chair of the ECOG Patient Representative Committee, explained that NCI initiated its Central IRB (CIRB) as a pilot project in 2000. The Institute expanded the CIRB's scope in 2001 to encompass all Phase III adult cancer cooperative group trials.

Before NCI implemented its CIRB policy in 2001, protocols approved by NCI's Cancer Therapy Evaluation Program (CTEP) could then be released to trial sites for local IRB approval. Once the sites obtained local IRB approval, they could begin accruing patients. But in March 2001, the policy change added two new steps to the process: CTEP began submitting all Phase III protocols to the CIRB, and the CIRB had to approve the protocol before any site (including sites that did not participate in the CIRB) could submit protocols to its local IRB. These two new steps take an average of more than 16 weeks to complete, and they must be completed for every Phase III adult cancer cooperative group trial.

In 2002, a joint task force of DCLG members and the Patient Advisory Board of the Coalition of Cancer Cooperative Groups reviewed the CIRB and reported an average delay of 15 weeks but that although NCI expected that the CIRB review would be reduced to 5-6 weeks. The task force asked how long the CIRB pilot would need to run before a definitive answer would be available and whether any objectives or measures had been identified to determine whether the CIRB was successful. Responses to these and other questions raised by the task force are still not available. Further the average review time had increased to over 16 weeks rather than being reduced to 5-6 weeks.

Six years later, ECOG advocates believe that the CIRB's promise has not been realized, delays persist, and usage remains low. In 2007, 76% of accruals to the Eastern Cooperative Oncology Group (ECOG) protocols came from sites not using the CIRB. The benefits of the CIRB still cannot be quantified, and NCI has not identified any clear targets or objectives to measure its performance and impact on patient outcomes. Furthermore, after a review of four ECOG studies, the advocates concluded that the delays imposed by the CIRB process have negatively impacted patient outcomes, resulting in reduced survival and remission times as well as increased mortality.

The ECOG Patient Representative Committee therefore urges NCI to reverse its decision to withhold CTEP approval pending CIRB approval.

NCI's CIRB

Dr. Jeff Abrams explained that NCI established the CIRB in 1999 to streamline or eliminate redundant processes and procedures, especially the redundant full-board reviews by local IRBs.

The program was designed to determine whether a CIRB could reduce the local administrative burdens for multisite trials while maintaining a high level of human subjects' protection. The program would also assess whether a CIRB would enhance the protection of research participants by providing consistent expert IRB review at the national level before the study was distributed to local investigators.

The CIRB's primary function is the initial and continual review of studies, including amendments and adverse events occurring in several groups. The local IRB's primary function is to consider the local context, oversee local performance, and review local adverse events.

NCI assesses key metrics each month, and an outside contractor has helped evaluate the CIRB from the outset. Evaluation activities have included a survey of key CIRB stakeholders and meetings by an external panel to evaluate the data collected and review the metrics. The user satisfaction survey found that the local IRB chair workload did not increase as a result of the CIRB, and most local IRB chairs were satisfied or very satisfied with the quality of CIRB reviews. Only 5% of local IRB coordinators who responded to the survey thought that the CIRB review increased the time required to begin their reviews. Most local principal investigators who responded reported that participation in the CIRB encouraged them to open more trials than they would have done otherwise.

The mean number of weeks from the initial CIRB review date to final approval was 14 in 2001, 7.5 in 2002, and 9.3 in 2003. NCI began tracking the mean number of weeks from submission date to final approval and found that it increased from 13.1 in 2004 to 16.4 in 2006. But once the CIRB approves a study, it can take 2 days to 2 weeks for the group to activate the study and 6-10 weeks to obtain local IRB approval. Among all 42 studies approved by the CIRB between December 2001 and May 2004, 9 were activated within 30 days of CIRB approval and 33 took 32 to 538 days to activate.

There are several benefits of CIRB participation: the ethics review occurs before the protocol is distributed nationally, the facilitated review allows local sites to open studies within days, the process encourages sites to consider studies in rare diseases, and central review is independent of the local oncology department. In addition, the process reduces the local investigator workload, eliminates the need for full local IRB review, and decreases local IRB time and costs.

