DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
37th NCI DIRECTOR'S CONSUMER LIAISON GROUP

Summary of Meeting
September 14–15, 2005

Marriott Residence Inn
Bethesda, Maryland

DIRECTOR'S CONSUMER LIAISON GROUP
NATIONAL CANCER INSTITUTE

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The 37th meeting of the National Cancer Institute (NCI) Director's Consumer Liaison Group (DCLG) was convened at 10:10 a.m., September 14, 2005, at the Marriott Residence Inn, Bethesda, Maryland. Mr. Doug Ulman presided as Chair.

Members Present:
Mr. Doug Ulman, Chair
Ms. Peggy L. Anthony
Mr. Bill Bro
Ms. Lourie Campos
Ms. Bobbi de Córdova-Hanks
Dr. Beverly Laird
Mr. Eric Rosenthal
Ms. Mary Jackson Scroggins*
Ms. Sue Sumpter
Dr. Marisa Weiss**
Ms. Cece Whitewolf
Col. (Ret.) James E. Williams, Jr., USA

NCI Office of Liaison Activities Staff:
Ms. Brooke Hamilton, Acting Director, Office of Liaison Activities
Mr. James Hadley, Advocacy Program Manager
Ms. Jane Jacobs, CARRA Program Manager
Ms. Devon McGoldrick, *NCI Listens and Learns* Coordinator
Ms. Elizabeth Neilson, CARRA Program Coordinator
Ms. Linda Ticker, Program Assistant
Ms. Anne Willis, Health Communications Intern
Ms. Lois McCourt, Health Advocacy Fellow
Ms. Bethany Piernikowski, Cancer Research Training Fellow

* Participated by teleconference for part of the day on September 14.
** Present only on September 14.

Speakers:
Mr. Greg Bielawski, NCI CARRA Member
Dr. Ken Buetow, Director, Center for Bioinformatics, NCI
Ms. Nelvis Castro, Acting Director, Office of Communications, NCI
Dr. Mark Clanton, Deputy Director, Cancer Care Delivery Systems, NCI
Ms. Andrea Collins, Deputy Committee Management Officer, NCI
Dr. Carolyn Compton, Director, Biorepositories and Biospecimen Research, NCI
Dr. James Doroshow, Director, Division of Cancer Treatment and Diagnosis, NCI
Ms. Susan Erickson, Director, Office of Policy Analysis and Response, NCI
Ms. Brooke Hamilton, Acting Director, Office of Liaison Activities, NCI
Ms. Claire Harris, Committee Management Officer, NCI
Dr. Frank Hartel, Director, Enterprise Vocabulary Services, NCI
Mr. John Hartinger, Acting Deputy Director for Management, NCI
Dr. Ernie Hawk, Director, Office of Centers, Training, and Resources, NCI
Ms. Jane Jacobs, CARRA Program Manager
Mr. Mike Katz, Vice President, International Myeloma Foundation
Ms. Lisa Krueger, Biologist, Division of Extramural Affairs, NCI
Dr. Beverly Laird, DCLG
Ms. Elizabeth Neilson, CARRA Program Coordinator
Ms. Cherie Nichols, Director, Office of Science Planning and Assessment (OSPA), NCI
Ms. Kathie Reed, Chief, Science Planning Branch, OSPA, NCI
Ms. Mary Jackson Scroggins, DCLG

Speakers continued:
Mr. Doug Ulman, Chair, DCLG
Dr. Andrew von Eschenbach, Director, NCI

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I. WELCOME

Mr. Doug Ulman welcomed members of the DCLG, the public, and the cancer community to this meeting.

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

Minutes. A motion to approve the minutes of the DCLG's May 26, 2005, teleconference was carried unanimously.

Col. (Ret.) James E. Williams, Jr., asked about procedures to follow up on action items from DCLG meetings. Mr. Ulman explained that of the 16 action items from the May meeting, 12 were completed and 4 were in process. The DCLG might consider a more formal process for reporting back on action items within a certain time frame.

Remarks. Ms. Hamilton thanked the DCLG members for attending the meeting, in spite of many competing demands. She also thanked Ms. Sue Sumpter, Ms. Peggy Anthony, Mr. Bill Bro, and Mr. Ulman for assisting in the development of the meeting agenda.

Ms. Hamilton reported former DCLG Executive Secretary Ms. Nancy Caliman's recent death from multiple myeloma. Participants observed a moment of silence to remember Ms. Caliman and all whose lives are affected by cancer. Ms. Hamilton announced that the DCLG's Summit Working Group had decided to dedicate the upcoming Summit to Ms. Caliman's memory.

II. UNDERSTANDING AND COMMUNICATING THE NCI PLANNING AND BUDGET PROCESS

Budget Planning Process. Ms. Cherie Nichols gave an overview of NCI's planning and budget process. The Office of Science Planning and Assessment (OSPA) filters and prioritizes the many strategic ideas that come through NCI from different sources, including the DCLG and other advisory committees. The annual Bypass Budget and reports, along with NCI's 5-year strategic plan, provide a picture of what NCI is doing, what it intends to do, and what progress it has made.

Policy Activities. Ms. Susan Erickson described NCI's interactions with Congress. She explained that Congress has three roles: appropriation, authorization, and oversight. The appropriators have the authority to provide funds, the authorizers are responsible for legislative action and authorizing money to fund programs, and those responsible for oversight investigate matters of public concern and monitor federal agencies and programs.

NCI's Office of Policy Analysis and Response coordinates NCI's participation in congressional hearings and sets up briefings for members of Congress and their staffs. The office also provides help to congressional offices for constituents who need assistance with cancer-related issues.

Ms. Erickson reported on efforts in the House of Representatives to reauthorize the National Institutes of Health (NIH), which was last reauthorized in 1993. In 2004, Congressman Joe Barton of Texas, the new chairman of the House Energy and Commerce Committee, said that NIH reauthorization was a high priority for the committee. A draft reauthorization bill was circulated on August 22, 2005.

The language of the draft bill is public, and interested DCLG members should contact Ms. Hamilton for a copy of the document. The draft bill creates two new budget categories: Institutes and Centers (ICs) that are mission specific and those that are research enabling (NCI falls into the former category). According to the draft bill, a single appropriation would be authorized for the entire group of ICs rather than for each one individually. However, the process to determine how funding would be distributed among the ICs has not been established. The bill would institute a common fund for trans-NIH research and an NIH Division of Program Coordination to facilitate the newly required biennial cataloging of research, as well as some strategic planning and priority setting.

This bill has not been introduced in the House, and it is not clear when this is likely to happen. If the bill is introduced and passed in the House, it will be taken up the Senate, but no one in the Senate has expressed public support for NIH reauthorization at this time. It is not clear if the bill will reach the Senate, and if so, how much support it would have. Congress has other pressing issues to address at present, including hurricane relief and appropriations, and how much attention will be focused on reauthorization is unknown.

Discussion. Col. Williams asked about the benefits to NCI from its Bypass Budget. Ms. Erickson replied that all of the NIH ICs can tell Congress what they would like to do, but NCI is the only one that can also tell Congress how much these opportunities would cost and what resources would be required. Mr. John Hartinger explained that the congressional appropriation exceeded the Bypass Budget only once in the years since 1972.

Mr. Ulman asked about the reauthorization bill's impact on the ability of advocates to participate in trans-NIH activities. Ms. Erickson explained that the makeup of the advisory committee for trans-NIH activities is not clear in the most recent draft of the reauthorization bill. Congress has heard from many people about the importance of advocacy representation on this group.

Ms. Lourie Campos asked for clarification on the two categories of NIH ICs. Ms. Erickson explained that the mission-specific group includes ICs that are focused on a particular disease or stage of life. The research-enabling entities have a broader focus. Under the proposed bill, the appropriations process would be simplified: one appropriation would be made for each of the two groups of ICs with a third to support the Office of the Director and a fourth to support trans-NIH research.

Ms. Campos asked how the appropriations system under the draft bill would be different from the current system. Ms. Erickson explained that NCI, like all of the other ICs, currently has its own line item. Mr. Hartinger added that in the new model, all funding for the ICs would be appropriated to NIH Director, Dr. Elias Zerhouni, and the system for allocating these funds has

not been developed. Congress would no longer appropriate funds for NCI directly to Dr. Andrew von Eschenbach. Ms. Campos expressed concern, saying that this is a very important issue that DCLG members need to communicate to their constituents.

Strategic Planning. Ms. Kathie Reed reported on strategic planning activities at NCI. The Challenge Goal of eliminating the suffering and death due to cancer by 2015 is a guide in the Institute's planning. Issuing that Challenge Goal and providing a strong directional framework for the Institute's thinking has galvanized people and helped NCI rethink some of its activities.

OSPA has been working with the Institute's leadership to identify investment areas to highlight for the 2007 Bypass Budget, which will be published in October. The focus for the 2007 Bypass Budget is on a more realistic budget to sustain current services and move forward toward the Challenge Goal. The Institute plans to request funding in five areas for 2007:

1. Expansion, integration, and outreach within and among Cancer Centers.
2. Medical informatics and health information systems for cancer research and care.
3. Bridges to link cancer science and technology.
4. Cancer clinical trials integration and streamlining.
5. Integrative cancer science.

NCI expects to publish its strategic plan in late November. DCLG members will receive a letter from Dr. von Eschenbach asking for their assistance in reviewing the draft plan. This draft will be available on or about October 20, with comments due on November 3.

Discussion. Col. Williams noted that strategic planning does not always have the desired results. He reported that the organizers of a recent men's conference found it quite challenging to bring two NCI-designated Cancer Centers together in support of the conference. The Institute needs feedback from the community so that it is made aware of this type of issue. Ms. Reed said that this could be addressed in the next Cancer Center directors meeting.

Ms. Campos noted that the 2006 Bypass Budget included overcoming cancer disparities as a priority, but this was not listed for 2007. Ms. Reed explained that not all of the issues are highlighted in each Bypass Budget, and the strategic plan will state what NCI needs to do overall. That only certain priorities are listed for 2007 does not mean that NCI will not continue to move forward on health disparities and other areas.

Ms. Whitewolf asked how to move from researching health disparities to doing something about them. Ms. Reed said that the strategic plan emphasizes the transition from basic research to the development and delivery of interventions. Ms. Nelvis Castro added that the Center to Reduce Cancer Health Disparities has a patient navigator program and a community network program that are implementing activities to reduce health disparities. In addition, NCI's Cancer Information Service has a partnership program that supports community organizations with technical assistance and capacity building. Ms. Reed noted that NCI was planning a workshop for staff on better coordination to achieve the health disparities objectives.

Mr. Ulman requested clarification on the request for increased funding for the 2006 and 2007 priorities. Ms. Reed explained that the new initiatives in the 2007 Bypass Budget would require

funding beyond NCI's current budget, because the Institute remains hopeful that additional funds will be available to support these areas. Mr. Ulman asked whether, if no substantial additional funds were available, the new priority areas would lead to decreased efforts in other areas. Ms. Nichols explained that some of these activities are already ongoing. Dr. von Eschenbach has said that the Institute will move into new areas, but it must find the funding to make this possible.

