NATIONAL CANCER ADVISORY BOARD

convened on June 8, 1999, at the:
National Institutes of Health
Building 31-C, Conference Room 10
Bethesda, Maryland 20892

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ATTENDEES

The National Cancer Advisory Board (NCAB) convened for its 110th regular meeting at 9:00 a.m., June 9, 1999, in Conference Room 10, C Wing, Building 31, National Institutes of Health.

NCAB Members
Dr. J. Michael Bishop (Chairperson)
Dr. Richard J. Boxer
Dr. Kay Dickersin
Dr. Alfred L. Goldson
Dr. Elmer E. Huerta
Dr. Frederick P. Li
Dr. Susan M. Love
The Honorable James E. McGreevey
Dr. Sandra Millon-Underwood (absent)
Dr. Arthur W. Nienhuis
Dr. Larry Norton
Dr. Amelie G. Ramirez
Dr. Ivor Royston
Dr. Philip S. Schein
Dr. Phillip A. Sharp (absent)
Ms. Ellen L. Stovall
Dr. Vainutis K. Vaitkevicius

President's Cancer Panel
Dr. Harold P. Freeman (Chairperson)
Dr. Paul Calabresi
Ms. Frances Visco (absent)

Alternate Ex Officio NCAB Members
Dr. Steven K. Akiyama, NIEHS
Col. Louis F. Diehl, DoD (absent)
Dr. Michael Hodgson, NIOSH (absent)
Ms. Rachel Levinson, OSTP (absent)
Dr. Alison Martin, FDA (absent)
Dr. Hugh McKinnon, EPA
Dr. Lakshmi C. Mishra, CPSC (absent)
Dr. T. G. Patel, DVA
Dr. Eugene Schwartz, DOL (absent)
Dr. Michael Viola, DOE (absent)
Dr. C. Wooley (absent)
Dr. Rachel Levinson OSPT (absent)

Members, Executive Committee, National Cancer Institute, NIH
Dr. Richard Klausner, Director, National Cancer Institute
Dr. Alan Rabson, Deputy Director, National Cancer Institute
Ms. MaryAnn Guerra, Deputy Director for Management
Dr. Robert Wittes, Deputy Director for Extramural Science; Director, Division of Cancer Treatment and Diagnosis
Dr. Norka Ruiz Bravo, Acting Director, Division of Cancer Biology
Dr. Joseph Fraumeni, Director, Division of Cancer Epidemiology and Genetics
Dr. Peter Greenwald, Director, Division of Cancer Prevention
Dr. Marvin Kalt, Director, Division of Extramural Activities
Dr. Edison Liu, Director, Division of Clinical Sciences

Dr. Barbara Rimer, Director, Division of Cancer Control and Population Sciences
Dr. George Vande Woude, Director, Division of Basic Sciences
Dr. Joseph Harford, Associate Director for Special Projects
Dr. Susan Sieber, Associate Director for Special Projects
Dr. Ellen Feigal, Deputy Director, Division of Cancer Treatment and Diagnosis
Dr. Paulette Gray, Deputy Director, Division of Extramural Activities
Ms. Cherie Nichols, Assistant Director for Science Planning and Assessment, Office of Science Policy
Ms. Susan Waldrop, Assistant Director for Program Coordination, Office of Science Policy
Mr. John Hartinger, Associate Director for Budget and Financial Management
Dr. Sherry Mills, Chair, Extramural Advisory Board
Dr. Allan Weissman, Chair, Intramural Advisory Board
Dr. Martin Abeloff, External Advisor and Chairperson, Board of Scientific Counselors, Subcommittee A; Professor and Director, Johns Hopkins Oncology Center
Dr. David Livingston, External Advisor, Chairperson, Board of Scientific Advisors; Professor of Medicine, Dana-Farber Cancer Institute
Dr. Matthew Scharff, External Advisor and Chairperson Board of Scientific Counselors Subcommittee B; Professor, Albert Einstein College of Medicine
Dr. Alfred Knudson, External Advisor, Special Advisor to the Director; Senior Member, The Institute for Cancer Research, Fox Chase Cancer Center
Ms. Sandy Koeneman, Executive Secretary

Liaison Representatives
Dr. John Currie, American Association for Cancer Education, Inc.
Dr. Edwin A. Mirand, Association of American Cancer Institutes
Dr. Margaret Foti, American Association for Cancer Research
Dr. Marc E. Lippman, American Association for Cancer Research
Dr. Robert Martuza, American Association of Neurological Surgeons
Dr. Robert W. Frelick, Association of Community Cancer Centers
Ms. Kerrie B. Wilson, American Cancer Society
Dr. John Stevens, American Cancer Society
Dr. Stanley Zinberg, American College of Obstetricians and Gynecologists
Dr. Bernard Levin, American Gastroenterological Association
Dr. Edward P. Gelmann, American Society of Clinical Oncology, Inc.
Dr. Eli Glatstein, American Society of Therapeutic Radiologists
Ms. Laura Liebermann, The Candlelighters Childhood Cancer Foundation
Dr. Lovell A. Jones, Intercultural Cancer Council
Dr. Armin D. Weinberg, Intercultural Cancer Council
Ms. Katharine R. Boyce, Intercultural Cancer Council
Ms. Martha M. Kendrick, Intercultural Cancer Council
Ms. Jean Ard, Leukemia Society of America
Ms. Carolyn Adige, National Coalition for Cancer Research
Ms. Dorothy J. Lamont, National Cancer Institute of Canada
Dr. Robert A. Phillips, National Cancer Institute of Canada

Ms. Paula Bowen, National Cancer Institute Director's Consumer Liaison Group
Dr. Eve I. Baran, National Science Foundation
Ms. Pearl Moore, Oncology Nursing Society
Dr. Jeffrey Norton, Society of Surgical Oncology, Inc.

CALL TO ORDER, OPENING REMARKS, AND CONSIDERATION OF MINUTES OF PREVIOUS MEETINGS
Dr. J. Michael Bishop

Dr. J. Michael Bishop called to order the 110th meeting of the National Cancer Advisory Board (NCAB), and acknowledged the liaison representatives who were in attendance. He welcomed members of the public and invited them to submit, in writing and within 10 days, any comments regarding items discussed during the meeting. A motion was made to approve the minutes of the February 1999 meeting; it was seconded, and the minutes were approved unanimously by the Board.

