NATIONAL CANCER INSTITUTE
NATIONAL CANCER ADVISORY BOARD
BETHESDA, MARYLAND

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The National Cancer Advisory Board (NCAB) convened for its 100th regular meeting at 8:30 a.m., November 19, 1996, in Building 31, C Wing, 6th Floor, Conference Room 10, National Institutes of Health.

LIST OF ATTENDEES

NCAB Members

Dr. Barbara K. Rimer (Chairperson)
Dr. J. Michael Bishop
Dr. Richard J. Boxer (absent)
Mrs. Zora K. Brown
Dr. Pelayo Correa
Dr. Robert W. Day
Dr. Kay Dickersin
Mrs. Barbara P. Gimbel
Dr. Alfred L. Goldson
Dr. Frederick P. Li
Dr. Sandra Millon-Underwood
Dr. Ivor Royston
Dr. Philip S. Schein
Dr. Phillip A. Sharp
Dr. Ellen V. Sigal
Ms. Ellen L. Stovall
Dr. Vainutis K. Vaitkevicius
Dr. Charles B. Wilson (absent)

President's Cancer Panel

Dr. Harold P. Freeman (Chairperson)
Dr. Paul Calabresi
Ms. Frances Visco

Alternate Ex Officio NCAB Members

Col. Louis F. Diehl, DoD
Dr. P.C. Srivastava, DOE
Ms. Sheila Newton, NIEHS
Dr. Hugh McKinnon, EPA
Dr. Marilyn A. Fingerhut, NIOSH
Ms. Rachel Levinson, OSTP
Dr. Alison Martin, FDA
Dr. Ralph Yodaiken, DOL
Dr. Lakshmi C. Mishra, CPSC

Members, Executive Committee, National Cancer Institute, NIH

Dr. Richard Klausner, Director, National Cancer Institute
Dr. Alan Rabson, Deputy Director, National Cancer Institute
Mr. Philip D. Amoruso, Associate Director for Extramural Administrative Management
Ms. MaryAnn Guerra, Associate Director for Intramural Administrative Management
Dr. Faye Austin, Director, Division of Cancer Biology; Chairperson, Extramural Advisory Board
Dr. Joseph Fraumeni, Director, Division of Cancer Epidemiology and Genetics
Dr. Peter Greenwald, Director, Division of Cancer Prevention and Control
Dr. Marvin Kalt, Director, Division of Extramural Activities
Dr. Robert Wittes, Director, Division of Cancer Treatment, Diagnosis, and Centers
Dr. Edison Liu, Director, Division of Clinical Sciences
Dr. George Vande Woude, External Advisor, Division of Basic Sciences; Director, Advanced BioScience Laboratories, Inc., NCI-Frederick Cancer Research and Development Center
Dr. Claude Klee, Chairperson, Intramural Advisory Board, Board of Scientific Counselors
Dr. Martin Abeloff, External Advisor and Co-Chair, Clinical Sciences Subcommittee A of the NCI Intramural Board of Scientific Counselors; Professor and Director, Johns Hopkins Oncology Center
Dr. David Livingston, External Advisor, Chairperson of the NCI Extramural Board of Scientific Advisors; Professor of Medicine, Dana-Farber Cancer Institute
Dr. Edward Harlow, External Advisor, Special Advisor, Office of Science Policy; Co-Chair, Basic Sciences Subcommittee B of the NCI Intramural Board of Scientific Counselors; Member, Massachusetts General Hospital
Dr. Alfred Knudson, External Advisor, Special Advisor to the NCI Division of Cancer Epidemiology and Genetics, Acting Director, Intramural Genetics Program; Senior ember, The Institute for Cancer Research, Fox Chase Cancer Center
Dr. Maureen O. Wilson, Executive Secretary of the President's Cancer Panel

Liaison Representatives

Dr. John Currie, American Association for Cancer Education
Dr. Edward Mirand, Association of American Cancer Institutes
Dr. Marc Lippman, American Association for Cancer Research

Dr. Robert Frelick, Association of Community Cancer Centers
Ms. Elaine Locke, American College of Obstetricians and Gynecologists
Dr. Eva Barak, National Science Foundation
Dr. Kathi Mooney, Oncology Nursing Society
Ms. Jean Ard, Leukemia Society of America
Mr. Thomas Brandt, Intercultural Council
Dr. Tracy Walton, National Medical Association
Ms. Kerrie Wilson, American Cancer Society
Ms. Laura Liebermann, Candlelighters Childhood Cancer Foundation

CALL TO ORDER, OPENING REMARKS, AND CONSIDERATION OF MINUTES OF PREVIOUS MEETING - DR. BARBARA RIMER

Dr. Barbara Rimer called to order the 100th meeting of the National Cancer Advisory Board (NCAB), and introduced guests representing cancer education and research associations and advocacy organizations. She invited members of the public to submit in writing, within 10 days, any comments regarding items discussed during the meeting. A motion was requested and made to approve the minutes of the September 1996 meeting. They were approved by the Board unanimously. Reporting on one action item from the September NCAB meeting, Dr. Rimer stated that she had written on behalf of the Board to Secretary Donna Shalala, Department of Health and Human Services (DHHS) about the Report of the Committee on Research Integrity. Final resolution on that report is pending. Dr. Rimer reminded members that this fourth and final NCAB meeting of the year is devoted to reviewing various aspects of National Cancer Institute (NCI) program operations.

FUTURE BOARD MEETING DATES—DR. BARBARA RIMER

Dr. Rimer called attention to the new date for the May 1998 meeting. She asked Board members to review the 1997 and 1998 meeting dates as listed and report any conflicts.

REPORT OF THE DIRECTOR, NATIONAL CANCER INSTITUTE - DR. RICHARD KLAUSNER

Dr. Richard Klausner reported that the NCI budget of $2.38B approved as part of the Omnibus Consolidated FY97 Appropriation Act represents a 6 percent increase, about $128M, over the FY96 appropriation. The National Institutes of Health (NIH) appropriations increased overall by 6.9 percent when the $90M targeted for the Clinical Center was included, and by 6.1 percent without the Clinical Center funds. Dr. Klausner stressed the importance of continuing to provide Congress with information and evidence that demonstrate that wise and careful scientific and administrative choices are being made, particularly with respect to involving many extramural communities in the planning and decision processes.

Decisions about the precise distribution of the NCI budget were not yet final. Dr. Klausner stated, however, that about $80M of the NCI's $128M increase for FY97 will be allocated to the extramural grants programs, intramural research will decrease as a precentage of the total NCI budget, representing approximately 17 percent of the NCI budget (compared with 20.8% in FY95), and the research management and support line will be flat. The latter had been reduced by 7 percent over the previous 2-year period.

Dr. Klausner next summarized FY97 projections for the Research Grant (RPG) pool, noting the 15 percent increase in dollars since 1995. The rate of growth for the RPG pool was about 8.2 percent compared with a growth rate of about 5.9 percent for the NCI over the same period. About $16 million will be dispersed through grant mechanisms other than R01s and P01s and will include an increase in training grants, support for the new K01 Temin Awards, and support for a new minority medical oncology program. A portion of the RPG pool will be held in reserve and used for funding exceptions.

Dr. Klausner reviewed the challenges in maintaining the different grants levels that have been committed to by the NCI. In 1996, the NCI was able to raise the percentile for R01 grants from the 15th to the 23rd percentile. Beginning projections for 1997 indicate a slight decrease to the 22nd percentile.

Many circumstances influenced the payline decision. First, raising the 1996 payline had increased the 1997 noncompeting requirements by $65M (9%). Second, a legislative requirement resulted in a $12M increase in the amount of monies awarded for Small Business Innovation Research (SBIRs) and Small Business Technology Transfer Research (STTRs). Third, the NIH tentatively agreed to forward fund or fully fund a certain number of grants in FY97. The NCI elected to allocate $25M to fully fund R29s (FIRST awards), thereby increasing by $20M the amount in the RPG pool earmarked for forward funding. The fourth influence on the FY97 percentile for R01s was the significant increase in grant submissions for R01s, R29s, and P01s compared with 1996 which raises the overall number of awards that would have to be made to reach the same percentile. For these reasons, the amount of money available for new and competing grants in FY97 was about $251M, a decrease of a little less than $10M.

Dr. Klausner reported that the NIH cost management plan for 1997 proposes that the competing cohort of grants be provided an average increase of 3.7 percent, more in line with inflation. In addition, the NCI has seen a significant increase in the number of grants being approved by the study sections; therefore, funding for the competing cohort was projected at an increase of 6 percent over the current levels.

Dr. Klausner stated that the NCI intends to fund as many or more P01s than were funded in 1996, but significant funding will come from the exceptions line because of uncertainties as to the number of grant submissions and their ratings. The 144 funded program projects represent 22 percent of NCI's RPG budget. In FY96, the number of new P01s increased by 28 percent, the majority of them in patient-oriented research.

The Accelerated Executive Review (AER) pool, which was about $6.7M in FY96, was expected to increase in FY97, reflecting a full year of funding. About 40 percent of the R01s received under the AER mechanism were for patient-oriented research, and about 40 percent of those were funded.

Dr. Klausner added that, under the NCI's new approach to exception grants, each division will be allocated a budget with the authority to make exception funding decisions on applications outside the payline for R29s, R21s, and R03 grants, as well as to make funding decisions to provide interim funding and administrative supplements without further

review by the Executive Committee (EC). In addition, divisions will be able to fund selected R01 grant exceptions outside the payline, provided the applications do not exceed $350,000 total direct costs for the first year and are within 10 percentile points of the payline. All other grant applications to be considered for exception fall outside the established payline and do not meet the above criteria will be brought to the EC.

Dr. Klausner reported that new programs and initiatives had emerged over the past year from the various working groups and through new planning processes that have been implemented in the NCI. As a result, it is expected that 10 concepts covering a broad range of topics were to be presented to the Board of Scientific Advisors (BSA) later in the week. Included were tobacco prevention initiatives in youth; chemoprevention initiatives aimed at genetically defined high-risk populations; the development of intermediate size Phase II/III trials for chemoprevention; new genetic approaches to the discovery, development, and diversification of natural products for drug discovery; the Cancer Genetics Network; AIDS oncology scientist development programs; and a series developmental diagnostics initiatives in the Cancer Genome Anatomy Project (CGAP). Dr. Klausner indicated that most of these initiatives, if approved, will be funded in the RPG line from funds held in reserve for that purpose as noted earlier.

