



## ***Division of Extramural Activities***

### **DCLG Supplemental Material** Meeting Minutes

**Wednesday, December 17th**

#### **Opening Remarks by Richard D. Klausner, M.D., Director, National Cancer Institute (NCI)**

Dr. Klausner welcomed the DCLG to NCI, and stated the DCLG's importance to helping NCI accomplish its mission. The DCLG is critical to helping the Institute find ways to communicate with the diverse communities concerned about reducing the burden of cancer in order to craft a shared vision of how to go about this. Other key points made in his remarks included the following:

#### **What Is NCI All About?**

NCI's mission is to conduct research that will reduce the burden of cancer through a process of asking questions and demanding evidence for the answers. Science must also be humanistic. The DCLG will help ensure that research at NCI is conducted not in a vacuum, but within a system that empowers everyone to utilize its results. The issues to be addressed are complex, and NCI is committed to being open to promising avenues of research which encompass a research portfolio that is linked, by tools and information, to the practice of medicine and public health. Dr. Klausner urged the DCLG members to read NCI's Bypass Budget, prepared each year in response to direction by the Congress, that describes what NCI is about. It outlines what needs to be done to reduce the burden of cancer, and sets forth a set of research priorities that cut across all forms of cancer.

#### **What Progress Is Taking Place?**

There has been a revolution over the past several years in our understanding of the fundamental nature of cancer, upon which future advances will be based. This new knowledge must be translated into prevention and treatment strategies.

Progress is measured in two ways: first by the increase in real knowledge about the disease, secondly by reduction in the burden of cancer. Progress has been made. For all Americans under 55, mortality rates have dropped over 25 percent in the last 20-25 years, and the incidence of lung cancer is dropping. While not enough, this is movement in the right direction, and it is evidence that the fundamental national policy of basing our approach to cancer on verifiable knowledge about the disease is paying off. Approaches to cancer prevention and treatment over the next ten years will begin to change as we apply the knowledge acquired in recent years.

#### **How Does the DCLG Fit In?**

NCI's research priorities need to be based on open discussion with all those who have a stake in the research activities of NCI, and NCI must listen to what they have to offer. NCI has sought the input of patients and advocates in its various processes, and is developing ways to widen the pool of consumer advocates to work with NCI. One purpose of the DCLG is to help us with this process of identifying

appropriate consumer advocates for NCI program and policy advisory committees.

## **Q&A with Dr. Klausner**

*What are NCI's views regarding the barrier that "profit-driven" health care poses to patient participation in clinical trials?*

This is a tough, multi-faceted issue and one of many that NCI is trying to address with providers. We hope that a growing demand for high quality care will occur either as a result of legislation or competition in the marketplace. NCI must create a clinical trials system that works well. Physicians and patients both must be convinced that optimal care for a patient occurs in context of clinical trials.

NCI's current approach to this problem is two-pronged: 1) undertake fundamental rethinking and restructuring of the clinical trials program to make it more valuable and more attractive to more adult cancer patients, as has already occurred with pediatric patients and 2) work with providers and payers to deal with system issues as well as misconceptions about experimental therapy. NCI has been attempting to raise some of these issues with payers and providers by setting out, through negotiations, some model agreements in which NCI covers the cost of clinical trials e.g., Department of Defense and Veterans Administration. These agreements are allowing NCI to gather data about the incremental costs associated with participation in clinical trials. Health care providers and insurance companies are asking who defines a clinical trial. This is an extremely important, reasonable, but politically complicated issue that NCI needs to come to grips with.

NCI is trying to engage physicians through professional societies not only in disseminating information but becoming active participants in the clinical trials system. For example, the American College of Surgeons is involved in the NCI cooperative clinical trials system. NCI also provides valuable, accessible and reliable information and is currently redesigning its PDQ database.

*What can be done to raise awareness among physicians about the importance of consumer advocacy and patient education?*

The question of how best to go about changing practices is a problem across medical specialties. We need new, better ways of communicating to physicians when there are new, improved ways of doing things. There is also the potential of managed care actually helping change physician practices for the better.

Physician attitudes towards patients being well-informed is a problem, but there has been some improvement. As patients become better informed, they also influence physician attitudes. NCI can facilitate this process by providing patients with reliable information that carries the imprimatur of the NCI, which they can take to their providers.

