

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

**MINUTES of the DIRECTOR'S CONSUMER LIAISON GROUP MEETING
Austin, TX**

March 26-27, 2009

Members Present

Mr. Doug Ulman, Chair	Ms. Marie Dahlstrom	Mr. Alan Kaye
Dr. Beverly Laird, Vice Chair	Ms. Gwen Darien	Dr. Deborah Morosini
Mr. Bill Bro*	Mr. Everett Dodson	Ms. Phyllis Pettit Nassi
Dr. Yvette Colón	Ms. Joyce Wilcox Graff	Ms. Wendy Selig
Ms. Kelly Cotter	Ms. Cheryl Jernigan	Ms. Arlene Wahwasuck

*Participated by telephone.

Speakers

Ms. Shannon K. Bell, Director, Office of Advocacy Relations, National Cancer Institute (NCI)
Dr. Patricia Chalela, Assistant Professor, Institute for Health Promotion Research, University of Texas Health Science Center at San Antonio
Ms. Kelly Cotter, Director's Consumer Liaison Group (DCLG)
Ms. Katie Dahlquist, Team Supervisor, American Cancer Society (ACS) Clinical Trials Matching Service
Dr. Margaret L. Kripke, Member, President's Cancer Panel; Professor of Immunology and Vivian Smith Chair Emerita, University of Texas M.D. Anderson Cancer Center
Mr. James Mansour, Chairman, Cancer Prevention and Research Institute of Texas
Dr. John Niederhuber, Director, NCI
Dr. Jane Perlmutter, Advocate, I-SPY2 Clinical Trial Team
Ms. Beverly Shaw, Director of Mission Delivery, ACS National Cancer Information Center
Ms. Karen Torges, Director of Strategic Collaborations, ACS High Plains Division
Mr. Joe Whalen, Facilitator

National Cancer Institute Staff

Ms. Shannon Bell, Director
Mr. Ben Carollo, Advocacy Relations Manager
Ms. Anne Lubenow, Special Assistant to the Director

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Welcome and Opening Remarks

Rules governing confidentiality and conflict of interest were reviewed, and a quorum was determined to be present.

NCI Developments and Meeting Priorities

Presenter: Ms. Shannon Bell

The overall goal of the meeting was to identifying strategic priorities shared by NCI and the community.

NCI program updates included:

- NCI's Cancer Therapy and Evaluation Program (CTEP) will begin sending clinical trial protocols to the central institutional review board (CIRB) and to local IRBs simultaneously.
- The NCI Community Cancer Centers Program (NCCCP) pilot program has been very successful. NCI hopes to continue and possibly expand this program.
- Though the Cancer Information Service Partnership Program contracts expire in January 2010, NCI will continue to offer its 1-800-4-CANCER information service. The DCLG will be asked to identify community representatives to be engaged as NCI considers next steps related to disseminating important cancer information.
- The Office of Advocacy Relations (OAR) is connecting several philanthropic organizations that would like to fund cancer research with appropriate research opportunities.
- OAR is helping the community understand the new National Institutes of Health (NIH) Research Conditions and Disease Categories coding system and how it differs from the coding system that NCI has used in the past.

DCLG member comments included:

- A document with figures from NCI's bypass budget and its actual budget would be useful to advocates. NCI's newest *Fact Book*, to be published shortly, might provide the needed information.
- It could be beneficial for NCI to encourage the NCCCP sites and NCI-designated comprehensive cancer centers to collaborate with hospitals in their regions.
- A list of DCLG members' advocacy activities at NCI and elsewhere would assist the board in harnessing the board's collective knowledge.

Innovatively Involving Advocates in Clinical Trials

Presenter: Dr. Jane Perlmutter

Unique aspects of the I-SPY2 clinical trial were presented:

- This is a phase II trial designed to rapidly identify promising new breast cancer agents and the patients who are most likely to benefit from them.
- The trial's adaptive design allows the investigators to change the design during the trial based on the data. For example, if one of the study drugs is not better than the standard of care, the drug can be dropped during the trial and new drugs can be added.

- The investigators are assigning drugs to patients based on the biomarkers of their tumors.
- The trial will test 5-12 new agents in 800 patients.
- Advocates have been involved in the trial from the beginning and all I-SPY2 scientific working groups have at least one advocate.
- Dr. Perlmutter has created a website (<http://www.gemini-grp.com/ISPYHome.pdf>) with a wealth of information about the trial, including FAQs for advocates and patients and an advocate training schedule.
- Trained advocates will counsel potential study participants about the pros and cons of enrollment and questions to ask their doctor. Advocates will also provide peer support during the trial.
- Eighty percent of participating patients will receive an investigational agent.
- The trial is managed by NIH and funded by the Biomarkers Consortium of the Foundation for NIH, a public-private partnership.

