

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

**MINUTES of the NCI DIRECTOR'S CONSUMER LIAISON GROUP**

**September 13–15, 2004**

The 27<sup>th</sup> meeting of the National Cancer Institute (NCI) Director's Consumer Liaison Group (DCLG) was convened at 8:00 a.m., September 13, 2003, at the Holiday Inn Select, Bethesda, Maryland. Mr. Doug Ulman presided as Chair.

**Members Present**

Mr. Doug Ulman, Chair

Ms. Peggy L. Anthony

Ms. Vernal H. Branch

Mr. William P. Bro

Ms. Lourie Campos

Ms. Nancy Davenport-Ennis

Dr. Beverly Laird

Dr. Sylvia M. Ramos

Mr. Eric Rosenthal

Ms. Mary Jackson Scroggins

Ms. Sue Sumpter

Dr. Marisa Weiss

Ms. Celeste Whitewolf

Col. (Ret.) James E. Williams, Jr., USA

**Speakers:**

Mr. Doug Ulman, Chair, DCLG

Ms. Vernal Branch, DCLG

Ms. Elisabeth Handley, Acting Director, Office of Liaison Activities, NCI

Ms. Cherie Nichols, Director, Office of Planning and Assessment, NCI

Ms. Cynthia Dwyer, Senior Grants Management Specialist, NCI

Mr. John Hartinger, Associate Director of Budget and Financial Management, NCI

Dr. Marisa Weiss, Chair, DCLG Working Group to Facilitate Dialogue

Dr. Edward Maibach, Director, Center for Strategic Dissemination, NCI

Dr. Rafael Gonzalez-Amezcuca, NIH Director's Council of Public Representatives

Mr. James Kearns, NIH Director's Council of Public Representatives

Dr. Julia Rowland, Chief, Office of Cancer Survivorship, NCI

Col. (Ret.) James Williams, Jr., DCLG

Dr. Nada Vydelingum, Deputy Director, Center to Reduce Cancer Health Disparities, NCI

Dr. Andrew von Eschenbach, Director, NCI

**NCI Office of Liaison Activities Staff**

Ms. Nancy Caliman, Executive Secretary, DCLG

Ms. Brooke Hamilton, Professional Societies Liaison and CARRA Program Analyst

Mr. James Hadley, Advocacy Program Manager

Ms. Elisabeth Handley, Acting Director

Ms. Jane Jacobs, CARRA Program Manager

Ms. Devon McGoldrick, Communications Intern

Ms. Elizabeth Neilson, CARRA Program Coordinator

Ms. Linda Ticker, Program Assistant

Ms. Sandra Williams, Emerging Leader Fellow

**Monday, September 13, 2004 – OPEN**

**I. WELCOME AND SELF-INTRODUCTIONS**

Mr. Doug Ulman thanked the DCLG members for participating in this meeting.

**Conflict of Interest Statement.** Mr. Ulman reviewed the rules governing confidentiality and conflict of interest, and Ms. Nancy Caliman determined that a quorum was present.

**Introductions.** Mr. Ulman asked DCLG members to divide into pairs and find out what their partners would change, if they could change one thing that would improve the lives of the people they represent. The DCLG members then introduced their partners to the group. Mr. Ulman asked the other meeting participants to introduce themselves and expressed appreciation to the NCI staff who help make the DCLG's activities run so smoothly.

**II. REVIEW OF THE FUTURE OF THE DCLG WORKING GROUP PROCESS**

Ms. Branch provided an overview of the DCLG's recent activities.

On April 24, 2002, the DCLG convened the Future of the DCLG Working Group to determine whether to advise the NCI Director Dr. Andrew von Eschenbach to continue or dissolve the DCLG and, if the group were to continue, identify optimal mission, goals, and structure. The Working Group began by interviewing advocacy groups and NCI staff members to determine their perceptions of the DCLG. NCI staff believed that the DCLG was valuable but had difficulty citing how it had made a difference. Advocacy groups knew that the DCLG existed but did not know what it did.

Following these interviews, the Working Group met with Dr. von Eschenbach, on June 7, 2002. The Working Group explained that the DCLG had not been fully successful in achieving its mission. They noted that the advocacy community needed to feel involved in priority selections, and the DCLG should focus on priorities identified as important by both the advocacy community and the NCI Director. Working Group members suggested that the DCLG would be more effective if its members were involved in the NCI planning process early on, and this would allow DCLG members to better communicate NCI progress to the advocacy community.

On September 12, 2002, the DCLG recommended to Dr. von Eschenbach that the DCLG survey the advocacy community, assemble a database of advocacy organizations, and develop a process for ongoing communication with the advocacy community. Dr. von Eschenbach gave his approval for the survey and a contractor was hired to develop and field the survey instrument. The DCLG received the results on July 23, 2003.

Of the 152 advocacy organizations contacted, 80 responded to the survey. Many of these groups were small, with databases of fewer than 10,000 individuals. These respondents agreed that NCI is having an impact on clinical trials and reducing the cancer burden, but it is less effective in translating research on healthcare disparities into community interventions and communicating how research priorities are set. The advocacy community wanted the DCLG to foster

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collaboration and work with NCI to develop strategies and priorities. Most respondents agreed that research, clinical trials, and survivorship are important issues.

The Working Group met with the full DCLG and NCI leadership on September 24, 2003, and recommended that the DCLG play a strategic and collaborative role in the following priority areas: survivorship, clinical trials, and health disparities. At its September 2003 meeting, the DCLG agreed on the appropriate DCLG composition and operating procedures.

**NCI and the Cancer Advocacy Community (CAC).** Ms. Davenport-Ennis suggested that the advocacy organizations that were surveyed and those represented by DCLG members invite NCI to their national or regional meetings.

Ms. Handley explained that more than 80 percent of the current CARRA members have now participated in NCI activities. The Office of Liaison Activities (OLA) is finding opportunities at NCI for advocates to participate in the Institute's daily activities, which is innovative for a Federal government agency.

Ms. Handley explained that the DCLG was created to provide advice and recommendations to the NCI Director. In contrast, CARRA members are involved in the Institute's daily activities. For example, they review publications and serve on peer review panels alongside scientists. Mr. Ulman added that the DCLG's role is not to criticize NCI, but to provide support and assistance. Putting the immense power of the advocacy community behind NCI will expedite the Institute's research and activities.

**Survivorship as a Priority.** Dr. Ramos was surprised that only 57 percent of advocacy organizations said that survivorship was an important issue for their organization. Col. Williams noted that this might be explained by the different definitions of survivorship used by different groups. Dr. Weiss added that the advocacy organizations were asked to list their highest priorities, so their responses do not mean that they do not care about survivorship.

Mr. Ulman explained that the DCLG had been instrumental in including survivorship among NCI's Extraordinary Opportunities (proposals for Extraordinary Opportunities are sent to the Director for consideration in the following year's Bypass Budget). Dr. Julia Rowland has agreed to include the DCLG in the Survivorship Extraordinary Opportunities leadership team.

Mr. Ulman noted that many of the organizations that responded to the survey are very small and have little time available to learn about NCI's activities. The DCLG can provide an important service by becoming spokespeople for both the Institute and the cancer advocacy community (CAC). Ms. Elisabeth Handley suggested that the DCLG consider how to communicate what happens at NCI to the CAC.

Ms. Caliman noted that when the survey results were presented to Dr. von Eschenbach, he asked the DCLG to focus its activities on three priorities: improving collaboration between NCI and the CAC, health disparities, and survivorship. He asked, however, that the DCLG not address clinical trials because NCI now has a Clinical Trials Working Group that has advocacy

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representation (including Mr. Mike Katz, a former DCLG member). The survey report is available on the DCLG Web site (<http://la.cancer.gov/dclg.html>).

**Providing Access to Information.** Ms. Whitewolf pointed out that many people do not have a computer or know how to use one. They need help gaining access to the Internet. Ms. Handley noted that the DCLG Working Group to Facilitate Dialogue has struggled with this issue and plans to turn to the CAC for assistance in solving this problem.

Dr. Weiss explained that the DCLG's Working Group to Facilitate Dialogue is proposing a Web site as a communications vehicle between NCI and the CAC because this platform is interactive and can be accessed by people in remote areas. But the Working Group is also considering other means of communication, including a summit where NCI and the CAC can learn from one another how to cross the digital divide.

Ms. Whitewolf suggested looking outside the medical community for expertise in providing access to information on the Internet. The high-technology industry might be able to offer assistance in this area. Ms. Branch added that information can be communicated through video and telephone conferences.

Ms. Davenport-Ennis suggested that the DCLG partner with the National Library Association to set up access points for the uninsured, under-insured, and homeless.

Col. Williams emphasized the need to communicate to the public the importance of obtaining information on cancer. Until people understand this, they will not seek out the information, regardless of how it is provided.

**Communications.** In response to a question from Mr. Rosenthal, Ms. Caliman explained that the DCLG last prepared an annual report in 2002 and that although it was not required to produce such a document, it would be a good idea to do so. Mr. Ulman said that the DCLG would produce an annual report to communicate the group's accomplishments.

Mr. Rosenthal suggested that DCLG members exchange information on their own organizations, including objectives, meetings, and other activities. Ms. Caliman explained that a roster has been distributed with contact information on all DCLG members (this information is not shared beyond OLA and the DCLG). Members can use this information to communicate with one another. In response to a suggestion from Mr. Ulman, Ms. Caliman offered to determine whether the DCLG Listserv can be used to communicate about DCLG members' organizations. She noted that DCLG members are also free to set up their own e-mail distribution list for this purpose.

Ms. Handley announced that NCI's *Cancer Bulletin* was about to publish a story on the DCLG and name the new DCLG members. This publication has a circulation of 17,000 and DCLG members should distribute the article to their own constituencies.

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**Survey Responses.** Ms. Scroggins emphasized the importance of communicating with the organizations that responded to the DCLG survey. If the DCLG disappoints these agencies, this will further erode their confidence in NCI.

Ms. Campos wondered why almost 40 percent of organizations did not respond to the survey. Ms. Branch explained that many were very small grassroots groups that have little time to respond. Once the DCLG can point to more accomplishments, more organizations will be willing to complete future surveys.

Dr. Laird suggested sending the survey out again to those who did not respond. She said that the response rate to the survey is not sufficient to demonstrate that the responses received are truly representative of the advocacy community's perspectives.

Mr. Ulman encouraged every DCLG member to review NCI's list of advocacy organizations. DCLG members with some connection to the non-responding agencies should try to reach out to those groups.

### **III. LUNCH**

The meeting adjourned for lunch and reconvened at 1:30 p.m.

### **IV. ORIENTATION TO NCI**

**a. History, Mission, Goals, and Structure of NCI.** Ms. Elisabeth Handley, Acting Director of the Office of Liaison Activities, explained that her presentation was designed to help DCLG members understand how NCI works so that they would be able to make recommendations to the NCI Director about activities within the Institute's sphere of influence.

She reported that NCI was established in 1937 and became part of the National Institutes of Health (NIH) in 1944, after Congress passed the Public Health Services Act. In 1971, NCI gained special status through the National Cancer Act, which stated that the NCI Director was to be appointed by the President and that NCI could make budget requests directly to the President. All other NIH Institute and Center directors are appointed by the NIH Director, who is also appointed by the President, and most Institutes must submit their budgets to the Office of Management and Budget (OMB).

NCI's mission is to be the Federal government's principal agency for cancer research and training. NCI conducts and funds cancer-related research and is the only Federal agency focused exclusively on this area. NCI does not provide medical care (except through clinical trials), issue regulations, provide treatment guidelines or screening recommendations (with a few exceptions), lobby Congress, set insurance coverage policies, or handle reimbursement issues.

NCI is part of the Executive Branch of the Federal Government and is an agency of the Department of Health and Human Services (DHHS). Because NCI is funded by tax dollars, it can only pursue activities that are within its mission. NCI is the largest of the 27 Institutes and Centers that make up NIH.

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NCI has five deputy directors and seven extramural and intramural divisions. The five extramural divisions work with researchers around the country and represent approximately 80 percent of NCI's budget. The two intramural divisions conduct research at NCI representing 15 percent of the budget. OLA and other offices and centers within the Office of the Director support the functions of staff in the seven divisions. More detailed information on NCI's structure is available on the Internet at <http://www.cancer.gov/>.