FUTURE BOARD MEETING DATES
Dr. J. Michael Bishop

Dr. Bishop called the Board members' attention to future NCAB meeting dates listed in the agenda. Dates have been confirmed through 2001.

REPORT OF THE DIRECTOR, NATIONAL CANCER INSTITUTE
Dr. Richard Klausner

Dr. Richard Klausner, Director, National Cancer Institute (NCI), reported on recent activities of the Director's Consumer Liaison Group (DCLG), reviewed the progress that has been made in special populations research, provided updates on the NCI's intramural and extramural programs, spoke about informatics and communication activities, and announced the release of a new human cancer genetics initiative.

Director's Consumer Liaison Group. Dr. Klausner reported on the accomplishments of the DCLG, which is a formal advisory committee that recently has achieved federally chartered status. In the past year, the DCLG has created its own agenda and pursued areas such as issues relating to patient participation in clinical research and clinical trials. The DCLG also collaborated with NCI staff and other experts to develop a primer entitled *Understanding Genetic Research and Population Based Studies*. The primer, which has been distributed widely and soon will be available on the NCI Web Site, addresses key issues that patients and the scientific community may be concerned about, such as implications for confidentiality and identifiability. In addition, the DCLG provided input for a project that developed a simplified and understandable informed consent document template for clinical trials participation, and it currently is helping to develop methods for

disseminating the new informed consent approach to advocacy groups and for encouraging patients to use the new consent template.

The DCLG also has been familiarizing itself with the NCI's peer-review process and all of its components toward the goal of incorporating consumer advocates in peer review, assisting in developing orientation programs and glossaries for advocate reviewers, and making recommendations to the NCI.

In addition, the DCLG members undertook an in-depth review of a variety of NCI communication initiatives and provided written feedback for the Clinical Trials Promotion Initiative, the Physician's Data Query (PDQ), the Cancer Information System (CIS), and the Patient Education Branch. The accessibility of NCI information through various channels was evaluated, and it was determined that major improvements were needed in this area. The DCLG presented a formal report to Dr. Klausner and also met with the appropriate authorities regarding the various components. Dr. Klausner commented that some of the DCLG members' terms will expire in 2000, and a new call for nominations will be issued in Fall 1999.

On behalf of the NCAB and the NCI, Dr. Klausner recognized the work of Ms. Eleanor Nealon, Director, Office of Liaison Activities (OLA), who is retiring from the office she created and lead for the past three years. He presented her with an award and thanked her for her dedication, her contributions as head of the OLA, and for the tremendous task of helping to organize and assemble the DCLG.

Special Populations. Dr. Klausner advised the Board that the Special Populations Working Group, which was recently established in response to the Institute of Medicine's (IOM) report, is seeking to: evaluate the extent of NCI's research on special populations; assist the NCI in becoming more accessible to the many communities being served by the NCI; and provide approaches for the NCI to use in response to the needs and cancer burden of all communities.

Dr. Klausner announced that a Request for Applications (RFA) has been released for a new initiative, "Special Populations Networks for Cancer Awareness Research and Training," which is a followup on previous leadership initiatives (e.g., the National Black, Hispanic, and Appalachian Leadership Initiatives). Dr. Klausner noted that the new initiative is a significant expansion of these previous programs, both financially and conceptually. It will facilitate the construction of cancer control community-based infrastructures—in population areas beyond those involved in the leadership initiatives—that will be capable of linking to NCI research activities. The initiative also will include the development of a Cancer Control Academy, a 3-day course taught by cancer control experts from the NCI, the Centers for Disease Control and Prevention (CDC), and other venues for the purpose of dealing with issues of cancer control in special populations. It is anticipated that a minimum of $30M will be set aside for the 5-year effort, and that 8 to 10 awards will be funded.

Dr. Klausner then discussed a new joint initiative between the NCI and the NIH Office of Research on Minority Health (ORMH) to establish a program that will facilitate partnerships and partnership development among NCI-sponsored cancer centers and minority institutions. Proposals from the cancer centers for the 1-year grant supplements, which will be funded by ORMH, must be submitted by mid-August. Dr. Klausner stated that developing these partnerships is extremely important, and he has asked the NCI staff to develop an RFA proposal, to be advertised in FY 2000, for cooperative agreements to fund collaborative projects between cancer centers and minority medical schools.

Dr. Klausner stated that in response to the IOM report, the Office of Special Populations Research (OSPR) will work toward developing flexible and widely accepted workable definitions for the medically underserved that will guide research, surveillance, and reporting. Actions to date include conducting a review of the literature and compiling definitions from other agencies. A working group of extramural experts has been formed to assimilate the information and develop the parameters. In addition, a roundtable planning meeting to include representation from other interested institutes, the ORMH, and the Office of Behavioral and Social Science Research will convene on July 23 to move toward a future national workshop on the medically underserved.

Dr. Klausner then spoke about the progress that is being made to develop criteria for incorporating or expanding areas for participation in the Surveillance Epidemiology and End Results (SEER) Program. The NCI and the CDC will work collaboratively to link their cancer registry programs, expand the nation's capacity to gather information, and identify state registries that might be included in a SEER expansion. It is anticipated that by Fall 1999, there will be solicitations to fund up to 4 registry-ready sites and up to 10 non-SEER sites to improve data quality for inclusion in the pool of data that is now being reported for cancer incidence.

Intramural Program Initiatives: Update. Dr. Klausner presented an update on initiatives in the intramural programs, with emphasis on the Division of Clinical Sciences (DCS). He discussed the NCI's need for clinical tenure track investigators with individual resources appropriate to carry out their clinical research missions, such as a minimum fixed research budget per year and access to data managers and research nurses. This approach has been initiated in the DCS, and is being adopted across the NIH as a standard for recruitment resources and for definition of clinical faculty.

Next, Dr. Klausner elaborated on other ongoing activities in the intramural programs, including: the recruitment of clinical investigators needed to implement the intramural research program; the establishment of a new head and neck cancer program and neuro-oncology branch; the formation of the Protocol Research Office; the development of a new clinical information system; the movement of intramural regulatory affairs from the Cancer Therapy Evaluation Program (CTEP) to a new office within DCS; the status and direction of intramural clinical trials; the effort being made to develop an institute-wide clinical trials information system that would link to all systems currently being developed; the development of the Clinical Services Support Center; the effort to define the roles and responsibility of cancer research nurses; the establishment of training

programs that reach out to other institutions; and the Vaccine Working Group's publication of a set of proposals for new trial designs and standards that are appropriate for immunologic-based interventions in cancer. Dr. Klausner noted that some of the innovative treatment protocols being developed for intramural trials will be presented at a future meeting.

