Division of Extramural Activities

Director's Consumer Liaison Group

Regular Meeting Minutes
Octoher 26-27, 1998

The 1st meeting of the National Cancer Institute (NCI) Director's Consumer Liaison Group (DCLG), as a chartered committee, convened at 9:00 a.m. on Monday, October 26, 1998 at the Doubletree Hotel, Rockville, Maryland.

DCLG MEMBERS

Paula E. Bowen
Susan Lowell Butler
Manuel H. Castillo
Kerry J. Dewey
M. Venus Ginés
Felicia Schanche Hodge
Michael Katz
Susan A. Leigh
Ruth Chiang Lin
Gena H. Love
Daniel M. Moore
Lillouise Rogers
Susan K. Stewart
Brad Zebrack

ABSENT

Susan McCarthy

NCI OFFICE OF LIAISON ACTIVITIES STAFF

Eleanor Nealon (Executive Secretary, DCLG)
Elaine Lee (acting in absence of Ms. Nealon)
Kristie Dionne
Tracy Kilmer
Maria Stamos

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OPENING REMARKS

The meeting was jointly chaired by Kerry Dewey, Gena Love, and Lillouise Rogers. Ms. Rogers called the meeting to order, welcomed everyone present, and invited all DCLG

members to introduce themselves.

Ms. Rogers announced that Eleanor Nealon, Director, NCI Office of Liaison Activities, and DCLG member Dr. Felicia Schanche Hodge had both recently received the Ribbon of Hope "Everyday Hero" Award from the National Coalition for Cancer Survivorship (NCCS). Ms. Nealon had also received the Cancer Research Foundation of Americas' "Front Line" Award for her work on raising awareness of breast cancer. Ms. Rogers commended both Ms. Nealon and Dr. Hodge on receiving these awards.

Ms. Nealon welcomed observers and those who wish to make comments on the meeting proceedings should submit them in writing to the Office of Liaison Activities (OLA) staff.

REPORT OF THE NCI DIRECTOR

Chartering of the DCLG

Dr. Klausner said that he had signed the necessary documents to charter the DCLG as an advisory committee in accordance with the provisions of the Federal Advisory Committee Act. The reasons for chartering are to emphasize the group's permanence and independence and to formalize its ability to give advice and make recommendations directly to NCI and the Department of Health and Human Services unfiltered through any other body. As members of a chartered advisory committee, DCLG members shall be considered Special Government Employees for the duration of their service on the committee. Dr. Klausner noted that the DCLG is in the vanguard of a new effort to increase interaction between the consumer advocate community and the National Institutes of Health (NIH).

Dr. Klausner cited two particular areas in which NCI would welcome advice from the DCLG: improving the effectiveness of communication between the scientific community and the public about the national cancer research effort and providing feedback about the effectiveness of initiatives such as the redesign of the clinical trials program and the Physican Data Query (PDQ) system.

Bypass Budget

Dr. Klausner noted that NCI had received an unprecedented 15.1% increase in its budget for Fiscal Year (FY) 1999. He then presented an overview of NCI's Bypass Budget for FY 2000, which was sent to the White House on October 23. He began by describing the progress made in the Extraordinary Opportunities initiated the 1996/97 Bypass Budget.

- **Cancer Genetics.** Cancer is the uncontrolled growth of a single cell whose genetic instructions (found in its DNA) have been altered. A succession of changes are necessary to transform a normal cell to a cancerous cell; the number of changes required is unknown, although it is believed to be not more than ten. NCI's goal is to identify and understand all of these changes and to use that understanding to develop more effective strategies for cancer prevention and early detection, as well as more accurate diagnostic procedures and therapies that can be directly targeted against cancerous cells.
- **Defining the Signatures of Cancer Cells: Detection and Diagnosis.** A key initiative in this effort is the Cancer Genome Anatomy Project, one of the goals of which is to create an index of all tumor genes. In tandem with this effort is the Director's

Challenge, which challenges NCI-supported scientists to develop within 5 years ways of using this wealth of genetic information to diagnose cancer by its molecular fingerprint.

- **Pre Clinical Models of Cancer.** Scientists are harnessing one of the most remarkable scientific discoveries of the past 20 years-the fact that human genes are almost identical to those of all other living creatures-to identify cancer genes. By altering genes in laboratory mice so that the mice develop cancer, it is possible for researchers to view the entire process of tumor development. A national consortium is being established to develop mouse models of human cancers and to test prevention and treatment interventions.
- **Imaging Technologies.** The goal is to develop imaging technologies with sufficient accuracy and precision to detect very small numbers of tumor cells, "functional imaging" techniques that enable oncologists to see the effect that a drug is having on tumor cells, and new approaches to image-guided therapy.

Other initiatives in response to the Extraordinary Opportunities include:

- A national Early Detection Research Network that will provide the necessary infrastructure to permit promising new molecular markers to be rapidly evaluated and developed into tests for the early detection of cancer.
- An Unconventional Innovation Program that will support a collaborative approach to developing unconventional, innovative strategies and technologies for detecting and treating cancer.
- Two new programs (Chemistry-Biology Centers and the Rapid Access to Intervention Development) that will support the rapid and efficient translation of new basic discoveries into the development and testing of new drugs.
- Expansion of NCI's clinical trials program in tandem with implementation of new procedures to increase the efficiency of clinical trials, broaden patients' access to trials, and increase recruitment of both patients and physicians to clinical trials.
- Development of a modernized clinical trials information system to lower the barriers for patients, families, and physicians who wish to learn about available clinical trials and to facilitate the exchange of information among researchers, physicians, and the public.
- New training and career development programs to nurture the cancer researchers of the future, including a new award to protect clinical investigators' time for conducting clinical research and mentoring young scientists and a novel program to attract minority and underserved young people to careers in cancer research beginning in high school.
- Further improvement of NCI's cancer surveillance activities, including enhancement of data collection and database linkages as well as expansion of the Surveillance, Epidemiology, and End Results (SEER) program.