The DCLG is one of eight Federal Advisory Committee Act (FACA) committees that advise NCI. In addition to the DCLG, these committees are the Board of Scientific Advisors, Board of Scientific Counselors, National Cancer Advisory Board, President's Cancer Panel, Advisory Committee of the Director, NCI Initial Review Groups, and Special Emphasis Panel. All of the committees have public members, including two former DCLG members.

NCI's planning process is driven, in part, by the NCI Director's Challenge goal—to eliminate the suffering and death due to cancer by 2015.

**Discussion.** Col. Williams asked about the Bypass Budget. Ms. Cherie Nichols explained that the National Cancer Act gave NCI the authority to bypass the normal budgetary channels and submit a budget directly to the President and Congress. NCI therefore prepares two budgets: the Bypass Budget, which is both a plan and a budget, and a regular budget, which is submitted to OMB through DHHS. The Bypass Budget is the NCI Director's professional judgment budget, reflecting the activities he believes are needed and the amount of money needed to conduct these activities. The Bypass Budget is submitted directly to the President, without any changes by intermediaries. NCI is the only NIH Institute with this authority.

Col. Williams asked what this authority has accomplished for the cancer community. Ms. Nichols responded that the cancer research agenda has grown tremendously since the passage of the National Cancer Act. But except for one year, NCI has never received the amount requested in the Bypass Budget. NCI receives its appropriations through the same process as every other NIH Institute and Center.

Mr. Ulman believes that the CAC does not understand what does and does not happen as a result of the Bypass Budget. The more the CAC is "brought into the fold," the more grassroots support NCI will receive to protect its unique authority.

Dr. Weiss emphasized the DCLG's role as an honest broker. The DCLG must remain politically neutral to preserve its credibility.

**b. Strategic Directions for NCI.** Ms. Cherie Nichols, Director of the Office of Science Planning and Assessment (OSPA) explained that the OSPA does science planning and facilitates implementation of these plans. OSPA also evaluates and assesses programs.

Dr. von Eschenbach established the Challenge Goal approximately one year ago. He believes that the Challenge Goal can be met because the financial resources, intellectual capacity, and enabling technologies needed are now available. But accomplishing the goal will also require a more complete understanding of the causes of cancer and the biological mechanisms of cancer

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initiation and progression, prevention to defend against cancer, early detection to make successful treatment possible, and improved quality of life for cancer survivors.

**Discussion.** Ms. Sumpter asked about the role of insurance in the Challenge Goal. Ms. Nichols replied that Dr. Mark Clanton, an NCI Deputy Director, is discussing with the Centers for Medicare and Medicaid Services (CMS) the possibility of reimbursing for care provided through research and clinical trials. If CMS agrees to cover these services, other third-party payers would be likely to follow suit. NCI also collaborates with the Food and Drug Administration (FDA) to move drugs more quickly through the pipeline.

**2006 Bypass Budget.** Ms. Nichols provided a preview of the 2006 Bypass Budget. Strategic investments in cancer prevention will include tobacco control research and development and energy balance research. Tobacco accounts for 30 percent of all cancer deaths, and obesity is involved in 14 percent of cancer deaths in men and 20 percent in women. Half of all deaths could be prevented if people stopped smoking and achieved energy balance.

Dr. Ramos asked Ms. Nichols to define "energy balance." Ms. Nichols explained that the energy an individual takes in should balance the energy expended. Ms. Nichols promised to include a definition of "energy balance" in the 2006 Bypass Budget.

The 2006 strategic investments in early detection include screening trials and a lung cancer screening library. In the area of prediction, NCI plans to focus on risk prediction markers and models for individual cancer risk and success of treatment. Several of the milestones in the 2006 Bypass Budget under overcoming cancer health disparities came from the Progress Review Group (PRG) report on this topic. One of these milestones is to provide cultural competence training to providers.

A blue ribbon panel is looking into the feasibility of integrating clinical trials that are supported by NCI. NIH is very interested in a national clinical trials system that collects data on trials that are and are not successful. Too many clinical trials are repeated because data on earlier, unsuccessful trials were never published.

In the area of advanced technologies, NCI plans to address bioinformatics infrastructure and tools. A quantum leap has occurred in genomics, but many different platforms were used that make it impossible to share data. NCI is working to ensure that data on genomics and proteomics can be shared.

Under integrative cancer biology, the Bypass Budget calls for an understanding of what occurs in the tumor's micro and macro environments. Molecular epidemiology is a large area, and includes expanding our understanding of specific types of cancer and how behaviors and environmental risk factors for cancer interact.

The 2006 Bypass Budget will be issued for external review. OSPA would welcome input from the DCLG, which can help ensure that NCI receives input from the community. OSPA plans to use the new *NCI Listens and Learns* Web site to obtain input on the Bypass Budget.

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**Other Planning Activities.** Between 1998 and 2004, NCI formed 11 PRGs to do disease-specific planning on 17 major cancer sites. All of these reports are now complete and available on NCI's Web site. These reports provide recommendations to NCI for national agendas in each disease. More than 1,000 scientific experts and consumer advocates participated in the PRG meetings. A progress report was just completed on the prostate PRG recommendations, which were the first to be issued.

OSPA has spent the last 2 years planning. The office now needs to move these ideas to results and is currently developing a 5-year strategic plan. NCI's annual strategic plan comes from the Bypass Budget. NCI's Executive Committee decided to develop integration and implementation teams to quickly implement activities in certain areas. Teams are currently being developed for imaging, lung cancer, bioinformatics, and rare and lethal cancers. The CAC can provide advice and suggest ways to involve stakeholders in the activities of these teams. Ms. Nichols would appreciate advice from the DCLG on how to accomplish this.

**Discussion.** Mr. Ulman expressed the DCLG's appreciation to Ms. Nichols for OSPA's frequent use of consumer input.

Ms. Whitewolf asked about the potential impact of the November election on the Bypass Budget. Ms. Nichols explained that the Bypass and regular budget are completed approximately 18 months in advance. Fiscal year 2004 ends September 30, and the Bypass Budget for 2006 will be completed on October 30. NCI is affected by changes in the administration, but every recent President, including President Bush, has strongly supported the elimination of cancer.

Ms. Whitewolf asked how the Bypass Budget addresses the significant number of cancer deaths due to tobacco and obesity. Ms. Nichols explained that the Bypass Budget includes milestones with budget amounts. NCI hopes to reduce the number of cancer deaths due to tobacco and obesity through the initiatives in which it proposes to invest.

Ms. Sumpter noted that NCI does not issue screening recommendations, but it has a goal regarding early detection. Ms. Nichols explained that NCI conducts research on screening modalities. Prevention guidelines are then developed by NCI's sister agency within DHHS, the Agency for Healthcare Research and Quality (AHRQ). AHRQ uses the results of NCI's research to develop guidelines. The one exception is NCI's guidelines on mammography.

Ms. Scroggins asked how research results from NCI are translated into action. Ms. Nichols replied that NCI can share its results with CMS and ask CMS to consider funding the services shown to be effective by the research evidence. Although NCI does not develop guidelines, it does influence their adoption and it plans to do more of this in the future.

Dr. Ramos asked about implementing the recommendations concerning cancer health disparities. Ms. Nichols explained that whether the activities in the Bypass Budget are conducted depends on the budget that NCI actually receives, and NCI almost never receives all the funds that it requests. Program staff prioritize the list of activities and select those that can be accomplished within the actual budget. NCI is encouraging other cancer research funders to help support the activities that its budget will not accommodate.



Mr. Ulman noted that once the CAC provides input on the Bypass Budget, it should be informed of the results of the plan. Ms. Nichols explained that NCI now publishes an annual report focusing on its accomplishments and showing what taxpayers receive for their investment in cancer research.

In response to a question from Ms. Whitewolf, Ms. Nichols said that NCI typically receives 20 percent less than it requests in the Bypass Budget document.

Ms. Davenport-Ennis wondered whether the CAC's activities are integrated into NCI. Ms. Nichols explained that prior to last year, OSPA developed a draft Bypass Budget and distributed it for comment to 400 individuals and organizations. The community complained that its input at this stage had little value because the document had already been developed. So OSPA decided to ask for comments while it was still shaping the document. OSPA now distributes the current Bypass Budget and asks for feedback. This input is used to shape the next Bypass Budget. Ms. Nichols noted that the DCLG was instrumental in ensuring that survivorship was addressed in the 2004 Bypass Budget. OSPA does incorporate comments from the CAC but would welcome the DCLG's assistance in coalescing the community's comments, perhaps in the form of a two- or three-page letter summarizing recommendations for changes or improvements to the document. Ms. Nichols encouraged DCLG members to call her or her colleague Kathie Reed if they have any ideas about this.

**c. Break**

**d. Funding Mechanisms and Approval Process.** Ms. Cynthia Dwyer, a grants management specialist, began her presentation by showing a video on progress in cancer research over the last 100 years.

Ms. Dwyer reviewed NCI's 2003 and 2004 budgets. In FY 2004, NCI's total budget allocation was \$4.7 billion and it spent \$3.2 billion on grants, compared to a \$4.6 billion budget and \$3 billion for grants in 2003. In the last 5 years, NCI's Grants Administration Branch has obligated and funded an average of 7,000 grants each year. The President's 2005 budget requests an increase of \$134 million over the Institute's 2004 allocation.

DHHS has three main funding instruments: grants, cooperative agreements, and contracts. When NCI awards a grant, it has no substantial programmatic involvement in the project and no expectation of a specified service or end product. In contrast, a cooperative agreement involves substantial programmatic involvement on the part of NCI and is usually the result of an application submitted in response to an announcement. The Grants Administration Branch does not issue contracts. NCI issues approximately 59 types of grant mechanisms, including Cancer Centers, Specialized Programs of Research Excellence (SPOREs), research career programs, research project grants (which include R01 awards), Ruth L. Kirschstein National Service Awards, and cooperative agreements. Each mechanism has its own policies and guidelines.

Non-profit and for-profit organizations, colleges and universities, hospitals, research foundations, governments and their agencies, and faith-based organizations may apply for NCI

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grants. When an individual from one of these institutions has an idea for a grant, he or she prepares an application, which is submitted by the organization's business office to NIH. The NIH Center for Scientific Review (CSR) assigns the application to a specific study section for review, as well as to the appropriate Institute/Center. The IRGs are composed of non-federal scientists and directed by federal scientific review administrators (SRAs). NCI also has several Initial Review Groups (IRGs) that review certain types of basic and clinical research and education and training grant applications.

When an IRG reviews an application, it assigns a score if the application is judged to have scientific merit. All of the reviewers assign numeric scores to the application, and a priority score is developed based on the average of the reviewer scores. The National Cancer Advisory Board (NCAB) then reviews the application, unless less than \$50,000 in direct costs is requested. The application is then reviewed by an NCI program director who prepares funding recommendations, usually based solely on score priority. The entire funding process takes approximately 9 months. Once the award is made, the program director reviews the grant's annual progress and an NCI grants management officer monitors the grant's administrative and fiscal aspects.

In FY 2003, NIH reviewed 34,710 new, continuation, and supplemental applications and awarded 10,393 grants. That year, NCI awarded 7,500 grants valued at \$3 billion. In 2003, the top 80 grantee organizations received three-quarters of the grant dollars available from NCI.

NCI has been at the forefront of electronic grants administration for many years. This fiscal year, the Grants Administration Branch reviewed about 80 percent of all applications electronically.

Ms. Dwyer distributed a booklet on the NCI grants process, *Everything You Wanted to Know about the NCI Grants Process*, which is also available at <http://www3.cancer.gov/admin/gab>.

**Discussion.** In response to a question from Ms. Branch, Ms. Dwyer explained that NCI does not limit the amount that a single institution or investigator can receive. Mr. John Hartinger added that no more than 100 percent of an investigator's effort may be funded by grants.

Ms. Dwyer noted that IRGs typically have 12–18 individuals. The amount of time it takes to review a single application depends on the type of mechanism and whether it is for a competing or non-competing grant. Applications for program projects, such as SPOREs, can take 3–5 days to review. NCI has worked hard to streamline the grants process for non-competing applications, which may take half an hour to review.