Extramural Programs: Update. Dr. Klausner briefly reviewed for the Board two new R21 funding mechanisms. "QuickTrials" supports clinical trials and/or associated laboratory studies and focuses on new approaches and new agents from academia, industry, or the NCI. The application and review processes will be streamlined—with an approximate turnaround time of 4 months from application to award. Rapid Access to Intervention Development (RAID), the other new resource assistance mechanism, is aimed at drug development and reaches out to academia and small businesses where good preclinical data exist for compelling new approaches to therapy. This new mechanism, which was introduced in FY1998, links grant-funded investigators to NCI contract or in-house resources to expedite development of novel therapeutic approaches to the point of proof-of-principle clinical trials.

Informatics and Communication Activities. Dr. Klausner explained that the NCI has been working to redesign and integrate its information infrastructures, particularly the NCI Web Site. Significant progress has been made, and the reengineered Web site is expected to be completed within 6 months. Dr. Klausner next commented on the NCI's two Web-based clinical trials databases. CancerNet accesses clinical trial abstracts and peer review cancer information summaries from the PDQ database. CancerTrials is a new Web site that has been developed to provide general information about cancer clinical trials for access by the public and the scientific community and includes a gateway to the PDQ database. Currently, CancerNet is accessed about 4 million times per month and CancerTrials is approaching 800,000 hits per month. The redesign effort will result in a new universal database that will integrate CancerNet and CancerTrials; provide consolidated glossaries that are easy to understand; simplify navigation methods and make menus easy to use; allow searches by stage of disease; and simplify Web-based protocol submissions.

Dr. Klausner briefed the Board on the new Common Scientific Outline (CSO), which is being used to develop a new coding system for extramural projects, grants, and contracts. The coding system is part of the effort to bring order to the task of evaluating and monitoring the NCI research portfolio. This coding approach is being applied to Web-based search and retrieval capacities, and approximately 7,000 NCI projects will be coded using this system in the next month. The Department of Defense (DoD) has agreed to import its 2,000 cancer research projects into the system; this will be completed within the next few months. The American Cancer Society and State of California also are considering the adoption of the CSO for coding their research projects.

Cancer Genome Anatomy Project (CGAP): Update. Dr. Klausner announced the public release through the CGAP Web site of 10,435 potential new variations in human genes, which were the product of the Genetic Annotation Initiative (GAI), CGAP's latest

component. The objective of the GAI is to genetically annotate genes important in cancer phenotypes by identifying common variations—known as single nucleotide polymorphisms (SNPs)—that may determine different levels of gene activity or pathways, and make them publicly available as a usable and accessible database to the entire research community. Although the SNPs in this first major public release must be validated, the statistical confidence level for each is 0.99. GAI scientists continue the search for SNPs in the CGAP database of sequence information using data-mining tools they developed for the task. They also are working on the validation and confirmation of potential SNPs that are identified. About 40 percent of the known and named genes have been annotated and are represented in the first public release from the GAI; that number is expected to increase to 67 percent in the next few months. Dr. Klausner demonstrated how the GAI database, which can be accessed free of charge from the CGAP Web page, can be used for molecular epidemiology studies. He reported that a consortium with the pharmaceutical industry is being organized to collaborate with the NIH in the discovery of random polymorphisms throughout the genome; all of the different projects will be linked. Dr. Klausner stated that the NCI plans to continue to establish enabling infrastructure projects such as CGAP and GAI and provide mechanisms to fund assistance from extramural investigators in completing the information, as a basis for innovative molecular epidemiologic studies of the future.

Questions and Answers

Dr. Larry Norton asked about intellectual property issues related to the SNPs. Dr. Klausner replied that the gene variations identified under the GAI, as with all CGAP information, are not patentable because they are immediately published and released to the public domain.

MINI-SYMPOSIUM: REPORT OF THE NATIONAL CANCER POLICY BOARD (NCPB) ON QUALITY CARE IN CANCER

Introduction—Ms. Ellen Stovall, Dr. Richard Klausner

Ms. Ellen Stovall, Executive Director, National Coalition for Cancer Survivorship, provided a brief background on her experiences as a member of the National Cancer Policy Board (NCPB), which was established in March 1997, is housed within the National Research Council and the Institute of Medicine (IOM), and is comprised of 20 members including consumers, providers, and researchers. Initially, to address quality of care issues, the Board began to develop a consumer checklist about quality cancer care and concluded that there were insufficient data to make specific recommendations. During the last 18 months, the Board systematically reviewed and analyzed the available data and produced the report entitled *Ensuring Quality Cancer Care*. The report was presented to NCI leadership and was well received as a possible blueprint for the types of additional surveillance data that might be collected to document better these outcomes.

Overview of the NCPB Report—Dr. Joseph Simone

Dr. Joseph Simone, Medical Director, Huntsman Cancer Foundation and Institute, and Vice Chair, NCPB, discussed the purpose of the NCPB report, which is to provide policy research, findings, and recommendations to improve prevention, control, diagnosis, and treatment of cancer. Dr. Simone noted that the NCPB's responsibilities included

examining implications on ongoing research and new technologies; proposing solutions to problems faced in the nation's battle against cancer; and serving as a common meeting ground for federal agencies and state and local health authorities that sponsor or conduct relevant work. Dr. Simone stated that, after determining that data were insufficient to make specific recommendations on a consumer checklist, the NCPB arrived at the following five research questions needing to be addressed: (1) What is the cancer care system in the United Sates, and how is it working? (2) What is quality cancer care, and how is it measured? (3) What are the main problems, and what steps can be taken to improve care? (4) How can we improve what we know about quality cancer care? and (5) What steps can be taken to overcome barriers to accessible quality cancer care?