Turning next to other initiatives, Dr. Klausner noted that the NCI has been reviewing its clinical trials agreements, such as the one with the Department of Defense (DoD). Although the infrastructure for those trials appeared to be strengthening, a less than optimal accrual rate persisted. To solve this problem, the NCI Office of Cancer Communications (OCC) developed an information and education plan to be implemented jointly with the DoD. In addition, the NCI is collaborating with the DoD and Rand Corporation to study the incremental clinical costs within this NCI-DoD system for individuals who enter clinical trials compared with those who do not. The NCI is also exploring the possibility of expanding the DoD agreement to cover Phase I, prevention, and diagnostic trials.

Dr. Klausner stated that the NCI has completed a second agreement with the Veterans Administration (VA) system. This agreement covers Phases I—IV of all trial types and intensifies and extends the integration that already exists between the VA system and the NCI clinical research and clinical trials system.

Other initiatives under way at the Institute were the review of clinical trials and the clinical trials programs of the NCI and extensive changes in the NCI AIDS program. Changes to the AIDS program included a redistribution in the use of funds that increased the percentage for extramural grants from 12 percent in 1995 to about 50 percent in 1996, increased funding to the AIDS Malignancy Consortium and AIDS Malignancy Bank for basic and translational research and clinical trials, and underwrote the development of about five AIDS oncology training programs at different cancer centers. Informatics have also been improved and databases linked.

Dr. Klausner reported the NCI decision to alter the nature of its extensive AIDS drug discovery program, a result of the review by intramural and extramural experts. Use of the cell based drug screen will cease as of January 1997, and a structure- and biology-based AIDS drug discovery program based upon the biologic, pharmacologic, biochemical, and genetic issues of resistance will be created.

Dr. Klausner also announced that the NCI will hold its first retreat for all principal investigators (PIs) in the Division of Clinical Sciences (DCS), Division of Basic Sciences (DBS), and Division of Cancer Epidemiology and Genetics (DCEG), during which each PI will present a poster. The goal is to discover ways to increase interactions across these intramural divisions. The NCI has been able to identify funds for which investigators within the intramural program can compete, especially for projects that interact across branch and division lines. Examples of the type of research envisioned are the DBS/DCEG project to develop a multivalent human papilloma virus (HPV) vaccine and the CGAP.

Dr. Klausner referred to progress that has been made in the development of the National Cancer Policy Board at the National Academy of Sciences. He suggested that the NCAB begin to prioritize requests and issues of policy concern that it would like that Board to address.

Dr. Klausner announced recent personnel recruitments. Dr. Donald Summers, University of California-Irvine, will be joining the restructured Office of the Director (OD), NCI, to provide oversight of the Frederick Cancer Research and Development Center (FCRDC); Dr. David Bragg, former NCAB member, will be joining the Division of Cancer Treatment, Diagnosis, and Centers (DCTDC) through the Intergovernment Personnel Act (IPA) to work on the restructuring and formation of a new diagnostic radiology program.

As a final item, Dr. Klausner presented highlights from the NCI analysis of U.S. cancer mortality rates based upon the 1994 and preliminary 1995 data from the National Center for Health Statistics (NCHS). The analysis was discussed in a joint press conference with the American Cancer Society (ACS) and the Centers for Disease Control and Prevention (CDC).

Dr. Klausner stated that the data demonstrated that the long rise in age-adjusted mortality rates in the United States appears to have plateaued and begun falling. The extent of the decline depends upon the standard used for age adjustment. The Surveillance Epidemiology and End Results Program (SEER) uses the 1970 population, but the NCI has also analyzed the data for every decade of age adjustment. For example, based on the 1970 adjustment, the overall mortality drop is 2.6 percent compared with a drop of less than 2 percent, if the 1990 adjustment is used. Dr. Klausner noted that the qualitative aspects of the conclusions are consistent regardless of the adjustment used, but the issue of how best to model age-adjustment standards should be revisited.

Highlights of the analysis based on the 1970 adjustment follow. Age-adjusted mortality increased by almost 6.5 percent for all ages from 1971 to 1990 but decreased by 2.6 percent from 1991 to 1995. For males, the drop was 4.3 percent versus the previous 7.8 percent increase, and for females, the drop was 1.1 percent versus a nearly 7 percent increase in the previous years. Broken down by age, the totals for males and females under 65 showed a drop of about 4.7 percent for the previous 20 years and 7.7 percent since 1991. Over age 65, there was a 15 percent increase in the previous 20 years and essentially no change since 1991.

Among African-Americans, a disproportionate excess remained in age-adjusted mortality compared with whites. However, in the 1971 to 1995 time period, the rate of decrease in mortality among African-Americans was greater for both men and women than for whites. In African-American males, age-adjusted mortality increased by about 30 percent from 1971 to 1990 and decreased by 8 percent from 1991 to 1996 according to these data. For white males, the previous increase was 6 percent and the drop, 3.6 percent. For African-American females, mortality increased by 12 percent before 1990 and decreased by 2.5 percent since then compared with almost no decrease for white females. Dr. Klausner noted that the gap in the mortality between African-Americans and white Americans could almost certainly close, if these trends continue as the numbers mathematically predict.

Dr. Klausner observed that the NCI should continue to issue an annual report card to the American people detailing specific progress or areas where there is no progress. Dr. Klausner emphasized the importance of learning why these changes are happening in different populations and for different sites.

REPORT OF THE DIRECTOR, NATIONAL CANCER INSTITUTE - QUESTIONS AND ANSWERS

Dr. Robert Day discussed the need to communicate that although the figures in this analysis are impressive, the number of cases of cancer continues to increase because of the aging population. Dr. Klausner agreed that all of his announcements and much press activity should and do attempt to make the numbers and their implications understandable. In addition to current strategies, NCI's Cancer Information Service (CIS) will work to find other methods to communicate this information.

In response to a question from Dr. Kay Dickersin, Dr. Klausner stated that the difference in mortality between African-Americans and whites has not yet been analyzed using the 1990 age adjustments. Analysis according to race and sites will continue and the information will be distributed to the Board.

Dr. Rimer asked how the newly developed research agenda of the National Prostate Coalition meshes with the NCI's agenda in this area. Dr. Klausner commented that the NCI has attempted to involve individuals throughout the community in its planning process. He emphasized the importance of speaking on research issues related to prostate cancer with some consonance as a complete community.

LEGISLATIVE UPDATE - MS. DOROTHY TISEVICH

Dr. Rimer asked Ms. Dorothy Tisevich to comment on the Kennedy-Kassebaum Bill, because of the perception that this legislation may solve the problems of access to genetic information. Ms. Tisevich observed that the Kennedy-Kassebaum bill appears to treat genetic information like medical information but the language does not go into the detail or afford the protection that separate bills would have provided. Many of those will be reintroduced in the 105th Congress.

Ms. Tisevich briefly reviewed the results of the recent election as they affect the makeup of the 105th Congress and by extrapolation the prospects for legislation of interest to the NCI in 1997.

Leadership and makeup of the committees that have jurisdiction over NCI programs have had few changes. Speculations are that Senator Ted Stevens (R-AK), who is regarded as a supporter of biomedical research, is expected to replace Senator Mark Hatfield (R-OR), retiring chairman of the full Senate Committee on Appropriations and who holds a seat on the Appropriations Subcommittee on Labor, Health and Human Services, and Education. On the House side, election results did not change the makeup of the appropriations subcommittee, but changes could occur when committee assignments are made. Ms. Tisevich commented that the NCI's authorizing committees will see rather significant changes in a few key positions.

In 1996, the NIH Revitalization Act was introduced and passed by the Senate but was not voted upon by the House. Representative Michael Bilirakis (R-FL) is expected to introduce similar legislation in the House in the 105th Congress. The reauthorization process renews expiring statutory authorities and provides an opportunity to extend, modify, and revise the existing authorities.

Ms. Tisevich gave a brief overview of legislation that is expected to be addressed in the upcoming 105th Congress. The One-Stop Shopping Bill to provide a central information resource for cancer patients to gain access to clinical trials was broadened to include all life-threatening diseases. A bill that was introduced by Senators John Rockefeller (D-WV) and Connie Mack (R-FL) would require that HCFA undertake a demonstration project in Medicare for access to cancer clinical trials for cancer patients. A genetic information bill (S.1898) introduced by Senator Pete Domenici (D-NM) in the 104th Congress provoked an outpouring of interest and concern on the part of the research community and the bill is being rewritten to reflect some of these concerns. This bill would have imposed a number of requirements on the use of any patient materials and tissues and caused concern that research would be slowed down. The final form of the revised bill is not yet known.

REPORT OF THE PRESIDENT'S CANCER PANEL - DR. HAROLD FREEMAN

Dr. Harold Freeman presented an update on the progress of the President's Cancer Panel (PCP) in addressing some significant issues related to managed care. The Panel has been concerned about the rapid growth of managed care and the potential impact on delivery of care to patients and on research. Managed care networks now deliver about one-half of all American healthcare. Approximately 33 percent of Medicaid and 10 percent of Medicare is covered under managed care. Furthermore, managed care organizations are tending to become for-profit.

As of November, the Panel has held three open meetings to address this topic, including regional meetings in Seattle, WA, San Antonio, TX, and Providence, RI. The fourth and final meeting was scheduled to be held in Raleigh, NC.

The Panel believes that issues affecting access to clinical trials of all types are important to address, because the ability to test findings on humans affects the progress of cancer science. Access to clinical trials appears to be a universal problem throughout the country, but testimony from patients and patient-care advocates differ from that of cancer center directors, both in San Antonio and in Providence. Cancer center directors indicate no problem accruing patients, but patient advocates told of difficulties in getting patients into trials. The Panel was concerned that eligible patients may not be admitted to a study, because their insurers will not reimburse for the cost of the trial. The Panel also noted that access to quality cancer care is directly related to the patients' intellectual ability and resources. Likewise, current decreases in insurance reimbursement are affecting the ability of healthcare institutions to provide care to uninsured and indigent patients.