Ms. Branch stressed the importance of including advocates in the IRGs, as they bring an important perspective. Col. Williams explained that advocates do sit on peer review panels, but Ms. Handley clarified that this is only when NCI is conducting the reviews. When the NIH CSR does the reviews, advocates are not involved.

Ms. Sumpter asked whether the priority scores are weighted to reflect the NCI Director's focus. Ms. Dwyer replied that many applications are submitted in response to program announcements

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and requests for proposals (RFPs) that are issued in direct response to the Director's goals. Priority scores are based on the science presented in the application but other factors are often taken into account when funding decisions are made.

Ms. Sumpter noted the difficulty of applying for grants. The process is so time consuming that many groups do not apply. Col. Williams noted that NCI provides assistance with grant preparation. Ms. Dwyer added that NCI continues to try to streamline the process. Dr. Weiss emphasized that NCI funds research and training grants. It does not fund the provision of services or care, except as part of research. Grassroots organizations will only be successful in applying for an NCI grant if they have a research engine.

Dr. Laird pointed out that as a CARRA member, she has sat on peer review panels. The scores of CARRA members have the same weight as the scores of the scientists. These advocates discuss any issues in the proposed project that might affect the patient. Moreover, issues concerning the inclusion of women, children, and minorities in the research must be discussed separately from the scientific merit.

**e. Building an NCI Budget.** Mr. John Hartinger, Associate Director of Budget and Financial Management, NCI said that both NCI and the rest of NIH are confronting the challenges associated with being in the post-doubling era. In the last 5 years, NCI's funding almost doubled from \$2.5 to \$4.8 billion, but funding is likely to increase yearly by only 2–3 percent for the foreseeable future. In the early 1970s, NCI represented a third of the NIH budget, but this has decreased to 18–20 percent in recent years. The President's current budget calls for a 2.8 percent increase in NCI's budget.

NCI is unique in that it prepares two budgets. Both travel on a parallel track but will converge at OMB in the next few weeks. The Secretary of DHHS and the Director of NIH set guidelines for the level of the traditional budget request. NCI then prepares the document, which goes forward with the rest of the NIH budget to OMB. The Bypass Budget is submitted directly from Dr. von Eschenbach to the President and OMB.

NCI starts formulating its OMB request approximately 30 months in advance. The 2006 Bypass Budget will be issued soon and NCI is working with NIH on the 2006 traditional budget. At any point in time, NCI is executing, presenting, and formulating three different budgets. After the budget is formulated by OMB and presented to Congress, NCI receives its funds and starts to make grant and contract awards.

Because part of NCI's funding has already been allocated for non-competing grant increases, and other commitments, NCI actually has \$2 million less than last year to support new initiatives. At the same time, the pool of applicants has been increasing and grants are becoming more costly. As a result, the application success rate is dropping.

Approximately 14 percent of NCI's fiscal year 2005 budget is uncommitted and available for new decisions. The 86% committed include non-competing grant costs, ongoing research contracts, ongoing intramural programs, and administrative and infrastructure support. All

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competing awards need to be funded from NCI's uncommitted funding estimated at \$668 million.

NCI is putting a great deal more emphasis on long-range financial planning. Last January, several advisory groups met with NCI leadership to discuss funding options. Last year, the budgets for all NCI divisions were cut by 5 percent. This year, the Director held budget hearings with each division director and office head to identify the highest priority programs and those that could be cut, so that this year's cuts will be based on programmatic priorities. NCI is also working to leverage partnerships through matching funds.

Last year, Dr. von Eschenbach's Bypass Budget announced to the public that it requested \$6.2 billion to take advantage of the realistic opportunities available in cancer research. This was the amount requested in the Bypass Budget. NCI received \$4.8 billion.

**Discussion.** In response to a question from Col. Williams, Mr. Hartinger explained that the President's budget for 2005 is \$4.87 billion. The House has passed this budget but the Senate has not yet acted on it. NIH determined that NCI was to submit a 2-3 percent increase.

The Bypass Budget allows NCI to express its scientific opportunities publicly. NCI received the amount requested in this document only once, in 1982, when it actually received more than it asked for. Dr. Ramos clarified that the Bypass Budget reflects what NCI would like to do.

Mr. Hartinger explained that the cancer community provides a great deal of input to the Bypass Budget about which scientific programs to include. The other budget is controlled by NIH, which specifies how much can be directed to each item. Mr. Hartinger believes that the Bypass Budget is a useful document because it shows what NCI would do with additional funds.

Ms. Branch asked about consumer involvement in the oversight of grants. Mr. Hartinger explained that NCI's program directors have primary responsibility for the science of grant-funded projects. Ms. Dwyer added that if program directors suspect that funds are being misused, they can reduce future funding. When problems arise, the directors often do site visits.

In response to a question from Ms. Whitewolf, Mr. Hartinger explained that NCI's entire budget supports research, although some of the funding is for administrative functions that support research indirectly.

Ms. Davenport-Ennis noted that NCI must spend all of its allocation in a single fiscal year, and cannot carry any funds over to the next year. Mr. Hartinger explained that NCI previously had the authority to carry funds over but it can no longer do so.

Ms. Scroggins asked about the cost of preparing dual budgets, and Mr. Hartinger replied that this probably costs NCI approximately \$1-2 million when staff time and community input is considered.

Ms. Handley emphasized that the Bypass Budget is a good communication tool and Ms. Nichols is trying to make it more accessible so that the lay public can understand NCI's priorities. In

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NCI's traditional budget, it cannot discuss what it would do with more money, but it can do so in the Bypass Budget. Sometimes parts of the Bypass Budget are discussed by the Congress and requests are made for additional funding for NCI. In addition, the scientific community reads the Bypass Budget to plan future research.

Mr. Ulman expressed the need to educate the community about the opportunities described in the Bypass Budget. The CAC would then invest the time and energy needed to support these initiatives.

## **V. INPUT FROM THE PUBLIC**

Ms. Caliman explained that the DCLG provides an opportunity at each meeting for public input and asked whether anyone wanted to address the Group. No member of the public asked to provide input.

**Adjournment.** The meeting adjourned at 5:00 p.m. and reconvened at 8:30 a.m. on Tuesday, September 14, 2004

### **TUESDAY, September 14, 2004 -- OPEN**

## **VI. FACILITATING DIALOGUE—NCI LISTENS AND LEARNS WEB SITE**

**Report from DCLG Working Group to Facilitate Dialogue.** Dr. Weiss reported that when Dr. von Eschenbach became Director of NCI, he emphasized the need to deliver cancer research discoveries to the people whose lives are affected by cancer in the most responsible, compassionate way. The DCLG's challenge was to identify its role in this process, and it concluded that it needed to represent the voices of people affected by cancer to NCI. The DCLG also needs to make it possible for the CAC to review NCI's programs and provide input to enrich the quality, relevance, and potential impact of NCI's activities.

The DCLG decided to create a dialogue between NCI and the CAC in a way that would be accessible to both sides at any time of day or night. The communications vehicle needed to allow for quick updates and anonymous participation. The DCLG decided to start with the *NCI Listens and Learns* Web site.

**Demonstration of the Site.** Ms. Handley demonstrated the prototype of the Web site. In the future, the URL will be <http://NCIlistens@cancer.gov>. NCI will post a question on the site and ask for comments from the CAC and members of the public. Currently, NCI plans to post one new question every month. After opening the site for comments for a period of time, NCI will post a summary of responses and its own response to these comments. Users will be able to see all of the comments that have been posted. To make a comment, they must register.

Although the Federal government and NIH already seek advocate input, what NCI and the DCLG are proposing is revolutionary in that NCI will report back to the community how it will respond to its input and will make all comments visible. This represents an unprecedented level of transparency and accountability.

Ms. Sumpter wondered if the site would be easy to find and which advocacy groups would join the dialogue. Ms. Weiss explained that the DCLG and NCI have developed a marketing plan to build awareness and invited advocacy organizations on NCI's list, as well as individuals, to participate. Dr. Weiss requested input from DCLG members on the marketing plan. Several NCI directors have expressed an interest in posting questions on the site, including Ms. Nichols.

Dr. Ed Maibach explained that the current DCLG members must ratify the decisions of the previous group. NCI believes that with good input from communities of affected individuals, NCI will make better decisions about which paths to pursue. This process is a tactic to obtain that input and has never been tried before.

To find the Web site, the user could do a Web search or visit NCI's Web site [www.cancer.gov](http://www.cancer.gov). NCI's homepage will probably feature a direct link to the site. Organizations and individuals will have the option of signing up to receive e-mail whenever a new question is posted.

Dr. Ramos asked if the site could be presented in languages other than English. Dr. Maibach replied that this issue had been considered but it was important to first determine how resource intensive the site was. It is possible that the site will "open up the floodgates of public comment" in a way that NCI and the DCLG cannot summarize in a timely, accurate manner. The bias was toward trying to gain some experience with the process and identify financial resources to manage it well. At that point, incorporating other languages could be considered.

**CAC Organizations.** NCI's ability to have a significant number of CAC organizations enrolled in the dialogue will be critical to how it is perceived from the beginning. NCI will send an invitation to participate to its initial list of organizations and hope that a large percentage decides to do so. Mr. Ulman added that organizations would be asked to identify a single representative who will post comments on their behalf, so that smaller organizations are not overshadowed by large organizations. When large advocacy groups participate, they might pass on NCI's questions to their members for comment, and then summarize the comments for NCI.

Ms. Davenport-Ennis pointed out that many large CAC organizations have state chapters representing very diverse constituencies. The directors of these chapters should be allowed to participate in the dialogue directly. Dr. Maibach explained that the goal was to encourage a sense of democracy, so that each organization had the same opportunity to be heard. If large organizations were given many voices to respond, they would have an advantage over smaller organizations.

Mr. Rosenthal suggested that the issue was how an advocacy organization is defined and this depended, in part, on what was required to register. Perhaps a large organization, such as the American Cancer Society, should have a single central voice, but that voice could identify the chapters that provided the information. Alternatively, the chapters could respond through the consumer side of the site, noting that they represented parts of a larger organization.

Dr. Weiss pointed out that *NCI Listens and Learns* is flexible and if something did not work, changes could easily be made.

Dr. Ramos suggested that if small organizations perceived this forum as dominated by the larger organizations and their chapters, they would not participate. Local issues need to be addressed and smaller organizations need to have a say.

Dr. Maibach explained that currently, the plan was to summarize only the input from CAC organizations, not from the general public, because it was impossible to anticipate the amount of work, and therefore money, that would be required to adequately summarize feedback from the general public. However, the DCLG could still monitor public feedback.

The group Ms. Scroggins represents has partner members that are separate organizations under her group's umbrella. If her organization had to filter their comments, this would take time and might mute the process. She asked whether community-based organizations that are loosely linked to other organizations would be considered separate organizations.

Ms. Whitewolf wondered whether tribal governments, state government health divisions, and Indian representatives would be considered organizations. Ms. Sumpter suggested that if only the organizations that responded to the DCLG survey participated in the site, NCI would generate a highly skewed picture of the community's views. Ms. Handley explained that the advocacy organizations on NCI's list include many local and regional organizations. Although NCI plans to start with the 152 organizations on its list, it hopes to expand this list with the help of the DCLG. The organizations do not need to focus solely on cancer, as long as they have an interest in the issue. State and local organizations may participate.

Mr. Ulman stated that any organization with an interest in cancer that represents individuals affected by cancer would have an opportunity to join. If the DCLG decided to move ahead with this project, a high priority should be to increase the number of groups on the list. Each DCLG member would need to get the word out about the site. The opportunity to have hundreds of organizations participate is the DCLG's to take.

**Members of the Public.** Ms. Anthony asked about responses to patients who post questions on the site. Dr. Weiss replied that a moderator will review all comments and refer anyone seeking medical information to an appropriate resource, such as 1-800-4-CANCER. Ms. Handley explained that the moderator would be a contractor, as will the individual who prepares the summaries.

