

National Institutes of Health

National Cancer Institute

NATIONAL CANCER ADVISORY BOARD

Summary of Meeting
November 29-December 1, 1982
Building 31
Conference Room 6
National Institutes of Health
Bethesda, Maryland

Department of Health and Human Services
Public Health Service
National Institutes of Health
National Cancer Advisory Board

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The National Cancer Advisory Board (NCAB) convened its 44th regular meeting at 8:30 a.m., November 29, 1982, in Conference Room 6, C Wing, Building 31, National Institutes of Health (NIH), Bethesda, Maryland. Dr. Tim Lee Carter, Chairman, presided.

Board Members Present

Mr. Richard A. Bloch
Mrs. Angel Bradley
Dr. Victor Braren
Dr. Tim Lee Carter
Dr. Robert C. Hickey
Dr. Geza J. Jako
Dr. Joseph G. Katterhagen
Mrs. Rose Kushner
Dr. LaSalle D. Leffall
Dr. William E. Powers
Dr. Janet D. Rowley
Mr. Morris M. Schrier

President's Cancer Panel

Dr. Harold Amos
Dr. William P. Longmire, Jr.

Ex Officio Members

Dr. Robert Brandt, Labor
Dr. William Farland, EPA
Dr. F. Kash Mostofi, DOD
Dr. David P. Rall, NIEHS

Absent

Dr. Ed L. Calhoon
Dr. Maureen M. Henderson
Ann Landers
Mr. Sheldon W. Samuels
Dr. Irving J. Selikoff
Dr. Armand Hammer, Chairman,
President's Cancer Panel

Liaison Representatives

Dr. John S. Cook, Program Director, Cell Biology, National Science Foundation, Washington, D.C., representing the National Science Foundation.

Mr. Alan C. Davis, Vice President for Governmental Relations, American Cancer Society, New York, New York, representing the American Cancer Society.

Dr. Virgil Loeb, Jr., Professor of Clinical Medicine, Washington University, St. Louis, Missouri, representing the American Association for Cancer Research and the American Society of Clinical Oncology, Inc.

Dr. John F. Potter, Director, Lombardi Cancer Center, Washington, D.C., representing the Society of Oncology, Inc., and the American College of Surgeons.

Members, Executive Committee, National Cancer Institute

Dr. Vincent T. DeVita, Jr., Director, National Cancer Institute
Dr. Richard H. Adamson, Director, Division of Cancer Cause and Prevention
Mr. Philip Amoruso, Executive Officer, National Cancer Institute
Mrs. Barbara S. Bynum, Director, Division of Extramural Activities
Dr. Bruce Chabner, Director, Division of Cancer Treatment
Dr. Peter J. Fischinger, Associate Director, National Cancer Institute
Dr. Peter Greenwald, Director, Division of Resources, Centers, and Community Activities
Dr. Jane Henney, Deputy Director, National Cancer Institute
Dr. Alan S. Rabson, Director, Division of Cancer Biology and Diagnosis

In addition to NCI staff members, meeting participants, and guests, 20 registered members of the public attended the meeting.

I. Call to Order--Dr. Tim Lee Carter

Dr. Carter called the meeting to order and welcomed Board members, guests, and other attendees. He announced that Dr. Armand Hammer has been reappointed as Chairman of the President's Cancer Panel for 1 year, effective October 5, 1982. Noting the full schedule, he turned the meeting over to Dr. DeVita for a presentation on the Protocol Data Query (PDQ) system.

II. Introduction to the Protocol Data Query System--Dr. Vincent T. DeVita, Jr.

Opening Remarks

Dr. DeVita welcomed Mr. Richard Bloch to his first Board meeting, noting that Mr. Bloch had played a major role in the initiation of the PDQ system. He also announced that Dr. Robert Gallo of the National Cancer Institute (NCI) was one of five viral oncologists awarded a Lasker Award for Medical Research in recognition of his work in the discovery of oncogenes in human tissue and the first human T-cell lymphoma virus. Two other NIH scientists, Dr. Roscoe Brady and Dr. Elizabeth Neufeld, were awarded the clinical prize for their work in viral oncology. The current meeting was described as a mix of science and program review. The agenda included reports from all of the NCI Division Directors and Chairmen of the divisional Boards of Scientific Counselors (BSC) as well as scientific reports on certain areas of NCI research activities. The Board would hear reports on NCI's oncogene program that afternoon during its tour of the Frederick Cancer Research Facility (FCRF).

PDQ Presentation

The PDQ system is a new computerized data base being developed by NCI as part of the International Cancer Research Data Bank (ICRDB) program. PDQ is one of four data bases offered by ICRDB; the others are CANCERLIT, CANCER-PROJ, and CLINPROT. PDQ is essentially a modification of the CLINPROT file, which contains detailed information about active cancer treatment protocols in the United States and in other countries. PDQ is organized in a geographic matrix--that is, information is entered in the file by geographic area, making the system more usable. The major purpose of the PDQ system is to make current, state-of-the-art cancer treatment more immediately available to cancer patients throughout the United States by linking patients and physicians who may not be familiar with current cancer treatments to appropriate specialists and treatment facilities.