*What is the global reach of NCI's clinical trials efforts, especially Latin America, Africa and Asia?*

NCI has extensive international efforts, not only in Europe but in Asia, Africa, and elsewhere as well. For example, Costa Rica will be the site for a clinical trial testing a vaccine for preventing cervical cancer, the second-largest cause of cancer deaths worldwide. In the Middle East, NCI led negotiations to create a cancer consortium. NCI can provide the DCLG with more examples of the Institute's international research activities.

*Is there a way the role of NCI can be expanded to better protect the public?*

NCI is not a regulatory agency, nor should it be. It needs to be free of the pressures that such a role confers

in order to pursue scientific knowledge unencumbered by political considerations. NCI's responsibility is to identify issues and provide the information needed to ensure that public policy is based on scientific evidence obtained through well-designed research projects.

*What is NCI's position on alternative medicine?*

For NCI the overriding issue in alternative medicine is making sure that the Institute is open to hints and ideas about effective interventions from any source, but the usefulness of those ideas must be based on evidence, not anecdote. An idea must have certain characteristics to be considered by NCI. It must be based on observations and well formulated in a way that is amenable to verification. Moreover, all possibilities can't be tested in a clinical trial; the necessary resources are not available. Ensuring that patients are not harming themselves with any therapy is a major concern.

*What are NCI's mechanisms for sharing information with those of limited resources?*

The Cancer Information Service (CIS) (1-800-4-CANCER; 1-800-422-6237) is a free telephone source of cancer information, and it also has outreach partners in diverse communities. NCI is working to improve the public access to computer-based cancer information, including clinical trials, through such places as public libraries. The ways people obtain information is changing and NCI needs to prepare for a future when most people will obtain information through a combination of their telephone and television.

Motivating people to seek information is also important. Information must be both available and understandable. A new health communications research component is being established in the Division of Cancer Control and Population Science under Dr. Barbara Rimer and will look at ways to tailor messages for individuals, as well as groups.

*Why do there appear to be inconsistencies in NCI documents related to guidelines on mammography?*

After the National Cancer Advisory Board adopted new guidelines, new materials had to be developed to help people understand and use the new guidelines. All NCI publications should now carry the new guidelines and should be providing a single, clear message.

*What is NCI's position on prostate cancer screening, specifically PSA?*

NCI has no stated policy on PSA screening and cannot have one at this time because sufficient data about its value are not available. NCI is conducting several studies designed to provide important data on PSA and to aid decision making in prostate cancer screening. Although NCI is doing studies of PSA, it is also looking for other, cancer-specific markers.

### **Objectives/Goals/Activities of the Meeting**

Mr. Kean, the meeting facilitator, provided an overview of the meeting agenda and urged all DCLG members to be candid and open in discussing issues and offering ideas. He noted that throughout the meeting he would keep track of topics raised by the DCLG which, while they might not be directly relevant to the major areas under discussion, are important to record and to keep in mind as the DCLG continues to plan and work. Topics that were identified during the meeting are presented below.

### **New Issues**

- Time required to complete clinical studies
- Barriers to scientists' collaboration

- Reimbursement for clinical trials
- Physician views of consumer/patient education and advocacy
- Alternative medicine

## **DCLG Requests**

- Tour of NCI research facilities
- Summary of International activities
- Recommendations of the Informed Consent Subgroup
- Glossary of NCI acronyms and initials frequently used
- Mechanisms/procedures for genetic testing
- Pending cancer-related legislation (national and state)
- NCI yearly milestones

## **Negative Terms Used in Documents About Cancer**

- Patients "failed" the trial (It is the trial that failed the patient.)
- "Salvage" therapy
- "Target" population
- "Victim"
- "Sufferer"
- "Terminal"
- "Patient" vs. "Survivor": what is the appropriate terminology?

## **First Issue: Informed Consent - Streamlining Informed Consent in Clinical Trials**

### **Presenter: Mary S. McCabe, R.N., Director, Office of Clinical Research Promotion**

The NCI, the Office of Protection from Research Risks (OPRR), and the Food and Drug Administration (FDA) organized a Comprehensive Working Group to address concerns that the informed consent documents in NCI clinical trials have become complex, lengthy, and difficult to understand, thereby hindering the informed consent process. The Comprehensive Working Group met in October, 1995, to identify and discuss key issues and to develop plans to make informed consent documents in NCI-sponsored trials more understandable, so that potential subjects can make informed decisions about whether to participate in clinical trials. The Comprehensive Working Group was comprised of NCI, OPRR and FDA staff and representatives of a variety of disciplines, including Institutional Review Board (IRB) members, legal experts, ethicists, clinical investigators, nurses, patient advocates, community physicians, communications experts, and members of the pharmaceutical industry.