Ms. Campos was alarmed to hear that the comments of individuals would not be summarized. When individuals learn that their comments will not be summarized, they will interpret this to mean that their comments will not be heard. As a result, Ms. Campos would not be comfortable advertising this site on her organization's Web site.

Dr. Laird suggested that it does not make sense to collect data from the public if those data are not going to be used. Good qualitative data analysis software is available that counts key words and can provide an indication of public concerns. This software could be used to help summarize comments from the public.

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Ms. Scroggins emphasized the need to make it clear on the site that only the comments of CAC organizations will be summarized and the reasons for this decision. The site should also post a plan for getting the information for people who lack access to the Internet.

Mr. Ulman suggested opening the site only to the CAC at first. Dr. Weiss explained that many individuals are not connected to any organizations, and the Working Group had hoped to collect their input as well.

**Questions Posted for Comment.** Dr. Maibach said that no NCI program manager would be required to participate in the process. Dr. Maibach's office has already asked several program managers if they have topics that they are willing to post early on. If the site is very successful, program managers will want to participate. The DCLG will have the opportunity to determine whether NCI is asking appropriate questions. The same questions will be posed to both the CAC and individuals.

In response to a question from Ms. Whitewolf, Dr. Maibach explained that he is responsible for soliciting questions to pose on the site from NCI managers. At least half a dozen good issues have been submitted to start with, but Dr. Maibach will continue to encourage all of his colleagues to identify strategic decisions that could benefit from this type of input. Mr. Ulman added that the DCLG would review the questions that are posed on the site to ensure that they are appropriate.

Mr. Rosenthal asked if advocates could post discussion topics. Dr. Maibach replied that NCI would initiate all dialogue, but the DCLG has the right to formulate questions. Members of the public and CAC groups may submit suggestions for discussion topics, but they will not be able to post them.

**Marketing.** Mr. Ulman explained that the original marketing effort would be geared to organizations rather than individuals. Dr. Maibach added that NCI's Office of Communications (OC) developed the marketing plan, which was distributed to all DCLG members. NCI plans to promote the site through its listservs and direct mail to the 152 organizations identified for the survey. NCI will also approach the general public.

Ms. Whitewolf suggested that DCLG members promote the site to their constituents and encourage them to sign up as individuals.

Mr. Bro reported that the National Cancer Advisory Board, at a recent meeting, lamented the fact that NCI's budget would make it difficult to adequately promote CANCER.GOV and 1-800-4-CANCER. A survey had shown an overwhelming lack of public awareness of these resources. Perhaps the DCLG should first consider the role of the *NCI Listens and Learns* site in the context of the overarching question of how to better inform the public of these resources. When Mr. Bro discussed this issue with Dr. von Eschenbach after the meeting, the NCI Director suggested that the solution is not necessarily more money, but voluntary health organizations promoting the availability of these resources.



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**Results of Alpha Testing.** Col. Williams reported that on July 13, the Web site was tested at a SPORE meeting. NCI's SPOREs are an attempt to enhance translational research by bringing bench and clinical scientists together. A group of advocates involved in the SPOREs had the opportunity to test the *NCI Listens and Learns* site and provide their comments. Some concerns expressed included the following:

- People will use the site as a platform for personal, unrelated agendas.
- NCI will be overwhelmed with comments.
- It is difficult to discuss complex issues in a way that laypeople can understand so that they can provide quality feedback.
- Waiting 1–3 months for the NCI response might be too long.
- The schedule of response and discussion dates needs to be kept current.

Advocates also suggested including some graphics in the summaries to make them easier to follow. They were also concerned about those who lack access to the Internet. NCI does not yet have an answer to this problem, but hopes that this initial step will lead to other ways to communicate. This covers a great deal of what the DCLG and NCI hope to accomplish, but it does not achieve all of their goals. The DCLG must educate the public in how to use these tools and encourage the public to become computer literate and gain access to this medium.

**Motion-Approval of *NCI Listens and Learns* Web site.** Col. Williams moved that the DCLG accept the concept of the *NCI Listens and Learns* site. Ms. Branch seconded the motion, which was approved.

## VII. BREAK

## VIII. FACILITATING DIALOGUE—NCI LISTENS AND LEARNS WEB SITE— CONTINUED

**Next Steps on the Web Site.** Dr. Maibach suggested that the site be launched on a pilot basis initially. NCI will manage the contractor who will prepare the discussion summaries, and NCI and the DCLG will review the summaries and provide feedback. The summaries will then be posted for comments.

Dr. Maibach suggested that the DCLG create a revolving set of teams to monitor the dialogue for a single topic. DCLG members may choose to read through all of the postings and then review the contractor's summary, or they may decide to read the summary only.

Ms. Whitewolf and Ms. Scroggins wondered whether the DCLG would approve the questions to be posted. NCI managers will indicate how urgent their issues are but Dr. Maibach suggested that the DCLG could assist with prioritizing the questions. Dr. Weiss agreed, suggesting that the DCLG decide which questions have the highest priority for people affected by cancer.

**Initial Question.** Dr. Maibach explained that NCI's new Cancer Biomedical Informatics Grid (CaBIG), which is NCI's top strategic priority, will make it possible for the cancer research community to share data and collaborate in inter- and transdisciplinary ways that are not possible

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today. One application within CaBIG is CaMATCH, which collects details on a cancer patient's condition and provides a list of clinical trials for which she or he might be eligible.

Mr. Rosenthal pointed out that NCI's Cancer Information Service already provides information about clinical trials. Dr. Maibach explained that it was difficult for CIS staff to provide highly tailored matches. Some of the data for the system will be pulled from NCI's PDQ database, but the system will also draw on other information sources. Ultimately, NCI hopes to include drug industry trials in the system.

NCI would like to find out whether patients would be willing to enter their medical information into NCI's secure server in order to be matched with clinical trials. The dialogue could be used to collect perceptions of CaMATCH and, if perceptions are positive, how to position it.

**DCLG Working Groups.** Dr. Maibach recommended that the DCLG form working groups to address different aspects of the online dialogue. One of these groups should address marketing for the site but the first topic should not be posted until an aggressive effort has been made to recruit organizations for the dialogue. Launching the site prematurely could create bad will. Ms. Handley and Dr. Maibach would like to finalize promotion plans by September 24, so that promotion can begin shortly thereafter. The DCLG needs to determine how to launch the site.

The pilot will need to be evaluated to determine whether to continue the site, discontinue it, or continue it with modifications. The DCLG will also need to monitor how well the site is being received and understood. A broad outline of an evaluation plan has been created.

Ms. Handley suggested that the DCLG form working groups on the following topics:

- Operationalizing the online dialogue
- Promoting the online dialogue
- Evaluating the online dialogue
- Planning the Summit.

Dr. Maibach explained that in addition to Dr. Maibach's office, NCI's Office of Liaison Activities will help run the Web site.

**Soliciting Input from the General Public.** Ms. Whitewolf pointed out that the DCLG could not consider operational and other issues until it decided whether to solicit comments from both the CAC and the public, or only the CAC. Ms. Sumpter added that this decision was especially important because the proposed first question is more relevant to individuals than to groups. Dr. Maibach suggested reviewing the proposed criteria for including CAC organizations, and seeing whether organizations with which DCLG members are familiar would fit these criteria.

Dr. Maibach suggested that the proposed initial question is not pertinent only to individuals and the question will be expressed broadly enough to make groups feel that they have a valid point of view to express. Feedback from groups on this topic will be valuable.

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Col. Williams argued that men are not the strong supporters of advocacy that women are, so many men do not belong to advocacy organizations. It is therefore important to solicit input from individuals.

Dr. Laird suggested that once feedback from the public was solicited, even on a trial basis, it would be difficult to cut off. But Ms. Scroggins cautioned that if the public were permitted to participate, individuals must be told that their responses will be handled differently from those of CAC organizations.

Ms. Sumpter suggested that many advocacy organizations might not feel that they can represent all of their members adequately on an issue of this type.

Ms. Whitewolf proposed opening the site only to CAC organizations to start with. Dr. Ramos argued that the public should be involved from the beginning because their input is important. Ms. Handley agreed, noting that organizations might take positions that some of their members did not share. Allowing the public to post comments will provide an outlet for their opinions.

Ms. Scroggins pointed out that a large percentage of individual comments might come from members of organizations, because these individuals would learn of the site from the organizations to which they belong. But the site is also likely to attract those who are not connected to any organizations.

Mr. Ulman pointed out that the DCLG is the NCI's consumer liaison group representing both groups and individuals. During the beta test period, both tracks could be included and the analytical software mentioned by Dr. Laird could be used to summarize comments from the public.

Dr. Weiss asked whether it would be possible to summarize comments from both groups and individuals. Ms. Handley replied that this was a matter of resources. A request for proposals (RFP) for a contractor to summarize responses has been issued and NCI is now selecting the contractor. A separate solicitation has been issued for a moderator. If comments from both the public and the CAC organizations are summarized, the DCLG will have many more comments and summaries to monitor.

Ms. Whitewolf wondered whether any information would be collected on the individuals who signed up to determine whether a broad base of individuals was being reached. Ms. Handley explained that the site would allow people to register by providing their e-mail addresses, but no other identifying information. Providing participants with near-anonymity is the industry standard and people might not participate if they were required to provide personal information. Ms. Caliman added that NCI was not permitted to collect as much detail on individuals as on organizations because of privacy rules.

Mr. Rosenthal suggested launching the site in phases. Ms. Handley supported the suggestion, noting that this is a new endeavor and it is useful to gain experience before moving forward on a larger scale.

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Ms. Whitewolf argued against soliciting public comments without providing feedback from NCI. Ms. Handley explained that the summaries would be available to everyone. Members of the general public who participate would at least receive a "giveback" in the form of NCI's response to advocacy groups.

Dr. Maibach suggested that the options were to start with only CAC input or to start with input from both the CAC and the public. If both perspectives were obtained, the public should be told that, in the pilot phase, only comments from groups would be formally summarized and reasons for this decision should be provided. The site should also make clear that comments from the public would be monitored by the DCLG, NCI, and the CAC. A third option is to summarize the comments of both the public and the CAC. Ms. Whitewolf added as a fourth option starting with one track and adding the other at a later time.

Ms. Branch suggested summarizing the comments of one track during one month, and the other the next month. However, Ms. Sumpter pointed out that the number of public comments might be in the thousands, while the number from groups was likely to be much smaller. Ms. Handley explained that NCI and the DCLG have spent a great deal of time considering how to pitch the site to CAC organizations. It would not be good to ask them to sign up and tell them that their comments would only be summarized every other month.

Dr. Ramos believes that the public is likely to understand that their comments will not be summarized during the pilot phase and would be willing to wait to see what happens. Col. Williams suggested that the public might appreciate serving as a sounding board and might not be too concerned about having their comments summarized.

Mr. Ulman supported the option of soliciting comments from both the public and CAC organizations, and summarizing only the comments from the CAC. However, the Working Group on Operations should develop recommendations on how to summarize comments from the public. Dr. Maibach explained that the pilot phase would provide important information on how many resources were required to summarize the comments from the CAC.

Dr. Weiss pointed out that the summaries will be succinct and will not necessarily include every single comment. DCLG members can skim the comments to obtain a sense of the responses and make sure that the summary reflects the flavor of these responses.

Mr. Ulman recommended moving forward with both tracks. He suggested that DCLG members break out over lunch into three working groups focused on:

1. Operations—Discussion Leader: Ms. Branch
2. Promotion and marketing—Discussion Leader: Dr. Weiss
3. Evaluation and reporting—Discussion Leader: Dr. Laird.

## **IX. WORKING LUNCH**

After the working groups completed their discussions, Mr. Ulman suggested that they continue their work beyond this meeting. The other DCLG members agreed. The working group discussion leaders then summarized the discussions of their groups.

**Operations Working Group.** Ms. Branch reported that the Operations Working Group had proposed that one representative from each working group form a team to monitor the Web site for three months. Another team composed of different working group members would then take over for the next three months. The entire DCLG will need to see the summaries before they are posted.

Mr. Ulman added that the working group did not resolve the criteria for CAC organizations to participate in the dialogue. Ms. Branch noted that the group agreed that the organizations should be non-profits. The group will come up with guidelines for organizations to participate, and wants to make sure that national, regional, statewide, and local organizations are included.