In all regions visited so far, the Panel saw evidence that investigators are spending more and more time and energy getting patients into clinical trials, and support care people are spending an increasing amount of time getting people into the hospital for the trials. Other Panel concerns are the evidence that patients receive fragmented care at times and that for-profit managed care companies take money out of the medical care system and return nothing for research and development.

Of particular concern to the Panel was the testimony in both San Antonio and Providence that many managed care organizations are refusing to pay for standard patient care costs when patients are said to be on a research protocol even though managed care organizations would have had to pay anyway. The Panel also questioned the logic of the finding that managed care organizations are failing to reimburse for cancer care provided under Phase I and II trials, which have few patients and short duration, but are tending to support Phase III and IV, that are costly. Dr. Freeman noted that, according to Dr. Paul Calabresi, Rhode Island has passed legislation mandating coverage by insurers for certain Phase III and IV clinical trials, with apparently no financial impact.

Dr. Freeman reiterated the Panel's strong philosophical stance that the Nation cannot accept a healthcare system that allows the treatment of patients only if learning from their suffering does not take place. He cited this as a barrier to providing the best treatment to cancer patients as well as to translating research findings to the public in general. The Panel was firm in its belief that clinical trials represent an essential gateway to progress in the war against cancer and that the molecular biology revolution offers more opportunities for progress, which may not be used to its full advantage.

Based on testimony, the Panel assessed that research institutions, the pharmaceutical industry, and most likely, the government, are willing to share in the costs of clinical research, if their responsibilities are spelled out. The Panel was less certain that the insurance industry would be willing to play its part.

Dr. Freeman provided examples of recommendations included in the testimony heard to date: (1) that federal regulation of for-profit managed care may be appropriate; (2) that legislation mandate comprehensive cancer care coverage for children; (3) that support for clinical research could be made into an accreditation standard for managed care organizations; and (4) that more money should be made available for clinical research in general.

Dr. Freeman stated that, despite the many concerns, the Panel also recognized that managed care has succeeded in controlling costs. According to testimony heard in Rhode Island, the exploding cost of medical care in general has been the greatest threat to research. Most people, even managed care supporters, believe that a proactive approach is

needed to ensure that clinical research continues and that all Americans can continue to have access to clinical care.

Dr. Freeman highlighted areas of consensus resulting from the Panel meetings: (1) there are opportunities in managed care, but so far, costs reduction and a market-driven system have predominated; (2) there is evidence of perverse incentives for clinicians not to send patients into treatment; (3) there is evidence that the nation's academic health centers are threatened by this movement, and that the time faculty can devote to research is being reduced around the country; and (4) there is evidence that the for-profit, market-driven system, which is not putting in money into research, should be changed.

REPORT OF THE PRESIDENT'S CANCER PANEL - DR. HAROLD FREEMAN

Dr. Rimer announced that she has asked for a joint discussion between the NCAB and the PCP at the February meeting to digest some of the information and plan the next steps.

In response to a question from Dr. Michael Bishop, Dr. Klausner expressed the hope that the National Cancer Policy Board might want to address this difficult issue. He cited the anecdotal nature of the data as a problem to be faced in trying to make recommendations. A rigorous analysis of the data will be required.

OUTCOME OF THE NCAB RETREAT AND CHANGES IN SUBCOMMITTEE STRUCTURE - DR. BARBARA RIMER

Dr. Rimer reported that the Board at its June retreat and during discussion at the regular September meeting made progress toward achieving its goals. Roles and responsibilities for the NCAB were articulated in the areas of policy; secondary review of grants; stewardship and advisory oversight (to the Director and to Secretary Shalala); budget and planning; and advocacy.

The Board agreed that budget and planning, because of its importance should be a committee of the whole, with Dr. Ellen Sigal as the chairperson. The Planning and Budget Committee meeting will henceforth be held as an integral part of each NCAB meeting. In addition, the Board will continue to be an active participant in the budget bypass development process, and several members of the Board will serve on that committee.

The Board reached a consensus that the committee structure should be kept as flexible as possible, with fewer standing and more ad hoc committees, the latter depending on the needs of the time. At a minimum, the two standing committees will be Planning and Budget and Special Actions. Ad hoc or standing committee status is yet to be determined for Clinical Investigations and Cancer Centers. The Policy and Advocacy Committee is ad hoc at this time, and consideration will be given in the spring for some effort in the area of training. Procedures for proposing new subcommittees were also developed.

Dr. Rimer asked Dr. Marvin Kalt, Director, Division of Extramural Activities (DEA), to describe proposed changes in the procedures for the Board's secondary review of grants. Dr. Kalt noted that the first round of changes concentrate on those applications where Board consideration has a chance to make a difference. After a review of the NCAB grant books and the outcomes of applications actually funded, it was decided that the Board needed to receive only the first page of each of grant in the percentiles 1—15 unless there were human subjects, animal welfare, or individual concerns. The Board will receive full summary statements of applications from the 16th to 50th percentile in their own areas of responsibility, which they examine in detail. The Board will also receive the full summary statement of any application not percentiled or needing some special attention.

Dr. Kalt indicated that the second level of change promised to be more significant in the long term. A series of indexes by percentile and by area will be provided so that Board members have a readily available list to focus on, given the fact that the DEA sends Board books in sequence as the summary statements are prepared.

Regarding the third change, an electronic on-line Web-based system of summary statements available only to NCAB members will be tested beginning in February. This system will have free-text search capability and will enable individual Board members to execute their own sorts and gain access to summary statements of interest as soon as they are released electronically in the NIH system. These innovations will be evaluated during future grant review rounds to determine future directions.

PLANNING AND BUDGET SUBCOMMITTEE - DR. ELLEN SIGAL

Dr. Sigal chaired this portion of the NCAB meeting devoted to the Budget and Planning Subcommittee discussion of issues relating to the planning process. Specific areas of responsibility as defined by the Subcommittee are allocation/distribution of resources, monitoring or oversight, and exceptional funding and advocacy.

One area of oversight responsibility is the Bypass Budget, which is a scientific needs and opportunities budget developed on a 3-year cycle by the NCI. The Board decided on a 3-year cycle for its major review. An annual review will monitor the need to modify areas already defined, based on progress or some degree of reorientation, and to begin long-range planning for the new cycle. Yet to be addressed is the Board's role in terms of advocacy for the budget beyond the regular meetings.

Responses to Dr. Sigal's memo asking for new areas of extraordinary scientific opportunity focused on: (1) primary prevention; (2) education and training of clinical investigators; (3) translational research; (4) prevention and control curricula within colleges and professional schools and collaborative opportunities for faculty for the implementation of research; and (5) health services research. Dr. Sigal asked for additional recommendations, comments on those already submitted, and discussion as to how the recommendations can best be presented to the NCI Bypass Budget Committee according to the 3-year cycle.

Dr. Klausner emphasized the need to distinguish between extraordinary opportunities with criteria as articulated in the guidelines, and new initiatives, which have different criteria and are of a different magnitude.

Turning next to the NCAB's role in oversight of resource allocation and other budget issues, Dr. Sigal pointed out the need for members to have a clear understanding of the operational budget in preparation for substantive discussions during meetings. Dr. Klausner promised to provide for the February meeting a package of budget information divided across mechanisms and including numbers, dollars, and percentages.

PLANNING AND BUDGET SUBCOMMITTEE - QUESTIONS AND ANSWERS

In response to a comment from Dr. Bishop, Dr. Klausner agreed that help in thinking through how decisions are made in the RPG pool would be welcome, perhaps in the form of a subgroup of the Board

FY99 BYPASS PLANNING PROCEDURES - DR. EDWARD HARLOW

Dr. Edward Harlow called attention to the handbook developed in the Office of Science Policy (OSP) under the auspices of Dr. Klausner, which describes the Bypass Budget and outlines the iterative process for planning the Bypass Budget and for disseminating the information that is in the budget to the President, the Congress, and the American public. The general concept is that the Bypass Budget will be rewritten every 3 years, with annual updates or rewriting of major sections as dictated by changes.

Present plans call for a small committee made up of members of the NCAB and other agencies and the NCI leadership to begin to collect information on recommended opportunities about 2 years before the beginning of a new 3-year cycle (Spring 1998 for the FY99 rewrite). The planning committee then will be charged with developing an ordered priority list for Dr. Klausner to act on. Writing and production of the Bypass Budget document will be the final stages. Dr. Harlow solicited comments from the Board on the evolving planning process.

Dr. Harlow reported that a new concept called "immediate opportunities" is to be added to the latest Bypass Budget. The concept will identify initiatives to be taken on immediately or that may have been started in the past year.

Dr. Klausner pointed out that under this new concept, the Bypass Budget defines a request, not for a bigger budget than the general NCI budget, but for a budget plus a set of specific investments that can be argued to the American public, Congress, and the President. He emphasized the importance of recognizing that the vast bulk of NCI's budget and investments is not in the areas of extraordinary opportunities but in all other programs.

FY99 BYPASS PLANNING PROCEDURES - QUESTIONS AND ANSWERS

In response to a question from Dr. Ivor Royston about funding for new translational research initiatives, Dr. Klausner explained the difference between the maintenance and opportunities portion of the Bypass Budget. He noted that translational research will have to fit the specified criteria to be considered an extraordinary opportunity, but in his view translational research is totally integrated in the increases in both the maintenance and opportunities portions. He agreed, however, that translational research may need to be reevaluated to identify where it is happening.

Drs. Phillip Sharp and Kay Dickersin raised the issue that extraordinary needs brought on by a "sea change" in a national problem could be considered extraordinary opportunities. Dr. Klausner pointed out that an extraordinary need will undergo review based on the same criteria and will require the same set of milestones needed for new investments.

NCI PLANNING PRINCIPLES AND NCI PLANNING RETREAT SUMMARY OF ACTION ITEMS - DR. RICHARD KLAUSNER

Dr. Klausner presented an update on the October retreat at which the EC continued the development of a policies and procedures document for use within the Institute and for use by the NCAB in its execution of oversight responsibilities. Work on the document could not be completed because of the lengthy agenda and the amount of discussion it provoked.