The PDQ system is organized in two parts: PDQ-1 and PDQ-2. PDQ-1 was opened on October 1 and is now available to professionals through the National Library of Medicine's MEDLARS System. When it opened, the data base contained over 700 active protocols; 641 additional programs (including 255 foreign protocols) have been identified and are in the process of being added to the file. Estimates are that within a few months, the data base will contain some 1,341 programs, including both NCI-supported and non-NCI-supported programs. Protocol file entries include the names and telephone numbers of contact persons and investigators, cross-referenced by cancer site, treatment plan, and location, as well as protocol objectives and criteria for entry of patients.

When completed in mid-1983, PDQ-1 also will contain the names of cancer specialists, organized geographically by specialty (e.g., radiotherapists, medical oncologists), state-of-the-art statements giving the range of treatment for every type of cancer, and references to relevant journal articles in the CANCERLIT file. Other data bases, such as CANCERLIT and CANCERPROJ, will be accessible, along with hard-copy printouts of their files.

PDQ-2 will contain all of the information in the PDQ-1 file in an interactive format that will include the disease structure and treatment alternatives by tumor type, subtype, and stage of disease. The file also will include broad statements regarding treatment options for every type of cancer. PDQ-2 was described as a conversion of PDQ-1 into a "user-cordial" format. Both PDQ-1 and PDQ-2 are expected to be completed and ready for implementation by July 1983.

An NCI Editorial Board, chaired by Dr. William DeWys, will review the PDQ data structure and interactive format, state-of-the-art statements, and all submitted protocols not sponsored by NCI. The PDQ file can be instantaneously modified and will be updated regularly. Several unresolved issues relating to the system were pointed out, such as its availability to patients and the general public, and whether to offer the system through commercial online services. It was suggested that these issues be discussed at a later Board meeting when PDQ-1 and PDQ-2 will be nearer completion.

Discussion

Several Board members expressed concern that the lists of cancer specialists to be included on the PDQ system be verified for accuracy and completeness with the appropriate professional societies. NCI staff members are working with professional groups to draw up the lists, and NCI is prepared to have medical societies examine the lists before the names are entered on PDQ. Further, NCI plans to write to all physicians to be included in the file for permission for such inclusion. NCI has discussed the program with the American Cancer Society (ACS) and American Medical Association (AMA) and will meet with AMA representatives in December. A suggestion was made that the issue of patient access could be approached "step by step," and that it might be wise to introduce the system to professionals before "going public." NCI will make the system available to community programs and may promote it in medical journals.

A demonstration of the PDQ system was conducted by Dr. Robert J. Esterhay, Special Assistant for PDQ.

III. Introduction to the Oncogene Program at the Frederick Cancer Research Facility--Dr. Peter Fischinger

The presentation at the FCRF included the following reports:

- Retroviruses and Oncogenes--Dr. Stuart Aaronson
- Cellular Transforming Genes--Dr. Mariano Barbacid
- Structure and Function of Transforming Proteins--Dr. Stephen Oroszlan

- Oncogenes and Recombinant DNA Technology--Dr. Thomas Silhavy
- Summary and Future Plans--Dr. Peter Fischinger.

IV. The Organ System Program--Dr. William E. Powers

Dr. Powers introduced the following motion:

"That those organ system grants that have been previously reviewed by the appropriate review committees and subsequently reviewed by the National Cancer Advisory Board with a priority score better than 185 (later modified to 180) be paid."

The motion was seconded by Dr. Braren. The vote on the motion was 7 For, 2 Opposed.

Discussion

This resolution concerned Organ System Program grants with priority scores within the range approved for funding by the Board at its October meeting but not funded by NCI. Dr. DeVita explained that funds allocated to the Organ System Program for 1982 were not sufficient to cover these grants. The amount of money involved for grants covered by the resolution was determined to be \$2.08 million, which would have to come from the FY 1983 budget. It was noted that the percentage of funded grants in the Organ System Program was the same (31 percent) as those in the regular grants programs and that this action by the Board would reverse funding priorities established by NCI in conjunction with NCAB. Dr. Rowley pointed out that the Board did not have equivalent information about other grant programs, such as the PO1 and RO1 grants, and therefore was not in a position to determine whether the funds might not be better spent for other types of "skipped-over" grants. Concern was also expressed about where the \$2 million would be found, the effect on other programs, and the question of different pay lines for different NCI grant programs. Dr. Powers noted that many of the unfunded grants had priority scores better than 165 and had been passed over for programmatic reasons. It was noted that the Board's intent was clear that these grants be funded.