Arguments against simultaneous submission of protocols to the CIRB and local IRBs include the fact that the CIRB often issues recommendations involving the informed consent form. As a result, local IRBs might need to review the amended consent form after they have approved the previous version, and sites might have to stop accruing new patients until the local IRB reviews the amended form. In addition, the CIRB sometimes makes recommendations that change patient eligibility or treatment. This means that patients who have already been accrued might become ineligible or receive incorrect treatment, and patients might undergo unnecessary procedures that are no longer part of the research plan.

Discussion

The DCLG did not question the theoretical value of the CIRB but wondered when the CIRB ceased to be a pilot and whether NCI has issued a final evaluation report. The program would benefit from a stronger, more quantitative evaluation before NCI makes its final decision. One member encouraged the DCLG to continue the discussion and become involved in this issue. The DCLG expressed concern about the barriers to communication between CTEP and consumer groups with legitimate concerns, and one member expressed concern about the involvement of groups representing patients in the CIRB review process.

Discussion with the NCI Director

Dr. Niederhuber expressed his deep appreciation to the DCLG members whose terms end in June 2008:

- Ms. Peggy Anthony
- Mr. Bill Bro
- Ms. Lourie Campos
- Ms. Nancy Davenport-Ennis
- Ms. Cece Whitewolf
- COL Jim Williams

Mr. Doug Ulman and Dr. Laird will remain as Chair and Vice Chair of the DCLG for one additional year to provide continuity.

Dr. Niederhuber expressed concern that the cancer community does not speak with a unified voice. Too many community members focus more on authorship and ownership than on working with one another. NCI needs help from the DCLG and other advocates to encourage the cancer community to think and speak with one voice and put patients rather than societies at the center of that voice. The fractionalization of the community makes it more difficult for NCI to make its case to policy makers. .

COL Williams commented that cancer community members focus too much on specific organs. The transition away from this organ orientation is becoming more important as science moves toward individualized medicine and biotechnology.

Dr. Butler noted that communities want to see more NCI efforts focused on prevention. Dr. Niederhuber explained that NCI's prevention research includes finding ways to detect the disease at its earliest stages, when it is easiest to treat successfully. NCI wants to do everything possible to prevent cancer or at least to convert it from a lethal disease to a chronic but survivable disease. Traditionally, medicine has focused on treatment for acute illness, but in the future, Dr. Niederhuber hopes that medicine will focus more on prevention.

Ms. Graff commented that although Congress did not invite Dr. Niederhuber to testify, it often invites celebrities to testify. Many organizations use celebrities to request earmarked funds.

Dr. Butler suggested that the DCLG members consider speaking as individuals to their congressional representatives about the need for increased support for cancer research.

Ms. Dahlstrom inquired about the status of NCI's patient navigator programs. Dr. Niederhuber explained that science and medicine are constantly moving, and NCI must therefore monitor all of its programs on a continuous basis. Patient navigation is very important, but NCI's mission is to conduct research and not to deliver health care, although NCI's research can influence health care delivery. Some programs that focus solely on navigation could be more effective if they were integrated into programs that address other issues, such as education and prevention.

Ms. Dahlstrom expressed concern about the resources dedicated to the elimination of cancer health disparities. Dr. Niederhuber said that whenever NCI makes a programmatic change to respond to budget constraints, the goal is to do a better job. NCI must constantly ensure that all of its programs are effective and must stop supporting programs that do not have the desired outcomes.

Discussion of NCI Issues

Members emphasized the importance of building a unified voice and including groups that do not feel represented. The organization One Voice Against Cancer (OVAC) was mentioned and a member explained that OVAC brings together more than 35 organizations, primarily those representing cancers that affect smaller populations. OVAC has substantial influence in advocacy.

Although NCI has had a flat budget for several years, it still receives a large appropriation from Congress. Advocates might do well to start focusing on all of the good that can be accomplished with these funds rather than on the fact that the budget is flat.

Members felt that policy makers and members of the public are not familiar with NCI's accomplishments. In order to address this issue, NCI could develop brief and visual materials that the Institute and advocates can use to show what NCI accomplishes with taxpayer contributions. There was agreement that the OAR Director work with OCE and OSPA to develop appropriate materials for this purpose.