At the first meeting, the Comprehensive Working Group chose to concentrate on informed consent in treatment trials involving individuals diagnosed with cancer, understanding that many of the issues also pertain to informed consent in cancer prevention and screening. After meeting for two years, the Working Group developed draft recommendations, an informed consent template, and four actual informed consent documents that have been revised using the template. These materials are currently being reviewed by focus groups composed of physicians, nurses, patients and IRB members. Because this is a highly important effort, the views of the DCLG are sought as well. Once recommendations from all these groups are reviewed, the drafts will be finalized for dissemination.

Following Ms. McCabe's presentation, DCLG members offered comments on the draft template and forms provided for their review in advance of the meeting. They applauded NCI's efforts to improve the form, but

also offered suggestions for further refinement. Key issues raised in this discussion included the following:

- The language of the form should be humane and sympathetic.
- The information contained in the consent form should be supplemented by additional written material, videos, as well as face-to-face counseling, if desired by the patient.
- Balance between risks and benefits is needed. The consent form should emphasize participation in a clinical trial as voluntary, and a positive opportunity to help and partner with researchers in finding better interventions.
- Patients should participate in drafting the language of the consent form. (Ms. McCabe pointed out that the IRBs determine what information is essential to include.)
- When translating the consent form into other languages, use culturally relevant language rather than direct translation.
- Patients would like to be able to talk with other patients in a trial they are considering.
- Some of the information in previous consent forms that has been deleted should be included, e.g., coherent definition of a clinical trial.
- A NCI clinical trials "hotline" to answer patients' questions about protocols should be established.
- The form should distinguish between risks unique to the trial and those that may occur with standard treatment.
- NCI should consider differences in informed consent for children and mentally impaired patients. (This is being done.)
- Training is important for those providing information on clinical trials to patients to be sensitive and responsive to patient concerns and desire for information.
- The consent form should assign numerical or other values to risks in order for physicians to counsel patients appropriately. (Ms. McCabe noted that this is being addressed. The Working Group is considering assigning relative values to different risks, which patients can then interpret in ways that are meaningful to them, as well as making it clear that there may be unknown risks.)

**Action Item:** *DCLG members will comment directly on the forms and fax them to OLA, who will forward them to Ms. McCabe. They should also make NCI aware of any special issues they want to pursue.*

**Action Item:** *Ms. McCabe will forward Working Group recommendations to the DCLG to review, since they cover some of the issues being raised, especially with respect to supplemental materials.*

**Action Item:** *Any DCLG members interested in working with NCI on the informed consent issue will let Ms. McCabe know before the conclusion of the meeting.*

## **First Issue: Informed Consent - Tissue Collection**

**Presenter: Sheila E. Taube, Ph.D., Associate Director, Cancer Diagnosis Program**

Major differences exist between the informed consent process related to clinical trials and that related to tissue collection. Patients participating in tissue collection agree to donate, prior to biopsy or surgery, a tissue specimen to be used for unspecified research in the future. There is no known benefit to the patient, but the donation is a contribution to the good in the future, and the request must therefore appeal to the patient's altruism.

Tissue specimens are used to explore basic mechanisms of cancer, look at etiologic factors, to develop new tests for diagnostics, and to predict the response to different treatments. The current project began in

recognition of the need for tissue specimens in breast cancer research, but now spans all cancer research. Tissue collection is driven by three premises:

- Human specimens are critical to progress in research and, ultimately, to the health of the population.
- The medical care of the patient donating a specimen must not be compromised as a result of the use of that patient's specimen in research. (The results of any research performed using the specimen will not be available for years, and therefore will not benefit the patient directly.)
- Personal identifying information about the individuals from whom the specimens are procured must remain private.

Based on these premises, a model system has been proposed to limit access to personal identifying information about the patients donating tissue. Certain information about the source of the specimen makes the tissue much more valuable as a research tool, but the identify of the donor is not known. In addition, there is a one-way flow of information to ensure that the results of the research do not go back into the patients' records. Thus, the "risk" to privacy associated with donating a specimen should be minimal, if any, when appropriate systems are followed.

