NATIONAL CANCER INSTITUTE
DIRECTOR=S CONSUMER LIAISON GROUP

Summary of Meeting
April 17-18, 2000

The 4th meeting of the NCI Director=s Consumer Liaison Group (DCLG) was convened Monday, and Tuesday, April 17-18, 2000 in Conference Room D, Natcher Conference Center, National Institutes of Health (NIH), Bethesda, Maryland. On April 17th the meeting was open to the public from 8:30 a.m. to 5:00 p.m.. On April 18, 2000 the meeting was closed to the public from 8:30 a.m. to adjournment. Mr. Michael Katz presided as Chair.

DCLG Members

Mr. Michael Katz, *Chairperson*
Ms. Paula Bowen (absent)
Ms. Susan Lowell Butler
Dr. Manuel Castillo
Ms. Kerry Dewey
Ms. Venus Ginés (absent)
Dr. Felicia Schanche Hodge
Ms. Susan Leigh
Ms. Ruth Lin
Ms. Gena Love
Mr. Daniel Moore
Ms. Lillouise Rogers
Ms. Susan Stewart (absent)
Dr. Brad Zebrack

NCI Speakers

Dr. Alan Rabson, Deputy Director, NCI
Dr. Jeff Abrams, Senior Investigator, Cancer Therapy Evaluation Program (Medicine Section), Division of Cancer Treatment and Diagnosis
Ms. Nelvis Castro, Chief, Health Promotions Branch, and Acting Associate Director, Office of Communications
Ms. Jane Reese-Coulbourne, Consultant to the Office of Clinical Research Promotion
Dr. Susan Sieber, Director, Office of Communications, NCI

NCI Office of Liaison Activities Staff

Ms. Elaine Lee (Acting Executive Secretary, DCLG)
Ms. Tracy Clagett
Ms. Kristie Dionne
Ms. Sabrina Ferguson
Ms. Maria Stamos
Dr Yvonne Andejeski

CALL TO ORDER AND OPENING REMARKS

Mr. Michael Katz called the meeting to order and welcomed all in attendance. He noted that Dr. Richard Klausner, Director of the National Cancer Institute (NCI), was unable to attend the meeting and that Dr. Alan Rabson, Deputy Director, NCI, will represent him at the meeting.

REPORT OF THE DIRECTOR

Dr. Rabson opened his presentation by paying tribute to Eleanor Nealon, Director of the Office of Liaison Activities (OLA), who died of breast cancer in late 1999. As Dr. Rabson noted, Ms. Nealon was instrumental in establishing (OLA) and the DCLG, at the behest of Dr. Klausner. Dr. Rabson echoed the sentiments of the entire group in noting that Ms. Nealon will be greatly missed.

Budget Hearings. Each year, the Senate and House Appropriations Committees hold hearings on the President=s proposed budgets for the various government agencies, including the NIH, which is one of eight health agencies comprising the Department of Health and Human Services (HHS). HHS Secretary, Dr. Donna Shalala, provided the first testimony in defense of the entire HHS budget; supporting testimony for the proposed NIH budgets followed Dr. Shalala=s presentation and this year was made by Acting NIH Director Dr. Ruth Kirschstein.

Regarding the budget for fiscal year (FY) 2001, President Clinton has requested more than $18.8 billion for NIH, a $1 billion or 5.6 percent increase over the agency's FY2000 budget. The proposed FY01 non-AIDS NCI budget totals $3.25 billion, an increase of $183 million over the FY2000 appropriations. Including funds for AIDS, which are provided through NIH=s Office of AIDS Research (OAR), the total FY01 budget request for NCI is $3.505 billion, an increase of $193 million over the current fiscal year=s budget. Approximately $2.15

billion is allocated to grants, including Research Project Grants (RPGs, such as R01s), the Cancer Centers Program, cooperative groups, and other similar research-based funding. Other components include training, Research and Development contracts, intramural research; cancer control, e.g. the Cancer Information Service (CIS) and Cancer Net, research management and support (RMS) for administrative activities, and construction. Dr. Rabson noted that the RMS and construction allocations are the smallest within the overall budget. He also pointed out that, although the total amount of money for the intramural research program increased between FY00 and FY01, the percent of the total budget dropped from 20 to 18 percent.

Dr. Rabson commented that NCI has tremendous support in Congress and that Dr. Klausner is highly respected in both the House and Senate. He added that Congress remains supportive of NIH and biomedical research, and Dr. Klausner has helped facilitate this support. In defending continued and increased funding for NCI, Dr. Klausner presented the following testimony to Congress:

- Cancer mortality rates among Americans continue to fall, according to data compiled by NCI=s Surveillance, Epidemiology, and End Results (SEER) Program. Both cancer death and incidence rates dropped between 1973 and again in 1999. The reason for the decrease in cancer incidence is not yet clear at this time. The numbers of people in the United States dying each year of cancer has leveled off, even as the population is aging.
- Increased understanding of the molecular basis of cancer has led to advances in cancer diagnosis and treatment. Some examples include:
  - the discovery that cancer is a series of gene mutations.
  - the sequencing and mapping of the entire human genome, which is expected to lead to identifying genes associated with specific diseases.
  - the Cancer Chromosome Aberration Project (CCAP) to develop a set of "tools" that will allow for readily defining and characterizing distinct chromosomal alterations associated with the transformation of healthy cells into cancer cells.
  - applying gene discovery to new technologies, including drug development and treatment (e.g., Alymphochip@ technology used to identify expressed genes in lymphoid cells).
  - the importance of making a correct diagnosis, which markedly improved by using molecular genetic technology in conjunction with pathology.
- The development and testing of anti-angiogenesis drugs is underway. These drugs impede the growth of tumor-related blood vessels. Without a network of blood vessels, the tumor cells eventually die. Some 25 to 30 new agents are in early clinical trials and testing; if shown to be successful in these studies, these drugs are likely to alter cancer treatment and management.

