DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
39th NCI DIRECTOR'S CONSUMER LIAISON GROUP

Summary of Meeting
March 29–30, 2006

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The 39th meeting of the National Cancer Institute (NCI) Director's Consumer Liaison Group (DCLG) was convened at 12:30 p.m., March 29, 2006, at the Natcher Conference Center, National Institutes of Health, Bethesda, Maryland. Mr. Doug Ulman presided as Chair.

Members Present
Mr. Doug Ulman, Chair
Ms. Peggy L. Anthony
Ms. Vernal H. Branch
Ms. Lourie Campos
Ms. Bobbi de Córdova-Hanks*
Ms. Nancy Davenport-Ennis†
Dr. Beverly Laird
Dr. Sylvia Ramos
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. Barbara Guest, DCLG Executive Secretary
Mr. James Hadley, Advocacy Program Manager
Ms. Brooke Hamilton, Acting Director, Office of Liaison Activities (OLA)
Ms. Jane Jacobs, CARRA Program Development Manager
Ms. Devon McGoldrick, *NCI Listens and Learns* Coordinator
Ms. Elizabeth Neilson, CARRA Program Coordinator
Ms. Linda Ticker, Program Assistant
Ms. Anne Willis, Advocacy Program Fellow
Ms. Jennifer Fritz, Health Communications Intern
Ms. Bethany Piernikowski, Cancer Research Training Fellow

* Participated by teleconference.
† Present only on March 29.
‡ Present only on March 30.

Speakers
Ms. Peggy Anthony, DCLG
Dr. Anna Barker, Deputy Director for Advanced Technologies and Strategic Partnerships, NCI
Dr. Michael Burke, Research Scientist, RTI International
Dr. James Doroshow, Director, Division of Cancer Treatment and Diagnosis, NCI
Ms. Susan Erickson, Director, Office of Policy Analysis and Response, NCI
Ms. Jane Jacobs, CARRA Program Development Manager
Dr. LaSalle Leffall, Jr., President's Cancer Panel
Ms. Elizabeth Neilson, CARRA Program Coordinator
Ms. Cherie Nichols, Director, Office of Science Planning and Assessment, NCI
Dr. John Niederhuber, Deputy Director, NCI
Ms. Mary Jackson Scroggins, DCLG
Mr. Doug Ulman, Chair, DCLG
Dr. Jaye Viner, Deputy Director, Office of Centers, Training and Resources, NCI
Col. (Ret.) James E. Williams, Jr., USA, DCLG

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THURSDAY, MARCH 30, 2006

National Cancer Institute
39th NCI Director's Consumer Liaison Group Meeting
Wednesday, March 29, 2006

I. Welcome

Mr. Doug Ulman welcomed members of the DCLG, the public, and the cancer community to this meeting. In particular, he welcomed Ms. Barbara Guest, the new DCLG Executive Secretary.

1. Conflict of Interest Statement

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

2. Minutes

A motion to approve the minutes of the DCLG's December 1, 2005, teleconference was carried unanimously.

3. Upcoming Dates

Mr. Ulman confirmed the following dates for future face-to-face DCLG meetings:

- October 25–26, 2006
- March 29–30, 2007
- October 24–25, 2007
- March 27–28, 2008
- October 28–29, 2008

Mr. Ulman also reminded DCLG members of the upcoming Summit, *Listening and Learning Together: Building a Bridge of Trust,* which will take place June 19–20, 2006.

II. Discussion with NCI Leadership

Dr. John Niederhuber, who was appointed Deputy Director of NCI in October 2005, provided an update on recent activities at NCI. Dr. Niederhuber began his remarks by expressing his appreciation and that of the NCI leadership for the many hours of personal time that DCLG members devote to their work on behalf of NCI.

1. Budget

Dr. John Niederhuber informed the group that the FY2006 budget was $4.842B for the NCI. However, after government-wide reductions, assessments and mandatory increases, NCI started FY2006 with fewer dollars than in FY2005. He reported that the number of competing Research Project Grants (PRGs) for FY2006 will be approximately the same as the previous year, with an average cost equal to what it was in FY2005. However, the pay lines and grantee success rates will again decline.

As part of the Institute's priority-setting exercise, the divisions listed all of the new initiatives they considered necessary to achieving their strategic goals. These new initiatives totaled approximately $160 million. After reviewing and ranking them, the NCI has decided to redeploy at least $50 million (and perhaps as much as $70 million) of its FY 2006 budget to support the highest priority initiatives.

The President's proposed NCI budget for FY 2007 is almost $40 million less than the 2006 appropriation. Dr. Niederhuber described some of the initiatives included in the budget request with implications for NCI. For example, NCI will contribute $1.8 million to NIH for a new program that will support young investigators as they make the transition to their first academic positions. Another $7.8 million will support the NIH initiative on genes, environment, and health.

DCLG Chair, Doug Ulman participated in a recent joint NCI board retreat. Acknowledging declining budgets, NCI sought guidance on a number of critical questions from the participants. Discussions included assessing the trade-offs that occur at different target levels of RPGs, pay lines, and individual program spending. Additionally, different FY 2007 budget scenarios were modeled. All participants agreed on the need for NCI to leverage partnerships with industry and other government agencies. They also urged the Institute to support training, provide preferential pay lines for first-time investigators, and develop metrics to measure progress.

2. NCI Intramural Research Program

NCI is committed to continuing investment in its Intramural Research Program (IRP), which includes basic, clinical, and population-based research programs. The IRP continues to review the research to identify unique programs and redeploy resources to support only the most outstanding projects based upon the recommendations from the Institute's Board of Scientific Counselors. Following the opening of the new NIH Clinical Research Center last year, NCI began recruiting for a new head of Medical Oncology. The IRP has trained many leaders in the cancer research community, and will continue to do so with 1,200 trainees currently in fellowship positions across the Institute. Dr. Niederhuber further reported that a drug development initiative is under way that will link the intramural and extramural research community. Finally, a new I2 Team (Integration/Implementation) has been created to address cancer health disparities.

3. Scientific Developments

Until recently, cancer was categorized according to the location of the tumor and how it looked under the microscope. In some cases, cancers were further broken down into histologic type. Cancers are now regarded as diseases of the genome. Truly conquering this disease will require understanding genetic changes at a very early stage. It is necessary to detect cancer when it is just a few abnormal cells or even earlier when it is a genetic predisposition.

NCI's strategic plan addresses the following frontiers in cancer biology:

- Tumor microenvironment: Extensive NCI-supported research has shown that the cells surrounding the tumor (including growth factors, blood vessels, and fat cells), known as the tumor microenvironment, play a role in the cancer development process. The dynamic process between the tumor and its surrounding tissue is an exciting research frontier.
- Presence of cancer stem cells: The target of the genetic changes that lead to tumor development may be the rare stem cells present in adult tissues. The transformation gives rise to cancer stem cells, which retain the adult stem cell ability to continuously renew tissue, but lack the regulation necessary to control such growth. We are learning a great deal about these cancer stem cells, which might open a new window to understanding cancer and how to fight it.
- Inherited predisposition to metastasis: Recent studies have shown that ability to promote metastasis might be an inherited trait that is independent of the characteristics of the cancer. This opens up opportunities to predict whose tumors will spread and allows aggressive intervention.

We have been living in an era in which the focus of clinical trials was how much drug the patient could withstand. Treatments were tough, quality of life was poor, and the question was not whether patients would survive but how long they could tolerate the treatment. Through the Institute's investment in research, a new era is beginning that focuses on characterizing the tumor extensively. New clinical trials are studying smaller numbers of patients more intensively to understand why some respond to treatment and others do not. The Institute is also collecting biospecimens and forming a bioinformatics grid to support the new research.