Dr. Simone stated that, based on the best available evidence, the NCPB concluded that substantial numbers of individuals with cancer do not receive the most effective care for their condition. Reasons include the underuse of screening tests, lack of adherence to standards for diagnosis, inadequate patient counseling regarding treatment options, and underuse of radiation therapy and adjuvant chemotherapy after surgery. The report outlined the following 10 recommendations: (1) ensure that patients, who are undergoing procedures that are technically difficult and have been associated with higher mortality, receive care at facilities with extensive experience; (2) use systematically developed guidelines based on the best available evidence for prevention, diagnosis, treatment, and palliative care; (3) measure and monitor the quality of care by using a core set of quality measures; (4) ensure quality care for each individual with cancer by providing recommendations from experienced professionals about initial management, an agreed-upon care plan that outlines goals of care, access to the full complement of resources necessary to implement the care plan, access to high quality clinical trials, policies to ensure full disclosure of information about appropriate treatment options, a mechanism to support services, and psychosocial support services and compassionate care; (5) ensure quality of care at the end of life; (6) increase investment (by federal and private research sponsors and various health plans) in clinical trials to address questions about cancer care management; (7) create a cancer data system that can provide quality benchmarks for use by systems of care; (8) enlist the support of public and private sponsors of cancer care research for national studies for tracking newly diagnosed individuals with cancer, using information sources with sufficient detail to assess patterns of cancer care and factors associated with the receipt of good care, and supporting training for cancer care providers interested in health services research; (9) enhance services for the un- and the underinsured to assure entry to, and equitable treatment within, the cancer care system; and (10) mount studies to determine why specific segments of the population do not receive appropriate cancer care (e.g., studies measuring provider and individual knowledge, attitudes, beliefs, and potential barriers to access).

Dr. Simone pointed out that the report already has been disseminated to the public, professionals, federal agencies, congressional staff, health plans, and insurers. In addition, two workshops have been planned that will extend the impact of the report. The first workshop will concentrate on improving the cancer care data system to provide quality benchmarks for use by systems of care, and the second workshop will expand and implement the volume-outcome relationship and other major findings. Dr. Simone noted

that the NCPB also has issued a tobacco policy report and will, in the future, provide a consumer quality care checklist, a cancer control policy, and a cancer research policy.

Questions and Answers

Asked for an assessment of how the report is being received, particularly in the private sector, and the potential for implementing the recommendations, Dr. Simone noted the importance of NCI's receptiveness and response when the report was introduced and the presence of representation from the insurance industry on the Board. He conveyed the NCPB's belief that databases of treatment outcomes are essential and will galvanize action and that guidelines and monitoring outcomes save money. Dr. Norton pointed out the importance of the NCI initiatives for common data elements and other informatics tools for the task of determining the core quality elements that will be used both for checklists and for guidelines. He commended the work of the Board, but cautioned that the first recommendation was controversial because it implied a centers of excellence concept, which is not feasible in various parts of the country. He asked about conclusions of the Board in regard to the effects of economic deprivation and cultural differences in implementing a centers of excellence concept. Dr. Simone pointed out that although the NCPB recognizes that complete and universal application of all recommendations may not be possible, strong mortality and morbidity data indicate that the issue of accessibility to centers of excellence must be addressed to have an impact on the outcomes of patients with cancer. In response to Dr. Li's observation that none of the recommendations addressed cancer prevention, Dr. Simone acknowledged that the report focused on the quality of care of the cancer patient. Cancer control and cancer prevention will be subjects of future NCPB reports. Dr. Bishop raised the issue of what possible actions the NCAB might want to take, and it was decided to delay the procedural discussion until the New Business session to be held in the afternoon. Dr. Klausner noted the need for a more specific plan of action to engage the participation of large health care delivery systems in implementation. Dr. Simone responded that future plans include providing a consumer checklist, strengthening the issue of volume-outcome, defining what additional data are needed, and determining what kind of a database is appropriate to address broad quality issues. He acknowledged that a more specific action team is needed to move forward, with help and leadership from entities like the NCI.

Perspectives of the National Comprehensive Centers Network (NCCN)— Dr. Robert Young

Dr. Robert Young, President, Fox Chase Cancer Center, reported that the National Comprehensive Centers Network (NCCN), a voluntary group of 17 large, geographically dispersed cancer centers across the nation, was created 4 years ago and linked to a database system comprised of data about shared treatment and outcomes for cancer patients. Major programs of the NCCN were (1) Oncology Practice Guidelines that would define a standard of oncologic care; (2) Oncology Outcomes Database to determine whether these guidelines were being implemented and, if they were, to ascertain whether cancer treatment outcomes improved; (3) a collaboration with the American Cancer Society (ACS) to translate the guidelines into more user-friendly documents; (4) NCCN Pricing Model; (5) NCCN/Quintiles Partnership; and (6) NCCN/Managed Care Partnership Development. Dr. Young reported that guidelines have now been developed for more than 95 percent of known cancers and that the presence of

and participation in cancer center clinical trials at any nodule is, by definition, adherence to the guidelines. He reviewed the goals of the outcomes database: to describe the patterns and outcomes of care in the member institutions; identify the most effective and cost-effective strategies for management of common oncologic conditions; monitor guidelines adherence; and create feedback loops to the guideline development teams. Comprehensive data elements being harvested in the database include demographic, clinical, and outcomes adherence information, with the addition to the later category of employment status, days lost from work, and hospital days. Dr. Young noted that the NCCN has a coordinating office at Dana Farber Cancer Institute, data coordination and storage at City of Hope National Medical Center, and self-funded data managers at each institution to begin the harvest of this detailed information.

Dr. Young summarized for the Board the NCCN's objectives for creating a database system: (1) to develop a central repository of shared treatment and outcomes data, based on a data dictionary that was generated to ensure uniformity for all terminology; (2) ensure the highest level of security, confidentiality, and data integrity; (3) provide nationwide accessibility via the Internet; and (4) use data collection systems that already exist at the participating institutions. He briefly described the client-server model used by the NCCN for data transmission, data security mechanisms that adhere to the National Research Council requirements, and measures to ensure data confidentiality.

Dr. Young demonstrated how the NCCN operates with a description of the Breast Cancer Pilot Project. He described the demographic characteristics of breast cancer patients in the database, clinical trial enrollment, data on treatment, and data indicating the degree of adherence with NCCN treatment guidelines. Conclusions drawn from the pilot project were that it was proof of the principle that outcomes data can be collected on breast cancer, that the data are of high quality, that most of the care in NCCN institutions is adherent to the guidelines but there is variation in patterns of care, and that member institutions are interested in receiving feedback on their patterns of care. In regard to the later, each institution receives, for every submission to the database, a return set of data that indicates the overall degree of adherence with guidelines within the NCCN and its own adherence. Dr. Young noted that this self-educating and self-disciplining mechanism has had high merit for improving the overall quality of care. He cautioned the Board about the high cost of this initiative; more than $2.5M was expended in the Breast Cancer Pilot Project alone to explore proof of principle. At present, the pharmaceutical industry has expressed some interest and provided some support for this endeavor; interest and support from the managed care community has been explored in some detail but with limited success so far.