Discussion and questions. The DCLG members questioned the relatively small proportion of the NCI budget that was allocated to cancer control. Dr. Rabson explained that funding for cancer control activities is expected to increase in the coming years. He pointed out that, under the direction of Dr. Barbara Rimer, the Division of Cancer Control and Population Sciences (DCCPS) has grown to include an increasingly diverse and specialized staff. Dr. Susan Sieber added that there are new and planned activities in DCCPS including a newly established Behavioral Research Program and the creation of the Health Communications and Informatics Research Branch.

In response to an inquiry from Ms. Love about the establishment of the Quality Cancer Care Committee, Dr. Rabson noted that DCCPS is taking the lead on putting together the plans for this committee which will be led by Dr. Robert Hiatt.

DCLG member Certificates of Recognition. In 1998, NCI established an advisory board of consumer advocates, Dr. Rabson recounted the accomplishments of the DCLG over the last two years which include:

- Identifying criteria for consumer involvement in NCI peer review
- Identifying the need for a genetics primer and working with the NCI OLA to create a new publication, A*Understanding Genetic Research and Population Based Research*.@
- Making recommendations for the development of an informed consent templates
- Suggesting that cancer research communications be included as an extraordinary opportunities i*n A The Nations Investment in Cancer Research for 2001*.@
- Reviewing selected NCI communications programs.

This year four members are rotating off the DCLG (one member resigned earlier). In recognition and appreciation of the outgoing members= contributions, Dr. Rabson presented certificates of recognition to:

- Ms. Paula Bowen
- Dr. Manuel Castillo
- Ms. Venus Gines
- Ms. Susan Leigh

The NCI and the DCLG thanked the outgoing members for their service and wished them well in future endeavors. Five new members will be announced shortly

STATUS OF COMMUNICATIONS REORGANIZATION

New Organization: Structure and Function

Dr. Sieber reported on the status of the reorganization of NCI=s Office of Communications (OC). As part of the review process established by Dr. Klausner for the reorganization of the OC, both the governance and the structure of the Office were reviewed. Based on the findings from the review, a strategic plan was presented to NCI=s Executive Committee (EC) in October 1999. Dr. Sieber commented that the plan had a corporate Aflavor@ and focused more on products and profits than services. The NCI OC Design Group, a subcommittee of the EC consisting of six members, met several times in October and November to discuss and address the suggestions and comments provided in the strategic plan. The Design Group extracted the most useful and applicable aspects of the plan and presented these points to the EC in December.

The reorganization of NCI=s communication activities is being undertaken because:

- NCI is receiving increased resources and must communicate the importance and achievements of cancer research to constituencies.
- Emerging technologies are making fundamental changes in the way we communicate.
- NCI has selected cancer communications as an Extraordinary Opportunity in the Bypass Budget.

Dr. Sieber also outlined NCI=s communications principles:

- Plan and execute communications with the same rigor as scientific researched
- Take proactive and coordinated steps to ensure the success of the communications mandate.
- Reflect a commitment to research in a caring and understanding fashion

The overall goals of the new communications office are to:

- Be more proactive and less reactive in developing and disseminating communications materials
- Raise the level of awareness of NCI=s services and products
- Communicate as effectively as we conduct science

Central themes for NCI=s communications efforts are:

- *Oversight*
  - Develop a coordinated planning process with priorities
  - Speak with a consistent voice
  - Devise an identity or Abrand@ and respond to issues as they arise

- *Functionality*
  - Be positioned to move in new directions, use new and emerging technologies
  - Increase efficiency and effectiveness in harnessing technology
  - Strengthen communications activities between science and medicine
  - Ensure that materials are appropriate and culturally sensitive
  - Increase public access and awareness
  - Leverage new resources
  - Have right expertise, right balance

- *Connectivity*:
  - Connecting communications efforts and activities across all NCI divisions; this will be key to the success of NCI=s OC reorganization efforts
  - Developing and accessing interactions, linkages, and creativity without Areinventing the wheel@

A new organizational structure for NCI=s OC has been created in an effort to address the changing climate of communications, NCI=s mandate to communicate and disseminate information, and the Institute=s (as a whole) and staff=s capabilities. The new organizational structure includes a Strategy Team and an Operations Team that will guide the efforts of the office (see appendix A). The Operations Team will consist of key NCI staff including the Director of OC and the Associate Directors of OC Programs. The proposed functions are outlined below:

Cancer Information Products and Systems is responsible for the products and systems associated with the ICIC (International Cancer Information Center), CCB (Computer Communications Scientific Publications Branch), and the Scientific Publications branch (SPB).

Communications Coordination through liaisons with each NCI division, will keep the lines of communications open across NCI. This group will take a proactive stance in identifying emerging issues of scientific and/or medical importance. It will also respond to the public about a variety of issues. Coordination will be essential in achieving the integration of information throughout OC. The groups will include a cadre of staff that will pull together, on an *ad hoc* basis, teams of three to five people to address and resolve emerging issues.

Outreach and Partnerships will oversee and coordinate outreach and assist in the development of partnerships with a variety of organizations, such as advocacy and professional groups and other government agencies. Additional activities will focus on outreach to and about special populations; specifically, those groups that carry a high cancer burden, compared with the general or overall

population. The current Health Promotion Branch and Office of Liaison Activities will be incorporated into this program.

Media and Public Communications. will house NCI=s Public Information Office (i.e., the Institute=s Apress office@) and the CIS.

Technologies and Services will provide graphics, publications, and meeting and events support for the entire Institute. The unit also will be responsible for ensuring consistency in presenting the NCI Aname@ across all NCI communications, and for developing and implementing emerging technologies.

At this time, no senior-level staff have been appointed to the five new programs units under the reorganization plan. Associate directors are expected to be announced by September. A Deputy Director for OC will also be named.

Formal announcement of the reorganization of the new structure is expected to occur some time in May.

Discussion and questions. Mr. Moore inquired about NCI=s involvement in the development of a Federal database of all clinical trials; he noted that on the current NIH/NLM website, www.clinicaltrials.gov, there are no links to NCI in the first two pages of the site. Dr. Sieber commented that the new clinicaltrials.gov site is maintained by the National Library of Medicine (NLM), as mandated by Congress. NCI is working with NLM on the database and has requested that the site provide a direct link or icon to NCI=s clinical trials site.