Criteria for Consumer Advocate Participation in Peer Review Dr. Klausner said that NCI has accepted the five criteria for consumer advocate participation in peer review that the DCLG proposed and has added a sixth criterion: Membership and active participation in a cancer-related advocacy organization. Although advocates do not officially represent the organizations to which they belong, it is important that they are connected to a community with whom they communicate about their experiences as reviewers.

Discussion

Clinical Trials. Ms. Stewart asked how patients would benefit from the expansion of the clinical trials program. Dr. Klausner said that NCI is investing in enhanced information systems to create a clinical trials network in which all patients have access to any trial that may benefit them, eliminating the restrictions that currently limit patients to certain trials. NCI is also exploring ways of eliminating the "hassle factors" that deter many physicians from participating in clinical trials. Ms. Leigh said that new CT programs should simplify the process for physicians. Involve physicians so we all "speak the same language to make it easier to have more comprehensive information about CTs".

Dr. Hodge commented that it is difficult for patients and physicians who do not have access to the Internet and other technologies to obtain information about and access to the most advanced cancer treatment. Dr. Klausner said that as technology advances and becomes less costly, many more people will gain access to the Internet. Investment in an enhanced clinical trials information system now will make it possible in the future for the Indian Health Service and other systems serving underserved populations to obtain information about and participate in clinical trials. In the meantime, NCI will need to improve the way it disseminates information through existing channels.

Dr. Castillo observed that negative attitudes toward clinical trials among physicians can be a barrier to patient participation. Dr. Klausner agreed that there is a need for widespread education to correct misinformation about clinical trials. He noted that he and Dr. Robert Wittes had written a response to a recent article in Newsweek that referred to participants in clinical trials as "guinea pigs."

Scientific Manpower. Ms. Butler asked whether there are enough scientists in the "pipeline" to translate all of the new scientific knowledge into clinical advances. Dr. Klausner said that he believes there are, based on increases in the numbers of applicants for research training programs and research grants. Because of economic pressures that stem from changes in the organization and financing of health care, greater incentives are needed to recruit and retain clinical investigators.

Patient Information. Mr. Katz asked whether there is a role for NCI in requiring full disclosure of information to patients who are considering entering a clinical trial-for example, ensuring patients are informed that taking a certain drug in one trial may preclude them from participating in other trials in the future. Dr. Klausner said that this falls into the realm of establishing standards of care, which he strongly believes is a role for professional organizations. NCI's role is to be an impartial scientific body, providing the information that enables professional organizations to set standards of policy and practice through the exercise of informed judgment.

Noting that scientists' understanding of how people absorb and act on health information is still very limited, Dr. Klausner said that the DCLG could be helpful in offering advice about the type of patient information that NCI should be producing and about the most effective ways of disseminating that information to patients and the public.

Mr. Moore commented that public libraries are an important source of information for many people and that more libraries should be encouraged to offer health information. Dr. Klausner

responded that NCI is involved in a demonstration project called SAILOR to link public libraries in Maryland with NCI patient information. If successful, the project could be expanded to include libraries around the country. In response to a suggestion by Ms. Leigh, Dr. Klausner said that NCI should explore disseminating health information videos through video stores. Ms. Ginés suggested using minority organizations. Ms. Lin mentioned they have interactive computers in the clinics in her Morristown Hospital.

Insurance Coverage of Treatment in Clinical Trials. Dr. Castillo asked what is being done to reduce the economic burden to patients of participation in clinical trials. Dr. Klausner replied that progress on this issue requires more information about the added costs, if any, of clinical trials participation and better criteria for identifying well-designed clinical trials.

Ms. Mary McCabe, Director, NCI Office of Clinical Research Promotion, said that three NCI-funded studies of the costs of patient care in clinical trials (conducted at the Mayo Clinic and in the Kaiser Permanente and Group Health of Puget Sound health systems) have been completed and results are expected to be published within the next few months. In addition, NCI is funding a large study by the Rand Corporation of the costs of patient care in clinical trials.

In response to a follow-up question by Dr. Castillo, Dr. Klausner said that NCI cannot become involved in paying for care for underserved populations but can add its voice to calls for action to resolve the serious problem of lack of access to medical care by poor and underserved individuals.

Process of Developing New NCI Programs. Ms. Dewey expressed concern that in many parts of the country the expansion of NCI programs that Dr. Klausner had described might be perceived as an expansion of federal bureaucracy. Dr. Klausner replied that new programs arose from an extensive consultation process in which NCI invited its constituencies to identify their needs. New programs are designed with the intent of minimizing bureaucracy and maximizing grantees' ability to attain their objectives.

UPDATE ON CLINICAL TRIALS FORUM ISSUES

Ms. Nealon thanked the DCLG members who worked on the clinical trials forum (Ms. Butler, Mr. Katz, Mr. Moore, and Ms. Stewart). She said their efforts helped to refine the issues and reach a decision about how to approach this complex topic.