We are moving into an era of predictive medicine in which each patient's genetic makeup will be characterized. When someone develops cancer, it will be possible to assess their tumor antigens, use multiparameter diagnostics to visualize the patient in the present and predict the future, and select drugs to redesign the behavior of the patient's biologic systems. To support this new research paradigm, NCI is building interagency collaborations with the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA).

Dr. Niederhuber believes that we are closer to individualized medicine and have made significant progress in the last few months alone. For example, the research on the human papillomavirus (HPV) and creation of an HPV vaccine took place at NCI. A recent study showed that patients with HER2/neu–positive breast cancer have a survival advantage if they receive adjuvant therapy with Herceptin. This therapy has probably decreased recurrence in a population of matched patients by 50 percent.

Dr. Niederhuber closed his remarks by stating that the ultimate goal is to intervene at the earliest possible stage, thereby lessening the burden of the cancer.

4. Discussion

Ms. Cece Whitewolf said that Dr. Niederhuber's presentation was the best she has heard on the biology of cancer. She asked about NCI's efforts to reach out to tribal governments in the Native American community and involve potential new investigators from minority communities. Dr.

Niederhuber replied that NCI has several programs for new minority investigators. For example, the Institute provides funding to encourage people of different ethnic backgrounds to become physician-scientists focused on cancer. When NCI's leaders came together to discuss the budget, they agreed that the programs of the Center to Reduce Cancer Health Disparities must be protected.

Dr. Niederhuber also pointed out that about 85 percent of cancer patients are treated in the community, and he would like to build a network of community-based, NCI-designated cancer treatment facilities. The standards and plans for these are being developed, and a pilot program is likely to be launched this year.

Ms. Vernal Branch supported the concept of community-based cancer treatment facilities because a great deal of cancer care is provided in community health clinics. She asked whether the 61 NCI-designated cancer centers conduct outreach to the community and to oncologists in minority communities. Dr. Niederhuber said that NCI wants to work with physicians in private practice and help different specialties work together to bring care to patients in a more efficient and effective way. Dr. Niederhuber hopes that ultimately, patients throughout the country will have access to every clinical trial, regardless of where they live. It is necessary to elevate care and access to clinical trials for all patients.

Dr. Sylvia Ramos asked Dr. Niederhuber to elaborate on NCI's partnerships with industry. Dr. Niederhuber cited NCI's working relationship with IBM as an example. IBM is very interested in NCI's cancer Biomedical Informatics Grid (caBIG™) and could help achieve NCI's goals for caBIG. NCI also works with the CEO Roundtable—a group of executives brought together by former President George Bush, and is collaborating with them on drug discovery. NCI is also partnering with other government agencies, including CMS and FDA, as well as the Departments of Defense and of Energy.

Ms. Nancy Davenport-Ennis stressed the importance of insurance reimbursement for clinical trials to have an effect on cancer care at the community level. She suggested that NCI could collaborate with nonprofit organizations on this issue. Right now, private practitioners receive less reimbursement to participate in trials funded by NCI than in those funded by industry. If the level of reimbursement is reduced even more, it will be hard to attract the number of doctors needed to continue to run those NCI trials. Advocacy organizations want to join with NCI to see trials moved into the community for faster accrual and more rapid collection of evidence on benefit and risk to bring products to the market. In particular, Ms. Davenport-Ennis suggested that NCI collaborate with the Health Information Management Systems Society.

Ms. Mary Jackson Scroggins referred to research showing that African Americans are less likely to be invited to participate in clinical trials than whites, although they are slightly more likely to agree if invited. Dr. Niederhuber replied that NCI held a retreat in the fall to discuss cancer health disparities. As a result, NCI is forming an Implementation and Integration (I^2) team to work on all aspects of disparities, including training and clinical trials. This team will develop recommendations for NCI. Dr. Niederhuber also believes that if NCI is successful in moving clinical trials into the community, this will have a major impact on disparities.

III. Facilitating Dialogue—Summit with Advocacy Community

Ms. Scroggins provided an update on *Listening and Learning Together: Building a Bridge of Trust.* The Summit will be dedicated to the memory of Ms. Nancy Caliman.

1. Registration

DCLG members received copies of the Summit brochure. Ms. Scroggins asked them to distribute the brochure whenever they have the opportunity, such as when they attend meetings. She also asked DCLG members to share the names of groups representing underserved populations with OLA. Former DCLG members will also be invited to attend. An electronic version of the invitation is available, and OLA will distribute this to all DCLG members.

At this point, 100 individuals and organizations have registered to participate in the Summit, but only 8 have submitted abstracts or summaries for posters. When spreading the word about the Summit, DCLG members should emphasize the opportunity for participants to bring posters and let others know about their organizations. Ms. Brooke Hamilton explained that the space can accommodate around 50 or 60 posters. DCLG members are welcome to display posters from the organizations they represent. Mr. James Hadley clarified that advocacy organizations will have space to display posters on boards, whereas federal agencies, such as FDA and CMS, will have table-top exhibits.

Ms. Scroggins reported that a limited number of scholarships will be available to participants through The Foundation for the NIH, with support from the American Cancer Society, Kidney Cancer Association, Susan G. Komen Foundation, Lance Armstrong Foundation, Patient Advocacy Foundation, and Oncology Nursing Society. The number of scholarships offered will depend on the amount of sponsorship funding received. The OLA/DCLG hopes to be able to offer scholarships to at least 30 attendees, approximately 10 percent of the 300 advocates expected to attend. A selection process for scholarships has been developed.

2. Agenda

Ms. Scroggins reviewed the draft agenda for the meeting, which will start with tours of the NIH campus. Because DCLG members were to take the NIH tour following Ms. Scroggins' presentation, they will not take the tour during the Summit.

After an opening ceremony, Mr. Ulman and Ms. Scroggins will welcome participants. The co-chairs of the NIH Public Trust Initiative will then make a presentation, followed by a multimedia presentation on the NIH. The first day will also include an opening plenary by a member of NCI's leadership, a presentation on NCI's clinical trials, and a video on the NIH Children's Inn.

The second day will start with an inspirational moment led by singer Wintley Phipps. Activities on the second day will include a presentation on survivorship, a presentation by an adult treated at NCI on a clinical protocol, a discussion of NCI health disparities research, and closing remarks. During the day's three breakout sessions, participants will have the opportunity to attend three of four scheduled offerings: Best Practices for Advocacy Organizations, Current

NCI Outreach Initiatives, Electronic Resources for Up-To-Date Cancer Information, and The Role of Advocates at NCI. The poster picnic will take place on this day.

A facilitator will ensure that all presentations end on schedule to allow plenty of time for questions, and many 15-minute question-and-answer sessions are built into the agenda. Ms. Branch suggested placing cards on everyone's seat so that participants can write down their questions. Someone could then collect their questions, group them together by topic, and read them to the presenters. Ms. Scroggins stated that this would prevent the same question being asked more than once, but she noted that participants might be skeptical of the question selection process if their questions were not selected. This would not support or reinforce the "building trust" element of the Summit.

Dr. Ramos pointed out that some participants might be intimidated about asking their questions in front of so many people and might prefer writing their questions on cards. Ms. Branch suggested that those who are comfortable could ask their questions at the microphone, while others could write their questions on the cards. Ms. Bobbi de Córdova-Hanks suggested explaining the time constraints at the beginning of the question-and-answer sessions and asking participants to limit their questions to two minutes.

Ms. Davenport-Ennis emphasized the importance of diversity in age and ethnic background for the speakers. She noted that a 12-year-old cancer survivor was an extremely compelling speaker at a recent conference. Ms. Whitewolf added that those who are deaf or blind should also be included, as should representatives of the gay, lesbian, bisexual, and transgendered communities.

Ms. Scroggins reported that every DCLG member will have a role at the Summit. Ms. Branch encouraged all DCLG members not to spend their time together, but to reach out to others who attend the Summit. Ms. Scroggins noted that DCLG members will be introduced at the beginning of the Summit so that participants can identify and approach them later.