The process of developing the informed consent form has been extensive, involving the participation of representatives from various groups, including advocates, ethicists, legal experts, and others. The original consent form was lengthy, and was written for people with moderate literacy. It was then tested with focus groups reflecting different ethnic origins, gender, socioeconomic backgrounds, and experience with cancer. A range of viewpoints was obtained, with some people wanting more information in some areas and less in others. From the focus groups emerged a recommendation for a Question & Answer sheet, to be distributed at some point in the informed consent process, that would supplement information in the form itself. Additional points made by Dr. Taube were:

- The form is designed for use in the routine care setting so that permission can be given before biopsy or surgery.
- Only tissue that is not needed for the donor's diagnosis or prognosis is available for research. Sufficient tissue (tumor blocks) will be retained for use in the patient's ongoing care.
- Having tissue specimens readily available speeds research with the potential for the public good and enables studies to be completed sooner.

The NCI is now collecting data to determine how acceptable the informed consent form and/or the process is to key groups. For example, the American College of Surgeons has suggested that a very stripped-down version of the present model form be added to the surgical consent form, so that there is only one form but a separate sign-off for tissue collection. The DCLG is being consulted for its perspective and to help NCI develop an acceptable, effective way to educate the consumer community about tissue collection and gain their support as willing partners in research.

Discussion between Dr. Taube and the DCLG touched on a number of issues:

- There are laws requiring the retention of tumor blocks, which cannot be depleted below a certain level.
- Storage space is becoming an issue, and some managed care organizations are pressing for changes in the law that would allow specimens to be discarded. Another competing interest is the fact that some physicians don't want to keep specimens any longer than required. A system that will ensure availability of specimens and allow tracking of the source in a way that protects the confidentiality of the source while expediting research is needed.
- In the past, tissue has been collected based on a statement in the surgical consent form that any leftover tissue could be used for research and education, but there was no separate agreement for

keeping tissue. This practice was viewed as coercive by many consumers, and a new form is being developed in response to this concern.

- Making the consent separate and explicit may have a negative effect on the tissue supply. The DCLG's assistance is needed to help promote understanding and avoid the development of such a situation.
- If a patient declines to be contacted in the future for information, their tissue may still be available for research purposes that don't require such contact.
- As with clinical trials, the request to keep tissue should be presented as an opportunity to participate in research. Suggested language is invited.
- A model for protection of tissue samples is to have a tissue bank trustee and require IRB review before granting requests for specimens. This approach is being carefully considered within the pathology community and by the IRBs. Concern was voiced by the DCLG about possible consequences of a change in trustee, particularly the threat to confidentiality.
- The issue of tissue ownership should be considered and efforts made to avoid possible abuse, since results of research are frequently patented.
- The timing of the consent is a critical issue. Consideration must be given to protecting donors from being alerted to a cancer diagnosis before becoming aware of it through their physician. The time of surgery is a sensitive one, but important logistical problems in tracking and associating tissue with the consent form are created if the consent is obtained after biopsy or surgery. For this reason a pre-surgical consent has been recommended. It was suggested that issues related to timing of consent be explored by DCLG. Consideration should be given to making the consent form generic, without reference to cancer.
- If a patient agrees to be contacted in the future, contact would be made through the tissue bank trustee.
- Structuring the consent form so that the patient must decide to "opt out" may help reduce the likelihood that patients will decline to donate a specimen.

## **Second Issue: Consumer Advocate Issues Involved in Population and Genetic Studies**

### **Presenter: Margaret A. Tucker, M.D., Chief, Genetic Epidemiology Branch**

Genetic and molecular epidemiology tries to disentangle patterns of disease in the population and explore how an individual's susceptibility and environmental exposures interact to produce cancer. NCI has formed a Molecular Epidemiology Coordinating Group of intramural basic science, clinical and epidemiologic researchers, which is focusing on an interdisciplinary approach to population studies. A major challenge to designing such studies is getting approval of the IRBs and adequate informed consent from patients.

The Coordinating Group is developing a document that will contain models for "best practices" associated with different kinds of studies. They would like input of the DCLG and the constituencies it represents on issues associated with population-based genetic research. NCI wants to ensure that privacy and individual autonomy are protected, while facilitating and supporting research. In the past, the government and the public have cooperated so that data on disease trends could be collected. Without the tracking systems that have collected these population-based data, continued accumulation of knowledge on issues related to cancer causation, as well as other important health problems, would not be possible.

A crisis in the conduct of population-based genetic research is developing as a result of a number of factors:

- New laboratory techniques that can detect genetic changes and provide information about individuals and populations.
- Heightened public concern about privacy.