The Operations Working Group agreed that the DCLG Working Group to Facilitate Dialogue should be dissolved, but that the group's members should be informed of progress on the initiative. Members should be thanked and asked to stay involved in a less formal way.

**Promotions Working Group.** Dr. Weiss explained that given NCI's limited resources, the promotion plan will have the "most bang for the buck" if DCLG members tap into their existing networks for an online promotional campaign. NCI would provide starter kits to help organizations promote the site, including a press release, e-mail letter, and links that can be inserted into Web sites. It will also be important to identify the most popular pages on cancer.gov for links and buttons for the site. DCLG members can promote the site at conferences they attend and other non-Internet activities in which they participate. NCI staff can also demonstrate the site at meetings they attend.

The Operations Working Group needs to decide when to launch the site and identify the most critical target audience for promotional activities. The promotional effort will begin when the site is ready to launch.

Col. Williams suggested that the general public will need a "hook" to bring them on board, and the best hook is likely to be the initial question. Dr. Weiss proposed doing some behind-the-scenes consensus building before launching the site publicly. If a group of CAC organizations are enthusiastic about participating, they could be asked to co-sign an invitation letter to the general public and other organizations. Ms. Scroggins suggested emphasizing that participants will receive something in return for participating—a response from NCI. Mr. Rosenthal proposed asking potential participants to help NCI so that it can better help them.

**Evaluation Working Group.** Dr. Laird explained that a planning model is helpful in developing an evaluation model. Dr. Laird proposed a logic model that lays out the broad goals and objectives and what is needed to achieve them. NCI has a contract with a company that conducts pop-up surveys, and the DCLG could use this company to solicit feedback on the Web site. Broad goals and objectives will include:

- NCI will obtain usable information from advocacy groups on issues for which NCI is considering options.
- The DCLG will help promote the site and act as an honest broker for the advocacy community.

To evaluate the site properly, the pilot needs to last at least a year. A survey of participants would be very valuable in determining whether groups believe that they are being asked to comment on important issues and are being listened to, and that the questions are being framed appropriately. If answers to a question from NCI show that participants do not understand the question, a process needs to be in place to make changes to the question.

The site will provide CAC groups with an opportunity to learn what consumers want. Moreover, the site could become a model for other ways to gather data at NCI.

**Launching the Site.** Ms. Scroggins argued that November is too soon to launch the site, and November and December are difficult times to attract attention. Ms. Whitewolf added that non-profits are busy with fundraising during the final months of the year. January or February might be a more realistic time to initiate the dialogue.

Ms. Branch suggested using the time between now and the launch date to begin promoting the site. For example, DCLG members could distribute information about the site at meetings they attend in the next few months. However, Dr. Weiss noted that promotion should not start before the site is ready because people need to have a good experience the first time they visit the site. Ms. Branch suggested telling CAC groups and the public to save the date when the Web site will officially open for business.

Mr. Rosenthal explained that the Promotions Working Group is considering planning the official launch to coincide with another event, such as the upcoming clinical trials summit. Col. Williams suggested that all DCLG members give the Promotions Working Group dates for upcoming meetings of which they are aware.

Mr. Ulman explained that the following must be accomplished prior to launching the site:

1. The first question must be chosen.
2. Criteria must be developed for organizations to participate.
3. The final promotion plan must be ready.
4. The final evaluation plan must be complete.

Ms. Handley added that once criteria for CAC organizations are developed, NCI and the DCLG need to reach out to these organizations. The site should not be launched until a certain number of organizations have signed up. OLA has drafted a letter to invite the groups, but it needs the DCLG's help to identify additional organizations.

Mr. Ulman recommended scheduling a full DCLG meeting via teleconference at the first available date (no sooner than 45 days following the current meeting). The group will address the four steps needed to launch the site. Between now and that meeting, the working groups should address these issues by teleconference.

Ms. Caliman noted that the groups invited to take the DCLG survey included a mix of national, regional, and state organizations, and a cross section of cancer sites. Some organizations are

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focused on health in general but do address cancer. The list does not include support groups with limited numbers of members.

## **X. FACILITATING DIALOGUE—SUMMIT WITH ADVOCACY COMMUNITY**

Mr. Bro led the discussion on a potential summit with the Cancer Advocacy Community (CAC). He explained that DCLG members would discuss why, who, where, and when to organize the summit meeting. Ms. Handley added that the Working Group to Facilitate Dialogue believed that it was important not to rely only on the Internet, because face-to-face contact is important. Mr. Bro added that the summit would provide an opportunity for NCI to garner input from the public on a given topic.

**Why.** Ms. Branch said that this would be the first opportunity to bring consumers and advocates together with researchers as a think tank to generate ideas. This will help NCI accomplish its 2015 Challenge Goal. Dr. Ramos pointed out that individuals in some communities live far away from major health and education centers and lack access to the Internet. This is one way to supplement the information provided on the Web. Ms. Scroggins suggested that the summit could develop or facilitate linkages between organizations, as many do not know that others are doing similar work.

Ms. Sumpter argued that people without access to the Internet are unlikely to have the resources needed to travel to a summit meeting. Large CAC organizations could probably afford to send someone to the meeting but the summit would disenfranchise smaller groups. She wondered if the meeting could occur through a teleconference so that travel would not be required.

Mr. Bro asked DCLG members to vote on the most important issue raised during the discussion. DCLG members clearly agreed that access to the summit was the most critical topic.

**Who.** Mr. Bro asked DCLG members to identify potential audiences and speakers. DCLG members suggested that the following be invited:

- Gatekeepers with access to large distribution channels, including media representatives and leaders of large listservs. These individuals can help reach people beyond the Internet (Dr. Weiss).
- People from the pool used to identify potential DCLG members—individuals actively involved in advocacy who can disseminate the message to a larger audience (Mr. Rosenthal).
- A diverse audience of lay people and CAC groups representing different populations (Dr. Ramos).
- CEOs of large corporations. It is advantageous for these corporations to include clinical trials in their insurance plans but these companies need to promote clinical trials to their employees (Ms. Davenport-Ennis).
- Universities, which approach the healthcare delivery system from an academic perspective and can make recommendations on how to improve it (Ms. Davenport-Ennis).
- Community health centers, which have been forced to solve problems creatively to form a safety net (Ms. Davenport-Ennis).

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- Churches, whose members have health issues, some with employees who help solve access problems for members (Ms. Davenport-Ennis).
- National groups focused on healthcare access for consumers (Ms. Davenport-Ennis).
- People outside the usual sources of experts, so that new insights are brought into the process (Ms. Davenport-Ennis).
- Every CAC organization that wants to participate. Unless everyone who wants to come is invited, the summit should not happen (Mr. Ulman).
- High-technology companies to address the need for computer access for people who need it (Ms. Campos).
- People not reached through the Internet (Dr. Weiss).

DCLG members agreed that all of these audiences are equally important, although some of them overlap. Mr. Ulman reminded DCLG members that the purpose of the summit is to help achieve the DCLG's goal of facilitating dialogue with the community and NCI. It might be necessary to focus on which population to target in order to facilitate dialogue.

**Where.** Mr. Rosenthal suggested holding the meeting in the Washington, DC, area, which is easily accessible to many advocacy groups and NCI staff. Dr. Ramos proposed holding the meeting in Chicago, which is more centrally located. Ms. Anthony supported rotating the meeting location from year to year.

Mr. Ulman pointed out that NCI is a daunting place because it is situated on a huge campus. Walking the halls of NCI would give the public a different perspective of its work. Also, having the meeting at NCI would keep costs down for NCI staff.

Ms. Scroggins proposed offering financial assistance for travel to the meeting. Ms. Branch suggested seeking scholarship money from corporations or industry.

Ms. Sumpter suggested that the meeting be virtual to reach people in the most cost-effective way possible, without denying access to those who cannot afford to travel. However, Mr. Rosenthal pointed out that the DCLG already planned to facilitate dialogue through virtual means and meeting face to face was important. Dr. Weiss suggested broadcasting the meeting on public access television.

DCLG members agreed that the meeting should be held at NCI but should also be accessible by teleconference and television. They also agreed that financial assistance should be provided.

**When.** Mr. Bro asked DCLG members to consider the ideal timing for the meeting to maximize attendance. Ms. Branch suggested holding the meeting in conjunction with the survivorship conference in the summer of 2006. Mr. Rosenthal suggested late spring or summer of 2005, as this would leave almost a year for planning.

Mr. Rosenthal pointed out that one-third of the DCLG members have 2-year terms and their terms will be up by the time of the 2006 survivorship conference. Ms. Whitewolf argued that holding the summit before or after the survivorship conference would require spending too many days in a row in meetings. Ms. Branch explained that the survivorship conference is likely to last



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only a day and a half. By planning to hold the summit in 2006, the DCLG would have enough time for the many tasks needed to prepare for the meeting.

Ms. Davenport-Ennis pointed out that if the DCLG planned to request appropriations from Congress to support initiatives that would be voted on within the summit, the meeting must be scheduled far enough in advance of the appropriations request.

A majority of DCLG members supported hosting the Summit in 2006.

**How.** Ms. Sumpter suggested that the summit be free to CAC groups and the public, in order to maximize input. The summit should also permit the submission of written questions to increase access. Mr. Rosenthal suggested that organizations be asked to pay some of the travel costs of their representatives.

Ms. Branch suggested partnering with a large advocacy group and members of the DCLG's Working Group to Facilitate Dialogue to help plan the summit. Perhaps a large advocacy group would sponsor the summit.

Dr. Weiss suggested that media broadcast partners could help identify ways to make the meeting interactive.

Ms. Davenport-Ennis noted that a working group must dedicate intense time and effort to planning this summit. The DCLG must decide which groups to contact for ideas and financial support. But the DCLG should not host a conference if advocates must pay to participate. The agenda must reflect diversity that would attract and engage participants in this summit and future work with the DCLG. The entire planning process must be flexible and adaptable. The DCLG should approach hospitals and the pharmaceutical community for support.

The DCLG agreed that it should form a Summit Working Group.

## **XI. BREAK**

## **XII. NIH COUNCIL OF PUBLIC REPRESENTATIVES (COPR) PUBLIC TRUST INITIATIVE**

Mr. James Kearns of the NIH Council of Public Representatives (COPR) explained that the council was formed in 1998 to facilitate greater interaction between NIH, its leadership, and the general public. COPR has 21 members of the public and is chaired by Dr. Elias Zerhouni, Director of NIH. COPR provides a voice for public input at NIH and increases awareness of NIH activities and programs.

Like DCLG members, COPR members:

- Are diverse and include patients, family members, healthcare professionals, communicators, and public servants. COPR is an official Federal advisory committee.
- Are members of the public.
- Do their work through meetings, work groups, and conference calls.

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- Must put aside their interests in specific diseases to focus on broader issues.

But COPR differs from the DCLG in that its members address all of the diseases in medical research, not just one disease, and the group is chaired by the NIH Director, not a COPR member.

COPR has convened work groups to produce reports and spark discussion on such topics as health disparities, human research protections, the organizational structure and management of NIH, and public participation and trust in medical research. This year, COPR submitted a report to Dr. Zerhouni, *Enhancing Public Input and Transparency in the NIH Research Priority-Setting Process*. COPR spent a year researching the topic and interviewing people outside the NIH.

Dr. Raphael Gonzalez-Amezcuca explained that in this report, COPR made 11 recommendations to NIH about enhancing public input and transparency. COPR members believe that public input should be an essential part of the priority-setting process for medical research. Moreover, seeking, valuing, and using public input in this process will strengthen the public's trust in NIH.

Dr. Gonzalez-Amezcuca highlighted several public Web sites available through the NIH home page, including the COPR Web site (<http://www.copr.nih.gov>). NIH publishes the *Public Bulletin*, a product of NIH-wide information sharing and coordination. The Medline Plus (<http://medlineplus.gov>), clinical trials (<http://www.clinicaltrials.gov/>), and the Health Information Index (<http://health.nih.gov>) sites are some of the most popular with the public.