3. Logistics

Ms. Whitewolf asked about comfortable seating for those in treatment. Mr. Hadley explained that the auditorium has space for wheelchairs and the auditorium chairs are comfortable with armrests.

Ms. Davenport-Ennis suggested providing participants with a list of hotels and restaurants near the NIH campus. Palladian Partners plans to include such a list in the registration materials that Summit participants will receive on-site. She also suggested providing medical support during the conference for those in treatment. Ms. Peggy Anthony offered to help with the medical support if needed.

Ms. Hamilton explained that the Summit would not offer shuttles to take participants to and from their hotels, but information on taxis would be available. Moreover, the headquarters hotel—the Hyatt Bethesda—is only one Metro stop away from the NIH campus.

Ms. Branch suggested that the name tags have stickers identifying the DCLG members. Ms. Hamilton explained that ribbons will be attached to name tags and asked DCLG members to identify what the different ribbons should say, in addition to "cancer survivor."

Mr. Ulman thanked Ms. Scroggins for overseeing this huge undertaking.

Thursday, March 30, 2006

IV. NCI Clinical Trials Working Group

Dr. James Doroshow provided an update on NCI's activities to restructure the national clinical trials enterprise. Dr. Doroshow reminded the DCLG that the Clinical Trials Working Group (CTWG) made recommendations focused on developing a system to prioritize NCI-sponsored clinical trials, standardize the information technology (IT) infrastructure and clinical research tools, coordinate clinical trials research, use resources more efficiently, and restructure the intramural and extramural oversight of NCI's clinical trials. For 2006, the CTWG has established specific implementation goals under each recommendation area.

Dr. Doroshow summarized activities since last summer. Nominations have been requested from the entire clinical trials community to expand the caBIG clinical trials work space. This large group will oversee a range of activities. For example, because up to one-third of trials supported by NCI do not produce reports, databases, or documents that can be shared with others, the group is developing a system that will require electronic reporting in a form that is searchable. The barrier here is not funding, but process and NIH policies.

The 2006 budget provides some funds to make trials conducted in NCI's Specialized Programs of Research Excellence (SPORE) and Clinical Trials Support Unit (CTSU) available across the country. This effort will use CTSU funds to facilitate interactions between the SPOREs and Cooperative Groups.

With NCI approval, new standard operating procedures will make it easier for pharmaceutical companies to receive FDA permission to use NCI data for new drug indications. This feature could save money and result in faster trial approvals.

NCI funded an analysis of barriers to conducting clinical trials that showed it takes 371 individual steps to advance from an idea to opening a Cancer and Leukemia Group B (CALGB) trial. This study found that after the CALGB executive committee approves a trial, it has no way to stop the trial from proceeding if it subsequently learns that the trial is not necessary. The CTWG is now considering ways of expanding this analysis to other groups to identify potential efficiencies and develop best practices that will inform the entire system.

The Investigational Drug Steering Committees (IDSCs) are well organized now. Their main goal is to oversee the drug development plans for all new agents that come through the Cancer Therapy Evaluation Program. The IDSCs have formed subcommittees on clinical trial design, correlative science, and other issues. This process will provide input from the best group of Phase I investigators in the United States. Scientific steering committees, which include advocates, have now been formed for gynecologic, gastrointestinal, and head and neck cancers. The gastrointestinal committee has already reviewed a Phase III trial and decided that it should not go forward.

Although no decision has been made, plans are being considered to form a steering committee of Community Clinical Oncology Programs (CCOPs) and advocates to address symptom

management and supportive care. The CCOPs conduct many symptom-management trials. A process for allocating funds for quality-of-life studies is also part of the CTWG mission.

The CTWG has received approval to form the first new advisory committee to the NCI Director in more than a decade, the Clinical Trials Advisory Committee (CTAC). CTAC's 25 members will include representatives from the National Cancer Advisory Board (NCAB), the Board of Scientific Advisors (BSA), the Board of Scientific Counselors (BSC), and the DCLG. The majority of appointees will be from the extramural clinical trials community. The new CTAC will oversee CTWG activities and will have the authority to change CTWG activities if certain recommendations are not effective, without requiring extramural approval. The initial meeting of the CTAC is planned for September 2006 and the announcement is pending in the Federal Register.

The Clinical Trials Operations Committee (CTOC) will have representatives from all intramural and extramural NCI divisions and centers with ongoing clinical trials. CTOC will report to the Deputy Director for Clinical and Translational Sciences and will review and approve all requests for applications (RFAs) and program announcements (PAs) that support clinical trials before NCI's Executive Committee (EC) reviews them. The CTOC will be the internal NCI counterpart of the external CTAC.

The CTWG has also appointed several staff members to the new Coordinating Center for Clinical Trials, which will implement, support, and operationalize CTWG initiatives with NCI divisions, centers, and offices, and support the CTOC.

The CTWG is establishing a structured system to evaluate its activities. The baseline evaluations will begin next month to assess the current status of the CTWG's recommendations, before changes are made. This evaluation will be repeated in approximately two years to obtain a midterm assessment of the CTWG's impact.

1. Discussion

Ms. Sue Sumpter noted that when the *NCI Listens and Learns* Web site asked for advocacy organization and public comments on NCI's clinical trials system, respondents asked for a comprehensive Web-based listing of all clinical trials. Dr. Doroshow said that this cannot happen without cooperation from pharmaceutical companies, and NCI cannot require that these companies provide information on their trials. But this should be the goal.

Ms. Sumpter asked whether negative trial results are published. Dr. Doroshow said that it is critical to publish all trial results, whether positive or negative, when trials are supported by government dollars.

Col. Jim Williams asked about outreach to minorities. Dr. Doroshow said that NCI plans to provide additional funds to the minority CCOPs to increase minority accrual to clinical trials, but it is unknown whether this will be effective. It would be wonderful if resources were the only limiting factor, rather than the many more difficult societal and cultural barriers. But if additional funding is not successful, NCI will revisit the issue.

Ms. Whitewolf asked about the procedure for minority communities to apply for NCI funding for clinical trials. Dr. Doroshow answered that the funding will go to established NCI-supported groups, such as the cancer centers and CCOPs that have programs to enhance recruitment. It takes many years to develop a request for proposals (RFP), so the CTWG has decided to supplement ongoing programs so that it can provide resources to the field immediately.

In response to a comment from Mr. Ulman, Dr. Doroshow explained that the analysis of barriers to conducting clinical trials showed that those planning clinical trials need to pay attention to business practices because this could speed up everything they do.

Col. Williams asked about the barriers imposed on the process by institutional review boards (IRBs). Dr. Doroshow said that most of the 371 steps in starting a clinical trial do not involve the IRB; a large percentage is self-inflicted and could be changed. It is important to analyze how NCI could optimize these steps.

V. NCI Translational Research Working Group

Dr. Jaye Viner reported that Dr. Ernie Hawk heads the Translational Research Working Group (TRWG) with Co-chairs, Drs. Lynn Matrisian and Bill Nelson. The goal of the TRWG is to take advantage of medicine's transformation from the 20th century reactive model to the 21st century model that focuses more on prevention, risk markers, and the development of less toxic interventions. Dr. Viner specified that the TRWG is focusing on translational science along the continuum from basic discovery through Phase II trials. The CTWG covers the process from Phase II through Phase III and IV trials.

The last decade has seen an enormous proliferation of NCI programs and their enormous potential to drive science forward to deliver better tools and diagnostics to clinics. Dr. Viner listed a number of NCI programs designed to move scientific discoveries arising in the lab, clinic, or population from the bench to the bedside and back. These programs are expected to contribute to the development of new clinical tools (e.g., interventions, tests, recommendations) that reduce cancer incidence, morbidity, and mortality. Given the current fiscal environment, the Institute must scrutinize the effectiveness of its programs so that it can modify them to achieve its goals more effectively.