Ms. McCabe said that the forum had been postponed because of the difficulty in combining discussion of three very different issues (informed consent, regional and national institutional review boards, and confidentiality of patient records) into a single event. Instead, two of these issues- confidentiality of patient records and informed consent-were being addressed at this meeting.

Confidentiality of Patient Information in Research

Dr. Lana Skirboll, Director, NIH Office of Science Policy, outlined current proposals by the Secretary of Health and Human Services (HHS) and NIH to protect the confidentiality of patient information in medical and research records. She explained that medical records contain information relating to a patient's treatment, including treatment in a clinical trial. Research records contain information that is not directly relevant to the delivery of health care,

such as early gene sequence analysis data. Although most researchers separate medical and research records, not all researchers do.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 set a deadline of August 1999 for Congress to pass legislation to protect the privacy of individually identifiable health information that is held by health-care providers or payers in both the public and private sectors. If Congress fails to meet this deadline, HIPAA directs the HHS Secretary to issue final enforceable regulations by February 2000.

The Secretary's recommendations, submitted in September 1997, limit the use and disclosure of individually identifiable health information in medical records and permit civil and criminal penalties for violators. The Secretary's recommendations covered research information that was related to patient care and researchers' access to medical records. The Secretary's proposal did not address research information unrelated to patient care. NIH is developing its own recommendations regarding confidentiality of research records that do not pertain to a patient's care. Under the HHS Secretary's recommendations, the following people or agencies could access individually identifiable information in medical records without patient authorization:

- health-care providers and payers.
- health oversight officials.
- public health officials.
- emergency care providers.
- law enforcement officials.
- researchers.
- relatives (when appropriate).

A researcher could release individually identifiable information to another researcher (e.g., for inclusion in a database) without patient authorization provided that:

- the study undergoes IRB review.
- informed consent is either obtained or waived, as required by the Federal Policy for the protection of human subjects; and
- identifiers are removed at the earliest opportunity, unless an IRB allows for this retention.

The need to obtain informed consent may be waived if the IRB agrees that:

- the proposed research presents no more than a minimal risk.
- the waiver does not adversely affect the rights or welfare of the subjects.
- the research could not practicably be carried out without the waiver.
- whenever possible, subjects will be provided with additional pertinent information.
- the importance of the research outweighs the privacy intrusion.

Under the HHS Secretary's proposal, patients have the right to access information about themselves that is in their medical records with the following exceptions:

- while a trial is in progress and the patient agreed to this withholding of information during the informed consent process and the information is made available.
- when the information could identify another individual who participated in a study under a promise of confidentiality.

- when access to the information is reasonably likely to endanger the life or physical safety of the patient or anyone else.

Dr. Skirboll said that NIH believes research records should be held at a higher level of confidentiality than medical records. Probably the most challenging issue surrounding research records is whether and under what circumstances patients can be denied information about themselves. NIH is considering adding a fourth exception to those listed above: patients may be denied research information about themselves when the information's clinical validity or relevance to patient care is not known. The justification for this restriction would need to be presented to and approved by an IRB. Patients would be notified of the restriction during the informed consent process and could decline to participate in the study.

Update on Legislation Concerning Confidentiality of Patient Information

Ms. Jane Daye, Legislative Analyst, NCI Office of Legislation and Congressional Activities, distributed a handout summarizing legislation introduced in the 105th Congress relating to confidentiality of medical records and genetic privacy and discrimination.

The bills, none of which was passed, dealt in varying ways with issues such as the removal of identifiers from medical records and confidentiality of medical records when an individual changes health plans, seeks insurance coverage, or seeks employment. All of the bills allowed access to health information by law enforcement agencies without the consent of the individual. None of the bills explicitly addressed the confidentiality of research records, although some were written so broadly that they would pertain to research information that was unrelated to patient care.

It has become clear, Ms. Daye said, that this is an extremely complex issue in which it is difficult to balance competing interests. A more wide-ranging public debate, including participation by the research and patient advocacy communities, is needed before legislation is passed.

Consumer Perspective on Confidentiality Issues

Mr. Katz said that confidentiality of health information is a complex issue because it involves many people with a variety of perspectives and varying interpretations of the facts. Even within the patient community, opinions vary widely about the importance of confidentiality of information about participants in clinical trials.

On one hand, individuals want their personal information kept confidential to protect their careers, maintain their ability to get insurance, and maintain their privacy. On the other hand, confidentiality procedures are costly. Lack of full disclosure could mean that at some point a health professional lacks information about a patient that is relevant to treatment. The creativity of researchers may be restricted if many hurdles are placed in the way of obtaining information. Free information flow is in the interests of science.

Certificates of Confidentiality

Dr. Susan Sieber, NCI Associate Director for Special Projects, said that NCI has developed policies and procedures by which extramural and intramural investigators can apply for certificates of confidentiality, which protect researchers from the involuntary disclosure of

research information. Certificates of confidentiality were introduced in the 1970s as a means of protecting confidentiality in research related to substance abuse. Over time, their use broadened to include most types of medical research. Authority to issue certificates of confidentiality was recently delegated from the HHS Secretary to those NIH Institutes that wished to assume it.

To date, NCI has received about 30 applications for certificates of confidentiality and has approved about 25. A draft manual of policies and procedures relating to certificates of confidentiality is in preparation and will be posted on NCI's website and distributed to the DCLG members.

Discussion

In regard to the NIH proposal that research information may be withheld from patients if its clinical validity or relevance is not known, Ms. Butler said that she felt it was unacceptable for researchers to decide what patients should and should not know. Mr. Katz said that he was more uncomfortable with the notion of an IRB making such a decision.