In response to other inquiries, Dr. Sieber stated that the OC reorganization is an effort to improve on NCI=s current communications efforts and activities. In addition, the Institute identified the area of communications as an extraordinary opportunity for the Bypass Budget and will support new research in health communications in partnership with DCCPS. Key goals of NCI=s communications activities are to improve outcomes, change behaviors, decrease cancer incidence and mortality, and improve patients= quality of life. Mr. Katz stressed the importance of NCI continuing to relay messages on cancer prevention and control research. Dr. Sieber responded by noting that the OC is working to ensure that research results are used by the OC.

Several DCLG members noted that there is not a clearly stated strategy for increasing public awareness (outreach and education) about NCI or its clinical trials, a goal which the group agreed should be a top priority for the Institute=s communications office. Ms. Castro commented that using and enhancing or adapting certain proven health communications models (see next section) should address some of these concerns. Dr. Sieber added that the purpose of the Office of Clinical Research Promotion (OCRP), is to address issues and aspects of clinical trials.

Regarding NCI=s new Abrand@ or Aidentity@, which is still under development, Dr. Sieber explained that NCI is seeking more than just a new logo. The Institute is interested in changing the perception that NCI is not only about statistics and numbers, but also cares about the treatment and education of cancer patients, their families and the public in general.

Dr. Castillo noted that, through his experience, especially at meetings and conferences, other health professionals do not appear to be aware of NCI=s communications and educational offerings, such as PDQ and the extensive roster of clinical trials. He then asked whether NCI or NIH has documented or surveyed the level of awareness of NCI among health-care workers. Dr. Sieber reported that Dr. Rimer=s group is conducting a survey on trends in cancer knowledge among health professionals. In addition, OCRP will be doing outreach to inform providers of NCI=s diverse and varied resources. Dr. Rabson added that NCI staff also try to reach health-care providers through meetings with representatives of professional societies.

Mr. Katz asked about placement of the CIS and the NCI Public Inquiries Office as functional sub-units under Media and Public Communications rather than in Cancer Information Products and Systems. He suggested that the CIS is NCI=s most important cancer information Aproduct@ and is accessed primarily via telephone and also via the Internet. However, he noted that those interested in the CIS online would need to know that it is an NCI product and Aembedded@ within the NIH and NCI sites. NCI includes Public Inquiries, under the Media and Public Communications unit because of its role in responding to critical issues. Dr. Sieber emphasized that the organizational chart presented, by its very nature cannot relay the intended interrelational nature of the different divisions and programs in OC; she explained that all units are expected to interact with each other even if they are shown as discrete organizational units.

MODELS FOR HEALTH COMMUNICATIONS

Ms. Castro described key issues and questions driving consumer-based health communications efforts and outlined the main stages of the health communications model used by NCI. The type of health communications processes used by the Health Promotions Branch (HPB) are based on NCI=s overall guiding principles and priorities, that is, to coordinate communications efforts and activities across the entire Institute and to follow a standardized approach to cancer communications.

The Health Promotions Branch follows procedures and models outlined in AMaking Health Communications Programs Work: A Planner=s Guide@ (referred to as AThe Pink Book@. This guide is undergoing revisions that include new hands-on modules to make it more interactive, and a new edition is expected to be available online in early summer. The older version can be found at http://rex.nci.nih.gov and clicking on ACommunication and Education Resources.@ The book can be

found by going to the Program Planning Publications and clicking on AMaking Health Communications Work.@

When developing health-based communications, HPB considers several questions before planning begins including:

- What is the purpose of the communication effort?
- Who is the intended audience?
- What do we want as the outcome (e.g., what do we want people to do?
- How will we support this effort?
- What communications tools will be used, and when and where will these tools be used?

Ms. Castro then described the six primary stages in the health communications model that NCI uses. The various stages and the objectives for each are outlined below.

Planning and Strategy Selection

- Review available data
- Identify existing activities and gaps
- Write goals and objectives
- Gather new data (primary research)
- Determine intended audience(s)
- Assess resources
- Draft communications strategies
- Write program plan and timetable

After completing analysis of the available data, a plan is proposed that outlines strategies for completing the project. This plan also is used to track how the project is progressing and assists in identifying strategies that are helpful and not helpful. Ms. Castro noted that, on average, it takes approximately two months to review data and put together an overall plan.

Selecting Channels and Materials

- Identify messages and materials
- Select channels of communication
- Clarify the role of public service media campaigns in the project

In this phase, staff develops messages that are relevant, appropriate, and culturally sensitive using accurate scientific information and identified appropriate channels for delivery. Ms. Castro noted that NCI may use radio, newspapers, the Internet, or other vehicles. She added that NCI also partners with private companies to deliver messages.

Developing Materials and Pretesting

- $ Develop and test message concepts
- $ Develop draft materials
- $ Pretest materials
  - S Identify what pretesting objectives
  - S Identify pretesting methods
  - S Determine what and how much to test
  - S Plan and conduct pretests (including developing testing instruments/tools)
  - S Evaluate and use pretest results to modify message/product
  - S Identify reasons to not pretest

Pretesting of messages or products with different audiences is key to the success of the final communications activity, product, or service. A message is Apackaged@ in different formats and then shown to focus groups who will evaluate the products for readability, appeal, and other factors. Ms. Castro noted that pretesting is especially important for controversial issues. This stage usually lasts the longest, often at least three months. Pretesting may not be done when time, staff, and/or finances are very limited.

Implementation Phase

- $ Prepare to introduce the communications program, products, or activities
- $ Follow and track progress
- $ Establish process evaluation measures
- $ Work with intermediaries
- $ Seek out opportunities to collaborate with the private sector
- $ Review and revise program components

Implementation of a program is often done at a specific time, for example, tied to Breast Cancer Awareness Month, or through an event or series of events, such as the Race for the Cure.