The principles that guide the role of advocate engagement in I-SPY2 include:

- Meaningful engagement throughout the project.
- Adequate training.
- Opportunities for novice and experienced advocates.
- Compensation analogous to that of scientists.
- Clear expectations and accountability.
- Assessment and continuous improvement.

Advocates in Research Working Group Update

Presenters: Ms. Shannon Bell

Ms. Kelly Cotter

The DCLG formed the Advocates in Research Working Group (ARWG) in 2007. The working group's goal is to provide recommendations for involving advocates in ways that accelerate progress, benefit patients, and improve public health. The group includes many NCI staff members, extramural investigators, and advocates.

The working group has focused on creating an ideal model for advocacy at NCI and centers funded by NCI based on feedback from 100 researchers and advocates. The group has also completed more than 50 interviews to determine where and how advocates are currently being used at the Institute. Preliminary results indicate that 27% of advocates are involved in NCI events (including conferences and workshops) and 23% participate in the peer-review process.

The group has identified the following areas where a process must be codified in order to have successful advocate involvement:

1. Recruitment, retention, and promotion
2. Matching the right advocate with the right activity
3. Creating engagement principles
4. Providing access to training, information, and resources
5. Tracking and evaluating advocate involvement

The ARWG has formed planning teams to develop implementation plans for each of the five areas. Based on these plans, the working group will write a report that offers a set of implementation recommendations.

The DCLG was asked to consider the following questions:

- What points or components of the final report will be most important in the community?
- How can the report frame these points in a way that resonates with NCI?
- Who can serve as partners to implement the recommendations?

DCLG members offered the following suggestions:

- Include examples in the report to show how a successful advocacy model might work.
- Emphasize the involvement of advocates from underserved and minority populations.
- Recommend a phased approach:
 - Start by identifying a small set of NCI activities that would benefit most from involving advocates (because, for example, these activities do not currently involve advocates).
 - Start by working with NCI staff members who are particularly open to involving advocates.
- Consult with other groups, such as Susan G. Komen for the Cure and the ISPY-2 trial, that are considering how best to engage advocates.
- Recommend training for investigators and NCI staff members on how to involve advocates in their work.

Engaging Advocates in the President's Cancer Panel

Presenter: Dr. Margaret Kripke

In 2007-2008, the President's Cancer Panel report, *Strategies for Maximizing the Nation's Investment in Cancer: Three Crucial Actions for America's Health*, identified the most important steps for reducing the cancer burden in this country. The three crucial actions identified were:

1. Preventing and treating cancer must become a national priority.
2. All Americans must have timely access to needed health care and prevention measures.
3. The scourge of tobacco in America must end.

In 2008-2009, the panel studied environmental factors in cancer. Its most important finding was that we do not know the impact of environmental factors on cancer incidence. The panel is currently developing recommendations on this topic and will issue its report in the fall of 2009.

The DCLG offered the following comments:

- A single document with all of the panel's recommendations over the past 20 years could be compiled to identify common themes or areas where progress has been made and gaps still exist.
- The panel report might have greater impact if it could be presented to the President in person.

Approaches to Keeping the Community Informed

Presenters: Ms. Katie Dahlquist

Ms. Beverly Shaw

Ms. Karen Torges

The American Cancer Society's (ACS's) National Cancer Information Center offers support by telephone and email on such issues as cancer diagnosis, treatment, care, prevention, and early detection; national and local resource referrals; and community involvement support, including volunteer opportunities. Special services include responses to more complex questions from oncology nurses, a quitline for smokers, assistance choosing healthy food and physical activities, and assistance with health insurance issues.

The ACS clinical trials matching program educates patients and health care professionals about clinical trials as a treatment option with the goal of increasing enrollment. The service prescreens patients to identify the most appropriate trials and tracks national enrollment trends and barriers to trials. The service is available by telephone and on the Internet. Twelve percent of patients who talk to an ACS clinical trials specialist enroll in a trial.

It was reported that ACS offers a package of resources in more than 1,400 hospitals across the country, including information on clinical trials, assistance with lodging and transportation, emotional support, and cancer education. In addition, ACS's telephone-based navigators help connect people to care and resources in their communities.

DCLG members identified the following concerns:

- Health care providers do not collaborate enough. For example, providers in a given region are sometimes unwilling to refer patients to another facility in the same region.
- Is the ACS collecting the information of callers and using this information in future fund-raising efforts?