Dr. Skirboll emphasized that although this proposal is under discussion, no decision has been made. She noted that there may be circumstances in which having information, the relevance of which is unknown, is burdensome to the patient. Once an individual has the information, he or she may be required to reveal it to an employer, an insurer, or another third party who may misinterpret or misuse the information. Ms. Stewart said that patients should have the right to decide whether they want such information, having been informed of the potential burden it may present.

Ms. Ginés asked whether immigration officials would have access to personal health information without authorization. Dr. Skirboll said that this is an issue that needs to be explored. She noted that the most vocal participants to date in the debate about medical records confidentiality have been managed care and pharmaceutical companies and that patient organizations have not yet become actively involved. NIH has proposed that research records should not be disclosed for any purpose relating to law enforcement.

The NIH proposals also emphasize that researchers should retain individual identifiers in research records only when absolutely necessary (such as when individuals are being followed up in a longitudinal study). Other proposals are that researchers be required to separate research records from medical records and that information from a research record be revealed to a patient only if he or she (or a duly authorized agent) requests it.

Dr. Skirboll noted that any requirements for confidentiality of research information will need to take account of the fact that in the future individuals may be identifiable by their genetic characteristics. This will necessitate data encryption that ensures researchers analyzing patient data are blinded to individual identifiers.

Dr. Hodge commented that genetic research is a sensitive issue for American Indians. Dr. Skirboll responded that genetic discrimination legislation has stalled in Congress because the insurance industry, although willing to concede that individuals' genetic information could not be used to deny coverage, wanted to retain the right to use family history as a criterion for denying coverage. As knowledge accumulates about the genetic basis of many disorders, however, an individual's genetic information will be apparent in their family history, making

the distinction meaningless.

Ms. McCabe distributed to DCLG members a draft version of "Confidentiality, Data Security, and Cancer Research" by Dr. Wittes. This paper intended to explain a number of complex issues involved in confidentiality of research information, such as the problems in maintaining confidentiality and the researchers' need to have access to certain identifiable information. She asked that DCLG members comment on the tone and content of the paper and offer suggestions for how it should be disseminated.

Informed Consent Project

Ms. McCabe summarized the work of the Comprehensive Working Group on Informed Consent in Cancer Clinical Trials, which culminated in the publication of the recommendations and templates that DCLG members had already received. Membership of the working group included consumer advocates, health professionals, and experts in law, ethics, and communications. The group's charge was to address the problem that informed consent documents have become too long and complex and do not provide a sound basis for informed decision-making. Ms. McCabe noted that the group did not address issues relating to genetics and tissue-banking, both of which are being considered by other NCI working groups.

Comments made by DCLG members on the draft informed consent document, as well as comments gathered in a series of focus groups, had been incorporated into the final document. NCI is now beginning to disseminate the document to IRBs, cancer centers, and individual investigators around the country. The document is also available on the World Wide Web (http://cancertrials.nci.nih.gov). Ms. McCabe said that she would welcome comments from the DCLG on how cancer advocacy organizations might contribute to dissemination of the informed consent document.

Discussion.

Ms. Butler asked why the language on confidentiality was unchanged from the draft version of the document. Ms. McCabe replied that the Comprehensive Working Group felt it was necessary to be honest that absolute confidentiality of personal information could not be guaranteed, but was also obliged to be somewhat vague because public policy relating to confidentiality of medical and research records is still evolving. She noted that the template is intended to be a generic document. Many details will depend on the circumstances of a specific trial and can be spelled out more precisely in the informed consent document for that trial.

Ms. Stewart suggested that it might be helpful to include some background information for patients on why the experimental treatment being studied is considered promising. Ms. McCabe responded that there is always tension between keeping a document simple and providing complete information; some individuals will want more information than others. Ms. Leigh said that there might be a need for informed consent documents at different reading levels. She also commented on the need for health professionals who talk to patients about participation in clinical trials to have good communication skills.

Ms. McCabe said that she is setting up an evaluation of the impact of the informed consent recommendations on IRBs, investigators, patients, and other affected groups. In addition, NCI

is soliciting research projects on innovative approaches to informed consent.

Ms. Bowen asked at what point in the informed consent process patients should be told that participation in a particular study may preclude them from taking part in other trials in the future. Ms. McCabe said that it is difficult to offer generic advice about this because it depends on the characteristics of specific trials. Ms. Nealon said that patient information materials about clinical trials might suggest that patients ask what effect their participation in a study could have on their ability to take part in other trials.

Mr. Katz asked whether it was intended that research centers revise the informed consent documents for ongoing clinical trials in accordance with NCI's recommendations. Ms. McCabe said that because informed consent documents must be approved by IRBs, it is more practical to introduce the changes for new trials rather than retroactively change informed consent documents for ongoing studies. She acknowledged that this means it could take a long time for the recommendations to have a widespread impact. The advocacy organizations that DCLG represent can contribute to an education process that needs to occur to persuade researchers and IRBs of the need to adopt the proposed changes.

Members discussed how they and the consumer advocacy community in general could play a role in disseminating NCI's recommendations for changes in the informed consent process. It was agreed educating of investigators and institutions about the need for change is paramount. Advocacy organizations that have scientific or medical advisors can bring the NCI recommendations to the attention of those advisers and encourage them to implement the changes as well as to influence their colleagues to do the same.