Financial Management. Mr. Hartinger explained that NCI was currently executing, or spending, the FY 2005 funds it received from Congress. The presentation process for the FY 2006 budget occurred earlier in the year. In the past, the director of each IC met with the House and Senate committees. However, the NIH director now meets with these committees and may choose to bring an IC director with him. The new fiscal year starts on October 1, and it is not clear if Congress will pass a Labor/Health and Human Relations appropriations bill prior to that date, or whether NCI will operate under a continuing resolution.

The Bypass Budget was specified in the Cancer Act of 1971, which said that this budget would be submitted directly to the President, although it would be available to Congress for review. Work on the 2007 Bypass Budget began in early 2005, and it will be submitted shortly to the Office of Management and Budget. The Administration has developed the 2007 Department of Health and Human Services (DHHS)/NIH budget. In February, the President will submit his budget, and Dr. von Eschenbach will defend it, and will identify the Institute's priorities and needs. The difference between the Bypass and the DHHS/NIH budgets is likely to be less than in the past, but NCI will still have an opportunity to present its needs to the public through the Bypass Budget.

Between 1998 and 2003, when NIH's budget doubled, NCI's budget increased by about 80%. Since then, increases have declined from 3.2% in 2004 to the 0.4% proposed for 2006. The House has accepted the President's budget, although the Senate has proposed a slightly higher increase.

Given the relatively flat budget in the past few years, every time Dr. von Eschenbach initiates a new project, he must deny funding to another project. Last year, every division in NCI had to reduce its budget by 5%. This amount was reallocated to Dr. von Eschenbach and the Executive Committee for projects directed toward achieving the 2015 Challenge Goal. This year, each division has been directed to present a 5% budget cut to Dr. von Eschenbach. In addition, the deputy directors have met with each division and have identified more budget cuts worth 5%. As a result, 10% of the Institute's budget will be available for redeployment.

A significant portion of NCI's budget has already been committed to such areas as mandatory salary increases, rent and utilities, and the NIH Roadmap. In response to a question from Col. Williams, Mr. Hartinger explained that in the past, NCI had the authority to fully fund grants for multiple years, but Congress removed this authority from all of the ICs. Col. Williams pointed out that indirect costs are very high at some institutions. Mr. Hartinger agreed, noting that a great deal of effort has been undertaken in recent years to change the formulas for calculating indirect cost rates, but this is beyond NIH's control.

Because of the increases in NCI's mandatory commitments, the proposed 0.4% budget increase is likely to translate into at least a 0.9% decrease. Other reductions could be imposed due to Hurricane Katrina. At the same time, NCI has seen a major increase in the number of grant applications submitted and in their cost. Several institutions are now eligible for Cancer Center grants, and a great deal of demand exists to expand this program. Training costs and demand for training are also likely to increase. NCI must also find funds for clinical research infrastructure, including biorepositories and the cancer Biomedical Informatics Grid (caBIG).

Discussion. In response to a question from Mr. Ulman, Mr. Hartinger explained that about 10–15 institutions will be eligible to become Cancer Centers in the next few years.

Mr. Ulman asked about accomplishments during the period when NCI's budget increased rapidly. Mr. Hartinger explained that as a result of the activities during this period, many new opportunities have now arisen that could lead to important outcomes. Ms. Nichols added that NCI has always more to do than its resources allowed. The Bypass Budget gives NCI an opportunity to have a dialogue with the community on how to work together. If congressional funding is lower than needs, NCI must work with the community to make the needed investments happen.

Mr. Ulman suggested that it might be difficult to explain to the community why all of the initiatives in the Bypass Budget have not happened. They do not understand that the Bypass Budget is almost never fully funded. Mr. Eric Rosenthal said that the Bypass Budget shows the world that cancer has a special status, but real standing is not clear because the requested funding is not provided. Ms. Nichols said that the Bypass Budget process informs the community of what is important at NCI. It is the Director's professional judgment of and plan for what is important in the national cancer program. No other IC has that type of authority, so it is a precious resource. Mr. Hartinger explained that the Bypass Budget provides NCI with its only vehicle for identifying its priorities.

Lobbying and Political Activities. Ms. Claire Harris explained that the Committee Management Office is responsible for ensuring that members of the NCI advisory committees and boards, as special employees of the government, are in compliance with government regulations concerning financial reporting and ethical conduct.

Ms. Andrea Collins explained that DCLG members are prohibited from engaging individually or as a group, in their official capacity, in any activity that encourages any person or organization to lobby members of Congress. DCLG members may appear before individuals or groups to inform or educate the public about a particular policy or legislative proposal, and they may communicate to members of Congress at the request of any Representative or Senator. All communications to members of Congress initiated by DCLG members in their official capacity as DCLG members should be coordinated through the Office of the Assistant Secretary for Legislation.

Ms. Sumpter often speaks at national conferences and encourages her audiences to advocate for more funding. She asked whether it is appropriate to disclose her membership in the DCLG

when she speaks. Ms. Collins said that Ms. Sumpter may say that she is on the DCLG, but she cannot speak for the DCLG or NIH. She is free to express her personal views.

Ms. Collins suggested that any DCLG member who is contacted by a member of Congress and asked to represent the DCLG let Ms. Hamilton know to ensure that the request is handled appropriately. In response to a question from Ms. Sumpter, Ms. Collins said that DCLG members may tell Senators and members of Congress that they are on the DCLG but are not speaking on its behalf.

Ms. Collins specified that DCLG members may not use government equipment, staff resources, or appropriated funds to lobby or express their private views. As private citizens, DCLG members may express their personal views but not the views of the DCLG or NCI to anyone. All personal activities must occur during off-duty time. For example, if a DCLG member attends a DCLG meeting, he or she may attend a political fundraiser in the evening, after the meeting ends for the day, as long as this does not interfere with participating in the DCLG meeting.

DCLG members are prohibited from accepting gifts given to influence them as committee members. They may not serve as an expert witness except on behalf of the United States, unless they have been authorized to do so by an agency ethics official. They may not use their titles or positions to solicit charity from anyone with interests that could be substantially affected by the committee activities.

Communications Tools. Ms. Castro discussed NCI communications tools that are useful for learning about its plans, priorities, and progress, and how these tools might be used within the advocacy community.

Ms. Castro referred the DCLG to several sources of NCI news and information, including:

- *NCI Cancer Bulletin*—The *Bulletin* presents regular updates on NCI activities, and DCLG members may use its stories in their own newsletters. Because this is public information, they do not need permission to use these stories. The *Bulletin* now includes a community update section, and the *Bulletin* staff would be happy to work with DCLG members to publish their commentaries.
- 2015 Internet portal—The 2015 Web portal just went live and identifies resources related to the Challenge Goal.
- cancer.gov Website—NCI continuously provides new information and revises how it presents that information on the site. One of the newest features is a dictionary of cancer terms, and the Office of Communications is developing another dictionary in Spanish. In the future, a Spanish version of cancer.gov will be available.
- cancer.gov/newscenter site—The news center section has the latest information from NCI in the form of press releases.
- Cancer Information Service (CIS)—CIS offers phone services and a partnership program.

Discussion. Ms. Sumpter asked if articles from the *NCI Cancer Bulletin* can be edited for publication in an advocacy group's newsletter, or whether they should be published in their entirety. Ms. Castro replied that the stories should be published in their entirety. If an organization edits a story, it should let NCI review it prior to publication.

In response to a comment from Col. Williams, Ms. Castro explained that about 7 years ago, NCI realized that very few individuals from minority communities were contacting the CIS. To respond to this situation, NCI established the CIS partnerships program, and the number of calls from individuals from minority communities to CIS has increased.

Mr. Ulman thanked all of the panel members. The DCLG is eager to provide feedback on the strategic plan and will discuss how to make a contribution in the other areas that were discussed.

III. KNOWLEDGE MANAGEMENT AT THE NATIONAL INSTITUTES OF HEALTH

Dr. Frank Hartel explained that most of NIH's research portfolio investment is reported to Congress and others in terms of investment in 230 reportable disease categories. An NIH steering committee recommended that a knowledge management activity be established to improve some aspects of disease-category reporting in response to a 2003 Institute of Medicine (IOM) report. The report pointed out that variation in reported funding levels was not acceptable, and that a robust, consistent, and defensible approach to disease coding was needed.

About 3 years ago, a small pilot project was conducted to see if knowledge management technology could be used to solve this problem. The results of the pilot were encouraging, so the process was scaled up to determine whether the perceived advantages could be maintained. These advantages include eliminating differences in coding methodologies that currently exist between the 27 ICs; creating trans-NIH definitions ("fingerprints") for the NIH disease categories; and improving the transparency, reproducibility, and robustness of the budget reporting of these terms.

The knowledge management process was built around Collexis, a text-searching tool designed to examine large quantities of data to identify patterns and establish relationships. Collexis begins with a fingerprint—in this case, the disease category. The fingerprint for a particular disease is the collection of concepts that might be mentioned in any grant application related to that disease. These concepts include the disease name, known causes, and sequelae. Each concept is given a weight depending on how central it is to the disease.

The first challenge is to develop a list of relevant concepts and give them appropriate weights. Collexis tools are then used to determine which concepts are mentioned in grant documents. The technology compares the concepts found in the grant documentation and what is known about all grants relating to the disease. The goal of the process is to explain how grant money is allocated to reportable disease categories.

If NIH used this technology operationally, it would change the allocation of funds. Since no gold standard is available against which to assess the tool's value, utility is the principal criterion. If the allocation that comes out is useful, then this process is probably a good idea.

Discussion. Col. Williams asked how this project would improve cancer research. Dr. Hartel replied that the goal of portfolio management is to use information about the current portfolio and state of the science to steer future investments.

Ms. Campos asked for clarification on the disease category fingerprints. Dr. Hartel replied that these reflect project fingerprints from current grants. The technology searches grant applications to determine the extent to which they match disease categories. This is really a bookkeeping exercise to track the money allocated to the Institute's grants.

Dr. Marisa Weiss asked if the new tool would become part of the public domain so that the institutions supported by NCI could collaborate. Dr. Hartel explained that no decisions have been made about sharing this tool; however, Collexis is a proprietary product.

Ms. Sumpter noted that if the disease categories are reduced to a mathematical algorithm, then the merit of the research project is not taken into consideration. Dr. Hartel replied that these 230 reportable disease categories are simply bookkeeping conventions that the federal government has used for many years. They do not reflect a scientific order of merit. It is useful in many contexts to know how many dollars have been allocated to a particular disease. These categories should be thought of as convenient budgetary groupings, not scientific categories.

Ms. Sumpter asked how broad-based research, such as nanotechnology, that applies to a range of cancers is classified. Ms. Lisa Krueger replied that some of these grants are given the codes for the types of cancer being studied. But NCI continues to try to categorize grants appropriately. For example, if a grant addresses both breast and ovarian cancer, the system needs to recognize that both diseases are being studied and assign the correct percentages.

IV. UPDATES FROM NCI WORKING GROUPS

Clinical Trials Working Group Presentation. Mr. Mike Katz, a former DCLG member and 15-year myeloma survivor, presented an overview of Clinical Trials Working Group (CTWG) activities. Mr. Katz served as a patient participant in the CTWG, which was established by the NCI director and the National Cancer Advisory Board (NCAB) to make recommendations regarding NCI's clinical trials infrastructure.