Issues addressed during the retreat included evaluation; some aspects of planning; NCI financial management (formalizing the processes that the EC and divisions use to propose, format and allocate operating budgets); and coordination and communication within the Institute as a function of the OD.

Evaluation. The process for evaluating the quality of research being funded and how the laboratories are functioning depends on a variety of peer-review mechanisms and on two sets of quadrennial reviews. In regard to the latter, site visits of the Intramural Research Program (IRP) are conducted by the Board of Scientific Counselors (BSC), and reviews of division directors for both the IRP and Extramural Research Program (ERP) are conducted either by the BSC or the BSA.

Also discussed at the retreat was the possibility of instituting a mechanism for the quadrennial review of the ERP analogous to the operating path in place for the IRP. The BSA, the divisions, and each of the programs will work together to establish the size of the program that is to be reviewed, as well as the characteristics, criteria, expectations, and mechanisms of review tailored for each of the diverse ERP programs. Design of the review process will be the responsibility of ERP division directors in collaboration with the BSA. One final type of evaluation will be the annual review of the Director by the EC.

Four Aspects of Review. Because evaluation is integral to the planning process, the NCI divisions and programs will receive four types of review. Funding decisions relate to the nature of the review undergone by each component. Three of the four types of review are already in operation: (1) the quadrennial reviews of the IRP and ERP by the BSC or BSA to evaluate NCI's success in accomplishing what it sets out to do; (2) the Program review groups to evaluate how well major programs achieve major NCI objectives; and (3) the Working groups—"think tanks" aligned with bypass opportunities—to articulate new opportunities for implementation.

The fourth aspect of the review will be the NCI's evaluation of projects, needs, and opportunities in specific areas to be provided through a new mechanism called the Progress Review Groups (PRGs) that is being designed under the direction of Dr. Harlow.

A difficult aspect of planning for review is the integration required among the EC, NCAB, BSC, and BSA, to achieve an overall evaluation of the portfolio and to distribute funding among the varied areas of research. Part of the answer is the development of a robust scientific information system, which is under way. The operating principle in recent years for evaluating intramural versus extramural research has been a commitment to reduce the proportion of the total allocated to intramural research. But the current review and evaluation mechanisms are not designed to compare the balance between different mechanisms or deal with training issues. Dr. Klausner noted that the EC meets annually to discuss the progress of review groups and make decisions about terminating old groups or initiating new ones.

Financial Management and the Budget Formulation Process. Dr. Klausner explained that the EC is responsible for setting RPG parameters for implementing the budget as soon as legislation is enacted or as soon as a budget can be projected. The philosophy guiding the EC in this task is that other budget areas are to be built around NCI's goals for the RPG pool.

Each division then has the opportunity to create and bring new concepts for Request for Applications (RFAs) and Request for Proposals (RFPs) before the EC for approval and prioritization. After prioritization of new or significantly changed recompetitions, division directors formulate operating budgets and meet with the Director to defend them. A tentative budget is then assigned to each division subject to uncertainties as to amount of money freed from the RPG pool.

New research and development concepts, those being recompeted because of a change in scope, and new RFAs are subject to approval by the BSC or BSA. Standard procedures and format have been developed for each mechanism brought to the EC, BSC, or BSA.

Reorganization of the Office of the Director. Dr. Klausner reported that much discussion at the retreat focused on improving communication across the Institute—between the EC and NCI staff and within the EC—and new procedures have been established. As part of the solution to this problem, the OD also was reorganized to reflect its broad range of functions.

The guiding principle was the development of an infrastructure to enable the OD to function as a customer and service organization, providing service to NCI divisions, boards, and the public. To make the various components work well, the OD was organized into three teams that cluster to management, public policy, and information/informatics functions. Other OD components are the OSP and the NCI-FCRDC oversight office.

Three aspects of the new Liaison Office, which is part of the public policy team, are liaison with consumers, with all of the major professional societies, and with federal agencies like the CDC and the Food and Drug Administration (FDA) and organizations like the ACS. A newly organized Director's Consumer Liaison Group will develop standing relationships with consumers and advocates and provide a source of individuals to serve on committees.

As a final step in the reorganization, Dr. Klausner stated that Associate Director for Special Projects, Dr. Harford, will function as the chief of staff for the OD to link all components of the OD and ensure that the service functions work. He will represent the OD on the EC and serve as an interface between the Director and the different teams. Dr. Harford is also charged with presenting to the EC and the Director a plan for evaluating functionality to ensure that customer satisfaction is achieved.

NEW BUSINESS - DR. BARBARA RIMER

Dr. Rimer explained that the first new business session represented a chance to put items on the table for discussion on the second day of the meeting and at the February meeting. Agenda items already proposed are: a joint meeting with the PCP to plan the next step in the managed care discussions; a discussion with the head of the National Cancer Policy Board and Dr. Joseph Simone to identify potential policy issues to be addressed; a decision about how to include the Friends of Cancer Research (FOCR) on a future agenda; and a discussion of NCI's further analysis of the latest cancer survival statistics and the initiatives that are planned.

INTERCULTURAL CANCER COUNCIL COCHAIR REMARKS - DR. LOVELL JONES

Dr. Lovell Jones described the Intercultural Cancer Council (ICC) mission as involving every segment of the population to reduce the higher incidence, suffering and death from cancer among minority, culturally diverse, and medically underserved populations. The ICC has a broad-based membership, representing many minority organizations, as well as, leading mainstream anticancer groups. Members include physicians, researchers, survivors, and community-based health professionals.

For the ICC and for institutions like the NCI, the challenge is how to sort most effectively through the issues that contribute to these cancer disparities and structure activities to address these issues. Research is needed to address the lack of essential baseline data concerning the causes of disproportionate cancer rate among many minorities.

Discussions with NCI staff about the issue of cancer and minorities and what needs to be done led to the institution of the Biennial Symposium Series, and subsequently to the organization of the ICC. In April 1997, the Sixth Biennial Symposium on Minorities, the Medically Underserved, and Cancer will be held in Washington, D.C.

Although the ICC has only been in existence for about 18 months, it has been able to attract attention to the issues surrounding cancer and the medically underserved, including coverage in the print media, professional society publications, and the Congressional Record.

ICC activities over the past year included a meeting with Dr. Klausner to discuss collaborations to address these issues. The ICC also undertook programs to educate members of Congress and recommend legislation. One outcome of these efforts was legislation to fund a study by the Institute of Medicine (IOM), which was signed into law in September. The legislation provides sufficient funds for the IOM to conduct a one-time review of the status of research into cancer among minorities and the medically underserved at the various Institutes, centers and divisions of the NIH over the past 5-10 years. The legislation also calls for the establishment of a mechanism for an annual report on the status of NIH cancer research in those areas, but the ICC recommends a 3-year evaluation to coincide with NIH authorization legislative cycle. IOM officials are working now with the NIH and the NCI to organize the study with plans to have the final report ready for Congress by January 1998, in time for that year's legislative cycle.

In another initiative, ICC is working with the President's Cancer Panel to organize an evaluation of the SEER data (NCI), the National Cancer Data Base (ACS/American College of Surgeons), the Behavioral Research Factor Survey (CDC/National Center for Health Statistics (NCHS)), and the National Ambulatory Data Base (CDC/NCHS). The review conducted by the Joint Commission for Data Review will focus on the accuracy and comprehensiveness of the data on all minority groups.

Dr. Jones briefly summarized ICC beliefs on the status of American efforts and future directions in the struggle against cancer. Dr. Jones pointed out the although the SEER data analysis indicates a decline in cancer morbidity and mortality, the validity of this decline must be determined. He described the sense of complacency that the NCI report has engendered among community-based organizations--primarily African-American--in several cities and advised caution in how the data are presented and portrayed in terms of how people respond to it the data.

Dr. Jones next discussed profitable directions in cancer research for the future: focusing policy and resources on those cancers with the highest incidence of mortality in special populations; greater minority participation as PIs, researchers, and decision-makers; full integration of survivors in all cancer programs; treatment delivery that achieves cultural competence among healthcare providers serving minority communities; greater minority enrollment in clinical trials; and programs to educate minority scientists and physicians at multiple levels from elementary school on. In conclusion, Dr. Jones emphasized the importance of cancer prevention and treatment research as it affects minorities on humane and equitable grounds, as well as for its impact on the economics of healthcare.

CANCER CENTERS PROGRAM REVIEW GROUP REPORT - DR. JOSEPH SIMONE AND DR. ROBERT WITTES

Dr. Klausner commended the Cancer Centers Program Review Group report as fulfilling the objectives of describing the elements of a robust and responsive Cancer Centers Program and evaluating the goals and processes in a way that the NCI could begin to act on these issues. Input from the NCAB and the BSA will be sought to guide the development of a new set of guidelines, which are expected to become operative early in the new year.

Dr. Simone stated the Review Group organized its review according to five categories: 1) background and opportunities for the future; 2) structure and function of centers; 3) review criteria, process of review, and guidelines; 4) distribution and use of centers' funds; and 5) centers as regional and national resources.

The Group considered the rapidly advancing state-of-the-science, changing healthcare environment, and some review and management processes as challenges and opportunities for the centers. The goals specified in Cancer Center Support Grants (CCSG) were considered appropriate: to facilitate excellent cancer research and promote collaboration among all institutional cancer disciplines. The Review Group believes centers should have a substantial, broad portfolio of peer-reviewed cancer-focused research in place and that the core grant should produce added value to the cancer research effort and not serve as the initiator of a base of cancer-related activities.

Dr. Simone explained that principles guiding the development of the Cancer Centers Report were to develop a process for reviewing the added value that the CCSG provides scientifically and to provide increased flexibility and accountability—both financially and programmatically—for the cancer center director and how cancer centers are run.

Dr. Robert Wittes, Director of the DCTDC, then reported on the status of the Institute's response to the Report. The Institute's response will take the form of a set of rewritten guidelines that will describe the philosophy that underlies the program, together with a section devoted to the actual policies and procedures for submitting and reviewing the grant. Early drafts of the new guidelines have been circulated for comments to a few Group members and center directors concerning overall direction, and helpful responses have been received. Development of the new guidelines will be an interactive process between the NCI and the community as represented by the Review Group, with the goal of ensuring that the Cancer Centers Program reflects the philosophy and tone of the report.