The NIH Roadmap, a major NIH initiative, calls for re-engineering the clinical research enterprise, which involves engaging the public in clinical research. To help meet its goals of building trust among the public, promoting greater communication between researchers and the public, and educating the public about the value of clinical research, NIH established the Public Trust Initiative, whose goal is to improve the public's health by promoting public trust in medical and behavioral research.

After conducting extensive research on the current state of public participation and trust in medical research, COPR decided to hold a workshop to explore trends and opinions. The workshop, *Inviting Public Participation in Clinical Research: Building Trust Through Partnership*, will take place at the October 2004 COPR meeting.

COPR plans to invite patients who do and do not participate in research, as well as institutions that fund research. Participants will represent a range of geographic areas, ethnic backgrounds, and diseases. COPR has invited 50 individuals to participate. Speakers will present success stories and challenges and the participants will break out into small groups to discuss barriers to trust, current trends, and ways to improve trust. The conference will end with a town hall meeting where participants will openly discuss what they learned throughout the day.

After the information is synthesized, COPR members will work with NIH to develop recommendations for improving public participation and trust in medical research. They will present these recommendations to Dr. Zerhouni and the NIH Public Trust Initiative staff. COPR will post the meeting proceedings on the COPR Web site.

**Discussion.** Mr. Ulman asked about the discussions at COPR meetings. Dr. Gonzalez-Amezcuca and Mr. Kearns agreed that the discussions are very lively. Ms. Branch, who has attended a COPR meeting, pointed to several similarities between COPR meetings and those of the DCLG.

Ms. Branch asked when COPR began planning its conference. Dr. Gonzalez-Amezcuca explained that the process began in the spring of 2003 with a presentation on trust. A COPR work group has been meeting weekly since the COPR's April 2004 meeting to plan the conference.

Dr. Ramos asked if COPR solicits public input on its work. Dr. Gonzalez-Amezcuca explained that each COPR member solicits input from his or her own constituency. Mr. Kearns added that the conference on trust would provide NIH and COPR with public input.

In response to a question from Mr. Rosenthal, Dr. Gonzalez-Amezcuca explained that he is not aware of statistics on trust in medical research. But the media are expressing some alarm and the trend seems to be moving toward not trusting. Fewer people are volunteering for clinical trials, even though more are eligible. Almost every day the newspaper publishes an article on conflict of interest, and action must be taken now to reverse this trend.

Mr. Kearns stated that Harvard has a public trust initiative. According to one of the initiative's experts, the greatest problem with respect to patients and doctors is trust, not just in clinical trials but also in basic medical care. This is part of what COPR hopes to explore.

Ms. Sumpter wondered whether an NCI staff member could attend the COPR conference and report back to the DCLG. Also, the DCLG could learn from the COPR's planning experience so that it does not start from scratch in planning its own summit. Ms. Jennifer Gorman Vetter, COPR Coordinator, explained that Ms. Paula Kim, a former DCLG member, and an OLA staff member would attend the conference.

Ms. Whitewolf asked whether a member of COPR's conference planning team could join the DCLG's Summit Working Group. She also wondered how expenses of participants would be handled. Ms. Gorman Vetter explained that all expenses of participants would be covered.

In response to a question from Dr. Ramos, Dr. Gonzalez-Amezcuca said that 6 months ago, work group members began suggesting people to invite. They also obtained names of potential participants from the NIH leadership. Ms. Gorman Vetter added that COPR and Palladian Partners did extensive Internet research to identify additional researchers, community groups, and others. Admission is by invitation only.

Ms. Gorman Vetter explained that because of the nature of the breakout sessions and the information that COPR and NIH wanted to gather, the work group decided that the number of participants needed to be limited so that groups could remain small. The information gathering will occur on the first day of the meeting. On the second day, COPR will have its formal meeting, which is open to the public. At that meeting, COPR will summarize what happened the previous day. Currently, COPR anticipates that the meeting will have about 70 participants—50 invited guests and 20 COPR members.

Ms. Caliman asked how COPR identified people who choose not to participate in clinical trials. Mr. Kearns explained that COPR has spoken to at least one physician with patients who have dropped out of clinical trials. Dr. Gonzalez-Amezcuca added that COPR has invited several researchers who also identified appropriate patients.

Ms. Scroggins asked how COPR decided on the optimal number to invite. Dr. Gonzalez-Amezcuca replied that this was a function of the activities planned and the budget. The facilitator pointed out that exchanging ideas is easier in smaller groups. Mr. Kearns added that with a limited number of participants, everyone could have a say.

In response to a question from Ms. Handley, Dr. Gonzalez-Amezcuca said that COPR members had originally planned to write a journal article on trust and even began an extensive literature search on this issue. Some COPR members have suggested writing a white paper or a research paper. But it is not clear what will happen at the meeting except that a true dialogue among different perspectives will take place.

### **XIII. INPUT FROM THE PUBLIC**

Mr. Ulman opened the floor for public comment, but there was none.

Ms. Handley distributed the current list of criteria for a CAC organization to register for the *NCI Listens and Learns* Web site. She also distributed a copy of the lists of CAC organizations that received the DCLG survey. She asked DCLG members to add information, when possible, to entries that are incomplete and to provide as much information as possible on additional organizations, including a contact person, telephone number, address, and e-mail address.

Ms. Brooke Hamilton asked that DCLG members send any changes or additions to the list to her at [hamiltbr@mail.nih.gov](mailto:hamiltbr@mail.nih.gov). Ms. Hamilton pointed out that if information on an organization is not complete, this means that the organization did not return OLA's calls. If DCLG members know anyone in these organizations, they should encourage them to contact OLA.

**Adjournment.** The meeting adjourned at 5:15 p.m. and reconvened at 8:30 a.m. on Wednesday, September 15, 2004

### **WEDNESDAY, September 15, 2004 -- OPEN**

### **XIV. ISSUES IN CANCER SURVIVORSHIP**

**Report from the Office of Cancer Survivorship.** Dr. Julia Rowland, Director of the Office of Cancer Survivorship, reported that since the DCLG was created, it has been rare at NCI not to have consumers involved at every level, especially in her office. But the information collected by NCI is not being disseminated to the community. The DCLG is poised to help NCI accomplish this.

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Interest in cancer survivorship has exploded in the last 2–3 years and three different reports have been issued during this time. The Institute of Medicine (IOM) issued the report, *Childhood Cancer Survivorship*, based on both a review of the scientific literature and presentations and review papers by leading clinicians and researchers in pediatric oncology. The President's Cancer Panel issued its annual report, *Living Beyond Cancer: Finding a New Balance*, based on testimony from survivors. Its recommendations are similar to those of the IOM. The Centers for Disease Control and the Lance Armstrong Foundation have issued *A National Action Plan for Cancer Survivorship: Advancing Public Health Strategies*.

Congress has asked NCI to increase its survivorship activities, given the rapid growth in the number of cancer survivors. There were approximately 3 million cancer survivors in 1971, when President Nixon signed the National Cancer Act. Today, that number has grown to almost 10 million. Unfortunately, available data tell us little about the health status of these people, but efforts are under way to address this.

The most dramatic improvements in cancer survival and care have occurred in the childhood arena. Most childhood cancers used to be a death sentence but today, almost 80 percent of children diagnosed below the age of 15 can expect to be alive in 5 years; many will be cured of their original disease. This success has propelled enthusiasm concerning the capacity to change the picture of cancer to a disease that is potentially curable for some and perhaps merely chronic for most.

The largest proportion of survivors are breast cancer survivors, followed closely by prostate cancer survivors. One of the smallest groups of survivors are those with lung cancer, even though this is the second most common type of cancer affecting both men and women. Most people who are diagnosed with cancer today will live a long time with their illness; about 50 percent of those diagnosed today will die of cancer, but this may not happen for many years. Over sixty percent of survivors are over age 65, but limited data are available on the health and quality of life of these older survivors.

Dr. Rowland predicted that baby boomers (those born between the years 1946 and 1964) would put enormous pressure on the health care system. In 2011 the first members of this cohort will turn 65 and large numbers will enter the period when they are at greatest risk for cancer. However, the current system is not prepared to handle that volume and this significant healthcare challenge needs to be addressed.

Great strides have been made in controlling and curing many cancers but the success rates vary by population. About 64 percent of adults diagnosed with cancer today will be alive 5 years from now. Most cancer patients are treated in the community, but most state-of-the-art techniques are delivered predominantly in large clinical centers. Advocacy serves a powerful role in discussing how to deliver new treatments in other settings and among diverse populations and communities.

The Office of Cancer Survivorship (OCS) was established at NCI in 1996. Its goal is to enhance the length and quality of life for all cancer survivors. It serves as a focus for the direction and support of research that will lead to a clearer understanding of how to prevent or reduce adverse physical, psychosocial, and economic outcomes associated with cancer and its treatment. When

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the Office was established, a survivor was historically defined by the medical community as someone who had been disease free for 5 years. Today, OCS uses the National Coalition for Cancer Survivorship definition, which says that someone is a survivor from the time of diagnosis for the rest of his or her life, regardless of whether the individual dies from cancer or an unrelated illness or event. OCS also considers family members to be secondary cancer survivors.

OCS focuses its research on individuals who are 2 months or more post-treatment and generally excludes individuals with metastatic disease or at the end of life. OCS reports annually on research addressing this segment of the cancer control continuum (i.e., on studies identified as meeting these more narrow criteria) across NIH. In 2003, NIH funded 179 post-treatment cancer survivorship grants, of which NCI funded 86 percent. Slightly more than half were descriptive or prospective. Most of the rest focused on intervention research. The majority of studies continue to be conducted among survivors of breast cancer, a disease which serves as a paradigm because it affects women of all ages from diverse backgrounds and involves therapy that encompasses the full range of cancer treatment modalities.

Research indicates that no cancer treatments are benign and being cancer free does not mean being free of the cancer. Problems can occur in physical/medical, psychological, social, or existential and spiritual domains. It is not enough to let people outlive their disease; it is necessary to consider what will happen to them after treatment ends. The adverse effects of treatments must be minimized.

It is necessary to focus more on emerging late effects, including cardiac late effects in children. Fertility must be preserved and more evidence-based models are needed for post-treatment follow-up care. Little information is available on underserved, minority populations because most data are from white and middle class breast cancer survivors. More attention also needs to be paid to a patient's ability to function. In pediatrics, providers focus on how to preserve a child's ability to play with others or go to school and something similar is needed in the adult arena. Options need to be presented early on to patients so that they can base treatment decisions on their priorities and the impact of each option on desired levels of future functioning.

OCS recently re-issued a Request for Applications (RFA) on Long-Term Cancer Survivors to address long-term late effects. For purposes of this initiative, long-term survivors were defined as those 5 or more years post-diagnosis. NCI received 125 responses, indicating that the investigator community is poised to do this science. NCI funded 17 of these grants, two in partnership with the Centers for Disease Control and Prevention (CDC) and one with support from the National Institute on Aging.

OCS has a Web site designed more for investigators than consumers, but it is open to expanding and building upon the consumer side of its information. OCS runs a biennial conference in collaboration with the American Cancer Society. It has helped develop educational booklets for survivors and their family members (*Facing Forward* series). OCS also sponsors meetings to bring the research community together to identify key areas of survivorship science and care that warrant greater attention and strategies to address these gaps.

**Discussion.** Dr. Ramos has never seen a study that convincingly demonstrates a direct relationship between diet and cancer, but surveys routinely show that patients change their practices concerning nutrition, spirituality, and exercise after diagnosis. Dr. Rowland explained that OCS tried to address this in its booklets for patients. She also said that health behaviors are the current "big rage." It is commonly believed that walking more will make us all healthier. But some survivors who have been exposed to cardiotoxic regimens should not participate in certain types of exercise. NCI is currently supporting a number of studies examining physical activity, risk, and outcomes.

Ms. Campos reported that many minority communities believe that surviving cancer is all that a survivor should expect. Dr. Rowland stressed the importance of communicating with underserved minority communities about the need for all survivors to identify and discuss the potential chronic and late effects of treatment with their healthcare providers. She noted that the provider community is increasingly recognizing its responsibility to monitor for and address these consequences of disease and treatment in national efforts to reduce the burden of cancer.