Questions and Answers

Dr. Bishop asked how the project is being funded. Dr. Young explained that, except for the limited support from the pharmaceutical industry, the 17 participating institutions have provided all of the funding. Managed care has postponed consideration until the NCCN has 60 percent of the cancers. In response to a question from Dr. Klausner, Dr. Young noted that the data for all breast cancer patients from the initial five institutions were entered into the database.

Perspectives for Populations—Dr. Jane Sisk

Dr. Jane Sisk, Professor of Health Policy, Mt. Sinai School of Medicine, presented, as background to the National Academy of Sciences (NAS) report, the following definition of the concept of quality in health and medical care adopted by the NAS: the degree to which either health services for individuals or populations increases the probability of desired health outcomes and populations and reduces the probability of undesired outcomes, given the state of medical knowledge. She pointed out three emphases implicit in the definition: (1) this type of research deals with probabilities; (2) the focus is on what goes on in a health care or medical care encounter; and (3) what is considered good quality in one era may differ over time as knowledge evolves. She emphasized that health care providers, plans, or integrated delivery systems can be held accountable only to the extent that there have been relationships, i.e., evidence, established between content of care and the likelihood of an effect on health related outcomes.

Dr. Sisk reported that, even recognizing the need for additional evaluation of health and medical care to establish these relationships (or evidence), the NAS found that there were significant shortfalls between evidence and evidence-based guidelines of what was recommended versus what actually is being done in practice. The first recommendation of the report focused on the relationship between higher volume and better health-related outcomes. Dr. Sisk noted that those relationships have not been found with physicians in cancer care, perhaps because of the lack of available data. She also pointed out that the report emphasized that there is insufficient evidence about how to care for particular cancers in terms of improving health-related outcomes.

Dr. Sisk remarked that a recurring theme of the report is that the patterns that have been found when looking at breast cancer care, an area for which evaluation data exist, are characteristic of the medical care system throughout the United States. Examples of areas where significant shortfalls exist are follow up, pain relief, and appropriate care for ethnic minorities. Dr. Sisk emphasized that problems with quality cannot be attributed to managed care. Studies have found that managed care plans delivered care at least as good and sometimes better than other arrangements. Data needs are vital, and the traditional ways of capturing data are increasingly becoming inadequate, particularly as patient care has moved from the inpatient arena to more ambulatory arrangements.

Dr. Sisk stated that the NAS report highlighted three major research priorities for quality of care: (1) conduct randomized controlled trials about interventions for diagnosing and treating cancers, particularly under average conditions of use; (2) address the problem, as a society and health care community, of finding a way to reduce ethnic and socioeconomic disparities; and (3) figure out how to implement the scientific evidence that currently is available. Dr. Sisk noted that although research in this area and implementation of the findings of scientific evidence are in the early stages, recurrent themes are that system-wide approaches seem to be more effective than those aimed at individual patients or clincians, that examples of outstanding quality of care in some areas should be evaluated to inform what might be done to improve other areas, and that the volume-outcome relationship should be addressed definitively. Dr. Sisk announced

that future board activities include a data workshop and a workshop on implementation that focuses on the volume-outcome relationship.

Summary of NCI Research Opportunities and Quality of Cancer Care—Dr. Rachel Ballard-Barbash, Dr. Robert Hiatt

Dr. Rachel Ballard-Barbash, Chief, Applied Research Branch, Division of Cancer Control and Population Sciences (DCCPS), discussed the progress that the NCI has made in the last decade in terms of building capacity, monitoring patterns of care, and evaluating quality of cancer care. In the 1980s, the NCI recognized that data being collected by SEER were limited because the focus was on reviewing issues related to patterns of care. An effort was begun within the former Division of Cancer Prevention and Control to focus on the study of cancer-related health services. Priorities were given to cancer sites that contributed most to the cancer burden of treatments and other modalities that proved to be effective in reducing cancer mortality.

Dr. Ballard-Barbash noted three primary categories of activities that have occurred at the NCI in the last 10 years including: (1) patterns of care, which are characterized by patient, provider, health system, and regional factors; (2) time trends, recognizing the need to disseminate state-of-the-art care following major new findings; and (3) effectiveness research to determine whether the benefits that have been predicted from clinical trials actually are achieved in community practice. Initial descriptive efforts focused on patterns-of-care studies, interpreting trends from the population perspective, examining the entire spectrum of cancer phases from prevention through treatment, and looking beyond individual patient and physician factors at the role of organizations in systems that influence care. Over the decade, the NCI has moved forward in terms of building capacity by extending data resources (e.g., three rounds of National Health Interview Survey [NHIS] cancer control supplements), developing valid measures and methods, disseminating data and methods resources for use by the research community, and conducting major ongoing population-based projects.

Dr. Ballard-Barbash stated that recent reports by the NCPB, the President's Cancer Panel, and the Cancer Surveillance Research Implementation Plan (CSRIP) concurred that the NCI should support quality of care research by implementing the following recommendations: (1) invest in clinical trials to address questions about cancer care management; (2) develop a cancer data system that provides data-driven quality benchmarks for use by systems of care to monitor and evaluate quality of care; (3) develop training in health services research; (4) conduct studies to determine why specific segments of the population do not receive appropriate cancer care; and (5) improve quality of cancer care by public and private collaboration in the areas of delivery of service, access, and data-monitoring and evaluation of quality care.

Dr. Ballard-Barbash concluded her report by summarizing the current gaps in knowledge, data, and resources that have been identified. She then listed four categories of research directions for the NCI: incident cohorts of individuals with specific cancers; cross-

sectional patterns of care studies; methodologic research to improve and develop valid core outcome measures and to refine and extend statistical methods; and expanded capacity within cancer registries by linking data from multiple health surveillance systems and by expanding the routine collection of data elements relevant to quality of care.