Dr. Wittes enumerated the NCI's response at this time to the 22 specific recommendations in the Cancer Centers Report, noting that those responses will undergird development of the guidelines document. A February deadline is targeted for NCAB review of the final version of the guidelines so that grants coming in for the June 1 deadline can be submitted in accord with the new guidelines.

Dr. Wittes first listed 16 of the 22 recommendations that the NCI could agree to implement straightforwardly. He then addressed the six recommendations that will require thought and assistance from the NCAB. They were related to changes in the review process, use of developmental funds for interim support for training, development of a rigorous merit-based system for funding centers, and addition of the word "research" to all center designations

Dr. Day expressed the view that CCSGs evolved apart from much of the thrust of the Cancer Centers Program, that they are indeed a support grant and should be regarded as such. He firmly endorsed scientific excellence and productivity as the only criteria by which centers should be judged. Speaking in his capacity as chair of the NCAB Subcommittee on Cancer Centers, Dr. Day added that the Subcommittee, in the past and recently, has adopted the 20 percent NCI support as the cap level.

Dr. Bishop assessed the report as having spoken effectively to his longstanding concerns about the Cancer Centers Program. He asked whether the Review Group had heard evidence that the Centers Program has fulfilled a special function and been worth the effort. Dr. Sharp and Dr. Simone confirmed that official testimony and informal information gathering witnessed to the fact that the CCSG enabled centers to promote and develop cancer-related research programs that would not have been possible otherwise.

Dr. Bishop questioned the claim that centers are a defense against managed care, even while asserting that the individual CCSG budgets are small and the designation as "research" centers is deleterious because of managed care. He lauded the emphasis on science over process and the expanded definition of population research. His third point related to the issue of research versus healthcare delivery. He strongly favored retaining the term "research" in the designations to signal that these are research centers based on their goals and functions, and on legislative expectations.

Dr. Philip Schein commented that cancer centers—particularly those designated comprehensive—had a broader sense of mission than the view articulated in the report, which could create a gap between discovery and translation in the public health policy. He called for a more explicit description of the communication process, and he reiterated his concern about the future viability of clinical cancer research centers, if that designation is discontinued as a separate category for funding.

Ms. Ellen Stovall stressed the need to ensure that the report does not, by default, endorse the status quo in terms of distribution. She favored retaining "research" in the designation and that the Board and the NCI work together to better communicate the benefits of research and the fact that research becomes tangible when applied to people.

Dr. Vainutis Vaitkevicius added that the report maximizes the ability to do more and better research but is silent about how to address accessibility.

Dr. Pelayo Correa stated that the report does not offer much that will help centers expand their role regionally, and suggested that making funds for development available in the R03 grant pool will put the centers on a more equal footing. Cancer centers should also share the mission of the NCI in all areas, including population-based research, epidemiology, and behavioral research, which are presently underrepresented in the Centers program as a whole. Dr. Correa also noted that planning grants are a valuable part of the program and help to raise the standard of research in communities, help communities to recruit researchers, and benefit science in general, even if they do not culminate in a P30 grant.

Dr. Royston argued against combining the designations for clinical and basic science research centers as recommended in the report.

Dr. Simone addressed some of the concerns expressed by NCAB members. He stated that the Review Group did discuss geography and came to the conclusion that proximity to a cancer center does not guarantee excellence in cancer care. Moreover, specifying the requirements of a geographic mandate will present problems. The Group's interpretation was that access to information, protocols, or clinical research could be made available through the network of CCOPs and cooperative groups around the country. In response to Dr. Royston's question, Dr. Simone pointed out that one reason for reducing the number of designations was to provide an opportunity for a broader array of types of centers to develop. In laying a map for the next 10 years, the Review Group attempted to remain open to novel approaches because the origins of advances in cancer diagnosis and care are not known.

Dr. Rimer asked Board members to submit particular concerns in writing to Dr. Day, who will be formulating the

Board's response to the report, and to Dr. Wittes, who will be developing guidelines for implementing the recommendations. Dr. Wittes asked for discussion of the points of uncertainty that he had outlined, including the whole matter of funding. He also asked that the Board agree to review guidelines in tandem with the NCI as successive drafts are developed. Dr. Correa moved approval of the Cancer Centers Report in principle but asked the chair to appoint an ad hoc group to work on issues of concern such as mission. The motion was seconded and approved.

COORDINATION OF ADVISORY COMMITTEE ACTIVITIES AND INTRAMURAL REVIEW - THE OFFICE OF ADVISORY ACTIVITIES - DR. MARVIN KALT AND DR. ROBERT HAMMOND

Dr. Kalt explained that the Bishop-Calabresi report's recommendations to improve the oversight and structure of the Intramural Program of NCI laid the groundwork for separating the management of the intramural review process from the intramural divisions. The responsibility for the oversight of that review was given to the DEA, and the advisory board structure was changed. At the same time, the Office of Advisory Activities (OAA), with Dr. Robert Hammond as chief, was created within the DEA to coordinate the reviews.

Dr. Hammond reported that OAA's oversight extends to the research of individual PIs and to the leadership of laboratories and branches in the IRP. Site visits are conducted by the BSC-A for the DCS and the DCEG; and the BSC-B, for the DBS.

Following the recommendations in the Bishop-Calabresi report, clear guidelines for the site visit review process and criteria for review were developed and codified in a document entitled The Intramural Organization and Principles Handbook. Changes to the manual will be made only with input from the Intramural Advisory Board (IAB) representing the PIs, along with the EC, and the BSC.

Dr. Hammond summarized the four principles guiding development of the guidelines: 1) review oversight is independent of the division under review; 2) the review is PI-based in that the tenured PI has responsibility for the administration of resources and justification for the research performed; 3) reviewers make explicit recommendations for resource allocation; and 4) criteria are specific to intramural review. In regard to the latter, the intramural review process encompasses a PI's entire research portfolio over a period of time. The reviewers focus on two major areas: the scientific merit of the proposed projects; and the quality of past research and--related accomplishments. The evaluation should reflect the PI's overall accomplishment in the field and overall capacity to do innovative research.

Besides responsibility for the intramural review process, the OAA facilitates linkages across the various Boards, working groups, and panels to assure synthesis and integration of overall activities. It also serves in an advisory capacity to other staff and units assigned to conduct similar types of advisory functions--for example, the working groups and program review groups--to assure the proper conduct of meetings, documentation, and coordination of such activities. Other functions involve tracking prospectively in terms of outcomes and advice to the Institute. Future efforts include working with the OSP to develop a Web-based calendar and scheduling system.

COORDINATION OF ADVISORY COMMITTEE ACTIVITIES AND INTRAMURAL REVIEW - THE OFFICE OF ADVISORY ACTIVITIES - QUESTIONS AND ANSWERS

In response to a request for clarification, Dr. Hammond explained that site visits contain elements of both prospective and retrospective review. More weight is accorded to the prospective review in the case of a new investigator without a long track record; a seasoned investigator would have more of a retrospective review. A question also was asked about budget levels. Dr. Hammond explained that the BSC makes budget recommendations for individual PIs and for the overall branch to the division director but does not set the budget.

MEETING OF OFFICE OF CANCER SURVIVORSHIP - DR. ANNA MEADOWS

In introducing Dr. Anna Meadows, Dr. Klausner reiterated his commitment to address the large number of very important questions that can only be addressed by research into the whole range of issues under the rubric of survivorship. He reported that Dr. Meadows, head of the new NCI Office of Cancer Survivorship (OCS), chaired a recent meeting to begin the articulation of a research agenda for the NCI in the broad area of cancer survivorship.

To indicate the extent of the problem, Dr. Meadows noted that about seven million persons are considered long-term survivors of cancer, with 5 or more years since diagnosis. For research purposes, it was agreed that the NCI will focus on individuals off therapy at least 2 years from their diagnosis. To determine the best treatment strategies, the NCI will need to balance risks and benefits. Research will be necessary to determine the outcomes of treatment for survivors; the medical facilities needed for follow up; the kind of surveillance required; how available medical systems comply with their needs; intervention and education programs; strategies for the prevention of additional cancers; and basic mechanisms of the disease.

Dr. Meadows listed federal agencies, scientific organizations, and advocacy groups represented by the 50 persons in attendance at the meeting. Seven groups worked in small sessions to discuss the available databases, necessary infrastructure, and target populations; quality-of-life issues such as what limits quality-of-life and how limitations can be addressed; medical or physiological outcomes; economic outcomes, the cost to both patients and society; reproductive and sexual problems; and second cancers, including use of advances in genetics research. Dr. Meadows observed that research for many of these issues must have the goal of quantifying the results of treatment, not merely describing them; therefore, researchers with the ability to work across many disciplines must be identified.

A final challenge is to develop strategies for communicating research findings, providing intervention to modify behavior, and improve the quality-of-life. Cancer survivors as a group can be used as a model for learning about effective educational and communication processes, which can also be applied to other population groups.

Dr. Meadows summarized the task before the OCS as prioritizing these questions and information needs to form a research agenda, examining the existing NCI and NIH review processes to make them more amenable to grant applications for survivor research, and identifying clinical research expertise in the diversity of disciplines needed for patient-oriented research. Dr. Meadows closed with a challenge to the Board to help decide how great the effort will be for this research.

MEETING OF OFFICE OF CANCER SURVIVORSHIP - QUESTIONS AND ANSWERS

Dr. Klausner called for comment from Ms. Stovall and Dr. Frederick Li, who participated in the meeting. Dr. Li assessed the meeting as productive, but pointed out that the meeting has raised the expectations of survivorship groups. Dr. Li acknowledged the obstacles that exist including the need for prioritization of the long list of activities and identification of funding. Beyond research, the information must be made useful and applicable to increase and improve the quality-of-life for cancer survivors. Ms. Stovall observed that this type of effort has been a fervent hope of advocacy organizations since their founding. She agreed that the agenda is huge and much is yet to be done. She joined others in anticipating information on funding.