Ms. Whitewolf noted that Native Americans do not survive long with cancer but researchers do not want to study their experiences because their populations are too small. She would like to see more research on traditional nutrition in Native communities and the association between cancer and tobacco or diabetes in Indian communities. Dr. Rowland believes that the difficulty of conducting research in Native communities is not so much the small populations, but the difficulty of obtaining access to tribal databases. The advocacy community is well positioned to help negotiate access to these data if they are used appropriately. OCS conducts many large dietary studies and noted that some data is available on such traditional foods as blueberries and corn.

Ms. Anthony supported the need for more research on the impact of cancer treatments on functional outcomes. Physicians need to think ahead and stop assuming that the patient will die. Dr. Rowland replied that this is why OCS emphasizes that survivorship begins at diagnosis, so that discussions of these issues will occur early on. Patients need to assume that they will be around in the future, and data support this assumption.

Ms. Scroggins asked about the relationship between the increasing survival rate and the increased incidence of cancer. It is difficult to recruit patients, especially underserved populations, to clinical trials but data on 5-year survival rates might help. Ms. Scroggins also wondered why OCS does not study metastatic cancer. Dr. Rowland explained that her office is very interested in patients with metastatic cancer, especially as more of these individuals are living longer with advanced disease. However, these studies (with one or two exceptions) are supported elsewhere in the NCI and are not held in the OCS portfolio.) They are also not included in the annual NIH wide grant portfolio review conducted by OCS.)

Dr. Weiss has treated some survivors for several years. Often, individuals facing a life-threatening disease have a strong interest in changing their lives, but that interest is not sustained over time. She wondered how to help people continue their efforts to maximize their health. Many physicians discuss self-care with patients, but they cannot do this for individuals who do

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not come into the office. Survivors must view the follow-up period as an important part of care and maintain compliance with medications over time.

Ms. Sumpter asked about guidelines for follow-up care. Dr. Rowland explained that a limited set of surveillance guidelines for survivors of adult cancers (e.g., breast, colorectal, prostate) are available to the public online. In addition, detailed guidelines, developed by the Children's Oncology Group, for pediatric cancer survivors are also available in print and on the web. Unfortunately, this latter material is not user friendly. However, an exciting new interactive, survivor driven, web-based program, referred to as "Passport to Care," promises to help meet this need in the near future. Ms. Sumpter emphasized the need to make these data more available to consumers in a way that they can understand.

Ms. Sumpter was dismayed to hear that so few survivorship grants were funded and wondered how to help increase the amount of funding for this type of research. Dr. Rowland noted that the advocacy community has always played a major role in helping funding authorities make decisions about budgets. Public advocacy works. Advocates also can encourage patients who are finishing treatment to obtain regular care.

Ms. Whitewolf asked whether the OCS portfolio analysis examines research on ethnic groups. Dr. Rowland replied that NIH tracks the populations that participate in research. Every investigator is required to report on the population mix in each study.

Ms. Davenport-Ennis suggested that OCS study the insurability of cancer survivors after diagnosis and treatment, and the restrictions imposed on them for future personalized care. OCS should also study the role of the Centers for Medicare and Medicaid (CMS) in making initial reimbursement decisions and the impact of those decisions on the private insurance community. Dr. Rowland responded that several investigators at the NCI and in the extramural investigator community are addressing different aspects of this issue. She noted that obtaining, retaining and paying for health insurance are challenges faced by many survivors and their family members because so many people obtain insurance through employment. But the issues raised by Ms. Davenport-Ennis apply to anyone with a life-threatening disease.

Mr. Ulman noted that Dr. Rowland would like to know how the public obtains information on cancer and what the best vehicles are for communicating this information. The DCLG has asked her and her staff to identify ways in which the DCLG can help, perhaps by defining issues on which the DCLG could elicit feedback from the public.

Dr. Rowland closed by asking the DCLG to view OCS as their public resource. OCS appreciates hearing from the DCLG. OCS is currently putting together a list of recommendations it has received from the now almost two dozen reports including language in this area, along with action steps for each recommendation. OCS will follow up with the DCLG on the results of this exercise.

## **XV. BREAK**



## **XVI. REDUCING CANCER HEALTH DISPARITIES: TRANS-HHS CANCER HEALTH DISPARITIES PROGRESS REVIEW GROUP REPORT**

**Trans-HHS Cancer Health Disparities Progress Review Group.** Col. Williams said that the American healthcare system should be measured by how well it takes care of its poorest citizens. Major changes will be made within the next few years as baby boomers reach the age of 65 and beyond. They will be very vocal about what still needs to be done in healthcare. This large group of elderly individuals will make a vast difference in the system.

Col. Williams referred DCLG members to the executive summary of the report by the Trans-HHS Cancer Health Disparities Progress Review Group (PRG). Col. Williams hoped that the DCLG would identify some aspects of this initiative in which to participate.

He said that racism is the bottom-line problem in health disparities. In some parts of our country, the mortality rate of infants is worse than in some third-world countries. NIH and NCI work hard to serve communities but many communities do not benefit from national programs. Col. Williams stressed the importance of evidence-based programs, as discussed in the PRG report. Fourteen NIH agencies have health disparities programs and perhaps some of these should be consolidated to form a critical mass.

The PRG's call to action includes recommendations under discovery, development, and delivery. The recommendations are broken down into those that can be achieved in 1, 2, or 3 years. One of the recommendations that may be relevant to the DCLG is to establish partnerships and support for the development of sustainable community-based networks. The report also calls for education and training programs to create a diverse and culturally competent cancer care workforce.

The findings of the PRG have now been presented and plans to implement the recommendations will soon be developed.

**Cancer Health Disparities Research.** Dr. Nadarajen Vydelingum, Deputy Director of the Center to Reduce Cancer Health Disparities, reported on the history of cancer health disparities research. Prior to 1980, minorities and special populations were not integrated into the public health or NIH research agenda. There was no recognition of the role of poverty, race, and cancer and no tailoring of prevention, screening, treatment, or research to special populations. Programs within NCI focusing on health disparities were individually driven, with little institutional support. The first year in which NCI published data on incidence and mortality among black Americans was 1975.

The notion of cancer disparities was first recognized on a national level in a report published in 1980 by then-Secretary of Health, Education, and Welfare, Patricia Harris. In the late 1980s and early 1990s, NCI reports discussed cancer among African Americans and NCI launched special initiatives to reach African Americans, Hispanics, and the Appalachian population. NCI also identified the lack of access of poor, elderly, and ethnic minorities as a significant burden in reducing morbidity and mortality from cancer. In 1996, then-Director of NCI Dr. Frederick Klausner established the Office of Special Populations Research (OSPR). In 1999, the office

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issued the first RFA for Special Populations Networks. That same year, the IOM issued a report on the unequal burden of cancer and recommended that NCI improve efforts to understand the causes of health disparities in cancer.

NCI completed its response to the IOM report with a strategic plan to reduce health disparities. To ensure implementation of this plan and reduce cancer health disparities, Dr. Klausner elevated the organizational status of OSPR to that of a center, now called the Center to Reduce Cancer Health Disparities, which is based in the Office of the Director. This year, the Center will issue two RFAs to support community networks and patient navigation to reduce cancer health disparities.

Today, a national language of disparities exists. *Healthy People 2010*, a national health initiative led by DHHS, calls for the elimination of disparities, which is also one of NCI's top priorities. The political will to continue to address cancer health disparities is strong. Bills supporting the Patient Navigator, Outreach, and Chronic Disease Prevention Act of 2003 have been introduced in the Senate and House in support of initiatives to address health disparities. The focus on health disparities is now nationally driven, with multi-institutional support.

Since the Trans-HHS PRG, different DHHS agencies have begun to work together for the first time. Although NCI is a research agency, it is beginning to address delivery. By pooling resources and bringing down barriers, the kinds of programs needed to find answers will grow exponentially.

Dr. Vydelingum described two new programs sponsored by the Center to Reduce Cancer Health Disparities. The new Community Networks Program will help determine how to reduce disparities or components that contribute to creating them, improve the use of beneficial interventions, and integrate health policy research into the research focus. The Patient Navigation Program supports projects that guide patients through the health system, from screening, through diagnosis and treatment. The navigator could be someone from the community with appropriate language ability who can work with patients on an individual basis.

The Center involves the rest of NCI in its activities, and Dr. Vydelingum chairs a cancer disparities overview group with representatives from throughout NCI. This group is trying to find the best ways to communicate its intentions to the rest of NCI and beyond.

**Discussion.** Ms. Campos compared NCI's new Community Networks Program to the CDC's REACH (Racial and Ethnic Approaches to Community Health) program and asked how the Networks will communicate with NCI. Dr. Vydelingum replied that the initiative would probably support 22 programs around the country. Each program will have an evaluation representative appointed by the PI, and each evaluator will report to the Center. Community Networks will be a continuation of the Special Populations Networks and several applicants for this round will be from Special Populations Networks PIs. Each Network will develop at least four sub-projects.

Ms. Branch inquired about a toolbox to train navigators. Dr. Vydelingum explained that some pilots are currently operating and new investigators are receiving information on how to develop

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tools for navigators. This program uses the cooperative agreement mechanism and involves a great deal of input from NCI staff.

Ms. Scroggins asked about the impact of NCI's health disparities programs on the people these programs are designed to serve. She also wondered about communications between physicians and underserved populations. Dr. Vydelingum explained that the Center's programs are based in the community. Community advisory groups will be established and the projects will involve community-based participatory research. The Special Populations Networks had a mandate to bring more minorities to research. Over the last 5 years, each of the 18 Networks has submitted up to four applications for pilot investigations and NCI has funded more than 150 minority investigators in pilot studies. This provides these new investigators with experience in competing for grants and will help them become independent investigators.

Mr. Ulman suggested that the DCLG could help communicate NCI's successes to the community, which would enhance their willingness to facilitate dialogue. Mr. Ulman offered the DCLG's assistance with the Center's activities. Dr. Vydelingum promised to keep the DCLG up to date on the Center's two new programs.

Dr. Ramos noted that Internet-based patient navigator programs could be made available to people in rural areas. But using these programs requires funding for computers and training in using the technology. Dr. Vydelingum explained that the navigator concept is based on a person-to-person approach.

Ms. Whitewolf requested an update on interactions with agencies involved in Native American communities. Dr. Vydelingum reported that DHHS has recently proposed an advisory council for Native American issues.

Ms. Sumpter argued that the most significant sources of health disparities are economics and access to health insurance. More needs to be done to ensure that everyone has access to insurance. Dr. Vydelingum agreed and explained that the cost-benefit ratio will be an analytical point in the navigator RFA.

Dr. Vydelingum closed by announcing a think tank of experts who will address the cost to the nation of health disparities on December 6-7, 2004. He promised to update the DCLG on the outcome of this meeting.

## **XVII. INPUT FROM THE PUBLIC**

No members of the public came forward to provide input.

## **XVIII. WORKING LUNCH—PLANNING FOR THE AFTERNOON/NEXT STEPS**

Ms. Davenport-Ennis announced that the oral chemotherapy demonstration project is in the recruitment phase and would like the help of the DCLG with its goal of enrolling 50,000 people. The program will examine the cost of developing oral products for which no intravenous product exists and for which CMS does not currently reimburse.

Mr. Ulman asked DCLG members to provide suggestions for presentation to Dr. von Eschenbach during the DCLG's upcoming session with the NCI Director.

- Mr. Bro suggested that DCLG members demonstrate commitment to the Director and show that the group is prepared in the near term to make progress on at least two issues, the *NCI Listens and Learns* Web site and the summit with the advocacy community.
- Dr. Weiss would like a commitment of resources so that the Web site can be executed properly.
- Col. Williams said that NCI has historically dealt with discovery and development, but this group focuses more on delivery, which has not been an NCI emphasis. The DCLG can be a great aid to the Director in outreach and community efforts, which some NCI staff may feel is not in their portfolio. In activating the constituency, DCLG members can bring pressures to bear and emphasize priorities in ways that are not open to insiders.
- Mr. Rosenthal raised the issue of term lengths for DCLG members. Mr. Ulman said that some concern has been expressed about the fact that DCLG members thought they were applying for 3-year terms but actual terms are for 2, 3, or 4 years in order to have staggered terms. Mr. Rosenthal replied that his shorter term made him uneasy about the process. Ms. Handley emphasized that the selection of the group involved difficult choices and that this time is atypical because so many members rotated off the committee. Mr. Ulman added that DCLG members are not prohibited from serving again. A member suggested that Mr. Ulman discuss the issue with Dr. von Eschenbach privately. Mr. Ulman agreed to this suggestion and will report back to the group by e-mail.
- Dr. Laird emphasized that if the *NCI Listens and Learns* Web project is to be successful, it must be implemented in a way that is useful to NCI staff. It also requires a minimum 1-year pilot phase and periodic evaluations leading to continuing improvement.