CONSUMER ADVOCATE PARTICIPATION IN PEER REVIEW

Dr. Marvin Kalt, Director, NCI Division of Extramural Activities (DEA), said that consumer advocate representation now occurs in nearly every facet of planning, evaluation, and oversight of NCI programs. Most chartered committees now have a consumer representative. For several years DEA has involved consumer representatives in the review of Requests for Applications (RFAs) and Requests for Proposals (RFPs), and recently began to have consumers on panels reviewing NCI's cancer centers and clinical cooperative groups.

Within the past two years, 55 consumer advocates have served as reviewers; some individuals have served on multiple review panels. Consumers have participated in the review of 12 RFAs. Eleven consumers were involved in the review of the cancer survivorship RFA in March, 1998. To date about 130 people have been identified who meet the criteria for serving as consumer representatives in peer review. Although this group includes survivors of various types of cancer, it is currently weighted toward survivors of breast and prostate cancer. NCI will be issuing a solicitation for additional consumer reviewers in early 1999. Dr. Kalt said that for some, but by no means all, types of reviews, tumor site is a relevant issue to consider in the selection of consumer representatives.

Orientation is critical to the successful use of consumers in peer review. Whenever possible, NCI tries to pair a novice consumer reviewer with one who is experienced. NCI intends to develop a video and written guidelines to orient new reviewers about the process. Dr. Kalt invited DCLG members to participate in the development and scripting of the video. In addition, training materials are being developed for DEA staff on the information that needs to be conveyed to consumer advocates when they are first approached about participation in a

review.

Dr. Kalt noted that NCI's policy (and the policy of NIH as a whole) is to reimburse all reviewers only for attending meetings and not for time spent reading applications and writing reviews. To reduce the financial burden of participation in reviews, consumer representatives may be advanced funds to cover their travel costs.

The most important benefit of consumer participation in peer review, said Dr. Kalt, is that many more applications and proposals will be designed with consumer issues in mind. Every NCI competition announcement now notes that consumer advocates will be involved in the review process.

Discussion

Ms. Butler suggested that the orientation video for consumer reviewers should be narrated by a consumer advocate. Mr. Katz said that mentoring of new consumer reviewers by more experienced ones could be a good way of helping newcomers to the process learn what to expect. Mr. Moore suggested that scientists on review panels should receive orientation on the role of consumer reviewers. DCLG members recounted some of their personal experiences as reviewers.

Mr. Katz said that he would like to have a fuller discussion about the scope of consumer involvement in peer review and the most appropriate use of consumer reviewers. It was agreed to consider organizing a panel presentation on the peer review process as an agenda item at the next DCLG meeting.

REPORT ON DCLG MEMBERS' RECENT ACTIVITIES

A document was distributed that summarized DCLG members' participation as individuals in a variety of advocacy activities. Members reported the following activities in addition to those listed:

- Ms. Rogers commented on the draft Bypass Budget, publicized the NCI's efforts to expand minority participation in clinical trials at a Y-ME meeting and in a Y-ME newsletter, reviewed NCI's draft of the Bypass Budget, completed the National Breast Cancer Coalition's Project LEAD, and was featured in a local newspaper article about the tamoxifen prevention trial.
- Mr. Moore organized a town meeting in Decatur, Illinois to coincide with The MARCH in Washington. The comments of cancer survivors attending the meeting were videotaped and sent to the local Congressional representative and to Illinois' two senators.
- Dr. Castillo organized a weekend "camp" for adult cancer survivors that took place in September; talked to local journalists in Dayton, Ohio, about cancer services for minorities; and in November will take part in a forum about African American participation in cancer clinical trials.

Several members reported that they mention their membership in the DCLG wherever they go and that their audiences are generally pleased to learn that NCI has formed a committee to serve as the voice of the consumer advocacy community. Members also said that the information they receive from OLA about NCI programs is very useful to their communities.

Ms. Butler requested that materials be copied on one side of the paper only so that they can be readily transmitted by fax.

Ms. Leigh reported on The MARCH in Washington, DC, in September, which attracted about 150,000 people and drew considerable media attention. She said that the National Coalition for Cancer Survivorship is discussing building on the momentum created by The MARCH. They plan to create an action network involving all cancer advocacy organizations, partnering with the National Breast Cancer Coalition to offer training in advocacy skills, and organizing annual candlelight vigils in communities across the country to remember those who have died of cancer and celebrate those who have survived.

Ms. Bowen reported on the May 1998 meeting of the National Cancer Advisory Board. This meeting included a report from the President's Cancer Panel, a presentation of the reports of NCI progress review groups on breast and prostate cancer, and discussion of the Office of Inspector General's report on the Cancer Information Service and NCI's response.

FOCUS ON NCI'S ACTIVITIES FOR SPECIAL POPULATIONS

Office of Special Populations Research

Dr. Otis W. Brawley, Assistant Director, NIH Office of Special Populations Research (OSPR), said that his office was established about 18 months ago with the following mandate:

- to establish NCI's research agenda for special populations (which include minorities, the poor and underserved, and the elderly).
- to serve as a central contact point for other divisions of NCI, other government agencies, Congress, and outside organizations that are seeking information about cancer research in special populations.

OSPR is responsible for tracking the accrual of minorities and women to NCI-sponsored clinical trials and for overseeing NCI's guidelines on the inclusion of minorities and women in clinical trials. Under contract with NCI, the November 1999 issue of *Annals of Epidemiology* will spotlight these activities. OSPR staff authored or co-authored six of 12 research articles in the November 1998 issue of *Clinical Trials in Urology*, which focuses on prostate cancer in black men.