Dr. Klausner reported that he has asked for a written report of the recommendations and priorities, to which the Institute will respond with a prioritized plan for funding. He observed that two types of recommendations were discussed. One was the need for fundamental changes in NCI's infrastructure and databases and alterations in how large-scale trials are approached. The second type involves a large number of more specific research questions and projects.

Dr. Ralph Yodaiken asked if an NCI Web site specifically for survivors had been considered. Dr. Meadows pointed out that only validated information can be included on a Web site and many research questions remain. A subgroup of the Supportive Care Board of Physician's Data Query (PDQ) is looking into survivorship information for the Web.

Dr. Dickersin cautioned that care should be taken in prioritizing items on the research agenda because survivorship encompasses a huge range of topics. She also recommended that survivorship research involves a different approach and as such requires bringing new people and new structures into the process.

Referring to new survival statistics which suggest substantial increases, Dr. Schein recommended addressing issues such as mitigating the chronic toxicity of modalities that are currently available to manage cancer successfully. This is vital for adults, but may be more so for pediatric patients.

Mrs. Zora Brown applauded the fact that the myths and anecdotes around the survivorship of African-Americans are beginning to dissolve, for example, ascribing the increased mortality for African-American women to poverty and access to service. She suggested as an agenda item, research to use the finding of a possible biological difference to begin to look at cancer as it affects African-Americans.

Col. Louis Diehl suggested a collaboration between the advocacy groups and cooperative groups to do a retrospective analysis of outcomes in 20-year survivors, particularly in the breast cancer, Hodgkin's, and non-Hodgkin's databases.

In summary, Dr. Rimer commented that a number of opportunities and challenges have been identified, as well as a number of Board members who would be interested in working with the OCS.

NEW INITIATIVES WITHIN THE INTRAMURAL PROGRAM - DR. EDISON LIU

Dr. Klausner introduced Dr. Edison Liu, Director of the DCS, to discuss plans for reorganization of the division in general and the Clinical Center in particular. Dr. Liu stated that the overall problem identified during his early review of the DCS was that although the Nation has a unique resource in the intramural clinical program and excellent individuals, the infrastructure was not optimal for the actualization of clinical translational research. The reorganization promotes the divisional principles of scientific excellence, programmatic integration, and concentration on cancers with the greatest public health concerns.

After reviewing the structure, function, and budgets of the major branches and interviewing individual scientists, an Adult Medicine retreat was held to discuss goals, similarities, and future directions. An advisory committee of intramural and extramural advisors was convened to assist in developing the plans, and the proposed structure was presented to the BSC for approval. The principles of the reorganization mirrored the overall principles of the division: organize units to maximize programmatic unity; organize structure to be flexible in scope and membership to permit a competition of ideas and individuals; and establish incentives for cross-program interactions to acknowledge and foster clinical as well as basic science expertise.

In the current DCS structure, four branches--Navy Medicine, Medicine, Biomarkers/Prevention, and Clinical Pharmacology--were coalesced into a new, larger Medicine Branch with Dr. Carmen Allegra as chief. Two components--the Oncology Training Program and Clinical Investigations Group--cut across all the departments and operate under the direction of the chief to provide the clinical unity. Individuals within the four former branches were reorganized to conceptual units according to the mission statement: Immunology/Experimental Transplantation, Cell and Cancer Biology, Genetics, and Developmental Therapeutics. Scientific direction resides in the individual departments and the Office of the Chief serves as a facilitator, not a director of the science.

DCS clinical directions include coordinated programs in breast, prostate, and gastrointestinal cancers; neuro-oncology; and transplantation. Problems to be addressed in implementing the new organizational structure are inadequate laboratory space to house investigators recruited for the new programs, inconsistent senior scientific mentoring, limited programmatic flexibility at the division level, lack of programmatic unity, and questions about clinician/scientist and tenure. Dr. Liu noted that he plans to ask the BSC members to assist in the mentoring of investigators by reviewing and critiquing their science.

The new budgetary concepts to be implemented are term-limited resources and base resources. These involve establishing a comfortable resource base for investigators to begin with and then providing intramural research fund awards for which they can compete.

NEW INITIATIVES WITHIN THE INTRAMURAL PROGRAM - QUESTIONS AND ANSWERS

Ms. Frances Visco noted the absence of consumer representation on the advisory committee and urged attention to this detail for future reference. She asked if Dr. Liu had explored the fundamental question of whether there should be an Intramural Program. Dr. Liu stated that this question was thoroughly explored and the conclusion was reached that there is a place for an intramural division that is clinically based.

Dr. Royston observed that medical oncology, including experimental oncology, has rapidly become an outpatient practice, and he asked how the Clinical Center was going to operate relative to that practice. Dr. Liu noted that a process was in place before his arrival which, where practical, shifted inpatient care to a type of intermediate and outpatient care. One ward was converted successfully to a day situation, and the plans are to move further in that direction. Other projects to be pursued will require considerable inpatient care, especially the expanding transplantation programs.

Dr. Sigal asked what opportunities for contact and work with extramural investigators have been built into the DCS program. Dr. Liu briefly described programs to be developed, including a structure by which intramural and extramural investigators can use NCI's clinical resource, to try out ideas that cannot be vetted extramurally.

CANCER GENOME ANATOMY PROJECT (CGAP) - DR. RICHARD KLAUSNER AND DR. SHEILA TAUBE

Dr. Klausner reminded the Board that the CGAP was a major initiative that evolved from the deliberations of the Developmental Diagnostics Working Group. This group was convened to help the NCI determine how to accelerate the development of molecular information about cancer and how to use that information to change the process of discovery and the choice of therapy.

The CGAP is based on the knowledge that cancer arises, develops, and is predisposed by the accumulation of changes, and the expression of genetic information, and the behavior of any cancer is written in the molecular fingerprint. The project deals with two issues: 1) to define cancer at the molecular level, in terms of the complete molecular fingerprint, and 2) to access and interpret the information in any particular cell or individual once the complete index of possibilities is known.

CGAP goals are to define genetic differences between cancer cells and non-cancer cells, define the impact of these differences on gene expression, and define the cellular pathways and networks affected by altered gene expression to discover the behavior of tumors. This new approach promises to affect many aspects of the fight against cancer, including detection (e.g., potential biomarkers), diagnosis, prognosis, treatment, and prevention.

Dr. Klausner explained that the first step developed by the NCI as recommended by the Working Group was to create and make accessible to everyone as complete an index as possible of all expressed genes from any cell--cancer, precancer, or normal. To implement this part of the plan, a 2-year program has been designed to integrate NCI components and collaborate with other institutes, federal agencies, and institutions to attempt to sequence approximately 1,000,000 clones at the rate of 10,000 a week, using the laser microdissection technique.

Collections of well-documented libraries will be created, first of all, for the most common cancers (e.g., prostate, breast, colon, lung) and their normal counterparts. The goal will be to create standardized approaches to the creation and documentation of the libraries. All documentation will be on the NCI Cancer Genome Anatomy Web site, which is being created with the National Library of Medicine (NLM). These libraries will be sent to large-scale sequencing facilities for full-insert sequences, which will be put immediately in the public database and become available for use by everyone.

In collaboration with the Department of Energy (DOE), these libraries also will be made publicly available through arraying procedures in the form of index arrays. Progress already made includes demonstrating that the microdissection works to develop high-quality libraries, developing arraying procedures, and developing the nomenclature for using the libraries.

Dr. Klausner discussed problems related to interpreting the information in cancer cells, for example, differences in comparing DNA content across the genome from a normal cell and a cancer cell from that normal tissue. He noted that technologies must be developed which will provide all the potential information and then make it possible to access, read, and coordinate that information to discern signal from noise and relevant, informative genes from gene products.

Dr. Klausner briefly described high throughput technologies that will be needed, such as array technologies and silicon chips capable of holding as many as 256K DNA sequences that can be read automatically. The silicon chip can be read for sequence changes, if the object is to screen for genetic predispositions or changes, but more importantly, it can be used to identify biomarkers that will be expressed or mirrored in patterns of changes of genes.

In summary, Dr. Klausner noted that the first part of this project--assembling the libraries, making them available for dissemination to the community, arraying and sequencing them—will cost an estimated $7M to $8M over 2 years. Funding is being arranged in a collaboration with the DOE and other institutes. Some pharmaceutical and large biotechnology companies also have agreed to co-fund parts of this project. The object is to expedite development of this information and make it available in the public domain where it can spur further research in developmental diagnostics.

Dr. Klausner introduced Dr. Sheila Taube to present initiatives planned and underway to exploit the opportunities presented by the CGAP and to describe the goals and activities planned for the second phase.

Dr. Taube described the two components of this developmental diagnostic project as the CGAP, a discovery phase in which the necessary information and technology are being developed and the Cancer Clinical Applications Project (CCAP), an applications phase in which the tools will be developed and tested for their value in clinical translation.

A series of initiatives is planned to encourage and facilitate the development of these technologies for gene discovery. The first concepts--one dealing with technologies for development of full-length cDNA libraries and another for development of novel technologies for evaluation of molecular alterations in tissue--were to be presented to the BSA later in the week. These concepts, if approved, would be publicized in time to use FY97 funds.

Other initiatives under consideration for the CGAP are mechanisms to assure that new tools, technologies, and devices are made accessible to the scientific community. As reagents and devices are identified that will facilitate cancer biology research, the NCI plans to solicit their production and make them available to researchers.

To promote communication and ensure that progress is made in these areas, a workshop is planned for early 1997 to bring together members of the clinical cancer research community and industry and representatives from agencies such as the FDA and the National Institute of Standards and Technology (NIST).

A Program Announcement (PA) to be published in the NIH Guide will solicit program project applications for the development of high throughput technologies to detect alterations in tumor specimens. An initiative under consideration will establish groups of investigators focused on development of new diagnostic devices, similar in concept to the drug discovery groups. The objective of these groups will be to further stimulate the development of applications of new technologies to meet specific clinical needs.

Recognizing that the validation of these new techniques will depend on the availability of tumor specimens with requisite clinical information, the Developmental Diagnostics Working Group met recently to discuss collection and distribution of tissue specimens. The several issues that emerged were: identifying the available resources; helping to link investigators to existing resources; addressing human subjects regulatory issues; and developing a dynamic system to anticipate specimen needs.