Assessing Effectiveness

- $ Conduct outcomes evaluations
- $ Conduct impact studies
- $ Determine which additional evaluations to run based on communications goals and objectives
- $ Identify examples of program assessment questions
- $ Conduct evaluations options based on available resources
- $ Identify elements of evaluation design

An example of a specific outcome is tracking the number of calls to the CIS after cancer related topic is discussed in the media. Outcome evaluations are based on the communications goals and objectives identified at the beginning of the program, the resources available, and the program assessment questions.

Feedback to Refine Program

- $ Apply what has been learned
- $ Revise the program if needed
- $ Share the lessons learned and information obtained
- $ Prepare a final evaluation report

Ms. Castro explained that the entire process, from planning through evaluation, including implementation, can take six months to one year.

With respect to more general business, Ms. Castro noted that, as the OC reorganization occurs, HPB will also undergo some changes, including a name change. She also mentioned two upcoming events that will feature NCI communications activities and approaches: A Cancer Communications Conference, slated for December 2000, a Akick off@ event for the Extraordinary Opportunity in Cancer Communications, and the Cancer Control Academy, a training seminar for special populations network grantees= scheduled for summer 2000.

Discussion and questions. Several attendees suggested that the terms Atarget audience@ and Athe patient failed treatment@ should be avoided; Aintended audience@ and Athe treatment was not effective@ are, respectively, alternatives that could be used.

Ms. Castro stated that the health communications model she presented is the primary process that the NCI OC uses for outreach. For example, this process has been used in its breast and cervical cancer messages and for its 5-A-Day program.

In response to a question about the HPB, Ms. Castro noted that the Branch has an annual budget of approximately $1.5 million, which supports a staff of five, including marketing research and evaluation

personnel, plus contractors. Key HPB programs include the 5-A-Day and breast and cervical awareness projects. The HPB collaborates with other NIH Institutes and other government agencies, such as the CDC, on a variety of projects.

Mr. Katz followed up on prior discussions by posing the following questions:

1. Does NCI or the HPB have a framework for setting priorities, and if so, could a specific example be provided?

2. Can the DCLG provide grassroots feedback in NCI=s communications efforts?

3. Are these issues future agenda items for the group?

Regarding question two, Mr. Katz suggested that identifying a clear example of a project in the implementation phase that has some outcome results could help in showcasing the HPB health communications model. Ms. Castro responded that the breast cancer program currently will be in the Afeedback and evaluation@ phase this year. NCI will be conducting this phase of the program in partnership with the Health Care Financing Administration (HCFA). She offered to bring the results of the evaluation and feedback to a future meeting of the DCLG and will work with Liaison Activities to accomplish this goal. With respect to setting communications priorities, Ms. Castro explained that, in the past, her office has responded to requests to take on specific projects. In the future the OC Strategy Team will be working to identify resources, key issues and set priorities to develop communication materials and messages.

Ms. Dewey asked how advocates can become more involved in NCI=s Communications beyond providing input for priority setting, participating in focus groups, and other similar activities. Ms. Castro cited several examples in which advocates and communities have become very involved in issues that have led to guiding NCI=s communications Aagenda@. She noted the activities related to the development of a plan for an education and awareness campaign about I-131 fall-out from the Nevada test site. Activists initiated this effort and several advocacy groups, along with NCI and CDC, are developing the plan. Dr. Schanche-Hodge mentioned involvement of Native Americans in the I-131 Group, noting that NCI has provided information to the community, has actively encouraged and sought advocate involvement, and is now supporting conference calls for the group. Of key importance is the possible impact on the community. Ms. Castro anticipates that NCI will use a similar strategy for future projects, adding that NCI increasingly will be involving more advocates, patients, and consumers in the planning phases of various communications projects.

Another question related to NCI=s process is identifying advocates to participate in activities and how the DCLG might assist in this process. Of particular interest is whether the Institute chooses from the same pool of candidates, or if it adds new names to the pool on a regular basis. Dr. Sieber stated that although NCI has a fairly large pool of advocates from which to draw, it does use many of the same people over and over. Dr. Sieber added that NCI is very interested in making this process more systematic as well as in increasing advocate representation in NCI study sections.

NCI RESPONSE TO DCLG RECOMMENDATIONS FOR COMMUNICATION

Dr. Sieber reported on NCI=s response to the DCLG=s recommendations of June 1999 on behalf of Dr. MaryAnn Guerra, Deputy Director for Management, NCI. Dr. Sieber presented a detailed response (handout) that matched the DCLG=s recommendations to NCI=s response(s) and identified the office within NCI that would be responsible for implementing NCI=s response. A timeframe for implementation indicating whether the task was already completed or was considered a short- or long-term goal also was provided. (Appendix B)

The DCLG=s first recommendation was that NCI take a stronger and more visible leadership role in reaching consumers with cancer information and to increase public awareness of NCI=s high-quality cancer information resources. This recommendation included several additional points focused on **(a) appropriateness of NCI materials for intended populations, (b) accessibility of services, (c) PDQ redesign and the overall NCI web structure and usability, and (d) marketing and promotion of NCI web services.**

NCI=s response to the recommendation includes the reorganization of the Institute=s communications structure. Dr. Sieber noted, improved communications was a primary principle in the restructuring plan. In addition, the CIS is launching a new campaign to increase the public=s awareness of NCI and all of its products. The reorganization will soon be implemented. The DCLG members raised questions about the importance of outreach impact/outcome measures.

Appropriateness of materials. Activities related to the OC will be expanded. For example the Outreach and Partnership Program will focus on population and organizational need. DCCPS, OSPR, and OC will work together to evaluate results of research on communications materials, including research promoting public awareness of clinical trails. OC also will oversee various components (e.g., language, cultural relevance, role of community) of translating materials and messages to different media and audiences, including both consumers and health care professionals. Specifics regarding timeframes, progress measures, and priority setting are being discussed with the operating team; further details will be clarified as permanent Associate Directors are hired.