NCI's SPORE program is designed to facilitate translational research and is currently organized around organ groups. The SPORE programs emphasize achieving feasibility testing in humans within five years. Some of the same mechanisms underlie disparate disease states in different types of cancer and possibly other diseases as well, and NCI is now considering whether the SPORE program should include a focus on underlying mechanisms. Also, given the SPORE program's traditional focus on organ sites, decisions must be made about such issues as which organ sites to include and how many SPOREs per organ site. Although more research is needed on some less common cancers, for example, so-called rare cancers could prove challenging in patient participation and specimen acquisition.

The TRWG was charged with evaluating the current status of NCI's investment in translational research and envisioning its future in an inclusive, representative, and transparent manner. The TRWG is building on the CTWG's experience, which may enable it to avoid some of the challenges that the CTWG has already overcome. The TRWG's steps are to assess prior and current efforts in translational research, define a group's scope of activity, map and evaluate existing programs through portfolio and process analyses, provide a vision and recommendations, and develop an implementation strategy.

The TWRG held its first roundtable meeting in February. This meeting brought together about 200 investigators and advocates, as well as representatives from the NCI, other federal agencies, and industry. They developed a draft model and recommendations, which will be publicized following review by the National Cancer Advisory Board. The TRWG will solicit public comments on these recommendations before convening a second roundtable in the fall of 2006, when the group will discuss the draft model, recommendations, and evaluation results, and solicit ideas regarding implementation. The working group will then develop an implementation plan, which it will present to the National Cancer Advisory Board (NCAB) in winter 2007.

The TRWG is still reviewing the paths that translation takes to identify the commonalities and bottlenecks, as well as the discrete roles of academia, industry, and NCI, and how to enhance those relationships in order to advance translational science.

1. Discussion

Ms. Sumpter pointed out that after NCI supports research to develop a drug, it might not be affordable to patients (an example of this is Velcade), and she asked why there have been fewer drugs developed in the past 10 years. Dr. Viner replied that NCI is very conscious of the public's investment in drug development through federally sponsored research, and that people with expertise in intellectual property are involved in the TRWG to resolve this and related issues.

Col. Williams noted that there can be a conflict between research and teaching, and that this is a problem in minority institutions where academia restricts movement through the pipeline because clinical research conflicts with teaching and does not contribute to tenure. Dr. Viner stated that concern has been voiced that researchers will avoid clinical research because it is so difficult to obtain funding. The TRWG is involving experts in training, including the American Association of Medical Colleges, to develop ways to make the rewards system more equitable. A new focus on team science is expected to advance the careers of all team members and will require changes in several areas, such as grant review and the academic reward process.

VI. President's Cancer Panel

Dr. LaSalle Leffall serves on the President's Cancer Panel (PCP) with Dr. Margaret Kripke and Mr. Lance Armstrong. Dr. Leffall's colleagues asked him to tell the DCLG how much the PCP values the Group's input. He invited DCLG members to submit written comments to the PCP.

President Richard Nixon established the PCP when the National Cancer Act was enacted in 1971. The PCP includes a clinician (currently Dr. Leffall), a basic scientist (Dr. Kripke), and a

public member (Mr. Armstrong). Members serve three-year terms, and the chairmanship is reappointed on an annual basis. The PCP reports directly to the President, and its mission is to monitor the development and execution of the activities of the National Cancer Program. It fulfills this mission by convening meetings at least four times a year and generating an annual report that is disseminated to the President, Congress, government agencies, cancer-related organizations, and the public.

In recent years, the PCP has considered cancer in Pacific Northwest tribes, survivorship, and translating research into cancer care. This year, the panel decided to review the status of its earlier recommendations from the survivorship and translating research reports. The PCP's next area of focus will be healthy lifestyles.

In its report, *Living Beyond Cancer: Finding a New Balance,* the Panel recommended electronic health records, protecting privacy while enabling research, and comprehensive health care reform. The Panel tries to include health care reform in all its reports. In its report on translating research, the panel's recommendations discussed team science and the culture of research, the infrastructure required for translating research, regulatory issues, education and communication, the impact of public trust and community participation, and access to successful translation. The PCP's report assessing its progress will be released at the upcoming meeting of the American Society for Clinical Oncology.

Next year, when the PCP focuses on promoting healthy lifestyles to reduce cancer risk, the panel plans to hold several meetings on tobacco, obesity, physical activity, and nutrition, in different locations throughout the country. These meetings will highlight ongoing research and knowledge gaps, existing model programs, influences on the adoption of risk-reduction behaviors, the impact of technology advances on lifestyle and activity levels, the economic costs associated with unhealthy lifestyles, and potential policy changes and implementation strategies.

1. Discussion

Ms. Branch asked whether more cancer centers will open survivorship clinics that care for patients after they complete their cancer treatments and promote healthy lifestyles. Dr. Leffall replied that this was a major recommendation of the PCP. The PCP presents its recommendations to NCAB, and these recommendations go out to all cancer center directors.

Ms. Whitewolf noted that the report on cancer in the Pacific Northwest tribes revealed that only one percent of the Indian Health Service budget goes to urban Indians, and the President's current budget eliminates funding for Indians. Native Americans require help to obtain the funds necessary for them to obtain the cancer care they need, where they live, so they are not forced to return to reservations, which cannot offer high-quality care. Ms. Whitewolf invited the PCP to meet with Indians and discuss what has happened to the recommendations in its report.

Ms. Lourie Campos noted that the President's budget for electronic health records does not include community health centers and safety net providers that provide for medically underserved cancer patients. She asked whether the PCP report addressed this need. Dr. Leffall explained that the Panel had recommended electronic health records for everyone.

Ms. Scroggins asked if the Panel has considered recommendations concerning the fact that doctors are not offering the best care to underserved populations. Physicians need to be trained differently and to be held accountable. Dr. Leffall believes that most medical schools now emphasize the need to offer the same high level of care to all patients.

Dr. Ramos asked Dr. Leffall to identify tangible results from the PCP's recommendations in the past. Dr. Leffall explained that the increased emphasis on care for the underserved came about as a result of the PCP's efforts. Every cancer group in this country has now recognized the need to reduce cancer health disparities as a priority.

VII. CARRA in caBIG™ Liaison Report

Ms. Anthony is the newly created DCLG liaison to the Consumer Advocates in Research and Related Activities (CARRA) members who are involved in the caBIG™ project. These advocates are working to ensure that caBIG™ has a direct impact on the cancer patient's journey from diagnosis through treatment and beyond by providing the tools necessary for more rapid translation of basic research to the clinic, centralized clinical trial information that is easily accessible to clinicians and feedback from the patient to the research community. The caBIG™ patient advocates have established goals for their activities in the areas of research, clinical applications of research, and communication/education.

Patient advocates have participated in RFP reviews and strategic planning. Many intend to participate in the upcoming annual caBIG™ meeting in April. They also ensure that the patient perspective is addressed in caBIG™ documents and work spaces.

As the DCLG liaison to these advocates, Ms. Anthony plans to bring more information on their activities to the DCLG in the future. She will attend the annual meeting in April and the upcoming teleconference on caBIG™ that is part of the "Understanding NCI" series. Ms. Anthony encouraged other DCLG members to participate in this call on May 17.

The advocates plan to present a poster at the upcoming Summit that will illustrate how caBIG™ products can influence the process from diagnosis to treatment. The advocates are exploring additional mechanisms to communicate caBIG™ achievements, issues, and concerns to the broader patient advocate community, and they have asked for the DCLG's assistance in this area.

Currently, caBIG™ has six patient advocates, and three more will join them. One of these advocates is Paula Kim, a former DCLG member.