NCI's clinical trials system is inadequate to answer the questions now being asked. In most cancers, for example, it is not known how much of a drug to give, how long to give it, or whether all patients need the same drug. Science is changing, and new drugs are targeted at very specific molecular lesions. It is becoming impossible to do the trials needed so that new drugs can be approved.

The clinical trials enterprise is huge, involving thousands of organizations, tens of thousands of scientists, and hundreds of thousands of patients. Mr. Katz characterized this system as "unadulterated chaos." It is critical to routinely incorporate new tools for cancer biology into clinical trials, select the people who will participate carefully, design research questions more carefully, and use new imaging tools to learn more from trials. Because trials cannot be done without patients, the issues that are important to patients must be addressed.

The CTWG developed recommendations in five areas:

- Coordination across all venues and individuals involved in clinical trials—A new comprehensive clinical trials database is needed, because NCI's PDQ does not have all of the information or the level of detail needed for some uses. The proposed database would cover all NCI-supported trials across all funding mechanisms and would include descriptions of trials as well as safety and adverse events. The system would require sophisticated access controls, because much of this information is confidential. The database is to be developed in concert with caBIG. In addition, the CTWG recommended incentives for collaboration of principal investigators, as well as among NCI, the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and industry.
- Prioritization/scientific quality—The current system for deciding which trials are done is not very efficient or transparent. The CTWG recommended the creation of an investigational drug steering committee to enhance the design and prioritization of early-phase drug development trials. A network of scientific steering committees would address the design and prioritization of phase II trials. Each disease site would have a steering committee to prioritize trials on a national basis. Each steering committee is to have community oncologist and patient advocate representation. Correlative studies, which are funded as part of clinical trials, would put in place standards for integrating new technologies, such as molecular imaging, into clinical trials.
- Standardization—NCI funds many systems to do the same thing. For example, the Institute supports clinical trials registration systems in the Cooperative Groups, Clinical Trials Support Unit, and Cancer Centers. An infrastructure will be developed that is the "best of the breed," and redundancy will be eliminated. The data structure will have standard case report forms and common data elements so that investigators are not constantly redesigning them.
- Operational efficiency—The CTWG recommended that Cancer Centers be compensated for the real costs of enrolling people into trials. Other recommendations were to increase patient awareness of and minority patient access to clinical trials. Barriers to initiating trials at sites should be removed so that patients can be enrolled more quickly once trials are approved.
- Integrated management—The CTWG recommended that the NCAB form a clinical trials oversight committee to advise the director on all clinical trials at NCI. In addition, the organizational structure needs to be rationalized and all of the major components put under a single umbrella.

Funding has been allocated to each recommendation. In addition, supplements have been proposed to reward institutions that accrue many patients to trials. Funding has also been allocated to awards for young clinical investigators to encourage them to go into clinical research. Minority supplements are designed to help accrue minorities into clinical trials.

The plans call for a strong measurement component, including a baseline assessment of the system and an evaluation of the impact of the proposed changes. Ultimately, the objective is to support trials that provide the results that are critical for guiding new therapeutics and diagnostics development, new biomarkers that enable better targeting of cancer therapies, and

revisions of major treatment guidelines to reflect the new knowledge gained. The hope is that this effort will significantly improve the clinical trials system at NCI and realize the potential for the development of new treatments and better use of existing treatments.

Discussion. Col. Williams asked whether the CTWG addressed alternatives to double-blind, randomized studies. He also noted that many academic institutions do not reward faculty for multiyear studies, making it difficult to recruit new investigators into the field. Mr. Katz replied that trials that do not take several years were discussed and are being conducted. Also, the FDA accepts non-randomized trials. When better biomarkers are available and patients can be selected with specific chromosomal abnormalities or epidemiological characteristics, smaller, more directed trials will be possible. Mr. Katz added that the academic issue is well recognized, and the CTWG has proposed realigning the incentive system, although it is not clear how to accomplish this.

Col. Williams asked about the possibility of funding investigators rather than institutions. Mr. Katz explained that funding tends to be associated with the individual who applied for it, and the CTWG's goal is to ensure that they are not disadvantaged because they are working on a project that is not regarded highly in academia.

Ms. Campos expressed concern about the lack of incentives for institutions that do not accrue large numbers of patients. Mr. Katz explained that some institutions spend a great deal of time and money to accrue patients, and they are not reimbursed for all of those costs. As a result, it might become impossible for some institutions to accrue patients. Several institutions accrue only a handful, and are very costly to the system. The CTWG therefore proposed setting limits for participating institutions; those that do not accrue a minimum number of patients cannot be members of Cooperative Groups, although they may accrue patients through other mechanisms.

To ensure that institutions accrue minority patients, a minority supplement has been developed. Ms. Campos asked if additional funds would be available for these supplements. Mr. Katz replied that the budget for implementing the CTWG's recommendations is preliminary, so it is too early to determine what level of funding will be available for each recommendation.

Ms. Anthony said that South Carolina does not have a law to ensure that patients on clinical trials are covered by medical insurance. A nationwide system is needed to protect patients from coverage refusal. Mr. Katz explained that the CTWG discussed this issue with the Centers for Medicare and Medicaid Services (CMS) but has not addressed private insurers.

Ms. Sumpter said that high accrual supplements and limited funding for minority accrual appear to be discriminatory. Some institutions might find it very difficult to recruit underserved populations, such as those in rural areas. Mr. Katz explained that the incentive funding is designed to compensate institutions for the high costs of accruing large numbers of patients so that they do not stop participating in clinical trials.

In response to a question from Ms. Sumpter, Mr. Katz explained that the centralized priority system will address trials funded by NCI, but it cannot dictate what pharmaceutical companies

do. PDQ accepts industry trials, but most pharmaceutical companies do not choose to provide their information to the database.

Ms. Whitewolf asked about funding to support the costs incurred by patients on clinical trials. Mr. Katz agreed that this is necessary if accrual of patients, especially those in certain underrepresented populations, is to increase.

Implementing the CTWG Recommendations. Dr. James Doroshow, chair of the CTWG, explained that the CTWG report was presented to the National Cancer Advisory Board (NCAB) on June 7 and to the Board of Scientific Advisors at the end of June. No resources have been set aside to implement the recommendations at this time, but many of the most important items will not cost any money.

One of the initiatives in the report is to reduce the length of time required to implement national clinical trials and the roadblocks to approving these trials. Many analyses have been made of the time it takes to start a study, from its arrival at NCI for consideration, to when the investigator or Cooperative Group receives a response. However, no detailed analysis has addressed how long the operations offices spend reviewing a trial in the nine Cooperative Groups, or any other issues that prolong the time it takes to begin these studies.

A group of management experts at Vanderbilt University have now presented data on roadblocks for investigator-initiated non-national trials. Initially, the biggest roadblock was the length of time it took for the Vanderbilt institutional review board (IRB) to approve the protocol. The dean of Vanderbilt decided to pay IRB members for attending meetings and performing high-quality reviews. There is now a waiting list of Vanderbilt faculty who want to join the IRB, and the time to approval has decreased from 3 months to 3–4 weeks. NCI is now funding a study by this management group of one Cooperative Group.

About one-third of all NCI-designated Cancer Centers have adopted the central IRB (CIRB), and the next step is to understand why this CIRB has not been more widely accepted. An expert in pharmacoeconomics will study the relative cost savings of using the CIRB compared to not using it. If use of the CIRB were found to save hundreds of thousands of dollars, this would likely start changing minds.

The CTWG has spent a substantial amount of time developing more detailed implementation plans for each initiative. These are not included in its report. Dr. Doroshow is recruiting staff for this effort. By November, he plans to assign tasks to each staff member to expedite the implementation process by codifying the items that were not included in the CTWG report.

Dr. Doroshow hopes to receive approval soon to establish the disease steering committees. A national oversight group will be developed to provide advice to NCI. This group will be responsible for monitoring implementation of the CTWG recommendations and helping NCI and its grantees make mid-course corrections.

Translational Research Working Group Presentation. Dr. Ernie Hawk discussed the emerging Translational Research Working Group (TRWG) effort that he is leading. Medicine is

shifting away from the notion of treating symptoms and toward the identification of disease processes in advance of symptoms, when normal function is still present. The field is also moving to molecular definitions of disease, which provides an opportunity to focus on earlier risk identification and interventions. All of these changes will be fueled by translational science, which builds on a scientific understanding of the disease process.

Dr. Hawk was charged with examining translational research at NCI. He believes that translational science covers the transformation of basic discoveries through the identification of markers of risk or outcome to early- and then late-phase trials. Several NCI programs are involved in translational research, particularly the Specialized Programs of Research Excellence (SPOREs), which were designed to conduct translational science. Some R01 (investigator-initiated) and P01 (multi-project) grants are also involved in translational research to build a bridge from discovery to development, as are the Cancer Centers.

SPOREs are required to move from molecular discovery into early-phase trials within 5 years. The SPOREs focus on the products of translational science, including the identification of molecular targets, biomarkers of risk and response, and interventions to modulate risk. They also create networks and consortia to facilitate the translation of novel ideas into clinical interventions. All of the SPOREs are focused on one of 14 organs or organ systems.

The TRWG will address whether this is the right way to organize the program and whether appropriate numbers of SPOREs have been allocated to each cancer site. Other questions are, which organs should be included, how should rare cancers be addressed, and how should allocation decisions be made.

The NCI designated Cancer Centers are translational science engines. Depending on how funding is categorized, 50%–60% of the NCI budget ends up in Cancer Centers to support research infrastructures. These centers conduct pilot projects and early trials, and they cover a major portion of the U.S. population.

The TRWG process plans to follow the model developed by the CTWG. Dr. Hawk plans to identify potential TRWG members who will represent a broad range of constituencies. The group will have a membership of about 40, and will include scientists, clinicians, and advocates. The work of the TRWG will draw on several recent reports to NCI on translational science, including the reports of some of the Progress Review Groups (PRGs) and the President's Cancer Panel. Some of the NIH Roadmap initiatives are also related to this issue. The effort will include the following steps:

1. Define the scope of activity.
2. Evaluate existing programs.
3. Create an ideal model and develop recommendations to achieve that model.
4. Develop an implementation strategy.

Discussion. Ms. Sumpter pointed out that childhood cancers and long-term survivorship do not fall under any specific disease category, and asked how the SPOREs dealt with them. Dr. Hawk explained that the TRWG would study this issue. Survivorship might fall outside the realm of the TRWG, but pediatric issues will be addressed. Although the TRWG will have a limited number

of members, the planning will incorporate opportunities for much broader input. Dr. Hawk characterized the TRWG as a fusion between the PRG and the CTWG processes.

Ms. Whitewolf asked about the inclusion of research on alternative therapies in the TRWG's deliberations. Dr. Hawk replied that he and his colleagues would consider including representatives of complementary and alternative medicine in this effort.