Accessibility of services. Dr. Sieber noted that CIS resources are available through two toll-free telephone services, one for the public and one for health professionals. In addition, people can receive material by fax, e-mail, the Internet and by mail order. OC efforts include partnerships with vendors to produce public kiosks as well as web-based health information Aportals@in public places such as shopping malls and libraries. New OC efforts include development of a CancerFax system that does not require handsets on fax machines; development of CancerVoice, an automatic text-to-speech conversion and speech recognition system to allow physically challenged persons or those without access to computers or fax machines to obtain information via phone. Research to find ways to provide access to cancer information by diverse populations is an objective of NCI=s Cancer Communication Extraordinary Opportunity. NCI=s homepage, www.cancer.gov now includes an AInformacion en Espanol@ button for information and access for Spanish-speaking persons. NCI is also establishing Centers for Communications Excellence to identify populations with the greatest needs. Another mechanism through which access and awareness could be improved is the Special Populations Networks (SPNs) for cancer control and research (discussed further below).

PDQ redesign and web structure and usability. NCI concurs with the DCLG that there is a wealth of knowledge available that could be better packaged and easier to use or access. NCI plans to continue to involve the DCLG to obtain input about usability. A DCLG member is also on the editorial board of cancerTrials. They can assist NCI in standardizing format presentation and inclusion criteria for trials included on PDQ. A users group will be formalized through the Technologies and Services Program. As a result of a suggestion from the group, NCI will clarify its activities, and those of the DCLG, under this recommendation and distribute that information. NCI also will step up efforts to improve its own communications and feedback to the DCLG in this matter.

Marketing and promotion of NCI=s web services. NCI has already taken several steps to make its website more visible, navigatable, and accessible. The Institute will continue to work on promoting the various aspects and the broad base of content of its site.

The DCLG=s second recommendation encourages NCI to pursue opportunities to proactively communicate NCI messages about cancer research, the people and the lives it affects, and the people who do the work through direct media. NCI=s responded that the Institute will be involved in more proactive communications through a variety of media. Regarding the DCLG=s recommendation that NCI Aput a face@ on the Institute, NCI will establish an Aidentity@ or Abrand@. It will gather input from consumer advocates, including the DCLG as it develops the brand. Responses to the remaining recommendations will be reviewed by DCLG members and feedback provided to Dr. Seiber.

Dr. Sieber announced that the Akick-off for The Extraordinary Opportunities in Cancer Communications is being planned as a 1 **2**-day communications/media event in December 2000 on the NIH campus.

This meeting, expected to draw some 300 attendees, will feature a broad range of communications advances; an Aexpo@ for industry and professional organizations; presentations by prominent cancer health communications experts; hands-on sessions on cancer information dissemination; and practical workshops on the practice of communications, the translation of research into practice, and research opportunities. A session will be devoted to SBIR awards in communications. This meeting should also serve to publicize NCI and its communications offerings and capabilities. The audience for this meeting is expected to be primarily health communicators, researchers in the health communications field, consumers, and cancer advocates. A short videotape of the meeting will be made; preparation of a short NCI promotion piece (on video and CD-ROM) for advocates and NCI staff orientation also is under consideration.

Discussion and questions. The DCLG members had questions about NCI=s timeframe for implementing the communications recommendations. They noted, for example, that the recommendations were submitted to NCI about 1 year ago and expressed concern that the Institute is not giving the recommendations a high priority. Dr. Sieber responded that NCI does place high value on the DCLG=s recommendations and reminded the group that reorganization of NCI=s communications activities began shortly after the DCLG report was received. She added that the reorganization of OC has taken more time and resources that originally planned. The DCLG members recognized the significant effort involved in the reorganization and noted that the NCI has accomplished a lot in the time since the group first met. With respect to identifying tasks as short- or long-term projects, Dr. Sieber replied that short-term tasks are expected to be completed within 3 to 6 months, whereas long-rage activities are expected to take from 1 to 4 years to complete. In addition, she noted, some activities are ongoing or already completed.

Regarding access to NCI services, Mr. Moore noted that it is possible to speak with CIS staff directly only during regular business hours (9 a.m. to 5 p.m., Monday through Friday); callers hear a recorded message at all other times. In contrast, the American Cancer Society (ACS) has professional, trained staff available 24 hours a day, 7 days a week. He and other members suggested that NCI consider expanding its phone services to follow the ACS model. Also suggested was that NCI include non-computer users to test the Auser friendliness@ of its computer and online services.

Mr. Katz and Ms. Dewey suggested that updates on the recommendations be included in each DCLG agenda. The group should continue to ask NCI for specific actions (planned and completed), measures, and timeframes for completing or implementing tasks, including NCI=s plans between meetings. Mr. Moore suggested, for the next meeting, that the DCLG focus on issues and tasks identified by NCI as short-term goals, that is, those points that NCI anticipates achieving within 6 months. Others agreed with this approach, and Mr. Katz reiterated the importance of seeking details on outcomes, measures, and completeness of projects and identify ways that the DCLG can assist NCI

in meetings its goals. Dr. Sieber replied that she (or someone from her staff) would be more than willing to provide updates at each the DCLG meeting.

Ms. Butler suggested providing Dr. Sieber with more background information on the rationale for each of the DCLG=s recommendations. Further, Mr. Katz suggested setting up one (or more) conference call(s) with Dr. Sieber and others involved in NCI=s responses to the DCLG=s recommendations to identify key areas of interest and focus, and discuss issues. NCI was encouraged to use the DCLG listserv to solicit feedback from the DCLG members regarding OC activities. Liaison Activities will assist in this effort. The group also expressed interest in receiving website use information/measures, such as the number of hits per day and length of each visit (at the very least) and disease-specific entry points, before the next DCLG meeting.

UPDATE ON NEW CLINICAL TRIALS SYSTEM

Dr. Abrams provided an overview and summary of a series of pilot projects, supported by NCI=s Cancer Therapy Evaluation Program (CTEP), designed to demonstrate the feasibility and effectiveness of implementing changes in cancer treatment and management targeted to a broad audience, including medical researchers, clinicians, and advocates. These pilot projects included the State of the Science (SOTS) meetings, Concept Evaluation Panels (CEPs), Cancer Trials Support Unit (CTSU), and the National Network of Treatment Trialists. The project also includes Cooperative Group Strategy meetings. The pilot project focuses on cancers of the genitourinary (GU) tract, lung, gastrointestinal (GI) system, and leukemia. The path of the pilot project starts with SOTS meetings, which cover GU and lung cancers, and Cooperative Groups Strategy meetings, which cover GI cancers and leukemia, to disease-specific CEPs and CTEP concept reviews, respectively, and finally, funneling to CTSUs.