Activities by NCI and advocacy organizations could be coordinated so that advocates can take advantage of activities in their region. If the two Native American NCCCP sites do not experience the same progress as other sites, NCI will need to understand Native American governance to determine why this happens.

Although NCI has had a flat budget for several years, it still receives a large appropriation from Congress. Advocates might do well to start focusing on all of the good that can be accomplished with these funds rather than on the fact that the budget is flat.

Smoking is permitted on the NIH campus, but this must stop. The DCLG unanimously approved a motion to support the NCI Director in his efforts to prohibit smoking at NCI. Dr. Niederhuber fully supports a smoking ban. NIH is considering ways to make the campus smoke-free but must first overcome some bureaucratic barriers, such as contracts with unions that cannot be

renegotiated until the contract terms end. The DCLG should connect with other NCI boards, such as the National Cancer Advisory Board, that have addressed this issue. These boards want to encourage institutions that receive NCI funding to decline funding from tobacco companies. The DCLG might also consider collaborating with the NIH Director's Council of Public Representatives (COPR) around this issue.

Ms. Bell distributed notes on the DCLG's Program Working Group discussion and asked for feedback.

DCLG Recommendations to the NCI Director

Dr. Colón reported on the proposed recommendations for the NCI Director. The Recommendations Working Group developed these recommendations based on the suggestions made at the DCLG's October meeting.

DCLG member comments on the recommendations were:

- Some of the recommendations imply that NCI should shift its focus away from supporting research.
- The DCLG's recommendations concerning cancer health disparities should focus on understanding the communities that experience disparities.
- The recommendations should be more specific, science based, data driven, and measurable.
- The DCLG needs to learn how much NCI spends on research in its priority areas and use this information in its recommendations.

DCLG members proposed the following additional recommendations:

- NCI should bring consumers together in a summit so that they can create a critical mass of people interested in cancer.
- NCI should increase the participation of older patients, including those with comorbidities, in clinical trials.
- NCI should not award funding to institutions that accept money from tobacco companies.
- NCI should reward investigators (possibly through a Director's award) with exemplary minority accrual programs who produce exemplary results.
- NCI should consider an institution's success in minority accrual in making decisions about cancer center renewal applications.
- Accrual targets should be based on incidence rates in minority populations in the catchment area.

The DCLG's recommendations will be submitted to the Director, on behalf of the Institute.

The Recommendations Working Group will refine its proposed recommendations based on this discussion and the presentations from the meeting. DCLG members should send additional recommendations to Ms. Guest.

Public Comment

No public comment was offered.

Closing Remarks

Dr. Laird noted that the DCLG’s next in-person meeting is scheduled for October 28-29, 2008, but these dates might change, and the meeting might take place outside the Washington, DC, area.

Dr. Laird suggested that DCLG members encourage other qualified advocates to apply for membership on the DCLG prior to April 15.

On behalf of the DCLG, COL Williams thanked Dr. Laird for her leadership during this meeting.

Certification

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

Date

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
March 27-28, 2008**

Action Items

- DCLG members will contact Ms. Cotter or Ms. Bell with the names of NCI staff who should be invited to join the DCLG's Advocates in Research Working Group.
- DCLG members will contact COL Williams with the names of advocates who might be interested in joining CTAC's (Clinical Trials Advisory Committee's) disease-specific steering committees and task forces.
- OAR will arrange a presentation for the DCLG on the relationship between NCI and the Indian Health Service. . (The DCLG requested a presentation on the Indian Health Service at its next meeting.
- NCI will inform the DCLG of whether the NCCCP is making efforts to recruit Native Americans to its patient navigation program.
- DCLG members interested in joining the American Health Information Community (AHIC) or whose constituents might be interested should contact Dr. Karen Bell.
- DCLG members will provide feedback on the Program Working Group notes to Ms. Bell.
- The Recommendations Working Group will refine its proposed recommendations based on this meeting's discussions and presentations.
- DCLG members should send additional recommendations for NCI to Ms. Guest.
- DCLG members will encourage other qualified advocates to apply for membership in the DCLG prior to April 15 (Extended to April 30, 2008).