1. Discussion

Ms. Branch requested some background information on caBIG™. Ms. Hamilton explained that, in a nutshell, the purpose of caBIG™ is to create a cancer research web so researchers can share all their information. Patient advocates have been involved in caBIG™ since its inception. After a CARRA member requested a DCLG liaison to the advocates working with caBIG™, the DCLG appointed Ms. Anthony in this capacity.

Ms. Jane Jacobs noted that the strategic plan for caBIG™ will include the advocate component, which shows how important the role of the advocates is in caBIG™—they are not just token participants.

Dr. Ramos asked about the time frame for providing comprehensive information to physicians treating patients within and after completion of clinical trials. Ms. Anthony explained that caBIG™ has posted the time frame for its activities on its Web site (https://cabig.nci.nih.gov).

VIII. *NCI Listens and Learns* Web site Evaluation Report and Discussion

Dr. Michael Burke explained that the *NCI Listens and Learns* Web site began as a pilot project in January 2005 and was designed to facilitate input and dialogue from the cancer advocacy community. The *NCI Listens and Learns* evaluation is designed to assess the extent to which *NCI Listens and Learns* meets the needs of NCI, cancer advocacy organizations (CAOs), the interested public, and the DCLG, and to identify ways in which the site could be improved.

The process part of this evaluation will address the conditions under which the site operates, whether it is operating as planned, and how CAOs are being reached. This part of the evaluation will also compare the site to other similar sites; although no other Web site shares the content, purpose, and format of *NCI Listens and Learns*. The evaluation will include a review of *NCI Listens and Learns* statistics and internal documentation, and in-depth interviews with stakeholders, including members of the public, NCI staff, DCLG members, and CAOs.

The team will finish its evaluation plan and instruments in April or May. Once IRB clearance is obtained, the team will spend approximately three months conducting interviews. Analysis and reporting will take another one to two months. Dr. Burke expects to report the findings of the evaluation to the DCLG at its spring 2007 meeting.

1. Discussion

Mr. Ulman asked if people who are not using the site would be interviewed. Dr. Burke replied that the evaluation team will interview non-users and different types of users, including those who have registered for the site but have not posted any comments.

Col. Williams wondered what would happen to *NCI Listens and Learns* until the evaluation results are available, which will not happen for another year. Ms. Hamilton answered that the site will continue and no major changes will be made until the evaluation results are reported.

Mr. Ulman stressed the importance of asking why interested members of the public and CAOs are not using the site. Perhaps they would be more interested if people other than NCI generated the questions, or perhaps they do not regard the questions as pertinent, or they think that this is not really a dialogue but a one-way conversation.

Ms. Whitewolf wondered whether the evaluation would seek responses from CAOs rather than individuals. Dr. Burke explained that the evaluation team would interview CAOs that have

posted comments, those that have registered and not posted, and CAOs that have not registered. He said the interview questions will also ask about their interest in and understanding of the topics.

Dr. Beverly Laird has read and commented on the draft evaluation plan, which will be distributed to the DCLG when it is finalized. The plan is very comprehensive and asks many of the questions raised by DCLG members. The interviews will ask different questions of different groups, which is appropriate. Dr. Burke added that this is primarily a qualitative evaluation to collect in-depth information about why this site is working or not working for its audiences.

Ms. Scroggins said that the DCLG wants to learn what makes users respond to some questions and not others—whether this is due to the complexity of the questions or the way they are phrased, for example. Visitors to the site have commented that the questions are overly complex. Col. Williams explained that the Operations Working Group is working on this issue. One difficulty is that when the Working Group receives the questions, it often has very little time to comment on them before they are posted.

Ms. Devon McGoldrick reported that after DCLG members asked to have the nanotechnology question rewritten, Ms. McGoldrick worked with the relevant NCI staff members to revise the question and divide it into two parts. The first will run in April and May, and the second later. Ms. McGoldrick does not have a bank of questions ready to be posted. Complicated negotiations are required for an NCI office to agree to accept public input and respond to that input. It is because these negotiations take so long that the questions are often received very late, with little time for feedback from DCLG members before they must be posted. Ms. McGoldrick works with the offices to determine which parts of a question are negotiable and what they really want to learn to put the question into a format that is appropriate for *NCI Listens and Learns*.

In response to a question from Mr. Ulman, Ms. McGoldrick said that the DCLG could post a question, although if it did so, it would need to prepare a response. Ms. Hamilton suggested that if the DCLG collected input through *NCI Listens and Learns*, it could use this input as data for recommendations to the NCI Director. Mr. Ulman suggested that in the context of the evaluation, it would be helpful to learn whether CAOs would be more inclined to participate if the advocacy community generated some of the questions rather than NCI.

Dr. Ramos suggested posting a question on what the public sees as the role of advisory groups like the DCLG.

Ms. Sumpter said that the DCLG has not made strong recommendations in the recent past. One way to show the advocacy community that the group is effective is to start doing this. Posting a question would show that the DCLG has an important role to play.

Col. Williams reminded the DCLG that the site was created to improve NCI collaboration with the advocacy community. Perhaps it is time to reconsider this purpose and make the site the voice of the DCLG. Ms. Whitewolf said that since the site was developed by the previous DCLG, the current membership has not made this their project. But if the DCLG developed its own questions, it would have more of a sense of ownership over the project.

Dr. Burke asked the DCLG to explain what kinds of recommendations it needs from the evaluation. Ms. Whitewolf said that the DCLG wants to know if the current format is working or if an alternative (such as blogging) would be more effective.

Col. Williams suggested that the evaluation include what NCI has done with the input it has received through the site. Dr. Burke replied that the evaluation would touch on this issue. Mr. Ulman said that the evaluation must look into what happens from the time an organization hits the submit button and whether the organization sees any results or value to its participation in the dialogue.

Ms. Sumpter believes that ease of use is a major issue and wondered to what extent the difficulty of using the site deters potential commenters. Also, she wondered how CAOs and members of the public view the responses supplied by NCI.

Ms. Sumpter thought the questions were all very complicated and written from the scientist's viewpoint. Ms. Hamilton noted that this issue has been discussed several times by the Operations Working Group. Col. Williams pointed out that the question posted in December and January was not a scientific question, and it generated a huge response. However, many of the comments were negative or did not really address the question that was posed.

Dr. Ramos believes that the public does not understand the questions, and the evaluation needs to determine whether the questions are a major barrier to participating in the dialogue. She asked if questions posted by the DCLG would interfere with the evaluation. Dr. Burke replied that as long as these questions are posted after the interviews are completed, this should not be a problem.

Ms. Sumpter said that the DCLG wants to know whether the site is viewed as an effective mechanism for communicating with NCI and seeing changes as a result. If the CAOs and public do not think that the site is effective, they should be asked for recommendations about what NCI can do differently. Perhaps *NCI Listens and Learns* is not the right mechanism for showing that NCI is listening. Mr. Ulman added that the recommendations should consider whether, even if the site is not working, it has the potential to be effective. This question will help the DCLG determine whether the site is worth fixing.

Dr. Ramos said another issue is whether the site is useful for NCI because it if is not, NCI staff will not post questions. Even if NCI regards the site as useful, certain improvements would perhaps make the site even more useful.

In response to a question from Dr. Burke, DCLG members asked for recommendations on changes to make the site more useful and perhaps on alternative vehicles to accomplish the purpose of *NCI Listens and Learns*. Mr. Ulman wondered if a monthly teleconference would be more effective, but the evaluation will not address this issue. Ms. Scroggins asked Dr. Burke to provide his own recommendations based on the findings, as well as the recommendations of the people who are interviewed.

IX. Legislative Activities

1. Appropriations

Ms. Susan Erickson began her report on legislative activities with an update on NCI and NIH appropriations. The President's 2007 budget calls for $28.6 billion for NIH, including $4.754 billion for NCI, which represents a slight decrease from 2006. If the budget is enacted, this will be the first decrease in the NCI budget since the passage of the National Cancer Act in 1971.