Dr. Robert Hiatt, Deputy Director, DCCPS, commented that the quality of cancer care issue is important to many different constituencies. He added that this issue is becoming more important because there is an increasing need for additional information to evaluate how the nation's changing health system is performing. Dr. Hiatt noted that the NCPB's report is consistent with the three recommendations made by the Surveillance Implementation Group (SIG): (1) support the collection of data on patterns of care, health status, morbidity, and quality of life as well as cohort studies of newly diagnosed registered cancer patients for the purpose of documenting levels and trends in these parameters; (2) develop research methods to measure dimensions of the cancer burden as well as methods to explain patterns and trends in cancer rates; and (3) work with partners to develop a National Cancer Surveillance Plan.

Dr. Hiatt concluded his report by highlighting three challenges in three areas that need to be resolved. Efforts are necessary to provide more consistency in national and local data systems in terms of the coding systems and data collection. Secondly, reporting systems that depend on physician participation often suffer because of the lack of free time that a physician has to devote to reporting patient information and because quality assessment raises the specter of interference in the doctor-patient relationship. The third challenge centers around the issues of data access and confidentiality. Currently, numerous legislative initiatives in the area of privacy have been introduced in the United States and industrialized countries worldwide; efforts are being made to find methods that balance the needs of an individual's privacy with the needs of the medical community to access data to improve public health.

Questions and Answers

Ms. Stovall led the discussion by commenting that any list of partners for the future in the area of quality of care should include advocacy groups. She then observed that the Board has an excellent opportunity, in its public forum, to promote the importance of the recommendations.

Dr. T. G. Patel elaborated on the Veteran's Administration's (VA) National Cancer Strategy Plan, which features recommendations similar to those in the IOM report. He described the operation of the VA's central cancer registry and the memorandum of understanding between the NCI and VA to increase accessibility to cancer clinical trials for all veterans. Toward that end, the VA Web page includes a link to the NCI's Web site for access to clinical trials information.

Dr. Frederick Li questioned why the NCI has not assisted in funding the NCCN. Dr. Young responded that the NCI has been very responsive to this issue but that no clear

plan has been realized at this time. Dr. Klausner commented that Dr. Hiatt's presentation rendered an excellent summary of the NCI's commitment to the whole area, and particularly to the need for databases and more support. He noted that the NCI, in terms of process and funding fairness, considers different possibilities and develops a process to arrive at workable funding decisions to implement areas of commitment, which could in the future include support for the NCCN.

Dr. Klausner pointed out that NCI-supported research over the years has produced much data, yet the NCPB report emphasizes lack of data. He asked Dr. Simone whether the NCPB perceives the problem as being one of dissemination or access. Dr. Simone noted that the NCPB is interested in data on dissemination in the broadest context of research information (e.g., whether failure to receive radiation therapy following surgery can be attributed to poor dissemination of information, patient choice, or poor local standards for radiotherapy). The NCPB also is interested in research data on baseline standards in the various health care communities and providers and variations from one place to another. Dr. Simone indicated further that data systems must be facile and flexible enough to produce relatively recent data to reflect trends and changes in therapeutic interventions for cancer; whereas, data found in the literature had been collected and recorded for as long as 10 years.

Dr. Klausner announced that the NCI plans for a follow up to the White Paper issued in the spring will include an October meeting to discuss best practices and standards that relate to confidentiality and data management for clinical trials, surveillance, registries, and other areas. The Board will be notified when a meeting date has been confirmed.
Dr. Richard Boxer pointed out that partnering with the communities health care providers and facilities would be a valuable dissemination and education tool, and he suggested that the cancer centers should be urged to collect quality of care information as part of their cancer grant obligations.

Dr. Susan Love expressed the view that the focus should be on the lack of accountability rather than lack of knowledge and that physicians in the past have had no accountability outcomes. She emphasized the need for clinical trials data to support prevailing standards of care.

In other discussion it was noted, that the although physician education in more within the purview of other agencies, the NCI funds research in the behavioral area to review ways to change physicians' behavior. The NCI also is working with the Agency for Health Care Policy Research (AHCPR) in the area of research synthesis, and sponsors initiatives targeted to disseminating the results of research. There was discussion of the potential effectiveness of enlisting the help of professional societies in disseminating and implementing the NCPB report on quality of care and of the role the NCI effectively plays in bringing people and organizations together to work on common problems. The point was made that most of the data needed by physicians are obtainable but will require the resolution of technical issues related to cumbersome and expensive methods for data entry, such as manually or electronically filling out forms. In closing, Ms. Stovall called

attention to the report of the President's Cancer Panel synthesizing its findings from the 1998 series of hearings on cancer care issues.

PROGRESS REPORT OF THE NCAB SUBCOMMITTEE ON CODING FOR RESEARCH IN MINORITIES

Dr. Susan Sieber, Dr. Frederick Li

Dr. Susan Sieber, Associate Director for Special Projects, Office of the Director, NCI, and Dr. Frederick Li, Chief, Division of Cancer Epidemiology and Control, Dana Farber Cancer Institute, presented an update from the NCAB subcommittee appointed to review the process and terms NCI uses to estimate funds expected on research on ethnic/racial minorities. She noted that the IOM report on "The Unequal Burden of Cancer" described substantial disagreement between the level of funding for racial/ethnic minority records identified in the IOM report and NCI's assessment of dollars allocated for research on minorities. The Coding Subcommittee was appointed to assist in attempting to evaluate the source(s) of this disagreement. She stated that Dr. Li and she would report on the progress of the ad hoc subcommittee appointed at the previous NCAB meeting to help NCI understand the size and mix of its grants portfolio for minorities and underserved populations. The overall charge to the group was to advise the NCI on how to analyze the minority research portfolio. Specific tasks included: to produce key definitions, particularly for "relevant" and "targeted" as they are used in relation to minority research; consider how detailed an analysis should be conducted with regard to specific minority groups; and consider how to deal with large, multiproject grants (e.g., Specialized Programs of Research Excellence [SPORES] and program projects [P01s]) whose coding can substantially impact funding summaries.

Dr. Sieber then reported on committee process issues, noting that the subcommittee, in a series of telephone conferences, first addressed the task of developing definitions for "relevant" and "targeted" because of their importance to any coding that is done. The group also is generating recommendations related to defining "special populations" and identifying principles that should govern how projects are coded. Subcommittee members have engaged in the exercise of coding grants selected by the NCI as examples of important decisions or dilemmas that NCI coders commonly encounter. It was expected that these coding exercises would highlight areas that needed clarification and lead to specific coding guidelines.