In 1997 OSPR assumed responsibility for NCI's Leadership Initiatives on Cancer grants (the National Hispanic Leadership Initiative, the National Black Leadership Initiative, and the Appalachian Leadership Initiative). Next year a new Request for Applications will be issued for a combined Leadership Initiative on Cancer in Special Populations, the aims of which will be to disseminate information and build research infrastructure to encourage more research on cancer in minority and other disadvantaged communities.

Dr. Brawley represents the NCI Director on the President's Cancer Panel, which is exploring the role of race and ethnicity (which are sociopolitical, not biological, categories) in health and disease. He presented some NCI estimates of cancer deaths by race and ethnicity in 1990, which are based on data from the 1990 U.S. Census. In addition, he presented data on the effects of race and ethnicity on cancer obtained from the Minority Community-Based Oncology Programs (in which a requirement is that at least half of the patients recruited must

be minorities). These data show:

- Blacks and Hispanics are more likely than whites to have other illnesses at the time they are diagnosed with cancer.
- In general, the number of blacks and Hispanics in NCI clinical trials is greater than the proportion of these minorities in the U.S. population as a whole.

Dr. Brawley described the NCI's Surveillance, Epidemiology, and End Results (SEER) program, which collects detailed information on all patients diagnosed with cancer in defined geographic areas (including states, cities, and tribal areas) around the country. These data are reported as rates of cancer occurrence and death per 100,000 people. A series of studies conducted by OSPR using SEER data have shown that when treatment is equal, race does not affect outcome. However, socioeconomic status and the presence of other diseases do affect outcome.

SEER data also show significant regional and racial differences in the treatment received by people with cancer. For example, among men with localized prostate cancer, 50 percent of blacks but only 10 percent of whites receive no treatment. In 1988, about 75 percent of both black and white women treated with lumpectomy for stage T1 breast cancer received radiation therapy. In 1994, the proportion of black women receiving radiation therapy dropped to 66 percent while that of white women remained at about 75 percent. Among women diagnosed with T1 or T2 breast cancer, more than 5 percent of black women but fewer than 3 percent of white women did not receive a lumpectomy or a mastectomy within 4 months of diagnosis.

Discussion.

Ms. Leigh asked whether the SEER program would detect second and third occurrences of cancer in the same person. Dr. Brawley said that the program has published a booklet (which is also available on NCI's website) about second cancers in the United States and Europe.

Dr. Castillo noted that the same virus may cause different diseases in populations of different ethnicity. He gave the example of a virus that causes a type of head and neck cancer in Chinese people but infectious mononucleosis in Caucasians. Dr. Brawley responded that unidentified environmental and genetic factors may contribute to these differences.

In response to another question by Dr. Castillo, Dr. Brawley explained the difference between efficacy and effectiveness, as defined by clinical trialists. Efficacy refers to how well a treatment works in a given population, whereas effectiveness simply refers to whether a treatment works or not. Most NCI cancer clinical trials are designed to measure effectiveness, not efficacy. Much larger numbers of patients would need to be enrolled to permit the measurement of efficacy in different population subgroups. In certain minority groups, there may be too few cases of a disease to recruit enough patients into clinical trials to measure efficacy in that population.

Race and ethnicity have important influences on cultural attitudes to medical care, Dr. Brawley said, adding that more research is needed on the interaction between culture and disease.

Special Populations Research and Outreach

Dr. Sherry Mills, Chief, Applied Sociocultural Research Branch, NCI Division of Cancer Control and Population Sciences, said that her office, which was created in September 1998, focuses on the study of social, cultural, and behavioral issues that affect the health of racial and ethnic minorities as well as rural, poor, physically challenged, and elderly populations. In particular, her office is interested in research to identify ways of modifying behavior to improve health.

Unlike Dr. Brawley's office, Dr. Mills' office awards research grants. Dr. Mills noted that a new small grants program in cancer control sciences was announced in the October 23 *NIH Guide to Grants and Contracts*. Awards under this program have been doubled from $50,000 to $100,000. This program offers an opportunity for new investigators to conduct behavioral research related to cancer control.

Dr. Mills' office is also interested in awarding grants to study health communication issues, such as how to frame messages about cancer prevention, how to effectively disseminate those messages, and how to determine whether the intended message has been received and/or understood. In addition, a project is underway to synthesize the results of cancer prevention and control studies funded by NCI over the past 15 years. Its goal is to identify lessons with the aim of identifying lessons learned as well as remaining gaps in information.

Dr. Mills said that she intends to set up a working group to evaluate her branch's research portfolio and recommend future research directions, and that DCLG participation in this group would be valuable. Her branch is also exploring opportunities to collaborate with the Office of Cancer Survivorship.

The branch offers a variety of training programs for new investigators in behavioral research and cancer control, including the Mentoring and Grantsmanship Information in Cancer Control (MAGICC) program, which offers guidance and mentoring on the preparation of grant applications. Information and grant application forms can be retrieved from the World Wide Web. An online technical assistance program is now available to link new investigators with successful grantees who can offer advice on various aspects of study design and grant writing.

Discussion.

Several DCLG members expressed interest in attending a MAGICC workshop if one could be organized to coincide with a DCLG meeting. Dr. Mills said that the workshop could provide insight into how grant applications are constructed and why they are expected to include certain things. Ms. Lee said that the workshop could be opened to other interested members of advocacy organizations provided that those organizations could pay the individuals' travel costs.