The next step is for the House of Representatives and the Senate to consider appropriations bills. At the House hearing on April 6, the NIH budget will be discussed. Dr. Elias Zerhouni will be the principal witness, and he has invited seven directors, including Dr. Niederhuber, to accompany him. The key players in the House are Rep. Ralph Regula (OH), the subcommittee chair, and Rep. David Obey (WI), the ranking Democrat. The date of the Senate hearing has not been set. Key players are Sen. Arlen Specter (PA), the subcommittee chair, and Sen. Tom Harkin (IA), the ranking Democrat.

Senators Specter and Harkin introduced an amendment to the Senate budget resolution that would add $7 billion to the health, education, labor, and pensions budget, including $2 billion for NIH. This amendment passed the Senate by a vote of 73–27. However, when a similar amendment was introduced in the House, it did not pass the Budget Committee. It is not clear if this amendment will reach the House floor.

2. Legislation of Interest

The American Center for Cures Act was introduced in December to establish the American Center for Cures as a new NIH Center. This new IC would promote more rapid translation of public and private research into therapies.

Another recent bill was the Conquer Childhood Cancer Act. Its purpose is to advance medical research and treatments for pediatric cancers. The bill would establish a population-based, national childhood cancer database and provide information services to patients and their families. It would also provide training in pediatric oncology. However, no funding is attached to this bill.

NIH reauthorization appears to have lost steam. This Congress will end in November after the elections, so unless a bill is introduced soon, it will not be acted on in this Congress.

The Senate Cancer Coalition has scheduled a hearing on April 25 to discuss targeted cancer therapies. The co-chairs are Senators Sam Brownback (R-KS) and Dianne Feinstein (D-CA). Dr. Niederhuber will testify, as will U.S. Surgeon General Dr. Richard Carmona, and Dr. Vincent DeVita of the Yale Cancer Center, a former NCI Director.

Ms. Erickson invited DCLG members to visit her office's Web site at www3.cancer.gov/legis for more information on legislative activities related to cancer.

3. Discussion

Ms. Campos asked what DCLG members could do about the items reported by Ms. Erickson. Ms. Erickson explained that it is not appropriate for NCI to provide direction to the DCLG on lobbying. Rather, her role, on behalf of the Institute, is to provide information on legislative activities to the DCLG, which can then decide how to act on that information.

Mr. Ulman explained that all DCLG members should stay up to date on these issues and communicate this information to their constituencies. The fact that the amendment to increase the NIH budget was defeated in the House shows that the House needs more education, which DCLG members can deal with through their own organizations and constituencies. Mr. Ulman suggested the reason for the Senate's support of the bill was that so many groups contacted their Senators and became involved in the process.

Ms. Branch pointed out that many organizations track legislation and provide alerts to tell their members what is happening. DCLG members can encourage their own organizations to track this information, which is available on legislative Web sites. Ms. Campos noted that individual citizens could also track this information. Ms. Branch emphasized that the DCLG cannot make recommendations regarding the legislation as a group, but members can do this as individuals and through their organizations.

In response to a question from Col. Williams, Ms. Erickson explained that NCI does not take a position on any bill pending before Congress unless the Administration has issued a statement of administration position, in which case NCI supports the Administration's position.

Ms. Sumpter asked about NCI's role in potential legislation to address the need for health insurance for all Americans. Ms. Erickson explained that NCI does not propose legislation, members of Congress do. Sometimes Congress asks NCI for technical assistance, which it is permitted to provide. A few years ago, several bills were introduced to provide comprehensive health care reform, but no large bills of this kind are currently in Congress. Mr. Ulman added that NCI cannot push legislation for specific types of cancer, but this can be done by advocacy organizations that find champions for certain bills. Ms. Branch suggested that legislation focus on quality health care for all, rather than funding for specific types of cancer or interventions.

Dr. Laird asked how to find out how different House members voted on the NIH budget amendment. Ms. Erickson explained that this information is available on the Web, if there is a roll call vote. The House budget resolution will go to the floor and will be voted on by the full House. When the bill comes to the floor, rules will be established on whether amendments will be accepted.

Mr. Ulman stressed that unless Congress is educated about cancer and health care, changes will never happen. He pointed out that although Senator Brownback, who chairs the Senate Cancer Caucus, says he supports research in cancer, he has twice voted against increased cancer funding.

X. DCLG Planning Working Group Meeting

The DCLG Planning Working Group met. **(Separate Minutes Attached)**

XI. The Cancer Genome Atlas

Dr. Anna Barker explained that The Cancer Genome Atlas (TCGA) is the first opportunity to apply the lessons learned from the Human Genome Project to cancer. Its goal is to develop an atlas of the genomic alterations significantly associated with all major types of cancer. This program is a collaboration with the National Human Genome Research Institute (NHGRI). TCGA will provide a molecular taxonomy, or a complete history of how these genetic alterations occur and when, which will make it possible to identify targets, stratify patients for clinical trials, and use this information for risk assessment and, ultimately, prevention.

TCGA will consist of the following major components:

- Data management, bioinformatics, and computational analysis—will manage data, develop databases and specific analytic tools, participate in caBIG™, and communicate with participating programs.
- Genome sequencing centers—will sequence large numbers of target genes from at least two tumor types and develop and integrate sequencing technologies. Sequencing will be done at existing NHGRI centers, and cancer is the first disease they will address on a large scale.
- Cancer genome characterization centers—will conduct high-throughput genome characterization, improve existing technologies, and release data into a publicly-available database.
- Human cancer biospecimen core resource—will verify the authenticity and perform the pathologic quality control on qualified tumors from the existing collection; centrally process specimens, develop and monitor standard operating procedures for prospective specimen collection, track all specimen-related operations through caBIG™, provide "standard" samples for comparison, and distribute materials.

A coordinating committee of principal investigators and NCI representatives, as well as an advocate representative (Mr. Ulman), who is a member of the External Scientific Committee, will oversee TCGA for the TCGA management team throughout the project. NCI and NHGRI believe that TCGA will drive the private sector to invest in technology development to decrease the time and cost of sequencing.

TCGA was publicly launched on December 13, 2005, at a news conference and advocates meeting. Milestones in 2006 include the issuance of NHGRI RFAs for genome sequencing centers and the NCI RFA for the biospecimen resource core, as well as awards for these RFAs. The pilot project should be ready to begin by the end of the fiscal year.

TCGA will provide taxonomy to determine which genes are important in specific cancers, inform diagnosis, and ultimately help prevent these diseases. Dr. Barker believes that this is one of the most important projects at NCI and that it will provide an unprecedented array of data to

fuel new discovery—and the project overall will alter the manner in which data are obtained on a large scale in a field like genomics.

Dr. Barker pointed out that the number of new agents approved for cancer has been steadily decreasing since around 1980. A distinct disconnect exists between the molecular science in which NCI invests and translating that into practice. Everything that has been done so far has been based on opportunities that arose, and no robust approach has existed to develop 50 new drugs a year. NCI has built an enormous information base in discovery, but it has not built the required translational infrastructure to accelerate delivery to patients. TCGA has the potential to produce an understanding of breast or prostate, and indeed all cancers, from the time genetic changes occur to when a secondary or metastatic tumor is formed. We stand on the threshold of molecular oncology, and without it, investigators will continue to develop and study drugs that are very toxic and non-specific. A paradigm shift is needed to develop drugs that change the course of these diseases. TCGA is a patient-centric program dedicated to finding genomic changes in each of us, which is the only way to truly achieve personalized medicine.

1. Discussion

Col. Williams asked if a presentation is available that DCLG members could use to discuss TCGA with their communities. Dr. Barker offered to work with the DCLG to create a presentation for advocacy organization members and the public.