State of the Science meetings are national forums to identify new research opportunities in specific cancers or important gaps in NCI=s research portfolios. Participants at SOTS meetings include clinical and basic scientists, researchers from industry, patients, advocates, and others.
Meeting results are widely disseminated through an array of media, including the website at http://www.webtie.org, which provides viewers with audiovisual records of each speaker=s presentation, including slides, oral presentations, and transcripts. The results from the lung, prostate, and leukemia meetings are available online. Dr. Abrams reported that approximately 355 users visited the site in February even without any publicity about the site. Meetings are advertised and promoted through direct mail, the *Journal of the National Cancer Institute*, Cooperative Group newsletters, e-mail notices, meeting exhibits, and the web site.

Challenges to implementing changes within the scientific and advocacy communities through the SOTS meetings been identified and include:

- $ Ensuring effective integration of laboratory and clinical researchers and the possible need for sufficient incentives for continued participation and commitment
- $ Keeping participants focused on research opportunities and gaps rather than the administrative process.
- $ Managing and overcoming the demanding and complex logistics of coordinating frequent meetings

Dr. Abrams explained that Concept Evaluation Panels conduct broad-based, disease-specific scientific reviews of Phase III concept proposals. The panels include clinical and basic scientists, statisticians, patient advocates, and others, with approximately one-third from the Cooperative Groups, cancer centers CCOPS/SPORES and NCI, respectively. CEPs will replace the current concept reviews centralized in NCI/CTEP.

Challenges to implementation facing the CEPs include:

- $ Lack of familiarity of reviewers with this new tool, producing a Asubstantial learning curve@. Modifications to the tool have already been suggested by users
- $ CEPs need to gain experience with scoring and prioritizing studies
- $ CEP participants and communications are hampered because of software and hardware incompatibilities and variable computer skills and expertise

The Clinical Trials Support Unit consolidates administrative functions now carried out by nine groups. CTEP funds the CTSU through a contract mechanism in collaboration with the National Coalition Cancer Cooperative Groups and the Oracle Corporation. The scope of the pilot project incorporating the CTSU involves:

- $ Participation by all adult cancer Cooperative Groups and their members
- $ Extended enrollment privileges to non-group members in years 2 to 3 if the initial experience is successful
- $ Up to 750 sites to be included by year 3

Major accomplishments of the CTSU thus far include:

- $ Surveyed Cooperative Group regulatory, financial, data management, and educational systems and tools
- $ Developed contract templates for delivery of accrual, leadership, technical expertise, and travel funds

- Made presentations about the CTSU to each Cooperative Group at annual meetings
- Developed a CTSU demo website
- Negotiated with several commercial companies that have developed remote data entry systems

The following short-term goals and tasks of the CTSU are slated to be completed by July 1, 2000:

- Compile single combined roster system from the Individual Group rosters
- Enter 17 Group protocols into the CTSU database
- Develop web-based and onsite educational and training materials
- Complete initial promotion and public awareness campaign

Long-term goals for the CTSU include:

- Increase protocols on the CTSU menu to approximately 50 (by 10/00)
- Deliver the pilot electronic remote data entry system (04/01)
- Complete negotiation of subcontracts with Group and non-Group investigator sites (09/01)
- Complete website for all Cooperative Group protocols with a referral system to specific investigators (10/01)
- Develop a web-based roster and IRB database for all Group and non-Group investigators (10/01)

Challenges to implementing the full CTSU system have been identified as:

- Managing the tremendous coordination effort between CTEP, Groups, and CTSU
  Activities to facilitate these efforts include the development of a website to post calendars of committee meeting dates, minutes, personnel, and important documents; and development and use of a listserv to spread information rapidly
- Integrating CTSU=s informatics systems with multiple Group and CTEP systems
  This activity will require extensive Abridging@ of diverse systems and consensus on common standards and requirements

A formal evaluation plan will be carried out. CTEP and DCCPS competed successfully for NIH=s 1 percent set-aside evaluation plans, including a recent award of $543,048 over 4 years to carry out the evaluation plan using a contractor. The metrics of the evaluation will consist of both objective and subjective endpoints tracked over time, specifically, clinical trial accrual rates and numbers, data quality, satisfaction questionnaire and/or focus groups to compare new electronic tools to previous methods

Another project, the Central IRB Project, has been implemented following extensive discussions with Office of Protection Against Research Risks (OPRR) and Food and Drug Administration (FDA). In this pilot project, NCI will sponsor a central IRB composed of about 30 representative Cancer and Leukemia Group B (CALGB) academic and community institutions. The central IRB will use standard operating procedures and provide approvals and minutes of its discussions to local IRBs, along with real-time study follow up. The local IRBs, in turn, may elect to approve the central IRB=s recommendations with a facilitated review. The CTSU will provide infrastructural support to the central IRB. Dr. Abrams pointed out that the CTSU will provide both logistical and administrative support to the central IRB pilot project.

Dr. Abrams identified other initiatives CTEP has undertaken to strengthen the scientific and clinical foundations of cancer research and treatment:

- $ Provided Funds in Cooperative Group Awards
- $ Revised Cooperative Peer Review Criteria
- $ Interdisciplinary Research Teams B Molecular Target Assessment
- $ Provided a Transitional Research Fund B Early Clinical Trials
- $ Provided for Correlative Study Funding for FY00

An informatics project, in collaboration with the Cooperative Groups, includes the development of a publicly accessible common dictionary (i.e., CDEs) (at http://ciinc.gov/cde) for clinicians. This CDE encompasses a common data dictionary of common terms, common definitions, a common format, and common valid values. It is anticipated that increased use of such a common clinical dictionary will lead to protocols with consistent formats, simplified reporting, and improved analysis. Dr. Abrams reported that version 1 of the browser for the treatment trials CDE (for breast, lung, GU, and GI cancers) was released on September 1, 1999, and that all Group protocols were required to start using common case report forms, designed according to the dictionary templates using standard CDE terns and meanings, as of January 1, 2000.