Mr. Ulman said that he would contact each DCLG member within the next week to determine areas of interest concerning the *NCI Listens and Learns* working groups. The DCLG's four working groups can then proceed with conference calls to discuss their assignments. The four working groups are:

- Operations
- Promotions
- Evaluation
- Summit

The Summit is scheduled for 2006 and the DCLG will meet again in March 2005, which will allow time to develop a logic model for the Summit. Ms. Branch suggested that the other three working groups assign a representative to the Summit Working Group. Ms. Anthony emphasized the importance of giving equal attention to the Summit and the *NCI Listens and Learns* Web site. Ms. Branch suggested that the Summit Working Group become operational by the March 2005 DCLG meeting. Mr. Ulman will establish timelines for the four working groups.

Ms. Handley said that assistance from the DCLG might be requested to help steer the CARRA program. The CARRA program is an innovative model for advocate involvement, and the DCLG

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should support it. But the DCLG should remain focused on its own mission and not be diverted to NCI daily activities, which are the domain of CARRA.

Mr. Rosenthal asked whether issues other than the areas identified as DCLG priorities could be addressed by the DCLG as special items, or if they must be included in the group's two projects. Mr. Ulman replied that other issues would be communicated through OLA and brought to the attention of the working groups. On many occasions, NCI will request participation from the DCLG, such as for the National Cancer Advisory Board, and Mr. Ulman will rotate these responsibilities.

## **XIX. UPDATE FOR NCI DIRECTOR ON THE MEETING**

Mr. Ulman welcomed Dr. von Eschenbach and summarized the proceedings so far. Specifically, he reported to Dr. von Eschenbach that:

- The *NCI Listens and Learns* Web site will allow the DCLG to serve NCI and the broader CAC, but the program must be assessed to ensure ample feedback.
- A summit of cancer advocacy organizations is planned for 2006, and should probably be held in Bethesda to bring the advocacy community to NCI.
- The DCLG is forming and will finalize *NCI Listens and Learns* working groups to focus on operations, promotions, evaluation, and the summit.
- Presentations from the Office of Cancer Survivorship and the Center to Reduce Cancer Health Disparities had enriched the meeting.

Members of the DCLG then introduced themselves to Dr. von Eschenbach and commented on their involvement:

- Ms. Anthony expressed excitement about the planned Web site, which is a promising way to disseminate messages from advocacy groups and NCI and to increase exposure for the cancer.gov Web site.
- Ms. Branch planned to help promote the Summit to bring together advocates and NCI in a brainstorming session.
- Ms. Campos said that spreading the message of survivorship, particularly to minorities, is important.
- Ms. Davenport-Ennis expressed her commitment to the issue of access and supported the Director's decision to put this on the NCI agenda.
- Dr. Laird thanked the Director for listening to cancer advocates, which demonstrates NCI's careful stewardship of public money. Her personal interest is in health program evaluation.
- Dr. Ramos believes that she will benefit from the process in the long run.
- Mr. Rosenthal said that this meeting had helped to underscore important issues that needed attention.
- Ms. Scroggins's areas of interest are improved access and quality of care and elimination of health disparities. The Summit will be unlike other such gatherings, and everyone who wants to attend should be able to do so.
- Ms. Sumpter emphasized the issue of access.
- Ms. Whitewolf was encouraged by the excitement of the group and commended those who put the group together.

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- Dr. Weiss was pleased that the group had embraced the Summit initiative. She hoped that the DCLG could help reflect the voice of NCI back to patients and communities.
- Mr. Bro commended the DCLG for its commitment to delivering results.
- Col. Williams suggested that this is a prime time for the DCLG to be a conduit to the community to help NCI deliver products and services.

## **XX. DIRECTOR'S REMARKS AND DISCUSSION**

Dr. von Eschenbach promised that this would be the first of many ongoing conversations, and his relationship with the DCLG will continue.

Although NCI focuses on research, research is not the end in itself, but rather the means to the end. The true purpose of NCI is to change the reality of cancer for those who are or will be affected by it. In refocusing its mission from eliminating cancer to eliminating the outcomes of cancer—suffering and death—NCI established the Challenge Goal of accomplishing this by 2015. The Challenge Goal is not just to continue to advance knowledge, but to translate that knowledge to effective interventions that can be delivered to everyone in need. The goal is not that people with certain types of cancer will no longer suffer and die, but that no one will suffer and die. NCI is beginning to transform this goal into reality, but one American a day still dies of cancer.

When Dr. von Eschenbach first arrived at NCI, he asked each NCI committee to refocus its contributions, and this process continues. The previous DCLG worked with NCI staff to determine how this group could most effectively serve the NCI agenda. Dr. von Eschenbach wants the DCLG to “push the envelope” and help NCI stop trying to solve tomorrow's problems with yesterday's solutions. In turn, the DCLG must understand that its advice and contributions need to be integrated into the NCI portfolio, and other issues will also shape the outcomes. The Director promised that he will always listen, but that does not mean that he will always do what the group wants. He urged the DCLG to keep the dialogue open.

As cancer is increasingly understood at genetic and cellular levels, the need is not just to discover and develop, but also to deliver. This requires reaching out to minority communities to disseminate information. NCI cannot create the needed connectivity without the help of the DCLG. By informing the community of the opportunities that are being developed, the DCLG will help the community anticipate what is coming next.

Activities that the DCLG has defined, such as the Summit, an emphasis on survivorship, and eliminating disparities are themes that resonate well. Dr. Eschenbach looks forward to the DCLG's input on these issues and its assistance in integrating them into NCI's portfolio. Dr. von Eschenbach is committed to the relationship and to ensuring that the passion expressed at this meeting is translated into actions that change people's lives.

Dr. von Eschenbach concluded by recognizing former DCLG Chair Barbara LeStage for her service and commitment.

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**Discussion.** Ms. Sumpter noted that 45 million Americans do not have access to health care and asked if this is beyond the scope of NCI. Dr. von Eschenbach distinguished between what can be controlled and what can be influenced, noting that NCI can significantly influence aspects of the issue. NCI plans to partner with other HHS agencies, including the FDA, CDC, and CMS, to address access. NCI also works with employers through the CEO Roundtable to address health care provisions and expand benefits. As current technology begins to fulfill its promise and a personal oncology model is established that defines the right treatment for the right patient to be delivered at the right time, quality will increase, cost will decrease, and waste will be eliminated.

Dr. Ramos asked Dr. von Eschenbach about priorities. He responded that new initiatives in the past have been funded by new dollars; in today's flat economy, supporting one initiative means saying no to another. Decisions are made in the context of the 2015 Challenge Goal, and discovery, development, and delivery objectives are addressed along the continuum of reaching the 2015 goal. Inputs are gathered from the broad community and decisions are based on this and the operational budget. Specific priorities are bioinformatics and addressing disparities. Other emerging issues include embedding technologies in the system and renovating clinical trials and the research infrastructure.

Ms. Anthony asked about prevention and control and moving toward a model of wellness, rather than the current disease model. Dr. von Eschenbach believes that by 2010, the 20/80 prevention/treatment ratio will be flipped, so that 80 percent of efforts are devoted to prevention and screening, which is more cost effective than treatment. Prevention must be tailored to an individual's personal preferences, and tools for individualized profiling can have a major impact on public health.

Mr. Ulman asked Dr. von Eschenbach to confirm his commitment and that of other NCI managers to work on facilitating dialogue with the DCLG. The Director agreed.

## **XXI. RECOGNITION OF FORMER MEMBERS**

Mr. Ulman introduced six former members of the DCLG—Mr. Mike Katz, Ms. Ruth Lin, Ms. Susan Butler, Mr. Hank Porterfield, Ms. Karen Packer, and Ms. Barbara LeStage. Dr. von Eschenbach presented them with plaques honoring their work.

Each of the honorees spoke briefly. Ms. LeStage expressed her appreciation to Dr. von Eschenbach for his commitment to and support for the strategic planning process, which has positioned the DCLG to serve as a conduit between NCI and the advocacy community. Mr. Katz commended the lofty goals of the group, and Ms. Lin spoke of what she, as a provider, has learned from survivors and how she has been able to share that with other providers. Ms. Packer was overwhelmed by the dedication and talent of the NCI staff, and Mr. Porterfield commended the brilliance of the new group and hoped contributions from the past would help them in their work. Ms. Butler said that the DCLG highlighted how important it was for advocates and NCI representatives to sit down face to face with each other, and it is clear that everyone in both communities cares about helping people live with cancer.

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Mr. Ulman told the former members that they were welcome at the DCLG's meetings and thanked them for paving the way for this group.

Col. Williams concluded the meeting by distributing a past issue of OLA's official newsletter, the *Nealon Report*. Eleanor O'Donoghue Nealon, who passed away in 1999 from breast cancer, was the first director of OLA and encouraged advocacy/research collaboration on her deathbed.

**XXII. ADJOURN**

Mr. Ulman adjourned the meeting at 3 p.m.

**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

Attachments:  
Roster

A complete set of handouts is available from the Executive Secretary.



**DCLG ACTION ITEMS**  
**September 13–15, 2004**

- Ms. Caliman will determine whether the DCLG Listserv can be used by DCLG members to communicate information about the organizations they represent.
- DCLG members will review NCI's list of advocacy organizations. Members should ensure that the information on their organizations is correct. They should also add organizations they know of that are not included on the list and provide as much information on these organizations as possible, including:
  - Organization name
  - Mailing address
  - Phone number
  - E-mail address
  - Contact person

If information on an organization is not complete, DCLG members who are familiar with the organization should try to complete the entry for that organization. All responses regarding the advocacy organization database should be sent to Ms. Brooke Hamilton, Office of Liaison Activities, at [hamiltbr@mail.nih.gov](mailto:hamiltbr@mail.nih.gov).

- DCLG members should review the list advocacy organizations that did not respond to the DCLG's survey. If members have a relationship with any of these organizations, they should reach out to them.
- The DCLG will discuss the launch of the *NCI Listens and Learns* Web site during a teleconference meeting to be held approximately 45 days after the group's September meeting.
- Prior to the DCLG's teleconference in late October or early November, members of the following DCLG Working Groups will meet by teleconference: *NCI Listen and Learns* Web Site Operations, Promotion, Evaluation and Summit. The Working Groups will help NCI address the first question (and subsequent questions) to be posted on the Web site based on emerging initiatives at NCI and within the cancer advocacy community. The DCLG will help to develop the criteria for cancer advocacy organizations to participate on the site. The group will develop a promotion plan for marketing the site to various audiences. Finally, the group will develop an evaluation plan to assess the effectiveness of the dialogue effort over a predetermined period of time (ideally a year).
- DCLG Chair Mr. Doug Ulman will set timelines for the working groups to begin their tasks in consultation with each working group chair.
- The DCLG will begin planning a summit conference to be held possibly in conjunction with the survivorship conference in 2006. The DCLG will talk to the NIH Director's Council of Public Representative (COPR) about their workshop model and build on the best practices from their effort to plan the DCLG summit process.
- Dr. Julia Rowland will share with the DCLG a grid that lists recommendations it has received along with action steps for each recommendation.
- NCI's Center to Reduce Health Disparities will keep the DCLG informed of the activities of its two new initiatives: the new Community Networks Program and the Patient Navigation Program. The Center will also let the DCLG know the results of its December meeting on the costs of health disparities.

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- The DCLG Working Group to Facilitate Dialogue will be dissolved and its members will be thanked and asked to stay involved in a less formal way.