Ms. Branch asked about the involvement of high-risk patients with a family history of cancer. Dr. Barker explained that samples from these patients would be more appropriate for other kinds of technologies, such as those in the NCI Cancer Genetic Markers of Susceptibility (CGEMS) program. She added that 90 percent of genomic changes are due to environmental influences.

Ms. Whitewolf noted that patients are sometimes reluctant to provide consent to use their specimens because of their religious beliefs, but TCGA requires all-or-none consent. Dr. Barker said that for this pilot project, those who are unwilling to consent to certain uses of their specimens will not be able to participate. However, it might be possible to involve these patients in the future.

Dr. Laird noted that advocates will wonder why genetic testing, such as for *BRCA1,* is so expensive when the government sponsored much of the research underlying this technology. Dr. Barker explained that all of the TCGA data will be open to the public, and specific rules governing patents will be developed. However, since Congress has not adopted a genetic privacy protection law, releasing such data will become more and more of a barrier as we attempt to move toward personalized medicine through projects such as TCGA.

XII. CARRA Program Update

Ms. Elizabeth Neilson and Ms. Jane Jacobs gave an update on the NCI Consumer Advocates in Research and Related Activities (CARRA) program. Ms. Neilson began by noting that OLA has four programs that work with advocates, including the DCLG, *NCI Listens and Learns*, the OLA

advocacy outreach program, and CARRA. Each of these brings a different perspective to the Institute and helps improve cancer-related research.

To arrange for an advocate to participate in an NCI activity, an NCI staff member submits a request to OLA, and Ms. Neilson, as CARRA Program Coordinator, matches the request to an OLA database that records the experience and skills of all CARRA members. From that search she recommends several qualified advocates for the staff member to consider. Since the program's founding in September 2001, CARRA has received 427 requests for advocacy involvement in NCI activities. Most of these requests are for activities related to peer review, but advocates have also been requested to review educational materials, serve on committees and editorial boards, represent users in web usability testing, work with the cancer Biomedical Informatics Grid (caBIG™) teams, and participate in meetings, workshops, and Progress Review Groups (PRGs).

Requests for CARRA members peaked in the program's first and third years, probably because many of the activities require a two-year commitment. In 2005, the program received slightly fewer requests than in the program's second year, probably because the Division of Extramural Activities has consolidated meetings to review grant applications, and has cut the number of site visits.

Most CARRA requests are for an individual advocate for a one-time activity. One-third of CARRA requests involve multiple advocates, and 15 percent are for ongoing activities such as caBIG™. Of the total CARRA membership (about 185 active members) most have been involved in at least two activities, and several have been involved in many.

Ms. Jacobs explained that OLA promotes the CARRA program but cannot require NCI staff to use CARRA members when they want direct advocate involvement in their activities. Overall, CARRA goals are to increase the number of opportunities for advocates to participate directly in NCI activities and to institutionalize the voice of advocates in NCI. Hopefully, what CARRA members do on an everyday basis strengthens the value and importance of the DCLG's voice.

Although participation in NCI-sponsored peer review is a major activity for CARRA, advocates do not participate in the peer review of a large number of R01 applications evaluated by the NIH Center for Scientific Review (CSR). CARRA initiated and has been hosting a series of meetings titled the Trans-NIH Dialogue on Public Members in Peer Review, which has been discussing many issues involved in the review of human subject research applications across the NIH. The NIH Director's Council of Public Representatives (COPR) has also been exploring this topic. Two CARRA members were invited to present a program overview and CARRA peer review participation to COPR members in April 2005; two COPR members attended the July 2005 CARRA Peer Review Training Workshop; and both CARRA and the Trans-NIH Dialogue discussions have been resources for COPR's consideration at their subsequent meetings.

In January 2006, two COPR members were invited to give a presentation at the NIH-wide Peer Review Advisory Committee (PRAC) meeting. As a result of discussions following that meeting, two CARRA members have been asked to participate in the June 2006 peer review meetings of the NIH Center for Scientific Review Clinical Oncology Review Section.

Ms. Jacobs also offered an update on plans for future CARRA recruitment. Because NCI program needs and scientific developments are moving at a rapid pace and into areas that didn't exist in previous recruitments, staff is considering some specific ways to increase CARRA's flexibility. At this point, staff anticipates being able to recruit members for targeted skills and experience, as well as a broader range of diversity.

1. Discussion

In response to a question from Ms. Sumpter, Ms. Jacobs stated that although OLA does not collect data on the total number of NCI projects to determine the percentage in which CARRA members are involved, the effectiveness of CARRA members is evaluated by questionnaires that they and NCI staff complete after each activity. In addition, one clear indication that CARRA is perceived as valuable by NCI staff is their continuing to voluntarily request CARRA members for their activities. Also, OLA receives informal feedback that indicates the advocates are very helpful and make a difference. When OLA publishes the new CARRA Web site, it will highlight examples of CARRA stories.

Ms. Jacobs reported that many NCI staff members support the CARRA program, one challenge is that some view advocates as very assertive people who push their own agendas. OLA trains CARRA members not to have an organizational or personal agenda and not to push any particular point of view when they are participating in NCI activities as a CARRA member. Instead, their role as CARRA members is to represent the people who will be involved in the project; and their job is to help NCI programs generate advances in ways to detect, diagnose, treat, and ultimately prevent cancer.

Col. Williams wondered how to keep CARRA members involved if not all of them participate in NCI activities. He suggested a certificate or pin to recognize their participation. Ms. Jacobs explained that CARRA members have action responsibilities even when they are not participating directly in NCI activities. They have a dual role of providing input to NCI and disseminating information from NCI to their constituencies. Col. Williams also noted that in some cases, CARRA members do not realize that they were invited to participate in an NCI program through CARRA. Ms. Jacobs agreed that this can happen. OLA provides NCI staff with lists of advocates from which to choose, and staff often keeps these lists. They then call a CARRA member from the list without informing OLA. Ms. Jacobs explained that OLA can determine whether advocates who participate in peer review are CARRA members or not, but no NCI tracking system is currently available for CARRA participation in other NCI activities. CARRA staff is continuing to address this issue.

Ms. Scroggins asked how the size of the CARRA pool was determined. Ms. Jacobs explained that this number was set in 2001 when the program was established. However, OLA is working on a revised recruitment system focused more on need and not restricted by limits on the size of the CARRA pool.

XIII. NCI Planning

Ms. Cherie Nichols reported on the new NCI strategic plan (available at www.cancer.gov/strategicplan). Since 2002, NCI has planned and set priorities through a number of efforts, including PRGs, Annual Bypass Budgets, and Division and cross-NCI planning activities. These efforts have produced more than 200 milestones which were refined into 7 broad priorities on which to focus:

- Molecular epidemiology.
- Integrative cancer biology.
- Cancer prevention, early detection, and prediction.
- Overcoming cancer health disparities.
- Strategic development of cancer interventions.
- Integrated clinical trials system.
- Bioinformatics.

The Institute then spent the next year developing strategic plans for these seven priority areas. These planning activities set the stage for an NCI Strategic Plan that was released in February 2006. This plan sets forth a framework within which NCI can lead and work with others to address some of the most perplexing challenges of cancer. NCI leadership and staff have conceived this plan with ongoing input from our NCI advisory groups and regular interactions with the cancer research and advocacy communities.

The leadership of the Institute next turned their attention to operationalizing and implementing the objectives and milestones outlined in the strategic priority areas. Integration/implementation teams were formed to consider the most important investments to make to move a particular field forward. The Institute has two teams focused on advanced imaging and bioinformatics. A third team on lung cancer has graduated to a program for lung cancer. Additionally, the Executive Committee has approved a new I^2 team to work on cancer health disparities.

The NCI Strategic Plan builds on existing priorities and integrates the recommendations from multiple planning efforts. The plan reflects the voice of the community because advocates participated in developing many of these recommendations through their membership in the PRGs and by reviewing and providing input on the bypass budgets. It is far reaching because it encompasses the cancer continuum from the preemption of cancer to ensuring the best outcomes for all. It sets forth the framework that NCI and the community will use to meet some of the most perplexing challenges. The plan is also timely because it is the first long-range strategic plan for the Institute in 30 years.