V. FACILITATING DIALOGUE—SUMMIT WITH ADVOCACY COMMUNITY

Ms. Mary Jackson Scroggins, chair of the Summit Working Group, participated in the discussion by telephone. She explained that the DCLG Summit Working Group, with assistance from Mr. James Hadley and other OLA staff members, has developed a draft agenda for the DCLG Summit. The Summit will last a day and a half and will be dedicated to the memory of Ms. Nancy Caliman. The title of the Summit will be "Listening and Learning Together: Building a Bridge of Trust."

The meeting will officially start at 1 p.m. on June 19. Participants who arrive earlier will have the opportunity to tour the NIH campus and attend some information sessions. The meeting will start with an opening ceremony, a brief welcome from Mr. Ulman and Ms. Scroggins, and an opening presentation by Dr. Zerhouni. The second day includes three separate breakout sessions, with four presentations, so participants will be able to attend three of the four presentations. The poster picnic will provide an important networking opportunity.

Col. Williams suggested that each day begin with an optional exercise program to promote a healthy lifestyle.

Ms. Whitewolf asked about the target audience. Mr. Hadley explained that this meeting is designed for advocates, who will come to learn about NCI and NIH and take that information back to their constituents. All who attend must provide a letter from the leadership of their organization confirm their affiliation. The Summit Working Group is trying to target hard-to-reach organizations, although larger organizations are also welcome to participate.

Ms. Sumpter wondered if the requirement to submit a letter would make participation more difficult for some. Mr. Hadley said that even the smallest groups have leaders who can provide a letter. Ms. Sumpter asked about the possibility of participating if an individual could not come in person. Mr. Hadley replied that scholarships would be available to support travel costs, although it is not yet clear how many. Ms. Hamilton added that the group is seeking co-sponsorship so that the event can be broadcast over the Web. Also, the letters from organizational leaders do not need to be printed on letterhead.

Mr. Rosenthal asked if the number of participants would be limited. Mr. Hadley replied that registration is to be capped at 300. Mr. Rosenthal stressed the importance of involving advocates who will disseminate the information provided to a wider audience.

Ms. Whitewolf mentioned three tribal groups that might be interested in attending, but two do not have enough money to support the travel costs and perhaps should not be invited. Mr. Hadley

said that all advocates are invited; some can pay their way, and others will need scholarships. The working group plans to discuss guidelines for scholarships at its next teleconference.

Ms. Bobbi de Córdova-Hanks asked DCLG members to help identify potential sources of scholarship money so that more support for travel costs will be available. Mr. Hadley added that the Summit could not accept funding from industry. He anticipates having enough scholarship money to bring together a representative group of the cancer community, including those who are traditionally underserved and underrepresented.

Ms. Anthony asked about the marketing plan for the Summit. She suggested that the question-and-answer sessions be facilitated, and she offered to help do so if needed. Mr. Hadley agreed that a communications plan was needed, and he will be meeting with the Office of Communications soon for this purpose. Mr. Hadley anticipates that registration will start in early 2006, and he plans to have a detailed time line ready by December. Mr. Rosenthal suggested that the DCLG's Promotions Working Group be involved in plans for marketing the Summit.

Ms. Sumpter suggested that all of the DCLG members be introduced at the Summit, since the DCLG is hosting the meeting. Mr. Hadley explained that the agenda makes it clear that the DCLG is the meeting's host, and Mr. Ulman is the first speaker and will be sure to introduce the DCLG members and explain how to contact them. He added that all of the current DCLG members would still be on the DCLG during the Summit, because the terms that expire in 2006 do not expire until the end of June.

Dr. Weiss suggested including tours of research laboratories and meetings with researchers. She also suggested meeting with individuals who have benefited from NCI clinical trials, and proposed inviting Ms. Jane Reese-Coulborne for this purpose.

Ms. Whitewolf suggested that the dietary needs of diabetics be taken into consideration when planning meals for the Summit. Ms. Hamilton noted that co-sponsorship would be needed to support meal costs.

VI. NATIONAL BIOSPECIMEN NETWORK UPDATE

Dr. Carolyn Compton explained that human biospecimens represent an area of science and medicine that cannot succeed without advocacy. NCI is very interested in biospecimens because they are the basis for the vast majority of translational research and all clinical trials, and they represent the future of individualized medicine. The focus on biospecimens is based on the results of the Human Genome Project, which caused such an explosion in technology that it is now possible to produce molecular data on an unprecedented scale, more rapidly and more cheaply than was ever thought possible.

NCI's Biorepositories. The NCAB challenged NCI to find out what biorepositories the Institute had, what they were used for, and what kinds of analyses they could be used for. With the help of the RAND Corporation, NCI assessed the biorepositories in its Cancer Centers and SPOREs and learned that it was funding a collection of more than 300 million specimens from 150 million cases with 20 million new specimens collected each year. The RAND report also showed that

NCI is investing more than $50 million each year in research on cancer from basic science to clinical validation trials in 8 Cooperative Groups, and that most of them support the collection and storage of specimens for proteomic and genomic research. However, none of these biorepositories operates according to national standardized operating procedures, and they do not employ standardized quality assurance/quality control measures. No informatics platform is available to permit exchange of data, let alone exchange of specimens. The investigation concluded that the NCI-supported biorepositories are not coordinated to optimize the value of this resource.

Some of the challenges of biorepositories include the scarcity and high variability in the ways that clinical data are generated, reported and annotated, and collected. Varying biospecimen collection and storage methods are used. Different informatics structures and data elements are appended to these specimens, making information exchange difficult or impossible. Approaches to patient consent and privacy protection also vary, which limits the use of specimens for the types of research that need to be done.

National Biospecimen Network (NBN) Blueprint. Based on these assessments, a group of experts was convened to develop solutions to these problems. This process resulted in the NBN Blueprint. These experts identified key requirements for a national network of biorepositories that could solve this problem throughout the United States. Specifically, this network needs to assess the diversity of cancer types and populations based on a continual review of researcher needs. It must allow for access to specimens in repositories through a timely, centralized, peer-review process. Patient privacy must be protected. Physical and data resources must be provided to investigators without intellectual property restrictions. Best practices need to be used throughout the biorepository world. A high degree of pathological and clinical annotation is needed, including notes on long-term patient outcomes and medical records, because biospecimen value increases exponentially when linked to clinical information. In addition, the network must be based on an informatics system so that all data about and derived from specimens can be shared among investigators. Communication and outreach efforts are also needed because the entire enterprise depends on patients who donate samples to this effort.

Prostate Cancer SPORE Pilot Project. A pilot project is now being conducted in the 11 prostate cancer SPOREs. All of these SPOREs have biorepositories, and all of them operate differently. They are now facilitating the exchange of data in a way that allows investigators to produce achievements that would not have been possible otherwise. The benefits and the problems of this network are being identified, and NCI hopes to scale this model up to a national level if it appears to be successful.

The SPOREs decided to focus this pilot on the prospective and retrospective analysis of promising prostate cancer biomarkers used to predict outcomes in patients who are treated with certain modalities. The SPOREs are collecting biospecimens in their own biorepositories, with a portion of them sent to a central facility to be processed according to standard operating procedures before being redistributed to participating investigators. Both the centralized facility and the individual biorepositories at each site are collecting high-quality biospecimens with detailed annotation using standardized protocols. They are also creating a common informatics structure, facilitated by caBIG, so that they can share a searchable Web catalog of specimens and

data. All of the participating institutions have agreed to use common policies to verify and validate the quality of the biospecimens and of the research data based on them.

Biospecimen Coordinating Committee. NCI has also developed a Biospecimen Coordinating Committee with representation from all divisions in NCI that fund biospecimen collection and storage. This group has reviewed all of the relevant literature on biospecimen collection and storage to cull best practices and identify gaps in the literature. The committee also proposed an evaluation system for existing biorepositories.

The Biospecimen Coordinating Committee convened two national workshops this summer to address the ethical, legal, and policy issues, best practices, and recommendations for establishing and maintaining biorepositories. Each group was presented with a synthesis of the literature in advance of the workshop, and participants were asked to answer important questions. Their responses will be used in white papers for public commentary. The goal is to formulate NCI guidelines for biorepositories in the future. The ultimate goal is to remove the top roadblock to curing cancer.

Next Steps. Unlike several other countries, the United States still has no national standards for biorepositories that collect and store biospecimens for research use. The U.S. third-party payer system is a liability for harmonizing what is occurring at the interface between science and medicine. The standard still needs to be defined, and NCI would like to play a leadership role in this process. If NCI's biospecimen initiative succeeds, the operating procedures used to run the biorepositories that are generating research data will be moved into hospital laboratories to generate the same kind of data for patient care.

Advocates can help by educating patients about the importance of biorepositories. They can also lobby third-party payers to invest in the future of medicine by funding operations that will raise these biorepositories to the level needed to increase the speed and efficiency with which we address cancer.

Discussion. Dr. Weiss expressed frustration with the excess costs of not handling specimens properly. As more is learned about early detection and high-risk benign diseases, the critical samples will be smaller and smaller and must be collected and treated correctly from the beginning. Dr. Compton replied that large samples of untreated tumor are very difficult to acquire for some cancers, and patients need to be educated about the need to donate additional samples for research purposes. Technologies are also needed that allow research to be conducted with very small samples.

Mr. Bro asked whether members of Cooperative Groups were involved in developing the NBN Blueprint. Dr. Compton replied that Cooperative Groups were part of the process. Other participants were leaders of international organizations, the College of American Pathologists, and biotechnology and pharmaceutical companies. The names of participants are listed on the NBN Website (http://prostatenbnpilot.nci.nih.gov/FINAL_NBN_Blueprint.pdf).

Ms. Whitewolf noted that some cultural and religious communities want to preserve ownership of their specimens, and they want these specimens returned after the research is completed. Other

countries have addressed this issue, and lessons regarding ownership should be taken from their experiences. Dr. Compton explained that unless informatics technology housekeeping systems existed, it would not be possible to find a patient's biospecimen to return it. Special consents and specimen tracking must be made possible by technology. However, the policy and legality issues are outside of NCI's purview.

Ms. Anthony asked how specimens from children were handled. Dr. Compton replied that when parents make a decision to donate a specimen on behalf of their child, this has implications for the privacy of siblings and other family members, as well as for the patient when he or she grows up and has the ability to decide on consent.

Ms. Sumpter suggested that if a national biorepository were developed, more adults might participate in clinical trials. Dr. Compton agreed. Because institutions compete with each other and produce their own data, it is not possible to add data together from different institutions because of the differences in analytes. If efforts could be coordinated and all institutions participated together to achieve statistical power, this would encourage recognition of the value of clinical trials and show that it was worthwhile to donate one's specimens.

VII. INPUT FROM THE PUBLIC

Ms. Margo Michaels, President of the Education Network to Advance Cancer Clinical Trials (ENACCT), asked Dr. Doroshow how the CTWG would inform the public of its more detailed plans. Dr. Doroshow replied that NCI's Office of Communications and Office of Education were represented on the CTWG, and they plan to work with the Cooperative Groups and the disease steering committees. However, the grantees and advocacy community should be more involved. All of the CTWG's activities will be posted on the Web.

Nancy Roach, founder of the Colorectal Cancer Coalition and member of the Consumer Advocates in Research and Related Activities program, noted that in the advocacy community, an important short-term need is identifying who to call about a clinical trial. Dr. Doroshow said that one of the CTWG's recommendations is to develop a database that is part of caBIG and meets many of the goals that PDQ was not designed to address.