Several questions were posed relating to the recruitment and retention of minorities in clinical trials. Dr. Mills noted that although NIH guidelines require minority participation in trials, they do not require subset analysis by minority group. She added that more educational efforts are needed to enable clinical investigators to work more effectively with primary care doctors whose patients they wish to recruit into trials, as well as to overcome many primary care physicians' mistrust of the research process.

Ms. Ginés asked whether there were opportunities for community-based organizations (CBOs) to partner with NCI on research projects. Dr. Mills replied that a number of successful

partnerships between CBOs and research institutions exist around the country and that her office hopes to broker more such partnerships. Partners need not be geographically close to one another. One of the most successful partnerships to date involves researchers from the University of Vermont and CBOs in the Florida Keys. Dr. Mills said that she would also welcome DCLG participation in a new research consortium on screening for colorectal cancer.

DCLG members agreed that they need more information on the extent of demand for consumer input within NCI, as well as a process for responding to such requests.

It was noted that if DCLG members are closely involved in the development of RFAs, conflict of interest rules may preclude them from applying to those programs.

Communicating with Special Populations

Nelvis Castro, Chief, Health Promotion Section, NCI Office of Cancer Communications, said that her office's goals are to

- address the needs of minority and underserved audiences in every outreach program.
- increase awareness of cancer prevention, screening, diagnosis, and treatment options among minority and under served audience.
- provide the most accurate and up-to-date cancer information to minority and underserved audiences in a culturally sensitive manner.

Targeted minority and underserved audiences include African Americans, Hispanics, Asians, Native Americans, the elderly, and people with limited literacy skills. Strategies used to reach these audiences include using culturally sensitive language and graphics; translating materials into other languages; reaching out to minority media outlets; and writing materials at an 8th grade or lower reading level.

Ms. Castro described a communication program that was launched in October 1997 to publicize NCI's revised recommendations regarding mammography screening for women in their forties. The primary audiences were women age 40 and over, including minority and underserved women, health care providers and payers, and health professional organizations. Audiences selected as gateways for reaching these primary audiences included cancer-related organizations, voluntary and advocacy groups, government agencies, and mass media.

The program was developed following focus groups and surveys to explore women's attitudes and decision-making behavior about mammography. Messages and designs for materials were pre-tested. Baseline surveys of mammography awareness were conducted to provide a basis for later comparison. Evaluation strategies to measure the program's impact will include using the National Health Interview Survey and other reliable sources to track the percentage of women age 40 and over who regularly receive screening mammograms.

Discussion.

Ms. Lin suggested that Ms. Castro might want to work with the New York affiliate of the American Cancer Society, which is translating information about various types of cancer into Chinese. Ms. Butler proposed that NCI consider partnering with the National Council of Women's Organizations, which has launched a new program focusing on older women's

health.

Ms. Ginés commented that breast cancer occurs in women under 40, although regular mammograms are recommended only for women age 40 and over. Ms. Castro said that in addition to urging women to get regular mammograms, the communication program stresses the need for women of all ages to discuss their risk factors for breast cancer with their physician.

In response to a question from Ms. Rogers about the availability of the information booklet *Understanding Breast Changes*, Mary Anne Bright, Acting Chief, Cancer Information Service, said that her office is making arrangements with OLA to provide them without charging for postage and handling.

The Cancer Journey: Issues for Survivors
A Training Program for Health Professionals

Sanjay Koyani, a Health Education Specialist in the Patient Education Branch of NCI's Office of Cancer Information, Communication, and Education, announced the availability of a new NCI training program for health professionals: The Cancer Journey: Issues for Survivors. Developed in partnership with the National Coalition for Cancer Survivorship, Ortho Biotech Inc. and cancer organizations nationwide, the training program provides professionals with the tools and information needed to effectively respond to the many issues cancer survivors and their families face. (Since this meeting, the program has won two major awards: 1) National Association of Government Communicators Award, and 2) CINE Golden Eagle Award.

The program consists of:

- Leader's Guide - Provides guidance and tools necessary to design, promote, implement and evaluate a cancer survivorship training program. Includes starting points for accessing cancer survivorship information.
- 30 Minute Videotape - Features cancer survivors discussing the range of issues they faced from the time of diagnosis through treatment and follow-up care.

A promotional package about *The Cancer Journey* will be sent to professional organizations that work with cancer survivors and their families, as well as advocacy organizations. The package will include a promotional brochure. Additionally, plans are underway to use Key outreach partners - NCI's Cancer Patient Education Network and Ortho Biotech's network of Oncology Nurse Educations- to promote and implement the training program at the regional/community level.

DCLG members will receive a copy of the program and promotional brochures in the mail, and are encouraged to share these resources with their colleagues. Additional copies may be ordered through the CIS by calling 1-800-4-CANCER. Comments or recommendations regarding the program are welcome.

Cancer Information Service: Opportunities for Collaboration with the DCLG

Ms. Bright presented an overview of the Cancer Information Service (CIS). Nineteen regional CIS offices serve the United States and Puerto Rico. Since its inception in 1976, the service has received 8 million calls, an average of 2,000 calls per day. Information specialists

complete a standardized training program and are recertified each year. The quality of the service is evaluated through the CIS Test Call Evaluations and Reporting System and the use of test callers and call monitoring by supervisors. Most calls to the CIS come from cancer patients and their families.