The strategic plan will be used to develop detailed operational plans at all levels, guide executive-level funding decisions, organize how the Institute measures and reports progress, influence the allocation of enterprise-wide funds, and support cross-institute research priorities. NCI will report progress on the strategic plan through its bypass budget, *Cancer Bulletin*, progress reports (two have been completed on breast and prostate cancer and another on pancreatic cancer will soon be available), congressional justifications, and snapshots of progress in specific cancers.

Key partners in realizing the vision in the strategic plan include professional societies, advocates, the President and Congress, other government leaders, cancer researchers, the public, advisory groups, and patients. As partners, advocates can participate in peer-review efforts, progress reviews, think tanks, workshops, the SPORE program, cancer center programs, CARRA activities, and more. They can also encourage their colleagues to do the same. Advocates can actively participate in cancer conferences and use these opportunities to voice their ideas, recommendations, and concerns. Other opportunities include attending advisory meetings, such as those of the NCAB, PCP, and COPR, and reviewing and commenting on priority-setting and planning documents, such as the annual bypass budget documents and the reports of the CTWG and TRWG. Advocates can provide feedback on the strategic plan and important initiatives when meeting with NCI leaders and staff, continue to educate the community and funders about the need to support cancer research, use established channels (such as *Listens and Learns*) to contribute their ideas to NCI, and use the strategic planning framework to inform their own priority setting.

XIV. *NCI Listens and Learns* Web Site Management Discussion

Ms. McGoldrick asked for DCLG feedback on what to do when comments posted on *NCI Listens and Learns* are not relevant to the question posed. DCLG members discussed the possibility of weighing in on posted comments to demonstrate involvement with the NCI *Listens and Learns* Web site. She wondered if DCLG members should participate in the dialogue before the NCI response is generated to the posted questions. It can take several weeks to receive the official NCI response to all of the comments. Ms. McGoldrick described the process followed by the contractors for inappropriate and "off-topic" comments posted to the Web site.

Ms. McGoldrick explained that a number of off-topic comments were posted in response to the question posed about how NCI could encourage people with cancer information needs to contact the Cancer Information Service (CIS). For example, one participant noted that NCI's Web site does not list all clinical trials and another said that CIS information specialists give out information that is in conflict with PRG recommendations, even though the PRG recommendations are not designed for treatment-related advice. Ms. McGoldrick noted that one participant commented that NCI does not listen and learn. Perhaps a DCLG member could say that NCI is listening.

Ms. Sumpter stated that if it takes several months to post the NCI response, those who comment might feel that NCI is not listening. But she wondered whether any individual DCLG member could post a quick response on behalf of the entire DCLG.

Ms. Branch questioned whether it would be appropriate for the DCLG to begin censoring the posted comments, since the Web site is intended to collect input from the public, and although NCI and the DCLG might not always like that input, it does represent what the community thinks. Ms. McGoldrick clarified the process of monitoring the Web site, explaining that only comments that violated the user agreement were deleted. Comments tangential to the discussion but not in violation of the user agreement remain on the Web site. Ms. Branch pointed out that when the site was first implemented, members of the Operations Working Group took turns

monitoring it, but they subsequently decided that this was not necessary. Perhaps this should be reconsidered.

Dr. Ramos thought that the comments by the moderator were appropriate and explained why the posting by the respondent might not have been what NCI was seeking. The comments seem sensitive and respectful. Dr. Ramos would not care to engage with those posting off-topic comments because this might start a very difficult discussion. Ms. McGoldrick explained that the moderator's response usually appears within 24 hours, but not immediately after the comment is posted.

Ms. Sumpter suggested that when DCLG input is needed, the moderator could contact the DCLG through the listserv, or perhaps a DCLG member could be appointed to serve as the designated contact person. However, Dr. Ramos pointed out that it might be difficult for the moderator to obtain a quick response from the DCLG if she wants to post a response within 24 hours. Ms. Anthony suggested that in this case, the moderator could post a comment saying that she plans to ask other experts for their opinions and will provide additional information in a few days. However, it is not clear that this is an appropriate role for the moderator, and each DCLG member might provide a different opinion.

Ms. Scroggins said the moderator should only ensure that everyone is adhering to the rules. Respondents should not feel stifled. She suggested leaving the system alone for the time being but continuing to monitor it to determine whether DCLG involvement might be appropriate in the future.

Dr. Ramos asked if the role of the moderator would be evaluated. Dr. Burke replied that the moderator will be interviewed, but an extensive evaluation of this process is not planned. Dr. Ramos wondered if the moderator might be inhibiting people from posting to the site. Dr. Burke explained that the evaluation will not target individuals who have received feedback from the moderator. Dr. Ramos wondered how participants in the dialogue feel when the moderator posts a remark in response to someone else's post.

Ms. Campos was not sure the DCLG members could provide helpful input when respondents post off-topic comments. For example, the question about the clinical trials Web site can only be answered by NCI, and if someone expresses anger and frustration, there is little that the DCLG can do to make them feel better. However, if someone says that they want to become more active in the cancer community, the DCLG could be helpful.

Col. Williams said that the Operations Working Group will continue to work with Ms. McGoldrick in monitoring the site. If an issue arises in the future, the working group will bring it to the DCLG for discussion.

Col. Williams reminded the DCLG of its initial plan to review the summary of comments before it is posted. The DCLG unanimously carried a motion not to review the summaries of comments before they are posted to the *NCI Listens and Learns* Web site. However, they will be notified when the summaries are posted.

XV. Next Steps

Mr. Ulman said that DCLG members will continue to work on the letter about the SPORE Program and requested feedback by Friday, April 7. The DCLG will begin providing written recommendations to the NCI Director on a regular basis.

A list of suggestions for activities on the evening of June 19 at the Summit was distributed. Mr. Ulman asked DCLG members to review these suggestions and discuss them over the listserv.

Mr. Ulman thanked the OLA staff for putting this meeting together. He planned to assign various DCLG members to write thank you notes to all of the meeting presenters and the NIH tour guides.

Ms. Scroggins asked DCLG members to share suggestions for the Summit with Mr. Hadley.

Ms. Hamilton asked if the DCLG liked the space at the Natcher Conference Center for their meetings. Most liked the space; although Dr. Ramos pointed out that it is difficult for those sitting in certain positions to look at the speaker when asking a question.

Mr. Ulman thanked the DCLG members for their participation and said that he looked forward to following up on next steps.

XVI. Input from the Public

No input from the public was provided.

XVII. Adjournment

The meeting adjourned at 3:50 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

- DCLG members should distribute the Summit brochure when they attend meetings or otherwise have an opportunity.
- DCLG members should submit the names of groups that represent underserved populations to the Office of Liaison Activities (OLA) so that these groups can be invited to participate in the Summit.
- OLA will distribute the electronic invitation to the Summit to all DCLG members so they can forward it to their contacts.
- DCLG members will review the options for activities at the Summit on the evening of June 19 and discuss the options over the listserv.
- DCLG members will submit to OLA suggestions for what Summit name badge ribbons should say (in addition to "cancer survivor").
- DCLG members will send suggestions regarding the Summit to Mr. Hadley.
- NCI will work with the DCLG to develop a presentation on the Cancer Genome Atlas that is appropriate for informing the advocacy community about this program.
- DCLG members will submit their comments on the Specialized Program of Research Excellence (SPORE) letter to OLA by Friday, April 7.
- DCLG members will submit their comments about the DCLG meeting structure and suggestions for future meetings to Doug Ulman by COB on April 10.
- Mr. Ulman will ask different DCLG members to draft thank you notes to the NIH tour guides and the meeting presenters.