To anticipate the need for new resources as science and technologies change, the Resources Development Branch was instituted as part of the Cancer Diagnosis Program in DCTDC. Dr. Taube noted that specific plans will be reported to the Board periodically.

CANCER GENOME ANATOMY PROJECT (CGAP) - QUESTIONS AND ANSWERS

Dr. Sharp reiterated his question about the relationship between this program, the Human Genome Initiative, and the other institutes. Dr. Klausner noted that the plan is being developed in collaboration with Dr. Collins and the Genome Center. The decision to proceed was considered vital to NCI's discovery program and the NCI will take the lead and collaborate with the other institutes.

Dr. Harold Varmus, Director of the NIH, added that other institute directors also are addressing similar issues that have to do with mutations that underlie disease or changes that reflect pathology or genetic background as it influences the choice of target organs with degenerative disease and response to inherited mutations. Many schemes that affect asthma, heart failure, and infectious diseases are being pursued by many other institutes. Information from all of these sources is being fed into and curated by the National Bioinformation Center under Dr. David Lipman, and this is dramatically affecting the ability of various institutes to share information of fundamental interest. Furthermore, the fact that some of the research is being done in mice, rats, and other organisms is influencing the ability of institutes to work in a coordinated, synergistic fashion.

Dr. Sharp questioned the fact that genomic typing is not slated for earlier development, because it provides a better foundation for diagnostic and predictive tools. Dr. Klausner pointed out that the initial solicitation for program projects explicitly calls for throughput technologies aimed at DNA, RNA, and protein.

Ms. Sheila Newton reported that the National Institute of Environmental Health Sciences (NIEHS) has initiated preliminary discussions about an environmental genome project with some of the same goals. Genomic instability is a big factor. She suggested the need for communication between the NIEHS and the NCI.

BOARD OF SCIENTIFIC COUNSELORS ACTIVITIES (BSC) - DR. MATTHEW SCHARFF

Dr. Matthew Scharff, newly appointed chair of the BSC Subcommittee B, stated that the role of the BSC had been described in the presentation about the new intramural review process, and the outcomes of recent site visits were presented in closed session. What was not mentioned was the enormity of the undertaking. The DBS has 33 laboratories with 187 PIs or tenure-track investigators, all of whom are to be reviewed every 4 years.

Dr. Scharff pointed out that the process for intramural review had been developed before BSC-B was organized. It is being implemented by staff in the OAA and OD, DBS. The single most important change in the review process is that site visitors and the committee are required to recommend continuation or discontinuation of projects or increases or decreases in resources. Site visitors are forced to make specific judgments as a basis for these explicit recommendations. In a second major change, each PI meets privately with the whole site visit committee or a subgroup. This provides the PIs an opportunity to discuss their science, but more importantly, they can express feelings about a number of other topics related to their particular laboratories, the leadership, and career prospects.

Dr. Scharff made the third point that the reports of the site visit committees and responses of the laboratories and individual investigators receive careful review and evaluation when they are presented to the appropriate BSC. Recommendations that result from the site visit receive formal comment before the BSC as a whole reaches its conclusion. An opportunity is also provided to present a minority report.

Dr. Scharff briefly listed the BSC-B membership and pointed out that appointments are staggered to ensure a natural rotation. He added that the workload is heavy and creates a problem in maintaining attendance. The first of the three meetings held since the two new BSCs were organized was a joint meeting for orientation and a review of recommendations made by the interim board.

During the second meeting, BSC-B reviewed the site visit reports for 4 laboratories with 19 PIs, including 5 investigators who were on the tenure track and one person who had been nominated for a tenure appointment. During the third meeting, another 4 laboratories were reviewed with 13 PIs, 6 of whom were tenure track. The BSC-B also acted on rereviews of two investigators. The Board met with the IAB to evaluate the review process and decide whether changes could or should be made to improve the process. Much of substance was discussed, and the decision was made to hold such a meeting annually.

Dr. Scharff briefly listed the laboratories scheduled for review in 1997, 1998, 1999, and 2000. He assessed the new review process as excellent and the site visits as proceeding very well. He pointed out, however, that the task is enormous and creates a problem in recruiting enough expert site visitors.

BOARD OF SCIENTIFIC ADVISORS ACTIVITIES (BSA) - DR. DAVID LIVINGSTON

Dr. David Livingston reported that the BSA has begun to become acquainted with the operations and leadership of each of the five extramural units for which the BSA provides oversight.

During the meeting scheduled later in the week, the BSA will review, discuss, and begin to comment on the report of the Cancer Centers Review Group and the NCI response. The BSA is also participating with the NCAB in the oversight of the Cancer Prevention, Clinical Trials, and Cancer Control and Behavioral Science Review Groups. Another activity to begin in the coming months is the review of the Drug Development Program.

In another new initiative, teams of BSA members and senior NCI leadership will be attending national meetings of groups that, in the aggregate, represent the majority of NCI grantees. The team will hold special sessions to hear commentary from members of the groups and respond to questions. In 1998, a BSA/NCI team will hold a session at the biennial Cancer Genetics and Tumor Suppressor Genes meeting in Cold Spring Harbor. Results of these meetings will be reported to the NCAB and to the NCI EC.

Dr. Livingston reported that a subcommittee of the BSA has developed procedures for reviewing concepts for proposed RFAs and contracts to ensure that BSA members have enough information to vote on them. The new procedures were to be tested on eight RFA concepts scheduled for presentation to the BSA the following day.

As noted, the extramural NCI divisions and their directors and the Office of the Director will be undergoing quadrennial reviews of their performance. Review of the extramural components and personnel is the responsibility of the BSA. During the coming months, a subcommittee composed of selected BSA members and NCI Division Directors will be engaged in formulating review procedures that will eventually become official procedures of the Institute.

DISCUSSION OF BSC AND BSA ACTIVITIES AND INTERFACE WITH NCAB

Dr. Rimer asked the Drs. Scharff and Livingston to comment on how the BSC and BSA review and analysis of the Cancer Centers Review Group report compares with that of the NCAB. Dr. Livingston commented that the BSA hopes to integrate its analysis with those of the BSC and NCAB to produce one comprehensive report.

Dr. Sharp asked whether the divisional reviews will include the portfolios of extramural research or just in-house operations. Dr. Livingston expressed the opinion that the review will be as comprehensive as possible. Areas needing clarification or improvement will receive more indepth scrutiny. Dr. Sharp recommended that the NCAB routinely receive abstract summaries of the reviews and the BSA or BSC recommendations on a laboratory-by-laboratory basis. Dr. Alan Rabson concurred that this could be done after the reviews have been presented to the appropriate BSC or BSA.

Dr. Day asked whether the Intramural Program and the extramural grant portfolio were integrated in any way, for example, by comparing the extramural support in that same general area of research and determining how that relates to the Intramural Program. Dr. Scharff pointed out that the intramural reviews are conducted by extramural people, who are addressing the issue of the quality of research in the context of the whole area as they see it. A second aspect of the review is to determine how individual PIs are integrating or communicating with other basic and clinical scientists in the Intramural Program and whether they have collaborations with extramural investigators.

Dr. Livingston added that the Clinical Trials and Prevention Review Groups are addressing questions related to linkages between intramural and extramural research. Similar questions will be addressed in the quadrennial reviews with the idea of building ever tighter links between intramural and extramural excellences. Dr. Rabson added that coordination of the intramural and extramural research is regularly addressed by the EC.

POLICY AND ADVOCACY SUBCOMMITTEE REPORT - DR. KAY DICKERSIN

Dr. Dickersin reported that the subcommittee attempted to clarify the roles of the NCAB and the new Subcommittee as well as the difference between policy and advocacy. The Subcommittee also dealt with the issue of whether policy and advocacy should be linked. As a result of this meeting, brief statements will be prepared describing what the Subcommittee thinks will be the purpose of policy within the NCAB and an advocacy subcommittee or the advocacy role.

Dr. Dickersin reported that the Subcommittee also discussed with Dr. Klausner the role of the NCAB versus the new National Cancer Policy Board. It was decided that the NCAB will interact with the National Cancer Policy Board about topics to be considered. To that end, the co-chairs have been invited to the February meeting to address topics of long standing and recent concern to the NCAB.

A motion was made and seconded to approve the minutes of the Ad Hoc Subcommittee on Policy/Advocacy. The minutes were approved.

CLINICAL INVESTIGATIONS SUBCOMMITTEE REPORT - DR. PHILIP SCHEIN

Dr. Schein reported that the Subcommittee followed up on a discussion of its previous meeting with intentions to define a specific item for the proposed Bypass Budget. After a brief review of the PCP meeting in Providence, the Subcommittee discussed specific problems facing translational research from many perspectives. The Subcommittee believed this situation should be recognized in the Bypass Budget.

Dr. Klausner gave an overview of NCI efforts to foster translational research. The Subcommittee also considered the improving P01 situation and long-term ramifications for translational research, the disincentives to enroll in clinical trials, and the need to redirect funding to innovative translational research.

After careful scrutiny of the current Bypass Budget, the committee proposed to modify Opportunity 5, entitled, "Investigator-Initiated Research: A Discovery Engine" to add emphasis within this general category to translational research. The proposed wording will be submitted to the Planning and Budget Subcommittee for review.

A motion was made and seconded to approve the minutes of the Subcommittee on Clinical Investigations. The minutes were approved.

25TH ANNIVERSARY ACTIVITIES - DR. ELLEN SIGAL

Dr. Sigal briefly reviewed the progress being made in the observances marking the 25th anniversary of the NCI and her role as NCAB liaison with FOCR.

Plans are under way for events to be held at cancer centers with senators and representatives from those geographic areas. The events will emphasize the anniversary, public education, accomplishments in the 25-year war on cancer, and tasks that lie ahead. Other events featuring House and Senate leaders and Secretary Shalala are in the discussion stage.

One February event is scheduled in Hollywood, CA, with special guest Ms. Sherry Lansing, President of Paramount Studios. Dr. Klausner will speak about cancer research and how the Hollywood community can help get the message about cancer to the American people through movie and television programming. The observances will culminate on Capitol Hill in March or April.