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THURSDAY, SEPTEMBER 15, 2005

VIII. *NCI LISTENS AND LEARNS* WEBSITE REPORT

Ms. Hamilton reported on the first 6 months of the DCLG's *NCI Listens and Learns* Website, which was launched in February. She also introduced Ms. Devon McGoldrick, the *NCI Listens and Learns* coordinator.

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Currently, 127 advocacy organizations have registered for the site, and 86 have appointed a spokesperson. Slightly less than half have posted a comment at some point, and some have posted more than one. To date, 428 members of the public have registered, but many fewer have posted a comment. Some of the topics posted on the site, such as the question about biorepositories, have received many more comments than others. On average, the site receives 27 comments per month.

The number of visitors to the site each month declined over the summer, possibly due to summer vacations. Of the 1,500–2,000 visitors to the site each month, 30%–40% view the page of that month's active discussion. The longer a topic is posted, the larger the number of people who look at it. Even after topics are closed to active discussion, visitors to the site continue to view these discussions. In August, for example, site visitors viewed all of the discussions that had been held to date. Approximately 80% of visitors to the site spend less than one minute on the site.

Ms. Hamilton reminded the DCLG that *NCI Listens and Learns* was designed as a 1-year pilot. When the DCLG makes a recommendation to the NCI Director about maintaining the site after the first year, it will need a comprehensive program evaluation. With the Evaluation Working Group's assistance, OLA has issued a request for proposals from potential evaluation contractors. The proposals have been received and will soon be reviewed.

The current question will remain on the site for a second month. In October, a question will be posted regarding an online guide for cancer treatment clinical trials. Topics are being developed for future posting on promotion of CIS and promotion of clinical trial accessibility/increasing accrual. OLA is updating the *NCI Listens and Learns* fact sheet and will send it to the DCLG members when it is complete. OLA sends those who have registered a notice at the beginning of each month to announce the new topic on the site. The office also sends a reminder in the middle of the month that the topic will close at the end of the month.

Discussion. Ms. Whitewolf asked whether the reaction of NCI staff to *NCI Listens and Learns* would be evaluated. Ms. Hamilton replied that the evaluation would include interviews with key stakeholders, including all NCI staff who have posted a topic, the DCLG, and people who do and do not use the site. OLA has also requested background research on similar sites.

Ms. Whitewolf inquired about feedback from the divisions that have posted questions on the site. Ms. Hamilton said that all of the staff who have posted a topic have been very positive about the experience, and they have found the summaries very helpful.

Col. Williams asked about the status of the suggestion that the comment button be moved so that it is higher up on the page. Ms. Sumpter added that people who are not technologically savvy might not realize that they needed to scroll down the page to see the "post a comment" button. She suggested that the button be placed next to the question. Ms. Hamilton explained that the site is undergoing usability testing, which will identify this type of issue.

Mr. Eric Rosenthal expressed frustration with the NCI staff's dismissal of certain recommendations or suggestions by various DCLG members, especially related to making the Listens and Learns website more accessible to visitors.

Ms. Sumpter pointed out that unless those posting a comment used special codes, their text was not divided into paragraphs, making their comments difficult to read.

Col. Williams commented that the site was not sufficiently user friendly for the general public. He wrote a very long comment on one topic, and the comment was never visible on the site. He wondered whether visitors to the site have a limited amount of time to post their comments. Ms. Deborah Price, Team Leader for Client Liaisons, Office of Technology, Strategy and Applications, Office of Communications, NCI explained that the site does not impose time limits, although comment length is restricted. She also suggested that if someone posted a comment and that comment was not shown on the site, the individual should contact OLA because this can be fixed. If a comment exceeds the space limit, it is still posted, although the end is cut off. The site includes a help screen on how to post a comment and other issues, and a button for sending an e-mail to the Web development team.

Ms. Sumpter said that some advocacy groups have forgotten their passwords. She wondered how to remind people of their passwords. Ms. McGoldrick said that she could look up passwords and send them to any person who requested them.

Mr. Bro said that he was not surprised that many visitors did not spend much time on the site. DCLG members were encouraged to publish links to the site in their organization newsletters and other materials. Mr. Bro's organization sends out newsletters to 10,000 people and typically includes a link to the current *NCI Listens and Learns* question. Many readers of the newsletter probably click on the link to see what the site is about and then leave. This is not necessarily a bad thing.

Ms. Anthony reported that one of the organizations she works with had trouble registering for the site. Ms. McGoldrick called the organization and talked them through the process. Others might be having the same problem; the registration process needs to be as easy as possible. Ms. Price explained that the technical team was eager to make these types of changes, even during the pilot period. However, a wholesale redesign of the site is not possible right now due to insufficient human resources.

Ms. de Córdova-Hanks noted that many of the questions posted on the site have been overly complex, and some survivors have found them difficult to understand. Ms. Whitewolf also expressed concern that in spite of DCLG suggestions for making the questions simpler, they are still overly complicated.

Mr. Ulman cautioned against evaluating the site based on anecdotes. He urged the DCLG to wait for the full evaluation to identify the shortcomings and successes of the site. He also pointed out that the biorepository question, which was very complicated, received a great deal of interest from advocacy organizations and members of the public. It would be helpful to learn whether the site was helping NCI program managers.

Ms. Sumpter said that anecdotal information is valuable. She expressed concern that if she, as a DCLG member, found the site difficult to use, the problem is likely to be even more acute for an older person, and many potential users might give up because of these problems. Mr. Ulman pointed out that since the site is still in its pilot phase, the degree to which modifications can be made at this time is limited. However, more changes can be made when the evaluation results are available. Ms. Sumpter expressed concern that if the site continues to be difficult to use and few people use the site, the DCLG will not be able to make a case for continuing the project. It is important to do everything possible now to make the site a success.

Dr. Beverly Laird shared a comment from Mr. Dwight Randle of the Susan G. Komen Breast Cancer Foundation. Mr. Randle told Dr. Laird that this service is great and adoption is simply slow but will pick up speed. He always intends to post a response to the questions on the site, but often does not have time to do so. Dr. Laird added that some advocates might be bypassing the site to communicate with NCI directly through channels that they have developed previously.

IX. CONSUMER ADVOCATES IN RESEARCH AND RELATED ACTIVITIES (CARRA) AND THE CANCER BIOMEDICAL INFORMATICS GRID

Panel Presentation—CARRA Program Update. Ms. Hamilton presented an historical overview of the CARRA program. When OLA was initiated in 1996, it received about 25 requests a year from NCI staff for advocate involvement. But as the number of requests increased, DCLG members found that responding to these requests was becoming overwhelming. They therefore decided to create a program that would offer a systematic way to involve advocates in NCI activities.

In the spring of 2001, OLA received more than 500 applications to the CARRA program. Members were selected to represent a balanced distribution of racial and ethnic groups, sexes, disease sites, and constituency groups. Once the 200 CARRA members were selected, they received orientation packets and participated in teleconferences.

CARRA Program Today. Ms. Elizabeth Neilson explained that CARRA currently has about 190 members. One-third are male, 23% are from a minority group, three-fourths represent people affected by adult cancers, and almost half represent a rural constituency. OLA has received 408 requests from NCI staff for CARRA member participation since September 2001. A majority of these requests involve participation in the peer-review process. Other NCI activities CARRA members participate in include reviewing educational materials, testing Websites, and developing research tools.

When an NCI staff member wants an advocate to participate in an activity, the staff member submits a CARRA request. Upon receipt of that request, the CARRA program staff searches the program database to identify at least five qualified CARRA members for every slot.

In response to a request from Ms. Sumpter for clarification on the assignment process, Ms. Neilson explained that OLA sends a biography of each CARRA member along with the list of names to the NCI staff member who requested advocacy assistance. The staff member then contacts the CARRA members to determine whether they have the appropriate skills and are available for the activity. NCI staff are not required to use CARRA members for their advocacy needs, but CARRA provides its members with orientation and training that makes them particularly valuable. NCI staff have been an integral part of the CARRA peer-review training, which has increased NCI staff interest in involving CARRA members in peer review. Ms. Neilson believes that most of the advocates who assist with NCI tasks are CARRA members.

OLA publishes an electronic newsletter for CARRA members, which DCLG members also receive, and provides quarterly teleconferences, mailings and e-mail notices, and member information updates. OLA has developed peer-review training workshops and teleconference orientation. Dr. Laird is a CARRA member and has helped develop the training curriculum for CARRA members, along with other CARRA co-facilitators for the peer review training.

Col. Williams pointed out that in the planning stages of CARRA, a concern was expressed that many advocates who are not part of CARRA have established links with NCI staff and are providing the same types of services as CARRA. Ms. Jane Jacobs explained that CARRA member participation must help NCI staff do their jobs, and in some cases, no CARRA member has the desired profile. OLA is about to start doing strategic planning for CARRA recruitment. The original plan called for 3-year terms, but OLA is rethinking that because science is moving so quickly, and CARRA members with new skills are constantly needed. OLA is also considering ways to include advocates who are already working with NCI staff and who meet the criteria for CARRA membership, in CARRA recruitment plans.

CARRA Program Growth and Development. Ms. Jacobs said that the program goals established for CARRA include increasing the number of opportunities for advocates to participate in NCI activities, and fostering an organizational culture that values the contributions of advocates.

Most CARRA activity has involved peer review. CARRA members are also involved in all of the caBIG workspaces, as well as projects involving nanotechnology and other new technologies. However, if the advocate voice is to be present in those activities from the beginning, CARRA members who can make contributions in these environments must be available.

CARRA members also participate in the communication of scientific research and are often involved at the beginning of processes. NCI is making more publications available in Spanish, and CARRA members are providing input into this process. CARRA is also helping ensure that everyone in the country is aware of NCI's information resources for the public.

CARRA is the most structured and developed program for involving advocates in work at NIH, although it is not the only such program. CARRA program staff are sharing their experiences with their colleagues from other Institutes and Centers (ICs) so that other parts of NIH can expand the involvement of advocates in their activities.

Many of the grant applications involving cancer are not reviewed by NCI peer-review panels, but by committees from the NIH Center for Scientific Review (CSR). Although advocates are involved in the NCI peer-review process, CSR has historically not included advocates in peer reviews. NCI is working with other ICs, and with the NIH Director's Council of Public Representatives (COPR), to explore future possibilities for broader advocate inclusion in peer review. To assist in that effort, the CARRA program is hosting a series of meetings titled "Trans-NIH Dialogue: Public Members in Peer Review"; and plans to post model materials and information about CARRA on its redesigned web site to be launched in 2006.

The challenges experienced during the program's first few years will play a role in the recruitment of the next group of CARRA members. OLA is gathering feedback from current CARRA members and welcomes feedback from the DCLG on how to design the next generation of CARRA recruitment, to include the experience, skills, and diverse audiences for optimum advocate contributions to NCI's work.