Dr. Li presented an interim report for the subgroup that has been focusing on minorities as defined by race and ethnicity. Another NCI-led NIH-wide activity is beginning the task of defining "underserved" for purposes of grant coding. Dr. Li stated that the subcommittee arrived at modifications of what was generally understood to be the definitions of "targeted" and "relevant," namely, that whether a grant is coded as targeted or relevant should be determined on the basis of the research question, not just the subjects to be included. If the research is specifically focused on answering a question about an ethnic minority group(s) or differences among ethnic groups in the United States, it is considered to be targeted. "Relevant" would refer to projects that focus on issues, tumor types, or problems that differentially affect an ethnic minority group or

groups in the United States, but produce data that also are applicable to everybody. Dr. Li noted that both definitions rely heavily on the individual perception and judgment of the coders.

Dr. Li spoke next of the coding exercise initiated by Dr. Sieber to move the group's work from abstract discussion to reality. After coding a series of grants that previously had been coded by NCI Staff, the committee arrived at the following recommendations: projects conducted outside the United States should not be considered relevant or targeted to a U.S. ethnic minority, but rather should be categorized separately from domestic projects; and for grants that involve multiple subprojects, each subproject should be evaluated and coded independently. The subcommittee also recommended the establishment of a multiethnic category for grants involving more than one minority, racial, or ethnic group. Asked to comment as a member of the subcommittee, Dr. Norton emphasized the complexity of the coding process and noted that the subcommittee chose to use the scientifically definable term "ethnicity" rather than "race" for these activities. He pointed out that the scientific communities agree that "race" has no biologic meaning genetically or anthropologically. In response to a request from the Chair, Dr. Li stated that the committee would be prepared to report again in December.

Questions and Answers

In response to his question, Dr. Klausner was informed that the subcommittee had not yet dealt with the issue of how to estimate the dollar investment in SEER. This issue was added to the charge of the subcommittee. Dr. Klausner also requested that the subcommittee address the matter of coding and clinical trials, particularly in regard to the effort that is being made to reach proportional representation. Since the goal in coding is to move toward analyzing what mechanisms the NCI should invest in to answer questions, Dr. Klausner suggested that the course of action might be to invest in a surveillance system that addresses the issues of participation.

NEW BUSINESS—DR. J. MICHAEL BISHOP

As a first item of business, the Board continued the earlier discussion about possible actions by the Board in response to the NCPB report on quality of care standards. Dr. Norton proposed that a statement be sent to the Secretary, DHHS, to the effect that the NCAB endorses the recommendation of the NCPB on quality of care in cancer and calls to the Secretary's attention the need to define, assess, and require adherence to benchmarks that measure and monitor quality of care in the Medicare and Medicaid programs. In response to Dr. Li's concern that a submission to the Secretary prior to receiving all of the recommendations would be premature, Dr. Norton suggested it might also be appropriate to call upon the NCI to assemble a summit of the various parties that are working in this area and reach a uniform recommendation from those parties. This summit could return its findings to the Board, which could, in turn, act on the summit recommendation. After considerable discussion, the Board reached a consensus to act on Dr. Norton's first proposal.

Motion: A motion was made that the Board should write a letter to the Secretary, DHHS, stating that the NCAB endorses the recommendations of the NCPB on quality of care, and call specific attention to the issues of defining, assessing, and requiring adherence to benchmarks of quality in the Medicare and Medicaid programs. The motion was seconded and passed unanimously.

LEGISLATIVE REPORT
Ms. Dorothy Foellmer

Ms. Dorothy Foellmer, Director, Office of Legislation and Congressional Activities (OCLA), reported considerable Congressional interest during the current session in medical records privacy, funding for medical research, and quality of care and access to care issues. She reminded the Board that interest in the area of medical records privacy is a direct result of the Health Insurance Portability and Accountability Act of 1996. This Act requires Congress to enact comprehensive legislation to protect the confidentiality of individually identifiable health information by August 21, 1999. If Congress fails to act by this deadline, the Secretary of DHHS would be required to promulgate regulations by January 2000. Ms. Foellmer stated that it was unclear whether any legislation will be enacted by August 21. (No Congressional action was taken).

Because of the potential impact of pending legislation on access to data needed for health research, Ms. Foellmer briefed the Board on the similarities and differences in three medical records privacy bills before the Senate Committee on Health, Education, Labor and Pensions (formerly the Senate Committee on Labor and Human Resources): Medical Information Privacy and Security Act (S.573), Health Care Personal Information Nondisclosure Act (S. 578), and Medical Information Protection Act (S. 881). Ms. Foellmer stated that these bills are similar in that they are all geared to protect the confidentiality of personal medical records and health care-related information by ensuring access by individuals to their own information and by restricting further disclosure of the information by holders of the health information. Most of the bills have broad definitions of what is considered to be protected health information; in most cases, this can be read to include information that is produced in a research setting. Most would permit redisclosure for certain purposes such as emergency situations, protecting the life or safety of a patient, or law enforcement. Ms. Foellmer then outlined some of the differences between the bills, pointing out that controversial provisions in the bills are (1) the preemption of state laws, (2) what is considered to be personally identifiable, and (3) who has access and through what vehicle.

Regarding the current status of these bills, Ms. Foellmer noted that staff have been directed to consolidate them and produce one bill for markup and that an extension of the August 21 deadline appears to be the most likely outcome. She then reported on (1) the status of the provision attached to the FY 1999 omnibus appropriation bill that would require the Office of Management and Budget (OMB) to modify the directive regarding release of grantee data under the Freedom of Information Act and (2) the progress of FY 2000 appropriation bills and the potential for NIH funding that is lower than needs dictate, the latter because of cuts of 10–12 percent required to meet mandated spending limits.

NATIONAL CANCER STATISTICS UPDATE: TRENDS AND PERSPECTIVES

Dr. Barbara Rimer, Dr. Brenda Edwards

Dr. Barbara Rimer, Director, DCCPS, introduced Dr. Brenda K. Edwards, Associate Director, Cancer Surveillance Research Program, DCCPS, to review the overall trends in cancer incidence and mortality in the United States as reported in the "The Annual Report to the Nation on the Status of Cancer, 1973–1996, with a Special Section on Lung Cancer and Tobacco Smoking." This report, which was published on April 21, is developed and released collaboratively by the NCI, ACS, CDC, and National Center for Health Statistics (NCHS). Dr. Rimer commended Dr. Edwards and her staff for their work in preparing and analyzing these data and for their dedication to the U.S. and international cancer surveillance mission. She emphasized that NCI's commitment in this initiative not only to describe the trends, but also to understand them as a guide to further action. She noted, for example, that the data point to the need for more basic epidemiologic research in some cases, and to the need for behavioral prevention strategies in others.