Discussion and questions. In response to query about the scope of the central IRB, Dr. Abrams noted that, at this point, the central IRB will review protocols for 17 trials of five diseases open under the CTSU; this responsibility is expected to expand to include up to 50 trials if the first round of 17 trials proves successful and OPRR approves the expansion. Regarding the possibility of multiple central IRBs, Dr. Abrams commented that this option is under consideration but is not a certainty.

In clarifying the difference between SOTS meetings and Progress Review Groups (PRGs), Dr. Abrams explained that SOTS meetings are focused on treatments for disease and bring in a variety of

participants representing a broad range of expertise. PRGs evaluate the entire research portfolio for specific cancers including basic science, diagnosis, detection, etc.

Dr. Abrams commented that central IRBs will not necessarily replace local IRBs. For example, review of in-house protocols will still remain under the purview of the local Boards. The role of local IRBs in large, national clinical trials is expected to involve facilitating some protocol reviews but may also involve deferring reviews under certain circumstances. Dr. Abrams added that the CTSU allows both physicians and patients, access to a greater number of clinical trials. Dr. Hodge expressed concern that the local IRBs, which are often most familiar with the specific needs of the community (e.g., cultural or language issues, special populations), may lose some control over the important role in addressing these needs. Dr. Abrams agreed with the relevance and importance of this issue and noted that there are policies to protect patients. In addition, the pilot project includes an online communication and discussion component in an effort to obtain broader participation and input from across the country.

DCLG UPDATE/NEW BUSINESS

DCLG Communications Review. Mr. Katz noted the DCLG Communications Report, submitted to NCI in June 1999 was a major activity of the Group. This report was prepared in response to NCI Director Klausner=s request that the DCLG provide NCI with feedback, advice, and recommendations about specific communications initiatives.

President=s Cancer Panel. Ms. Lee provided a brief summary of recent and upcoming activities of the President=s Cancer Panel, noting that the Panel will be hosting a series of regional meetings between April 2000 and March 2001. The focus of these meetings is Alocal problems, local solutions.@ Meetings are planned for Omaha (June), Vermont (September), Montana (October), Tennessee (November), and New Mexico (March 2001). This series will also include a focus on international cancer research, treatment, care, and prevention. Ms. Lee encouraged advocates to attend meetings, adding that NCI will assist in this effort by sponsoring DCLG members; those interested in attending should contact the Liaison Activities for more information, including the specifics of the meeting schedule.

Ms. Butler commented on the first PCP meeting held in March. This meeting, the first of the series, addressed the topic of applying research results to care for patients.

In 2001, the Panel will prepare a report of its findings from meetings held in 2000 and 2001 to present to the President. It will also be distributed to others involved in cancer research and delivery of cancer prevention and care.

Clinical Trials: Talking Points. Ms. Butler summarized her white paper that the DCLG may wish to use in addressing publicly the issues related to clinical trials. She recounted the Group=s discussion during its October 1999 meeting, when attendees noted that inaccurate Ascare@ stories may limit the ability of investigators to recruit trial participants.

In developing common themes for these talking points, Ms. Butler noted that there are many reasons why people do not choose to participate in clinical trials, including :

- There is a lack of knowledge about trials and their critical role in improving cancer care.
- Clinical trial participation is not widely perceived as an opportunity to receive state-of-the-art care.
- Physicians are not aware of trials appropriate in their patients.
- In the media, people read, hear, and see largely sensationalistic stories they cover only those trials where something goes wrong.
- Insurers are not likely to pay for experimental treatment or for routine care of patients on trials.
- Medicare currently will not fund clinical trial participation for Medicare participants.
- People may be uncomfortable with participating because they do not want to be Aguinea pigs@.
- Stringent participation criteria exclude many potential participants.

Recommendations offered by Ms. Butler to The DCLG members include:

- ABe who we are@, that is, speak as survivors as well as members of the DCLG.
- ABe prepared@ to ensure that messages are delivered as effectively and accurately as possible.
- ABe focused@ on the bottom line message that clinical trials are essential to finding a cure for cancer.

Ms. Butler also prepared the following themes to consider when developing talking points:

- Trials are a critical key to progress in improving cancer treatment.
- Despite the importance of trials in improving treatment and finding the ultimate cure, *fewer than 5 percent of cancer patients participate in clinical trials*. Dr. Vincent DeVita, former NCI Director, has commented that if only 10 percent of patients participated in clinical trials, it would be possible to determine the effectiveness of new therapies more quickly than is currently possible
- Education about clinical trials could be presented as a public service to the American people, who can learn more by contacting 1-800-4-CANCER, www.cancertrials.gov, or www.cancer.gov. NCI should make sure the media is aware of these resources and encourage them to publish and promote them.

- $ Participants in treatment clinical trials generally receive the best treatment known or a new treatment.
- $ In NCI-sponsored trials there is an array of safeguards to minimize risks and dangers to participants. Thus, NCI-sponsored studies actually undergo a higher level of scrutiny than other treatment regimens.
- $ There are numerous success stories about people whose lives have been saved by trials. Human interest stories reach people. Many DCLG members are cancer survivors who can relay their own Asuccess@ stories; the Group should also make an effort to encourage the media to identify a variety of successes with clinical trials.
- $ The argument that Aclinical trials cost insurers too much@ compared with standard treatment increasingly is being proven to not be true. Recent studies conducted by the Mayo Clinic and others show that patient-related incidental treatment costs in clinical trials are comparable to costs incurred in standard treatment. Further, NCI is now working with insurers/vendors to mediate this issue.

Ms. Butler offered to provide additional follow-up information to the DCLG members as needed and requested.