Presentation—Cancer Biomedical Informatics Grid (caBIG). Dr. Ken Buetow explained that the cancer enterprise is a complex web of institutions and organizations. The information part of the modern biomolecular enterprise is of unimaginable volume, complexity, and size. As a result, the tools and infrastructure we now have may not be enough to solve the problems that are being identified. To meet the 2015 Challenge Goal, these disparate organizational components and very complex and voluminous collections of information and/or data need to be brought together.

NCI has undertaken an aggressive program to transform the enterprise by weaving biomedical informatics into it. The caBIG goal is to create a virtual web of interconnected data, individuals, and organizations. This will change how research is conducted, how care is provided, and how patients/participants interact with the biomedical research enterprise.

caBIG is the first step in addressing this goal. The caBIG strategy is to use standardized and standard-based vocabulary, data elements, and data models to facilitate information exchange. This means agreeing on conventions of words used to describe cancer, how data are collected, and how those data are structured. The community will agree on ways to capture information in common ways. Once a common, widely distributed infrastructure is available, people will no longer have to spend time building a basic infrastructure and can then focus on innovation. A collection of interoperable applications will be developed to common standards, and cancer information will be widely available to diverse communities.

caBIG is founded on four key principles:

1. Open source—caBIG tools can be shared among the scientific and the broader community.
2. Open access.
3. Open development—the program is as transparent as possible.

4. Federated—the entire enterprise will help build this grid.

caBIG will make it possible to integrate information across the entire enterprise so that the individual institutional commitment of resources and components will form a national web of infrastructure, applications, and data. The real goal is to create an almost transparent interlinking infrastructure that joins the disparate components of the cancer enterprise. If it works well, it will be unnoticeable. caBIG is currently building that grid through a very technical enterprise that brings together a diverse collection of experts from different fields.

caBIG started as a pilot that was launched in NCI's Cancer Centers. The pilot's goal is to show that these centers can be joined together and, in collaboration, can develop new tools and systems. The pilot is initially focusing on three key domains and two cross-cutting workspaces:

- Domain workspace 1: Clinical trials management system.
- Domain workspace 2: Integrative cancer research.
- Domain workspace 3: Tissue banks and pathology tools.
- Cross-cutting workspace 1: Vocabularies and common data elements.
- Cross-cutting workspace 2: Architecture.

The domains represent cancer research areas that need an electronic infrastructure. The cross-cutting workspaces are identifying issues that must be addressed to share information. Work groups are addressing strategic-level issues, including data sharing and intellectual capital, training, and strategic planning.

caBIG is up and running, with participation from more than 50 Cancer Centers. Other NIH Institutes and DHHS agencies, including the FDA, are contributing to the program, which has more than 700 active participants. caBIG is delivering 75 different products and datasets this year. The technology that underpins caBIG has state-of-the-art controls that limit access to authorized users.

caBIG represents a new way of doing business across NCI. This coordinated development effort is woven directly into all of NCI's activities. caBIG is designed to be available to everyone, not just researchers and physicians. Consumers and advocates have been part of caBIG from the beginning. They are not simply add-ons, but are involved in the planning process and all of the program's activities.

Discussion. In response to a question from Ms. Whitewolf, Dr. Buetow explained that caBIG is the next generation World Wide Web. Like the Web, caBIG shares information on national and international activities. It will include Websites at NCI and others at local institutions, but all of them will use the same language and the same way of communicating with one another. Individuals from one institution will have access to databases stored at another institution.

Ms. Whitewolf asked whether, if her local clinic entered information into this system, others would have access to that data. Dr. Buetow replied that the data might never leave the clinic, but authorized users would have access to the data, and the clinic could maintain control of them. Like Google, the system will let users search information from all of the sources connected to caBIG, but unlike Google, users will be able to bring up information that is truly relevant to their

search. In some circumstances, however, only authorized people will have access to certain components.

Ms. de Córdova-Hanks asked whether caBIG could be thought of as a clearinghouse for information. Dr. Buetow said that unlike a clearinghouse, caBIG's information would not be housed in one place. It will be a virtual clearinghouse distributed across the entire cancer enterprise; information will be stored in clinics, foundations, Cancer Centers, and other locations.

Col. Williams asked whether consumers would have access to the caBIG information. Dr. Buetow replied that a goal is to empower consumers, physicians, and Cancer Centers to have access to the information.

Ms. Sumpter asked whether a centralized system of patient electronic medical records will be incorporated into caBIG. Dr. Buetow explained that caBIG is working closely with the national coordination center for health information technology in the President's office and the Secretary of DHHS so that caBIG contributes to the goal of developing electronic medical records. Ultimately, consumers will be able to enter their authorization information, see their own medical records, and share these records with physicians and researchers.

Presentation—CARRA Members in caBIG. Mr. Greg Bielawski characterized caBIG as a very important project to advocates and consumers. It is very different from other projects of CARRA members primarily because of its complexity and length. The advocates who are involved in caBIG have signed on for the entire 3 years of the pilot project. Mr. Bielawski is a member of the caBIG strategic planning group.

CARRA members were assigned to all of the caBIG workspaces and other work groups as well. They are identifying issues of importance to advocates and emphasizing their relevance when necessary. Some of the issues they are addressing are the security of records, adverse event reporting, and communication of results and benefits to the patient and advocate communities. CARRA members continually remind the scientists to keep patients in mind in their work. The seven advocates are also communicating among themselves regarding how to inform the advocacy community about caBIG and its importance to cancer research and ultimately to cancer patients.

Mr. Bielawski suggested that the DCLG appoint a liaison to the CARRA caBIG advocates. The CARRA members could provide updates on caBIG at DCLG meetings because of its high level of importance to advocates and patients. Some of the vehicles that might be used to communicate about caBIG to the broad advocacy community are the DCLG Website, *NCI Listens and Learns*, and the DCLG Summit. Advocates could be put on the agenda at caBIG annual meetings, and caBIG could be on the agenda for the NCI/American Cancer Society cancer survivorship research conferences.

Discussion. Ms. Whitewolf said that her community is still at the "horse and buggy" stage with respect to the information highway. She asked how her community could obtain computer infrastructures and learn how to use them. Mr. Ulman suggested that the DCLG bring information back to the advocacy communities to show that caBIG will benefit them in the

future. The program will have downstream results that will benefit all communities regardless of gaps in technology.

The DCLG carried a motion unanimously to form a DCLG working group that will serve as a liaison to the CARRA members working on caBIG.

Ms. Anthony suggested providing information on caBIG to the medical community through professional society meetings, including those of the Oncology Nursing Society and the American Society of Clinical Oncology (ASCO). Dr. Buetow noted that caBIG is actively engaging ASCO in a variety of contexts, and nursing associations are key participants in the caBIG workspaces.

X. DISCUSSION WITH NCI DIRECTOR

After the DCLG members introduced themselves, Dr. von Eschenbach thanked them on behalf of NCI and the entire cancer enterprise for the commitment, passion, and energy they bring to the support of NCI. He thanked Ms. Hamilton for all of her hard work and dedication.. He also noted that Mr. Ulman had "gone the extra mile" to put his passion and energy into advocating for an effective means of informing NCI and the community of the critically important issues that need to be addressed to have a real impact on cancer.

Dr. von Eschenbach noted that when the DCLG members introduced themselves, all of them had mentioned the ways in which they had personally experienced the pain associated with cancer. He asked those present to pause for a moment to recognize those touched by this disease.

2015 Challenge Goal. The NCI Director stressed that the reason for NCI's existence is to affect the lives of those who are threatened by cancer, and research is a means to this end. When Dr. von Eschenbach first arrived at NCI, he recognized that it would not be possible to eliminate cancer; in fact, the data suggest that the number of cancer diagnoses may increase before they begin to diminish. However, the NCI leadership recognized that, for the first time, it was possible to envision eliminating the outcomes of cancer—the suffering and death that result from this disease. The research that has been conducted to date has made it possible for cancer to be understood from the molecular perspective.

According to Dr. von Eschenbach, this relatively recent transition has "changed everything." Approximately 10 years ago, it became possible to study the genetic, molecular, and cellular events associated with the transition from cancer susceptibility through early development of malignant transformation to growth and spread of cancer and, ultimately, death. By being able to understand the process, it is now possible to develop more effective strategies and interventions that preempt the process. As a result, methods are becoming available to prevent more cancers from developing in the first place, detect them earlier in their development, and modulate their behavior so that patients can live with and not die from the disease.

Discovery, development, and delivery have become NCI's portfolio, with multiple initiatives across that continuum. This is circular, not linear, because the delivery of interventions to patients provides opportunities for insight and learning about the biology of cancer. The Institute

is developing many strategic initiatives across this continuum in an effort to fulfill NCI's commitment to reach its Challenge Goal of ending the suffering and death due to cancer by 2015.

The Institute's current budget is the largest it has ever had, and the enterprise has never been bigger or stronger. However, the opportunity is even greater than the enterprise, and it is essential to find ways to be more efficient in order to expand it. NCI is not just trying to identify the most critically strategic initiatives and opportunities but also to carry them out in the most effective and efficient way.

Role of the DCLG. The Institute is emphasizing collaboration, cooperation, integration, and synergy. caBIG and other initiatives are designed to provide the means for this coordination and integration. NCI must make decisions about which projects to undertake in the context of available resources, and it must sometimes say no to some efforts, not because they are not valuable but because other priorities are even more important. The more the DCLG understands this reality, the more it can help communicate to the rest of the community not just where NCI is going but how it expects to get there and what is needed to achieve the Challenge Goal.

The DCLG has an important role to play as a conduit between the community it represents and NCI. The DCLG brings NCI the cancer advocacy community's perspective so that NCI can integrate this information into its planning. At the same time, the committee carries back to the community insights and information from NCI.

Many of the Institute's efforts apply well beyond cancer, so the DCLG's sphere of influence goes far beyond the cancer community. For example, caBIG addresses a major priority for the Administration. Cancer has a major opportunity to lead the health care field in a major transformation that will contribute to the welfare and lives of millions of other patients.

Dr. von Eschenbach asked the DCLG members to serve as change agents and to give up their personal agendas. Each DCLG member has been selected for his or her extraordinarily rich background and perspective, but Dr. von Eschenbach asked each member to leave this background behind when meeting with the rest of the committee. The role of DCLG members is not to represent their organizations and communities, but to serve as a conduit between all of those communities and NCI. If organizations are to recognize that they do not need their own relationship with NCI because they can work through the DCLG to bring their issues forward, they must know that the DCLG represents not someone but everyone.

Dr. von Eschenbach distinguished between issues that NCI can control and those it can influence. Only NCI can control and direct the funds it provides for research. The Institute also has a leadership responsibility for the core national cancer program, but it does not control many aspects of this program. NCI is therefore trying to create relationships with these other parts so that it can influence their efforts and activities. NCI has created several mechanisms to develop the needed partnerships with other federal agencies, such as the FDA, CMS, and the Department of Defense. NCI can also play an important role in the bioinformatics arena, and although it may not be able to provide the computers needed by isolated communities, it could participate in a process that could have this result.

The NCI Director asked the DCLG to help ensure that the expectations created are in line with the realities. Otherwise, their experiences will be very frustrating because they will spend time on issues that NCI does not control, and they will frustrate NCI staff who will receive advice about issues that are not their core business.