DCLG Member Discussion

The DCLG discussed ways to increase productive collaborations between NCI and the community with a focus on areas with the highest return on investment. During this session, the DCLG defined collaboration and positive outcomes and identified variables critical to success.

There are many benefits associated with collaboration, specifically with the advocacy community. Possible immediately foreseen benefits included the faster development of new infrastructure and tools needed for translational research, more efficient use of limited resources, increased community understanding of NCI's mission and goals, and increased levels of trust between NCI and the community. Possible longer term benefits included reduced cancer incidence, improved quality of life, increased and more diverse enrollment in clinical trials, more focus on patient-centered values, more early-stage cancer diagnoses, and better informed and more empowered patients

The DCLG also identified several elements that characterize successful NCI/advocacy collaborations. These elements included clearly stated and accomplished shared objectives, novel

approaches and outcomes, equitable distribution and definition of partner roles, processes reflective of partner cultures, and opportunities for organizational learning and improvement.

The DCLG discussed key variables which help lead to successful collaborations. These included mutual respect for collaborator skills/perspectives, transparency, adequate shared resources, dedicated participants, political will to see outcomes through, equal compensation, communication, people to facilitate, and assigned responsibility/authority. Facilitating this requires that several components be addressed in advance. These components identified by the DCLG include identifying shared goals for the collaboration; identifying shared expectations about roles and what will be achieved; creating processes that promote equitable partnership and foster transparency; developing opportunities to enhance shared understanding of partner organization and NCI organizational culture; and identifying and including critical stakeholders.

Exploring Community Priorities and Expectations Related to NCI and its Mission

The DCLG discussed advocacy community expectations of NCI and the community's research-related priorities. The first theme was that NCI lacks visibility in the community and there is little of understanding about NCI's mission and priorities. The board believes it is important for the NCI to educate the community not only about its successes, but at a more basic level about the Institute's mission and goals. The board commented that this could be done by many types of NCI representatives, including staff members, researchers, or community partners—anyone who knows what NCI is and how the community benefits from its activities. The group mentioned that it could serve as one conduit to do this, and holding meetings outside of the Bethesda area would help promote their ability to contribute to this need.

The DCLG discussed what the advocacy community expects from NCI. The group identified a community desire for NCI to serve as a convener to encourage trans-disciplinary collaboration. The DCLG believes the community would benefit from NCI serving as a one-stop-shop for communicating to scientists and the public about everything that is occurring in the cancer field as well as serve as a role model for involving advocates and reaching out to the public.

The DCLG identified several ways to enhance this effort. NCI could conduct grand rounds in different regions to educate community physicians about the Institute's trials. NCI funded researchers could take a more active role communicating the value of NCI in their work. This could be something as simple as including a slide about NCI in their presentations. The board also noted that NCI's Office of Communications and Education produces beautiful materials but many community members find this information too daunting, so the office could benefit from communicating in a way that is more understandable, accessible, and engaging to communities.

The DCLG discussed community expectations related to the additional \$1.26 billion in stimulus funding that NCI will receive through the American Recovery and Reinvestment Act (ARRA). The board expressed that a sense of urgency is felt in the advocacy community, and that they hope this money will be utilized to move research forward faster and make research more effective. The board recommended that NCI use this opportunity to create more accountability for grantees related to the reporting of data, levels of collaboration, and reporting on benefits identified or created for patients. The board identified a desire to see greater collaboration in the

research community as well as a need to see new researchers entering this field, so the DCLG hopes this money can help promote that. The board hopes the ARRA money can accelerate research on issues related to personalized medicine.

With regard to specific projects, the board hopes that NCI will focus on preventive vaccines and treatments that can be made available very quickly. Additionally, the board hopes that previously eliminated programs could be re-energized with these funds. The board also sees the potential for NCI to fund research in populations or in organ sites where mortality has remain unchanged for long periods of time. The DCLG indicated that NCI would benefit from increasing its marketing efforts and rebranding the Institute. This would increase community awareness of NCI efforts and hopefully enhance clinician and patient awareness of trial and treatment options.

A question was asked regarding the limits that NCI can place on grantees, and it was explained that the NCI may be subject to limitations in the requirements it can attach to its funding. The nature and source of these limitations will be investigated and reported to the DCLG.

Kennedy-Hutchinson Senate Bill

The DCLG received a copy of a Senate bill that Senators Kennedy and Hutchison had introduced on March 26. Its purpose is “to modernize cancer research, increase access to preventative cancer services, provide cancer treatment and survivorship initiatives.” The bill addresses translational research, biomarkers, early detection, tissue samples, and clinical trials. It includes provisions for tobacco cessation and early detection of colorectal cancer.