Ms. Lisa Rubinstein, National Director, CIS Outreach Program, described the goals of the program, which works to provide equal access to health information through partnerships with national, regional, and state organizations. The program's current priorities are breast and cervical cancer education, clinical trials education, and science awareness. A random sample survey conducted two years ago to determine the impact of CIS outreach activities on partner organizations found that most partners focus on reaching minority and underserved audiences.

As an example of the work of the outreach program, Ms. Rubinstein described a partnership with the U.S. Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection Program, which offered screening services to underserved women. Project goals included increasing the number of eligible women screened and ensuring that diagnosed women received accurate treatment information. Demonstration projects were conducted in Massachusetts, Arkansas, Illinois, and Washington state. An evaluation of the project will be available in late May 1999.

In closing, Ms. Rubinstein discussed opportunities for collaboration with the DCLG. She explained how CIS can offer access to up-to-date, accurate cancer information and publications as well as technical assistance and links with regional organizations. For its part, the DCLG can offer contacts and suggestions for new partnerships as well as expertise in reaching special populations. In addition, DCLG feedback is solicited on the section of a draft RFP for renewal of the CIS contract that deals with increasing the outreach program's effectiveness. Ms. Rubenstein will notify OLA when the draft RFP becomes available and OLA will in turn notify the DCLG.

Discussion.

In response to a question by Ms. Dewey, Ms. Rubinstein said she would send DCLG members a list of the CIS Outreach Program Managers. Mr. Moore suggested that the outreach program consider partnering with the American Library Association to increase the availability of health information in public libraries. Ms. Rubinstein agreed with Dr. Castillo that partnership with religious organizations can also help to effectively disseminate health information.

In response to a question from Mr. Moore, Ms. Bright said that updating the CIS telephone system will include offering more options to obtain information during evenings and weekends when the service does not operate. It was noted that many people cannot access information by fax or over the Internet.

In response to a question from Ms. Dewey, Ms. Bright said that she would consider how the DCLG could facilitate efforts to keep CIS printed publications current with new scientific knowledge. Ms. Nealon agreed that maintaining the currency of printed publications is an ongoing challenge. She suggested that DCLG members who have access to the Internet could download up-to-date information from NCI's website and print it out to be copied and disseminated.

Working Group on Special Populations

Dr. Sieber said that the Advisory Committee to the Director (ACD) of NCI is in the process of setting up a working group on special populations. This group is intended to improve the channels of communication between the ACD, the Office of Special Populations Research (OSPR), and organizations representing the populations that are the focus of OSPR's work. It is proposed that the working group consisting of about 15 members, including representatives from medical and nonmedical disciplines as well as individuals who are familiar with the cancer experience. Ethnic and geographic diversity among the membership will be sought.

The group will meet about three times a year. Outside experts on specific issues will be invited as appropriate to become ad hoc members of the group. Issues that the group will consider include training and infrastructure-building to support special populations research, accrual to clinical trials, and enhancement of screening efforts. Dr. Sieber issued an open invitation to DCLG members to participate in the working group.

Discussion.

Mr. Katz said that the DCLG needs to better understand the full scope of and potential for consumer involvement in all of NCI's activities as well as the full scope of NCI activities pertaining to special populations.

NCI IDENTITY PROJECT

John Burklow, Assistant Director, Office of Cancer Communications, briefly described a new initiative that is in development to increase public awareness of NCI's activities and to better distinguish NCI from other organizations in the cancer field.

Discussion

DCLG members agreed that both the professional and lay audiences with which they are in contact are currently unaware of the range of activities that take place at NCI or that NCI supports. As a result, opportunities to obtain better treatment are lost and misinformation about cancer research persists. Ms. Butler said that NCI programs reach the public in a piecemeal fashion rather than through a coordinated education campaign.

Mr. Moore commented that different "publics" need different information. The general public needs to be persuaded that NCI's support of cancer research is important, whereas people with cancer need to be aware of the specific services that NCI supports for cancer patients.

Members suggested that the following materials, presented in simple and clear terms, would be helpful in informing the public about what NCI does: a handbook, a resource directory, and a fact sheet or bookmark listing NCI services for the public. They agreed that many NCI publications are written at too high a reading level to be helpful to many people. It was suggested that materials should provide differing levels of detail to meet the needs of people for whom basic information is enough as well as those who want to know more.

OTHER BUSINESS

Ms. Nealon reported that Dr. Klausner had approved the primer on genetic research and

population studies that was developed in response to a DCLG proposal to create a document providing basic information on the complex issues surrounding these topics. The primer is expected to be printed in early 1999.

In response to a question by Ms. Butler, Ms. Nealon said that the search is continuing for a permanent director for the NCI Office of Cancer Survivorship.

NEW BUSINESS

Ms. Ginés proposed forming a subcommittee on cultural diversity. DCLG members and NCI staff discussed the circumstances in which it is appropriate for the DCLG to establish subcommittees and the procedures for doing so. It was noted that federal regulations require subcommittees of chartered committees to be formally approved and to hold public meetings. In addition, the objectives of subcommittees should not duplicate the role of the DCLG as a whole. Members of the DCLG, individually or as groups, may pursue relevant projects they are interested in. They should keep the Executive Secretary, the Chair and other members informed throughout the process.

It was agreed that more information is needed on the scope of NCI involvement in partnerships with other organizations.

ADJOURNMENT

There being no further business, the 3rd meeting of the Director's Consumer Liaison Group was adjourned at 2:25 p.m. on Tuesday, October 27, 1998.