Through such vehicles as the *NCI Cancer Bulletin* and the *NCI Listens and Learns* Website, NCI tries to be as open and transparent as possible so that no doubt arises about what the Institute is doing and where it is going. Advisory groups provide advice, while the responsibility to lead, direct, and manage NCI belongs to Dr. von Eschenbach. He welcomed the input of the DCLG and promised that he would always listen to their advice, although he might not always follow it.

Discussion. Col. Williams pointed out that advocacy groups tend to be organ specific, but they need to come together to focus on the broader picture.

Mr. Bro asked Dr. von Eschenbach to comment on the most useful activity that the DCLG could take on to help meet the 2015 Challenge Goal. Dr. von Eschenbach explained that patients must become the center, rather than the passive recipient, of care. Researchers will learn more about the biology of cancer from individual patients than they will ever learn in the laboratory with all of the new technologies available. Dr. von Eschenbach asked the DCLG to help the public understand this new reality and become directly engaged in it. Unless the cancer research community connects to patients, it will not fulfill its mission, and people will die unnecessarily.

Ms. Whitewolf stressed the importance of making an impact on people with cancer during her term on the DCLG and asked how to accomplish this goal. Dr. von Eschenbach expressed concern that the new era of molecular oncology is highly dependent on technology, and this might widen disparities instead of eliminating them. Unfortunately, NCI has little control over this problem. Often, solutions emerge when communities refuse to wait for government to solve a problem and come up with their own solutions. The cancer research world is not tapping into the community in a way that leads to success stories. Perhaps DCLG members can bring their wealth of experience to come up with solutions and suggest to NCI others who may be facing similar problems and could benefit from these solutions.

Ms. Anthony reported her involvement with a cancer advocacy organization that exemplified Dr. von Eschenbach's point. Ms. Hamilton had asked Ms. Anthony to join a small organization from South Carolina that was meeting with several NCI staff members. This group wanted to help NCI move forward toward the 2015 Challenge Goal, and its representatives came away from the meeting with several suggestions that it is beginning to implement. Ms. Anthony thanked Ms. Hamilton for involving her and suggested that the DCLG do more of this kind of liaison work by bringing members' groups to the table to help meet the 2015 goals.

Dr. von Eschenbach explained that NCI uses the shared governance model. Dr. Mark Clanton and the other deputy directors work closely with Dr. von Eschenbach, and when one speaks, they all speak. Although the DCLG may have limited face time with Dr. von Eschenbach, they will have the opportunity to work with Dr. Clanton to make meetings like the one mentioned by Ms. Anthony continue to happen.

Dr. Clanton explained that the problems in the delivery system are systems problems. The solution is not just better insurance coverage or quality of care, but finding ways to affect all of the pieces of the care delivery system to improve all care. Systems thinking must be applied so that several points are affected simultaneously. Race, ethnicity, language, literacy, and community lie between the connections of science and delivery. Even if the knowledge problems and the delivery system are fixed, these connection points will continue to be a problem. DCLG members have expertise in these areas, and NCI needs the DCLG to bring information back from these areas so that the Institute can connect science and knowledge and improve the delivery system to have an impact.

Ms. Whitewolf said that a tribal board on which she sits is planning a symposium to bring together 25 traditional healers and 25 cancer researchers. She asked for assistance in identifying cancer researchers who would be willing to have a dialogue with traditional healers. Dr. Clanton explained that NCI has an Office of Cancer Complementary and Alternative Medicine headed by Dr. Jeffrey White, who could provide advice on this issue.

Dr. Laird asked that NCI continue to share new developments, such as caBIG, on a CliffsNotes level to help the DCLG prepare the public for these developments. Dr. von Eschenbach stressed that NCI is committed to being as open, transparent, and effective as possible in helping the DCLG understand the pieces that make up this agenda. NCI would like to explore with the DCLG how to keep that process going through presentations, interim communications, and broader access to the Institute's tools. The *NCI Cancer Bulletin* is a useful resource because it usually includes snapshots of what NCI is doing.

The community is beginning to see the balance between focused efforts toward a particular disease and investing in a more generic infrastructure that will "float all boats." Helping the community through that change process will be important. Dr. von Eschenbach expressed the hope that as the community understands the identity and stature of the DCLG, they will see it as their conduit to the NCI. They will welcome DCLG members at their meetings because they will see the group as a way to bring their messages to NCI. As this evolves, the DCLG's impact will increase. He asked the DCLG to continue to focus on how it can help NCI meet its Challenge Goal.

XI. WORKING LUNCH—WORKING GROUP MEETINGS

Evaluation Working Group. Dr. Laird stated that the request for proposals (RFP) for a contract to evaluate the *NCI Listens and Learns* Website was distributed and had resulted in two submitted proposals. She invited the working group members to review the proposals along with OLA staff. The budgets proposed in the two submissions were in the requested range.

Ms. McGoldrick will forward copies of the two proposals to Dr. Laird and Ms. Anthony, who volunteered to review them and submit their comments by September 21. (The award will be made at the end of September.) Dr. Laird and Ms. Anthony expressed the hope that the proposals would include plans to submit interim reports during the evaluation process.

The NCI staff will review/discuss the two proposals in a conference call on September 19. Sufficient time for obtaining Office of Management and Budget (OMB) clearance for the evaluation was built into the RFP's proposed evaluation plan.

Ms. McGoldrick noted that at the June 2006 Summit, OLA will set up a kiosk where attendees can view the *NCI Listens and Learns* site. The staff will register attendees and perform other functions, such as providing information.

Ms. Campos presented a recently developed draft agenda for the June Summit, noting that it would be sent to committee members for further consideration.

Dr. Laird encouraged OLA to consider hiring a facilitator for the Summit. She suggested that the evaluation of the Summit include questions about perceptions rather than about knowledge. The evaluation results could be helpful, especially in guiding future Summits. The working group members expressed an interest in helping develop the survey questions.

The group members reviewed a draft logic model containing possible questions for the Summit evaluation. They agreed that the questions must be revised and should address both short- and long-term outcomes. A final Summit agenda, including topics of breakout sessions, is needed to guide development of the questions. The survey should include questions that revealed attendance in the sessions of the meeting, whether the attendees would participate in future meetings, and how the attendees were supported (e.g., organizational funds). The survey takers should be anonymous.

Working group members agreed to communicate through e-mail to develop the survey questions. They asked that the meeting planners provide 15 minutes at the end of the Summit during which attendees could fill out the surveys and receive certificates for their participation. The survey also might be provided online for those wishing to offer their input later; however, this might lead to problems, such as multiple responses from some individuals.

Operations Working Group. Col. Williams opened the meeting and reviewed the agenda for this meeting of the Operations Working Group.

Col. Williams observed that the questions posted on the *NCI Listens and Learns* Website were generated by NCI staff, but in some cases, the questions had been perceived as not friendly to intended users. He suggested that guidelines might be needed for staff who write the questions.

Ms. Whitewolf proposed that the working group be involved earlier in the formulation of the questions, through conference calls. These calls should be planned in advance to accommodate everyone's schedules. Ms. Hamilton supported the concept of working group involvement in formulating site questions through teleconferencing.

Ms. Sumpter asked that more time be given to staff and the working group to develop questions.

Ms. Sumpter noted that the biorepository question drew so much response that it remained on the site for 2 months. Ms. Sumpter proposed that a 2-month period for posting questions be

considered to give the public more time to respond. The working group agreed to this recommendation.

After further discussion, the working group also agreed to work on question formulation with NCI staff through conference calls and to recommend this to the DCLG. This process will require more lead time than has usually been given to review the questions.

Ms. Hamilton reminded members that although the Evaluation Working Group is dealing directly with evaluation of the site, the entire DCLG would make recommendations to the NCI Director about the site's future after the 1-year pilot. Working group members should consider what other recommendations they might make at that time, such as redesigning the site or asking for more resources. The evaluation should develop some standard or benchmark for success, such as the number of hits over a given period of time.

Teleconferencing might serve as an alternative technology for improved public input.

Col. Williams noted that although the DCLG and the Operations Working Group have contacted advocacy organizations to encourage *NCI Listens and Learns* site registration and the appointment of spokespersons, some 40 organizations have yet to do the latter. The working group agreed that Ms. McGoldrick, the *NCI Listens and Learns* coordinator, would contact the remaining organizations by e-mail and list Operations Working Group members as points of contact. Ms. Hamilton will ask working group members to review the e-mail before it is sent. It was agreed that unless an organization asks to be taken off the list, OLA would simply keep extending the invitation to appoint a spokesperson.

Members briefly discussed the concept of asking registered advocacy organizations to contact their members to elicit more participation in the site.

Ms. Whitewolf suggested using teleconferences to help achieve the goals of *NCI Listens and Learns.* Col. Williams supported the concept of teleconferences when the public can respond, either during the event or after, such as through e-mail questions that elicit a response. Ms. Sumpter suggested that teleconferences be used more, for example, regular teleconferences to address subjects such as caBIG.

The working group agreed that members would monitor the NCI teleconference series that begins this Monday (September 19), entitled *Understanding NCI*. Col. Williams noted that monitoring the series might help the group make further recommendations for the *NCI Listens and Learns* Website.

Members congratulated Ms. Hamilton, Ms. McGoldrick, and other OLA staff members for doing a great job and providing prompt responses.

Summit Working Group. Mr. Hadley chaired the meeting in Ms. Scroggins's absence. Mr. Hadley recalled all of the advice he had received from Ms. Nancy Caliman and suggested that the working group begin its meeting by centering on the absence of Ms. Caliman.

Mr. Ulman noted that according to the draft agenda for the Summit, Dr. von Eschenbach's presentation would be preceded by Dr. Zerhouni's talk, even though NCI is hosting the meeting. Mr. Hadley explained that Dr. Zerhouni's comments would be brief, whereas Dr. von Eschenbach would be the plenary speaker and have more time for his remarks. Mr. Rosenthal suggested that Dr. von Eschenbach introduce Dr. Zerhouni.

Ms. de Córdova-Hanks suggested that the schedule not be too packed so that people have "room to breathe."

Mr. Bro noted that the Summit should include a discussion of caBIG, which is clearly a major NCI priority. Mr. Hadley suggested adding caBIG to the *Understanding NCI* teleconference series.

The minutes of the August 17 meeting of the Summit Working Group were approved unanimously. The group's next teleconference will take place on October 5.

Mr. Ulman suggested that those who receive a scholarship to the meeting be required to arrive early enough to participate in the campus tours. Ms. de Córdova-Hanks suggested that participants sign in. Mr. Hadley explained that all scholarship recipients would be required to sign a contract to ensure that when they arrived at the meeting, they attend all of the events.

Mr. Rosenthal suggested that participants, especially those on scholarship, be required to disseminate what they learned at the meeting to their communities. The DCLG members should be responsible for following up on the ideas that come out of the Summit for other projects. The Summit also provides an opportunity to assess potential new CARRA and DCLG members.

Mr. Ulman proposed listing opportunities for participation following the Summit, such as publishing a newsletter article or giving a talk. Mr. Hadley noted that a book would be assembled from the papers submitted by advocates. Ms. de Córdova-Hanks stressed the importance of letting advocates know that their papers will not be critiqued so that they will not feel intimidated.