In addition to the special events, the planning committee has been working with editorial boards to disseminate the message through the media. The message articulates the complexity of cancer as a disease and the challenges that lie ahead, as well as, publicizing accomplishments. The NCI kits have been distributed to all the cancer centers to encourage them to educate their constituencies, the public, local media, and survivors' groups.

NEW BUSINESS II - DR. BARBARA RIMER

Dr. Rimer announced that Dr. Sandra Millon-Underwood, Mrs. Barbara Gimbel, Mrs. Zora Brown, and Dr. Vaitkevicius will serve as part of a group to examine the cancer communications effort in response to the request for assistance from Dr. Klausner.

Dr. Kalt referred to the earlier discussion about coordination of the various advisory boards, and he announced the creation of one additional coordinating body to be called the Advisory Committee to the Director, NCI. The committee will be made up of the chair of the NCAB, and the chairs and co-chairs of the BSA and BSC. Two meetings a year are anticipated.

AIDS MALIGNANCIES PROGRAM REVIEW GROUP UPDATE - DR. ALAN RABSON AND DR. ELLEN FEIGAL

Dr. Rabson reviewed the background of the AIDS Malignancy Program. Soon after Drs. Klausner and Rabson assumed their new offices, they began to address forcefully the disproportional distribution of AIDS money within the Institute between the extramural RPG pool and intramural research. In 1995, the NCI was allocating $27M to extramural grants through the RPG and $104M to intramural research, within one year. This was rebalanced to emphasize extramural approaches, resulting in FY96 figures of $87M and $67M, respectively.

After an extensive review and with help from the newly released NIH Office of AIDS Research (OAR) Levine Report outlining priority areas for AIDS research, Dr. Klausner identified AIDS-related malignancies as a valid and important area for emphasis by the NCI. The decision was made to expand that program and Dr. Feigal, a member of the NCI Cancer Therapy Evaluation Program (CTEP), was named to head it. Dr. Rabson serves as the NCI's AIDS coordinator.

Dr. Feigal prefaced her presentation by saying that although the NCI has been involved in many facets of AIDS and AIDS malignancy research since the beginning of the AIDS epidemic in the 1980s, clinical research received no significant NCI extramural funding until recently. She reviewed the development of an AIDS Malignancy Program in clinical research from 1992 to the present. Milestones include collaborations with the National Institute of Allergy and Infectious Diseases (NIAID) to coordinate clinical trials, formation of the National Task Force on AIDS Malignancies, creation of the AIDS Malignancy Bank, the AIDS Malignancy Consortium, and the AIDS Malignancy Working Group.

The AIDS Malignancy Bank serves as a repository for tumor tissue, relevant biological fluids, and clinical and demographic data for use by the entire research community. Three main member institutions were funded and later expanded to 5, with 30 affiliated sites. By November 1995, the banks began operations. External review panels were formed to review proposals for using the specimens from this bank. Three cycles of proposals are reviewed each year. Progress from the first cycle of researchers using the bank will be reviewed in December 1996. Plans for future activities include tracking the types of research being pursued with tissue from the bank and publications.

Another initiative involves a set aside of additional funding within the cooperative group line to encourage investigators in NCI's Clinical Trials Cooperative Groups to pursue research in AIDS malignancies. Although the amounts set aside in 1994, 1995, and 1996 were relatively modest, adult and pediatric groups have been able to begin research activities in this area.

In 1995, the AIDS Malignancy Consortium was created to promote the conduct of early-phase developmental studies, particularly those that require laboratory-intensive investigations. This was done through the RFA mechanism and 14 cooperative agreements (U01) were given to 14 main member sites. Progress after 1 year of operation includes three active clinical trials within the consortium.

In 1996, the interdisciplinary AIDS Malignancy Working Group was formed of scientists from across the NIH and from the extramural community. The goal was to promote preclinical studies in basic biology, virology, and immunology that could foster the development of translational research that would eventually go into clinical trials. One outcome of the early meetings was the NCI Handbook on Resources in AIDS and AIDS Malignancies, which summarizes broad research questions, major findings and highlights, numbers of grants funded, and NCI contacts for investigators wanting to become involved with any of the research. Another initiative was an administrative supplement to cancer centers to fund research projects involving interaction with Centers for AIDS Research or AIDS Clinical Trials Units. Applications in response were received from 38 centers for more than 200 projects and approximately one-third of those applications received supplemental 1-year funding. A third initiative was the development of a concept for an RFA in the area of AIDS/oncology clinical research training to be presented to the BSA at its November meeting. The fourth activity of the Working Group will be the NCI-sponsored National AIDS Malignancy Conference to be held in April 1997. The 3-day conference will showcase research in AIDS or related areas that might have significance for AIDS malignancies.

AIDS MALIGNANCIES PROGRAM REVIEW GROUP UPDATE - QUESTIONS AND ANSWERS

Dr. Royston asked if the incidence of AIDS malignancy has changed because the number of HIV patients going on double or triple drug therapy has increased. Dr. Feigal responded that NCI and NIAID divisions will be interacting to follow the epidemiology of the disease, but it is too early to form conclusions.

INTEGRATION OF BIOTECHNOLOGY DEVELOPMENT INTO NCI PROGRAMS - DR. ROBERT STRAUSBERG AND DR. CAROL DAHL

Dr. Klausner introduced Drs. Carol Dahl and Robert Strausberg to present their vision on the integration of technology development into NCI programs. Most recently, both headed technology development programs at the National Center for Human Genome Research (NCHGR) and began interacting with the NCI as members of the Developmental Diagnostics Working Group. They moved to the NCI to support the new initiatives in technology as heads of the newly established Strategic Technologies Office (STO) in the OSP.

Dr. Strausberg briefly touched on his and Dr. Dahl's backgrounds and role in technology development at the NCHGR. Success in the Human Genome Project depended on a substantial technology development effort preceded by careful planning and the formation of interdisciplinary research teams that were not necessarily familiar with the NIH system. Also needed was a strong interface with academia, industry, and government.

In their 5 years on the Human Genome Project, Drs. Strausberg and Dahl worked as facilitators and integrators of technology development with the user community. This included explaining NCHGR needs to the technology developers and deciding whether there was an interface between their developing technologies and NCHGR technology needs. For the NCI, the task will be interfacing technology with the needs of basic and clinical cancer researchers.

Dr. Strausberg noted Dr. Klausner's vision that progress in cancer research should not be limited to access to supporting technologies. This vision served as a foundation for the establishment of the STO at the NCI headed by Dr. Strausberg and Dr. Dahl. The charge to this Office is to address the technological needs of the NCI research by increasing access to existing and developing technologies, stimulating and supporting the development of critical technologies for cancer research and preparing for future needs in technological development.

Dr. Dahl continued the presentation with examples of specific activities of the STO to promote the integration of biotechnology or technology development in general into NCI research programs. This effort will involve a partnership of the whole of the NCI and the cancer research community, and the STO is working to become the focal point for those who are seeking technologic assistance and those who are developing technologies but are not familiar with the NCI and NIH operations.

Dr. Dahl described specific activities to identify technologies, beginning with involvement with the Working Groups to identify relevant new technologies in the near-term and help them focus on future directions and needs to ensure that the technology is available to address particular questions. The STO has been reaching out to the cancer community to see what technologies are available, communicating NCI's interest in gaining access to their technologies, and helping to forge liaisons. Examples of this effort were the presentations by Drs. Strausberg and Dahl at the Gene Function Analysis and Genome II meetings. The STO is also working to identify new relevant technologies in other government agencies and industry through participation in activities such as the Advanced Technology Program and the Tools for DNA Diagnostics Program, which Drs. Strausberg and Dahl are co-managing, and through meetings with representatives of a variety of industries.

Dr. Dahl reviewed STO efforts to facilitate technology implementation, include interacting with the DCS to gain information on the division's needs based on new objectives, discussions describing the range of available technologies, and assisting the division scientists in forging the liaisons necessary to bring them in house. The STO is also attempting to build a partnership with extramural investigators by talking to various groups such as the chairs of the Clinical Trials Cooperative Groups and the Intergroup Rhabdomyosarcoma Study Group. In that regard, Dr. Strausberg chaired a meeting in Boston that was arranged to promote liaisons between clinical investigators and developers of technology.

Dr. Dahl discussed issued related to stimulating and supporting technology development to support NCI's needs. She reviewed the limitations and barriers to receiving NIH support for technology development, including unfamiliarity with the NIH peer-review system, and the fact that technology development is dollar intensive and not hypothesis driven. The NCI's action to address this problem was the creation of the Strategic Technology Task Force headed by

Drs. Strausberg and Dahl and Ms. Jo Anne Goodnight, Special Assistant for Program Coordination, DCB. This group is scheduled to report in January to the EC with specific recommendations for removing impediments and approaching technology development in a more supportive fashion.

Regarding the final charge to the STO--preparing for future needs--Dr. Dahl pointed out the three aspects of the task: assessing future needs, sharing the technology challenges and opportunities with the technology development community, and then identifying cross-cutting leveraging technologies for the future that can be recruited into NCI's portfolio of technologies that can be used in cancer research. One excellent source for ideas about future needs is the Working Groups. Other ideas can be gathered by surveying the industrial perspective on where companies perceive technology as moving, and STO staff have begun dialogues with industrial representatives by attending industry-oriented meetings and by going directly to the various companies. Close collaboration with other government agencies can also aid in identifying emerging technologies for the future.

Dr. Dahl noted that assessment of future needs will require involvement of NCI's entire staff, as well as the extramural research community in thinking about what will be needed in the future. She views the STO role as being the focal point of information from all sources and ensuring that the communicated future needs are included in the planning process. A stronger interface between cancer researchers and developers of technology is important to ensure that the technologies coming out are robust and suitable for clinical application and research.

Dr. Klausner added that the STO will focus on the whole spectrum of discovery, including communication and therapeutics technology to rehabilitation issues and behavioral or population-based sciences.

ADJOURNMENT--DR. BARBARA RIMER

There being no further business, Dr. Rimer adjourned the open session of the 100th meeting of the NCAB at 12:15 p.m.