Using graphs from the annual report, Dr. Edwards demonstrated the work being done to collect and analyze surveillance data and make it available in a number of ways to answer a variety of questions. She reminded the Board that the cancer mortality data, which are provided by the NCHS, are reported for the entire United States. Cancer incidence statistics, however, are from the NCI's SEER program's population-based registries and currently represent 14 percent of the U. S. population, including five full states and five metropolitan areas. Dr. Edwards stated that SEER statistics are used by the ACS as a basis for their annual predictions for new cancer cases and cancer deaths, which in 1999 were estimated at 1.2 million for the former and 560,000 for the latter.

Dr. Edwards presented statistics on trends that show declines from 1990 to 1996 of about 1 percent per year in cancer incidence and 0.6 percent per year in mortality that were true for most of the five major U.S. population groups. She demonstrated how these data can be analyzed further to show the different levels and burdens of cancer in males and females and differences in relative survival rates. Analyzing the data by looking at major cancer sites showed that the incidence of cancer in both males and females has declined in most of the major sites, the exceptions being non-Hodgkin's lymphoma (NHL) and melanoma for both sexes and lung cancer in females. Analyzing the data by sex and age showed declines in death rates across most age groups for both sexes, the exceptions being males older than 85 and females older than 65.

Next, Dr. Edwards reviewed the lung cancer statistics to illustrate how the annual report goes beyond presenting the overall cancer incidence picture to focus on major sites. Lung cancer accounts for 14 percent of all cases and 28 percent of all deaths. Categorized by sex, race and ethnicity, the data demonstrated great differences in the levels of lung cancer incidence and mortality across the five ethnic groups that have been reported, as well as declines in both incidence and mortality for males. Dr. Edwards noted that although the incidence and mortality rates for females are lower than for males, they continue to increase and are clearly a public health concern. She showed how the data on

lung cancer mortality rates by state can be color coded to give a graphic picture of what is happening across the nation for both sexes. To help characterize areas in the country with higher cancer rates than others, different parameters are being used. For example, a comparison of total lung cancer mortality data for Appalachia and the United States shows significantly higher rates for males in Appalachia; whereas, the overall rate for women is the same as for the total United States. When the data were analyzed by economic parameters, higher mortality rates were seen for both sexes living in economically distressed areas in Appalachia than in areas that were not economically distressed.

Dr. Edwards then demonstrated how the data can be analyzed to monitor the prevalence of major risk factors such as cigarette smoking. Using graphs of 1996 smoking data obtained from the Current Population Survey, she showed that the highest levels of smoking occur in Native American populations. She stated that many of those populations also are seeing dramatic increases in their lung cancer rates, notably Alaskan Natives. Dr. Edwards pointed out that the annual report also attempted to call attention to risk behaviors and smoking among high school students. Data on cigarette smoking prevalence were analyzed to show trends by sex for Whites, Blacks, and Hispanics from 1991 to 1997. Further analysis of the data on cigarette smoking suggested that smoking has not decreased among high school students and remains a major problem, particularly as the 1997 levels appear to be unacceptably high.

Dr. Edwards concluded the review of cancer surveillance statistics with a series of graphs that showed increases in incidence and mortality from 1990 to 1996, not only for NHL and melanoma, but also for kidney and liver cancer. These analyses also revealed very different rates among the five groups, for example, the high incidence of liver cancer among Asian Pacific Islanders and higher rates of melanoma in the White population. Dr. Edwards emphasized the importance of the significant increases in mortality in the five population groups across this reporting period. Annual increases of 1–3 percent were seen in many of the groups.

Next Dr. Edwards reviewed some problems that could be encountered in the area of statistics and data gathering as well as some of the new, exciting areas in which more surveillance activity will be done. Interest is moving toward the area of geospatial statistical techniques or geographical information systems (GIS). A potential challenge to the cancer surveillance effort was the issue of how to use data as much as possible even though the data reflected small numbers and high variability. The NCI is collaborating with the *Journal of the National Cancer Institute (JNCI)* and Oxford University Press on a pilot project to make surveillance data available electronically in *JNCI* articles. Work continues on statistical methods and modeling to devise new ways to estimate survival, measure prevalence, and extrapolate numbers to other areas or future years. Three other areas of challenge for the future include: (1) the need to begin to code deaths in 1999 according to the latest international classification of disease (ICD-10), which will have an impact on how surveillance data are reported; (2) the census in 2000 and self-reporting of racial/ethnic data, which may cause problems in data comparability and reporting; and (3) the change in age standardization to be used in all federal health data reporting. In regard

to the latter, Dr. Edwards reminded the Board that data reported by the NCI for the past few years have been age adjusted to the 1970 standard; whereas the NCHS has been using the 1940 standard. Dr. Edwards alerted the Board that cancer numbers will appear to be larger when the new government-wide standard is implemented, and she enlisted the aid of the Board in communicating the message that the higher numbers reflect a more modern way to report data, not a worsening cancer problem.

Questions and Answers

Dr. Amelie Ramirez asked if there were any plans for expanding the Hispanic database to cover the different Hispanic population groups. Dr. Edwards responded that several non-SEER registries have been identified that capture data on other Hispanic populations and a research working group in assessing the data and addressing problems of quality and misclassification.

Dr. Philip Schein inquired to what extent HIV patients contribute to the increased incidence of NHL. Dr. Edwards replied that all AIDS-related cancers are tabulated, although there is often a delay in reporting those data. Dr. Robert Wittes pointed out the increased incidence occurred over time and includes several different kinds, including B cell lymphoma and the demonstrably non-AIDS-related CNS lymphomas; therefore much of the increase is not related to the AIDS epidemic. Dr. Joseph Fraumeni added that the upturn in NHL incidence and mortality antedated the onset of the AIDS epidemic by several years and calculations show that roughly half of the increase in non-Hodgkins lymphoma is AIDS-related.

ADJOURNMENT OF OPEN SESSION
Dr. J. Michael Bishop

There being no further business, the open session of the 110th meeting of the National Cancer Advisory Board was adjourned at 3:32 p.m. on Tuesday, June 8, 1999.