Mr. Hadley pointed out that if the Summit is webcast, advocates can use the webcast to publicize the Summit in their communities. Funding is needed for webcasting and other tasks, but Mr. Hadley believes that once the save-the-date card is distributed, others will ask to participate or help with funding.

Mr. Bro asked whether the webcast would be live or retrospective. Mr. Hadley explained that it would probably be retrospective so that people could view it whenever they wanted. Mr. Bro pointed out that if the webcast were live, it might diminish attendance. Mr. Rosenthal agreed that the webcast should be retrospective, because broadcasting live would add many technological challenges, as well as the obligation to reply to people who made comments during the meeting.

Mr. Rosenthal suggested documenting the Summit activities in a report, possibly for a peer-reviewed journal. The DCLG should consider vehicles beyond the *NCI Cancer Bulletin.*

Mr. Ulman asked whether the media would be involved in the Summit. Mr. Hadley said that OLA has talked to the Office of Communications, which believes that the media will be interested in the Summit. They are open to inviting them. Advocates can tell the cancer story better than NCI in some cases, but they need to be taught how to work with the media.

Mr. Rosenthal said that the way to do this effectively is to use advocates together with a physician or scientist. Ms. de Córdova-Hanks suggested providing advocates who are likely to speak to the media with a mini training session. Mr. Rosenthal offered to talk to the Office of Communications about opening the Summit to the media.

Ms. de Córdova-Hanks emphasized that if a brochure is printed to publicize the Summit, it should be written in terms that are understandable to a lay audience. Some of the language in the agenda, such as the terms "intramural" and "extramural," is probably unfamiliar to the general public. Perhaps a tag line could explain some of these terms, such as "NCI intramural clinical trial view—a better bridge into the future of clinical trials." Catchy titles will get media attention.

Mr. Rosenthal agreed that printed materials should always be understandable to the public. But the audience for this Summit will be selective, and the meeting materials should not be too basic. One of the Summit sessions could explain acronyms at NCI. The terms "intramural" and "extramural" should not be on the cover of the Summit program, but the advocates who come to the Summit will need a certain level of knowledge to participate and disseminate what they learn to their communities. Ms. de Córdova-Hanks suggested a glossary of terms in the program.

Mr. Hadley pointed out that while the agenda uses the terms "extramural" and "intramural," the text below each item explains these terms. Mr. Rosenthal agreed that using a descriptive phrase is helpful.

Mr. Hadley noted that the brochure designed to bring people to the meeting does not need to use technical terms. Alternatively, it could say, "Do you know the difference between intramural and extramural research? Come to the meeting and find out!"

Mr. Bro said that the preliminary agenda and brochure are marketing pieces that must be simple and appealing to attract potential participants.

Ms. de Córdova-Hanks suggested that the brochure invite advocates and have the DCLG's signature under the invitation. She also suggested that the Summit provide an opportunity to participate in a physical activity.

XII. NEXT STEPS

Report of the Operations Working Group. Col. Williams reported that the Operations Working Group made the following recommendations:

- During the pilot period, the *NCI Listens and Learns* questions should be posted for 2 months.
- The DCLG and Operations Working Group should have more time to review the questions before they are posted on the Website.

- Ms. McGoldrick should contact all of the advocacy groups that have registered for the site but have not yet appointed a spokesperson to encourage them to do so.
- The Operations Working Group will monitor the *Understanding NCI* teleconference series to see if a similar venue might be incorporated into *NCI Listens and Learns*.

Ms. McGoldrick agreed to send the current version of the October *NCI Listens and Learns* question to the DCLG for additional feedback.

Ms. Sumpter said that the working group discussed the possibility of posting questions developed by the DCLG on the site. These questions might ask the public what they see as important issues.

Report of the Evaluations Working Group. Dr. Laird said that an RFP for an evaluation consultant was issued, and two proposals had been submitted. Ms. Anthony and Dr. Laird will review the proposals with NCI staff to score them. An award will be made by the end of the month, and the evaluation report will be shared with the DCLG.

The Evaluation Working Group also discussed the Summit evaluation. The individual who will facilitate the Summit might be called on to help evaluate the meeting, and the Evaluations Working Group is available to help the facilitator frame these questions. Ms. Hamilton explained that a contract has been drawn up with a facilitator to keep the sessions on time.

Ms. Anthony added that the working group reviewed the Summit logic model with Ms. Campos and found that the proposed agenda meets the Summit Working Group's goals.

Reporting of the Summit Working Group. Mr. Hadley reported that the Summit Working Group will continue to work on the agenda between now and December.

Ms. Sumpter suggested that the Summit include a presentation on caBIG, as well as a discussion of the role of CARRA. Ms. Jacobs suggested that CARRA recruitment information be distributed at the Summit.

Ms. Anthony stressed the need for DCLG members to have jobs at the Summit so that they are perceived as actively involved. Mr. Hadley noted that pictures and biographies of the DCLG members would be included in the Summit program. Ms. Hamilton explained that people would be stationed around the meeting space during the Summit with buttons or T-shirts to indicate that they were "NCI Ambassadors." Participants can then talk to them if they have questions or comments. DCLG members might serve as NCI ambassadors. Mr. Hadley said that the Office of Communications had suggested having people stationed at Natcher Conference Center cafeteria tables who can talk to participants during meals. All of these ideas are still under discussion.

***Understanding NCI* Teleconference.** Ms. Hamilton explained that hard copies of the promotional flyer for the *Understanding NCI* teleconference series are now available. Four calls have been scheduled between September and December. During the first session, Dr. von Eschenbach will discuss the 2015 Challenge Goal, and Col. Williams and Mr. Ulman will discuss the role of the advocacy community. The session will include time for questions. DCLG

members who want copies of the teleconference promotional materials should let Ms. Hamilton know how many they need, and OLA will provide them. The flyer is also available on the OLA Website in PDF format.

Mr. Hadley added that recordings of the calls will be available on the NCI Website so that people can listen to them at any time. He thanked Ms. Anne Willis for arranging the publicity for the series.

Next Steps. Ms. Hamilton said that she will be hiring a new DCLG Executive Secretary. The DCLG is scheduled to have two in-person meetings a year in addition to the Summit, and the next meeting will take place in the spring. Ms. Hamilton plans to propose dates for face-to-face meetings for the next 3 years to allow DCLG members to plan for these meetings well in advance.

Mr. Ulman asked those interested in serving on the working group to interact with the CARRA members assigned to caBIG to let him know. A chair will then be assigned.

Mr. Ulman said that if the DCLG is to serve as a conduit, as Dr. von Eschenbach had requested, the group needs stature in the community and must be regarded as a valuable resource.

The group had heard many presentations about some great ideas that were being implemented at NCI, and the DCLG has an important role to play in disseminating this information. But none of these exciting activities can be implemented without additional resources, so the DCLG will provide input on NCI's budget plans. If the DCLG does its job, it can have a huge impact on what NCI can do, and the downstream effect will be that people will no longer suffer and die needlessly.

Mr. Ulman requested that OLA provide contact information for the presenters at this meeting so that DCLG members can send them thank you notes. He promised to send correspondence to the DCLG within the next 2 weeks.

Mr. Ulman closed by saying that this had been a great meeting, and participants voiced many very constructive ideas. Everyone felt deeply that Ms. Caliman had been there with the group.

XIII. ADJOURNMENT

The meeting adjourned at 2:19 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 14–15, 2005

- DCLG members who would like to see the draft NIH reauthorization bill should contact Ms. Brooke Hamilton, who will distribute copies.
- Each DCLG member will provide feedback on NCI's draft strategic plan by November 3. They should receive the document on or about October 20.
- DCLG members should submit appropriate news items to the *NCI Cancer Bulletin* for publication in its "Community Updates" section.
- If DCLG members are aware of potential funding sources for Summit scholarships, they should let the Summit Working Group know.
- The Promotions Working Group will participate in the planning process for promoting the Summit.
- The Office of Liaison Activities (OLA) will send DCLG members a copy of the new *NCI Listens and Learns* fact sheet as soon as it is ready.
- DCLG members will advise the Consumer Advocates in Research and Related Activities (CARRA) office on ways to recruit new CARRA members who represent diverse backgrounds and have the knowledge and experience needed to work on NCI projects.
- The DCLG will form a cancer Biomedical Informatics Grid (caBIG) working group to provide advice and assistance to the CARRA advocates assigned to caBIG. DCLG members who are interested in serving on the group should inform Mr. Doug Ulman.
- Ms. Devon McGoldrick will send the latest version of the October *NCI Listens and Learns* question to DCLG members for comment.
- Ms. Hamilton will provide hard copies of the flyer promoting the *Understanding NCI* teleconference series to DCLG members after they inform her of the number of copies they need.
- All DCLG members will play an active role in the Summit—perhaps serving as "NCI ambassadors" that participants can approach for information on NCI.
- Mr. Ulman will develop suggestions concerning steps the DCLG can take to help NCI address its budgetary challenges.
- Ms. Hamilton will provide contact information for speakers at this meeting to DCLG members, who will write thank you notes to these individuals.
- Within 2 weeks of this meeting, Mr. Ulman will distribute an update on DCLG activities to all members by e-mail.

Action Items from the Evaluations Working Group

- OLA staff will forward to Dr. Laird and Ms. Anthony copies of the two proposals received for the contract to evaluate the *NCI Listens and Learns* Website.
- Dr. Laird and Ms. Anthony will forward their reviews of the two proposals to OLA staff by Wednesday, September 21.
- OLA staff will continue to develop recommendations for (1) a facilitator and (2) an evaluator for the Summit meeting. [#2 is possibly done.]
- OLA staff will refine the draft questions for the pre- and post-Summit evaluation survey. They will communicate through e-mail.

Action Items from the Operations Working Group

- The Operations Working Group will recommend to the DCLG that questions on the *NCI Listens and Learns* Website be posted for no less than 2 months during the pilot period, in part to encourage more response.
- The Operations Working Group will recommend to the DCLG that Operations Working Group members and OLA staff be given time to review questions before they are posted on the site in order to work with the originating authors to make the questions more user friendly.
- The Operations Working Group will recommend to the DCLG that Ms. McGoldrick e-mail organizations that have registered with the Website but lack spokespersons. This e-mail will provide Operations Working Group member names and contact information to facilitate organization response.
- The Operations Working Group will monitor NCI's new teleconference series, *Understanding NCI,* for tips on possible improvements to the *NCI Listens and Learns* Website.

Action Items from the Summit Working Group

- Scholarship recipients who attend the Summit will be required to arrive early enough to participate in the NIH tours, and they must stay for the entire meeting.
- All Summit participants will be required to disseminate their experiences from the Summit to the communities they represent.
- DCLG members will be responsible for following up on ideas that come out of the Summit.
- The papers submitted by Summit participants will be assembled into a book (but these papers will not be critiqued).
- The Summit proceedings will be documented in a report that might be submitted to a peer-reviewed journal.
- Mr. Eric Rosenthal will consult with NCI's Office of Communications about working with the media to publicize the Summit.
- The Summit will present information on caBIG, perhaps in one of the breakout sessions.
- The promotion brochure for the Summit will be written in terms that are easily understood by lay audiences.