- Insurance and employment issues related to genetics.
- Limitation in current ability to interpret the results of genetic testing.
- Increasing diversity of professional opinion regarding the importance of genetic testing.

The importance of any gene that is identified can only be verified with large-scale population studies. Some of the measures now being proposed to protect study subjects would limit the ability to conduct such studies. For example, one proposal would require separate consent forms for each gene to be tested in an individual tissue specimen. Most studies involve examination of multiple genes, and this approach would not only be bothersome to the individual, labor-intensive and generate massive amounts of paperwork, but would also substantially extend the time required to complete a study. It has also been suggested that participants should be notified of the results of all gene testing, which may not be useful for the individual and could create a major barrier to progress by slowing down cancer research.

Standards for what is adequate informed consent about genetic testing have shifted in recent years. A resulting difficulty is that opinions on informed consent vary widely. Stringent new legislative proposals would make maintenance of tumor registries impossible. There is a need to develop some consensus on what are reasonable basic standards for informed consent, and to balance the need to protect the rights of the individual with the ability to perform research that has important public health implications.

Notification of results of gene testing implies that the information is clinically useful to the individual in the early detection or prevention of the disease. Multiple studies are required to understand the role of any gene in disease causation, and many genes tested have little relationship to disease without the presence of other risk factors, e.g., exposure to cigarette smoke.

In terms of confidentiality issues, results of genetic testing don't vary substantially from other forms of sensitive information, e.g., illegal drug use, HIV status. Safeguards to protect the confidentiality of such information exist, such as encryption methods; the Privacy Act; and the Certificate of Confidentiality, which is designed to protect information from being subpoenaed. Monitoring existing safeguards may be better than imposing overly restrictive requirements that could limit public health research.

The current recommendation of the Coordinating Group to Dr. Klausner and Dr. Varmus (Director of NIH) is to convene a national meeting, similar to one held several years ago on policies related to studies using recombinant DNA, to develop guidelines on genetic testing. NCI needs the advice of the DCLG and its participation in the debate to represent the public in discussions of this critical issue. The questions for the DCLG are:

- What are the major issues from the consumer advocacy standpoint?
- How aware is the public about the consequences of privacy legislation?
- Can the DCLG survey constituencies to gather opinions on these issues?
- What is the DCLG's interest in working with NCI on this issue?

Key points made in discussion by DCLG members following Dr. Tucker's presentation:

- DCLG members need more information and education on all aspects of the issue, e.g., how population-based studies are designed and conducted, uses of research, how tests are done, possible ramifications, a primer on "Genetics 101."
- Members are concerned about the possible implications of genetic testing; confidentiality is an important concern. New approaches to confidentiality may need to be considered.
- Federal legislation is being drafted that would provide a floor, below which privacy standards could not go; however, the individual states have priority and many of the proposals are highly restrictive.
- NCI was asked to provide the DCLG with information on pending legislation related to cancer, both

federal and state.

- In genetic testing, counseling for patients is a priority.
- Public education is also important. The public needs to be better informed before reaching the point when they seek genetic testing.
- The media plays a large role in alerting the public without educating them. How can this problem be addressed?

NCI is aware of the complexities associated with genetic testing and population-based research, and fully intends to provide follow-up background information that will help prepare the DCLG to work with NCI to address these issues.

**Action**      *NCI will provide DCLG members with information on the range of issues related to*  
**Item:**        *population-based studies and genetic testing.*

### **Third Issue: Clinical Trials - Patient Access to Information**

**Presenters: Susan Malloy Hubbard, R.N., M.P.A., Director, International Cancer Information Center, NCI; Nancy Seybold, Web Editor, Office of Clinical Trials Promotion, NCI**

#### **PDQ Re-Design**

PDQ (Physician Data Query) is the NCI's database on up-to-date cancer treatment prevention, screening, supportive care, etc, and includes clinical trials database, and originated approximately 16 years ago with Dr. Vincent DeVita, then director of NCI, and was developed at the time personal computers were just becoming available. Ms. Hubbard, involved in the original development of PDQ, is leading efforts to re-design PDQ using new technology to enhance its usefulness.

Recent genetics-related information in PDQ that may be of interest to the DCLG includes the following:

- A new feature added to the PDQ/CancerNet system is a listing of certified genetic counselors.
- A new PDQ genetics board, chaired by Dr. Wylie Burke of the University of Washington, advises NCI, any recommendations by the DCLG will be forwarded to this board by OLA.
- A pamphlet on genetics designed for people with relatively low literacy levels is under development.