Mr. Katz commented that if the DCLG is to take a more proactive role in clinical trials dissemination efforts of NCI, it would be useful for group members to receive some sort of training in outreach and working with the media. Ms. Jane Reese-Coulbourne described a project that she is helping to test market that strives to achieve just that: to train advocacy groups on clinical trials, including how to disseminate clinical trials information in an effort to not only increase awareness but also to increase enrollment in trials. The full course, which includes videos, a speaker=s guide, role playing, and other strategies, takes a full day. She offered to present a capsule of the training program on the second day of the meeting and can follow up as needed.

Special Populations Working Group (SPWG). The SPWG reports to the Advisory Committee to the NCI Director and serves as a link between NCI and special populations. Dr. Zebrack reported to the DCLG members on the meeting of the SPWG held March 1-2, 2000. During the SPWG meeting, Dr. Zebrack highlighted the recent activities of the DCLG, including the DCLG=s involvement in formulating the extraordinary opportunity in cancer communications for the Bypass Budget, and the DCLG=s recommendations presented in the communications report.

Other topics discussed included the following:

- $ Part of this discussion focused on the inadequate translation of research discoveries to improved cancer care particularly for undeserved populations where there are disparities in access to and delivery of care. Current programs are reaching underserved populations in Alabama, Hawaii,

Illinois, Louisiana, Puerto Rico, Texas, and Virginia. However, there is inadequate infrastructure to support these programs= involvement in clinical trials. An MBCCOP success story, however, is the Study of Tamoxifen and Raloxifene (STAR) breast cancer trial, which was piloted in minority recruitment programs at nine U.S. institutions with collaborations with local community organizations. The STAR trial could be a model for minority recruitment in future endeavors.

- Opportunities for underrepresented minorities in cancer research, training, career development, education through the Comprehensive Minority Biomedical Branch (CMBB) in NCI=s Cancer Training Branch. As a result of vague notions of Aunderrepresented minorities,@ (1) foreign nationals from Asian countries that come to and leave the United States are counted as representing American Asian/Pacific Islanders, (2) distinctions are not made among different groups within the larger Asian/Pacific Islander population, and (3) poor, rural whites are excluded. These issues arose in a subsequent discussion of the definition of special populations, which was led by Drs. Richard Warnecke and Judy Kaye, who reported on the NIH=s efforts to define the term Aunderserved.@
- The definitions of Aspecial populations@ and medicall undeserved remain unclear.

Drs. Warnecke and Kaye reported that at a recent NIH meeting, representatives from several NIH institutes, the CDC, and other interested parties worked to (1) determine the best term for describing Amedically underserved populations, (2) define the concept described by the term, (3) develop a framework for measuring and monitoring vulnerable population groups, and (4) develop a plan for measuring and monitoring differential vulnerabilities to cancer in the United States. The group at the NIH meeting developed the following definition for Aunderserved@:

> Underserved populations may be defined as Apopulations at risk of poor physical, psychological, and/or social health who experience a lack of sufficient community, clinical, or individual resources to effectively meet their needs.@

Those attending the SPWG meeting discussed and then amended this definition as such (new text in italics):

> Underserved populations may be defined as Apopulations at risk of poor physical, psychological, and/or social health who, *because of social injustice,* experience a lack of sufficient community, clinical, or individual resources to effectively meet their needs.@

This definition, plus additional discussion and feedback by members of the SWPG, will be forwarded by Drs. Warnecke and Kaye to the NIH. Eventually, a report will be prepared and delivered to the

NCI director, distributed throughout the NIH, and published in various public forums. The final report will help guide funding for SEER-related research projects on special populations and may be used in planning Special Populations Networks.

Both Drs. Zebrack and Sieber reported that SPWG=s discussion surrounding the development of an appropriate definition for underserved populations was lively and intense at times. The SPWG sought a working definition that does not apply to Aanyone@ and that also does not use race as a sole determinant of identifying underserved populations. One suggestion of the DCLG was to replace the term Ainjustice@ with Ainequities.@ Dr. Castillo and others noted that three key risk factors influence whether an individual or population is underserved with respect to health and health care: (1) education level, (2) poverty, and (3) access to health care.

The NCI anticipates setting aside approximately $50 to $60 million for 18 Special Populations Networks (SPNs) for cancer control and research. The SPNs will be based within various communities to establish cancer control and research infrastructures to work within and serve these communities. To support the activities of the SPNs, the Office of Special Population Research is establishing a cancer control academy at the NCI for training and will link these community-based research networks to the full range of information and communication resources of the NCI.@

The DCLG asked if other DCLG members could attend SPWG meetings on a rotating basis. Those interested in serving on the SPWG for a 1-year term should contact Mr. Katz. A second request will be considered subject to resources available.

The December SPWG meeting concluded with a discussion of suggestions for new special populations initiatives.

Other business. Mr. Katz pointed to two key issues that the DCLG should consider further: (1) The role of advocates in the peer review process, and (2) the extent to which the Group is fulfilling its role as a consumer liaison group and how it can assist the Institute as a substantive collaborator, not simply as Aauditors@. He suggested that the Group discuss these issues in more detail in future meetings.

RECESS/ADJOURNMENT

The open session of the meeting was recessed at approximately 5 p.m., April 17. The second meeting day, April 18, was closed to the public in accordance with the provisions set forth in sections 552(c)(6) and 552(c)(9)(B), Title 5 U.S.C., as amended. Mr. Katz led the DCLG and NCI staff in discussions related to personnel, confidential matters and the future directions of the group.

_____	_____
Date	Michael Katz Chair NCI Director=s Consumer Liaison Group
_____	_____
Date	Elaine Lee Acting Executive Secretary NCI Director=s Consumer Liaison Group

Action Items

1. Ms. Castro will bring the results of the evaluation and feedback of a breast cancer program being conducted in partnership with HCFA back to the DCLG.

2. NCI also will step up efforts to improve its own communications and feedback to the DCLG regarding PDQ and the NCI website redesign.

3. NCI should present on the recommendations resulting from the DCLG=s review of selected communications programs at each meeting. A conference call with Dr. Sieber and others involved in responses to the recommendations would identify key areas of interest and focus. OLA will facilitate these calls.