The Latino Population and their Cancer Experience

Presenter: Dr. Patrecia Chalela

Latinos are the largest minority group in the United States. Of U.S. Latinos, 40% are foreign born, 22% live in poverty, and 48% do not have health insurance (compared to 13% of non-Hispanic whites). Nearly 36% of Texas’s 24 million people are of Hispanic origin, and 85% of these Hispanics are Mexican American. More than half (56%) of the 3.8 million Texans who live in poverty are Hispanic, and 44% of Hispanic Texans lack health insurance. It is important to remember that the Latino population is not monolithic and researchers should avoid broad generalizations about this group.

In both the United States and Texas, cancer is the second leading cause of mortality in Latinos, who have lower survival rates than other populations for most cancers. In general, Latinos have lower incidence rates for all cancers combined, but they have higher incidence rates of cancers associated with infection, including cancers of the cervix, stomach, and liver.

Redes en Acción, the National Latino cancer research network, has developed a national network for research, training, and awareness. One of its programs is training culturally relevant health workers to serve as patient navigators and help Latinas with breast cancer access services. Redes en Acción is also studying why participation by Hispanics in clinical trials is so low. The results will be used to work with cancer center researchers to design trial protocols that are more culturally sensitive for Latinos.

The DCLG asked Dr. Chalela to share the results of the patient navigator project with the group. Group members also suggested that Dr. Chalela work with education organizations because low levels of education play a role in the population's lack of health care access.

NCI Director's Report

Presenter: Dr. John E. Niederhuber

NCI's 2009 operating budget is \$4,968,973, representing a 3% increase over the Institute's 2008 budget. This is the first increase in the budget since 2005. This budget increase will allow the Institute to extend its payline from the 12th percentile to the 16th percentile.

The American Recovery and Reinvestment Act of 2009 includes \$10.4 billion over 2 years to NIH to promote economic recovery. NIH will invest \$500 million in construction and repair of its facilities. Another \$1 billion will support construction and renovations in the extramural community. NIH will also use the stimulus funds to support challenge grants, grand opportunities grants, large shared instrumentation, and education programs.

NCI will receive an estimated \$1.26 billion of the stimulus funds to spend over the next 2 years. NCI will use some of the funds to support grant applications that it has already reviewed and judged to be meritorious and that can make a significant difference in 2 years. The Institute will also use its funds to increase its payline to the 22nd percentile for young investigators and to expand training in basic, clinical, and translational research. Other plans for the stimulus funds include supporting some of the challenge and grand opportunities grants not funded through the NIH Office of the Director. NCI will need to prepare for potential increases in applications after the stimulus funding period ends, especially if NCI's base budget does not increase substantially.

NCI will need to account in a transparent way for every stimulus dollar it spends. This will require an unprecedented level of reporting by grantees and their institutions. NCI will then assimilate and summarize this information for dissemination to NIH, the Department of Health and Human Services, and the White House. Dr. Niederhuber asked the DCLG members to communicate to their constituencies how NCI plans to use its stimulus funds.

It was predicted that the stimulus funds would accelerate the pace of discovery in cancer genomics, leading to findings that can be used to develop new targeted therapies. The funds could also be used to scale up the NCCCP and show how this model can enhance screening, education, and access to care. NCI will use some of the stimulus funds to accomplish some of the goals identified in its bypass budget.

The Texas Cancer Program—Challenges and Solutions in the State

Presenter: Mr. James Mansour

The Texas legislature approved a bill authorizing \$3 billion over 10 years for cancer prevention and research grants. The bill required that up to 10% of the funds be spent on prevention and that grantees provide 50% matching funds. Voters approved a constitutional amendment to permit the state to create the Cancer Prevention and Research Institute of Texas (CPRIT) to allow CPRIT to

issue \$3 billion of general obligation bonds over 10 years for cancer prevention and research grants.

The funds will encourage collaboration, provide direct economic benefit to the state, attract private sector support for commercialization, and recruit good researchers from other states. Texas could become a haven for excellent scientists and their teams at one of the state's universities or companies. Peer review panels (which must include advocates) will assess applications, probably in three cycles each year. The institute will probably emphasize translation and clinical research.

Public Comment

Russell Dilts, Senior Program Director, Oncology and NCCCP, Ascension Health, reported on the progress that the NCCCP has made possible at his institution. For example, the number of trials offered in the community and the number of patients participating in cancer clinical trials in Austin is increasing.

Ms. Torges of ACS expressed the hope that the DCLG would consider holding at least one of its meetings each year in a different part of the country. It would be helpful to provide as much notice to local advocacy organizations as possible so that they have more time to bring interested stakeholders together to meet with the DCLG.

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