To help ensure that input is received from the pertinent communities before PDQ is re-built, a NCI Steering Group has been formed, led by Deborah Collyar, a breast cancer survivor who has an interest in clinical trials. This Steering Group has planned a meeting, to be held in February 1998, and Ms. Hubbard requested that the DCLG identify members to attend. Meeting participants will include extramural researchers, health care providers, advocates, representatives of the pharmaceutical industry and NCI staff. Participants will make recommendations about re-designing PDQ, including functions, content, interactive features, navigational aids, and identify barriers as well as strategies for maximizing accessibility. The DCLG members identified are Mr. Katz and Mr. Moore.

#### **Clinical Trials Web Site**

Ms. Seybold, has been charged with developing a NCI clinical trials Web site to help disseminate information on clinical trials through the Internet. The Internet offers some exciting possibilities for reaching the public in new ways.

Ms. Seybold demonstrated how a search of the Internet can produce information about cancer. She noted that the information is retrieved randomly, without regard to accuracy, quality or relevance. She then presented an early draft map of NCI's proposed Clinical Trials Web site. She wants to ensure that the kinds of information consumers are seeking is provided, and wants DCLG feedback on NCI's plans. This Web site will be integrated with the PDQ clinical trials database. It will provide focused information on topics like clinical trials and informed consent that will facilitate use of the information found in PDQ. Comments by DCLG members during the discussion that followed Ms. Seybold's presentation included the following:

- It would be valuable if people could sign up for areas of interest, to ensure that a notice is sent to the requestor whenever new clinical trials or other information relevant to their area of interest is added. Ms. Hubbard indicated that this is planned, using "push" technology to get people the information they need. She also noted that, as part of the re-design effort, she wanted those involved to be creative and not feel constrained by the current parameters of PDQ.
- PDQ includes privately-funded as well as NCI-sponsored trials. Approximately half of the 1,600 trials currently in the database are voluntary submissions from trials not supported directly by NCI. A system has now been developed to allow FDA review of pharmaceutical-sponsored clinical trials to serve as a surrogate for PDQ editorial review. Pharmaceutical companies can provide as little or as much information as they like. NCI is planning to promote this new system to the industry and hopes the DCLG and its sphere of influence will be an advocate to the drug industry to encourage their participation.
- NCI is pursuing possible collaboration with an existing listserve/message group system currently found on the Web to set up bulletin boards on special topics, rather than setting up a competitive system. The founder of the system is very cooperative and interested in ensuring the system is high quality.
- NCI is restricted in its data collection by regulations of the Office of Management and Budget, but is currently seeking approval to survey its customers in order to make the system more useful.
- As part of its attempt to be inclusive and complementary, NCI will link to other Web sites that meet standards of quality. These sites must submit an application attesting to quality and update procedures.
- The format and content of both professional and consumer-oriented clinical trial protocol summaries have been revised and they are being reviewed. Patients will also be able to access the complete PDQ database.
- NCI has an active collaboration with OncoLink and is ready to consider the forms of information it provides, as well as any others identified by those working with it to re-design PDQ.
- Ms. Seybold wants information on Web sites that DCLG members think she should be aware of, and feedback from those who are not Internet users.
- Ms. Hubbard's e-mail: sh68q@nih.gov; telephone: 301-496-9096. Ms. Seybold's e-mail: seyboldn@nih.gov; telephone: 301-594-0409.

### **General Discussion**

- Venus Ginés' has published a Spanish-language booklet and video on breast cancer, A New Hope.
- A suggestion was made that DCLG members share information about their projects at future meetings.

### **Thursday, December 18th**

#### **Developing Mechanisms to Identify Consumers to Serve on NCI Groups and Committees**

**Presenter: Marvin Kalt, Ph.D., Director, Division of Extramural Activities**

Dr. Kalt reviewed the various types of external advisory groups at NCI. They fall into three general categories:

1. Oversight and integration: These groups have fixed requirements for membership. They include the National Cancer Advisory Board (NCAB), the President's Cancer Panel (PCP), and the Advisory Committee to the Director of NCI (ACD). Membership on all these groups involves nominations from the community, and consumers have long been included.
2. Scientific/research think tanks: All of these groups have been formed since 1995 when Dr. Klausner became director. Each one has a finite life span and recommends directions for future research in specific areas or reviews NCI programs. Consumer representatives, frequently more than one, are included on these groups. The Director's Working Groups are organized around the extraordinary opportunities identified in the Bypass Budget.
3. Oversight groups, e.g., the Board of Scientific Advisors (BSA) for extramural research, and the Board of Scientific Counselors (BSC) for intramural research.

The scientific peer review groups represent another area where consumers can become more involved. Most incoming applications for proposed research funding are received by the NIH Center for Scientific Review and a number are reviewed there by standing committees. Other applications are referred to the appropriate Institute like NCI according to published guidelines. Applications responding to Requests for Applications (RFAs) are reviewed by the Institute using a Special Emphasis Panel with relevant expertise. Consumers serve on review committees for RFAs when consumer input is needed.

Appointment of consumers to the long-standing review groups is complicated by the need for reviewers with a breadth of knowledge across multiple disease sites. The DCLG can help NCI determine the degree to which consumers are comfortable participating when they may not have in-depth knowledge of the issues. NCI also welcomes input regarding orientation and training of consumers. Intrinsic to the development of any such training would be the participation of OLA and the DCLG. Other points made during Dr. Kalt's discussion with the DCLG included:

- In reviewing applications for grants consumers often have a perspective that scientists do not. Consumers can address issues that do not require a knowledge of the basic science, but they can bring a critical understanding of the patient's viewpoint. For example, practical considerations in conducting a study may never arise without the presence of a consumer to provide a reality check. Even the presence of a patient raises awareness of patient issues within a review group. The presence of consumers on the NCI review panels may also encourage researchers to include advocates in the development of a grant application.
- The DCLG can help in assessing whether clinical and population studies will be able to accrue participants.
- While a consumer may find serving on a review group a somewhat daunting experience, this is often the reaction of trained scientists as well. Someone entering the review process for the first time is not expected to understand everything. Moreover, the level of understanding of consumer participants very quickly rises in an impressive way. A member of the panel may also decide to abstain if he or she feels unprepared to make recommendations.
- Working with OLA every effort will be made to develop an orientation to educate consumer representatives, including assignment of "mentors."
- Names of those who applied to the DCLG will be provided to Dr. Kalt's office as an interim source of consumers while the DCLG develops mechanisms for identifying others.
- It would be helpful to have a checklist of criteria to use as a pre-screening tool in identifying

members of constituencies who might be appropriate for various assignments. Ms. Nealon noted that the criteria used for DCLG members could provide the starting point.

- An evaluation of the process of selecting DCLG members will be conducted early in 1998, and the findings can be incorporated into efforts to develop new mechanisms for consumer identification.
- The time commitments associated with service on NCI committees varies with the type of group. Service on ad hoc committees that meet only once usually involves 2-3 days. The time required for service on standing committees may be more substantial.

**Action Item:** *The DCLG requested information on the time commitments associated with various kinds of service.*

## **DCLG Operations and Processes**

The final portion of the meeting facilitated, by Mr. Kean, dealt with a range of topics associated with how the DCLG will function, including issues raised at the current meeting and plans for the next meeting.

### **Communication**

The results of the meeting should be communicated to the other DCLG candidates, who should also receive the names and contact information on DCLG members. Ways to disseminate information to other groups need to be developed. Setting up communication via the Internet was suggested.

The suggestion was made that reports from the DCLG be included in the Journal of the National Cancer Institute (JNCI) e.g., a regular column. Ms. Nealon noted that the Journal is now published by Oxford University Press, but that a proposal can certainly be made to the editor. The major issue, from the DCLG's point of view, is that some mechanism exist for communicating with the community at large. A Web site might help serve this purpose.

The DCLG is interested in NCI's networking contacts, e.g., regulatory agencies, cancer organizations. Can a Web site be developed that would be an NCI contact base for consumer advocates? The DCLG appointed a subcommittee to address these and other communications issues. The members are:

- Mr. Katz
- Ms. Love
- Ms. Stewart
- Ms. Dewey
- Mr. Zebrack

**Action Item:** *NCI staff will provide the DCLG with a calendar of scheduled NCI meetings. (Ms. Nealon noted that the NCAB and PCP meetings are possibilities.)*

**Action Item:** *The DCLG wants to be placed on the mailing list for the JNCI.*

**Action Item:** *The DCLG wants to create an internal newsletter.*

**Action Item:** *OLA staff will explore the possibility of a DCLG Web site.*

## *SubCommittees*

In addition to the Communications subgroup, the DCLG formed two subcommittees to address specific issues discussed during this initial meeting. The subcommittees and their members are listed below.

- Informed Consent subcommittee:
  - Dr. Hodge
  - Ms. Stewart
  - Ms. Lin
  - Ms. Butler
  - Ms. Rogers
  - Dr. Castillo
  - Ms. Ginés
- Genetics & Tissue subcommittee:
  - Mr. Katz
  - Ms. Bowen
  - Ms. McCarthy
  - Ms. Lin
  - Ms. Love
  - Dr. Castillo

Dr. Hodge was named the Group's historian.

**Action Item:** *Ms. Nealon will assign someone from OLA to work with each subcommittee.*

**Action Item:** *OLA will set up conference calls with each of the subcommittees to identify and address their needs.*

## **Meetings**

Twice-yearly meetings will not be sufficient if the DCLG is to have much impact. More frequent meetings will be required, particularly in the first year or two. OLA will send the DCLG calendars to identify dates for future meetings. The next meeting will take place in the Spring.

The DCLG identified the following issues as being important to consider for future meetings:

- Education (for the underserved, low literate, other cultures)
- Money & resources for research (increased funding biomedical and behavioral research)
- Access to quality care
- Survivorship (from diagnosis)
- Long-term survivorship (Ms. Nealon noted that the Office of Cancer Survivorship is located in the new division headed by Dr. Rimer.)
- Psycho-social intervention
- Access to information
- Supplemental (complementary) medicine
- Spirituality

The DCLG decided not to prioritize its issues list at this time.

Agenda items identified for the next meeting include:

- Reports from subcommittees on activities between meetings.
- Discuss what's going on in the (advocacy) field.
- Report on PDQ re-design.
- Sharing time to learn about the personal experiences of five DCLG members.
- Presentations from NCI leadership on education and communications.
- In-depth presentations by staff from different NCI programs. Ms. Nealon asked the DCLG members to read the Bypass Budget and identify subjects on which they would like to hear/learn more about.
- Clarification of what Dr. Klausner wants them to do. (How would he measure the success of the DCLG in a year?)
- Continued discussion of genetic population studies.
- Group photo.
- Optional tour of NCI facilities.

**Action Item:** *Researchers who presented at this meeting will be asked to clarify what is being asked of the DCLG in each of the areas to be addressed by the subcommittees.*

**Action Item:** *A conference call will be scheduled with the co-chairs for the Spring meeting.*

## **Operational Procedures**

Mr. Kean noted that any decisions made at this meeting can be modified in the future. The DCLG decided on rotating leadership, with three members being selected to serve as co-chairs and plan the next meeting with NCI: Mr. Moore, Ms. Leigh, and Ms. Ginés. An honorarium of \$150/day will be awarded to the DCLG members for the next meeting.

DCLG members agreed to staggered terms of no more than 3 years, after the initial 2 years of DCLG operation. If there are no volunteers to rotate off, selection can be made by "drawing straws." Group members expressed the hope of remaining involved with NCI following the conclusion of their terms as DCLG members.

## **Closing Comments**

Ms. Nealon introduced Dr. Marianne Alciati, who will be conducting an evaluation of the nomination process for the initial DCLG. Dr. Alciati will be contacting each DCLG member by phone to discuss their experience as a candidate for the DCLG, and also get their assessment of the first meeting.

Ms. Nealon noted that the OLA will set up conference calls and help take notes, prepare summaries, and otherwise provide staff support to the DCLG. She then briefly discussed future communication systems:

- Documents requested by the DCLG from NCI will be sent electronically whenever possible.
- NCI cannot reimburse DCLG members for phone calls placed, but OLA will return phone calls initiated by DCLG members.
- DCLG members should send e-mail to the Liaison Office to ensure that the message is read right away.

**Action Item:** *A conference call with the DCLG will be scheduled following the evaluation to be conducted by Dr. Alciati.*

**Action Item:** *The DCLG will be added to OLA's general mailing list, and they will receive the JNCI and the NCI Information Associate's package as well as a variety of other timely materials.*

**Action Item:** *OLA will provide sets of DCLG mailing labels to the DCLG members.*

The meeting adjourned at approximately noon on December 18, 1997.

Prepared by:

Eleanor Nealon  
Executive Secretary, DCLG  
Date: April 7, 1998