V. Restricted Authorization for Line Items--Dr. Victor Braren

Dr. Braren introduced the following motion:

"That the National Cancer Advisory Board, while being generally opposed to any congressional line item for special NCI programs, wishes to take a neutral position on the Moynihan Amendment to the NCI bill concerning the Organ System Program and a neutral position on any similar amendment."

The motion was seconded by Mrs. Kushner and passed by a vote of 6 to 4.

Discussion

Several Board members believed that it would be unwise for the Board to adopt a neutral position on future unknown programs. It was feared that

modification of the Board's previous position opposing "line items" in the NCI budget might eventually lead to further budgetary and program control. Dr. Braren pointed out that the resolution reiterated the Board's general opposition to line items, while affirming a neutral position on the Moynihan amendment and similar amendments.

VI. Resolution to Establish an Ad Hoc Subcommittee Relating to the Frederick Cancer Research Facility--Dr. Robert C. Hickey

Dr. Hickey thanked Dr. DeVita and his staff for the opportunity to visit FCRF on the previous day. He proposed the following resolution, which was seconded by Dr. Katterhagen and passed unanimously by the Board:

"That the Chairman of the National Cancer Advisory Board assign from members of the Board an ad hoc subcommittee to study and report on the governance and distribution of resources and possible needs at the FCRF and report back to the NCAB."

VII. Director's Report--Dr. Vincent T. DeVita, Jr.

Survival Statistics

Additional survival data from the NCI's Surveillance, Epidemiology, and End Results (SEER) program report on cancer patients diagnosed between 1973 and 1979 were provided to the Board. The data included a table giving 5-year survival rates in white and black patients for 15 forms of cancer and a table comparing survival rates for 18 types of cancer from the SEER program, the End Results program, and the Connecticut Registry. The SEER program is planning to add a registry for black and Hispanic patients. Types of cancer showing highest survival gains in white patients are endometrial, breast, and bladder cancers and melanoma of the skin; for black patients, improved survival is noted for endometrial, breast, bladder, and colon cancers. In the future it will be possible to compare survival data of patients from the same SEER registries, and the Board will be kept up to date on these survival rates.

Report on Dr. Marc Straus

NIH and the Food and Drug Administration have completed their investigation of the case involving Dr. Straus, and a final report has been prepared. The report is available from the Deputy Director, NCI.

Budget

NCI is currently operating under a continuing resolution, which maintains the NCI's budget at the 1982 level of \$943 million. The funding plans for FY 1983 are based on this level. There is a possibility that the FY 1983 budget could reach \$980 million, if the \$25 million increase currently being considered by the House is added to the President's budget level of \$955 million.

NCI will study where to find the \$2 million that has been added to the Organ System Program to fund passed-over grants and will report to the Board. In accordance with the decision of the Organ System Subcommittee to have a single extramural organ site and place grants in the regular review system, NCI will not issue any RFA's or other documents to announce the system until the subcommittee has determined that the announcement meets NCAB recommendations.

Program Review

Two major processes are involved in Institute management: the NCI budget process and the divisional BSC's. The NCI staff holds special meetings of the Executive Committee and senior Institute staff twice each year, in February and July, to determine the cross-over of resources within the Institute. These meetings lead to the development of a funding plan. Division Directors work with their Boards to develop funding plans within their Divisions. The budget is implemented by the NCI Executive Committee, which meets weekly. Funding decisions are arrived at by projecting an average pay line. If a program director proposes to fund a grant below the pay line, or if grants above the pay line are skipped over to fund a project, the decision must be justified to the Executive Committee. Major funding deviations are discussed with the NCAB Chairman and may be brought to the attention of the Board.

The Boards of Scientific Counselors provide direct oversight for their Divisions, are responsible for site visits for intramural programs within the Divisions, and provide concept review for every contract supported by the Division. Each NCI Division, with the exception of the Division of Extramural Activities, has a Board. NCAB carries out concept review of contracts supported through the Office of the Director. This system is unique within NIH and has worked very well for NCI, providing additional scientific review of contract programs and enabling the Institute to continue important programs despite diminishing resources. NCI currently supports some 900 contracts.

Discussion

The Board was told that reports on "action items" discussed in Executive Committee meetings could be sent to them. Procedures for establishing priority scores and funding grants were reviewed. Dr. Carter expressed concern that NCI funds be well and wisely spent. Grant monitoring procedures were explained.

VIII. Division of Extramural Activities Program Review--Mrs. Barbara Bynum

Mission, Organizational Structure, and Programs

The Division of Extramural Activities (DEA) administers, directs, and coordinates peer review activities for NCI grants, cooperative agreements, and research, resource, and intramural support contracts. These activities are carried out through the Contracts Review Branch and the Grants Review Branch.

An emerging function of the Division relates to the growing emphasis on program coordination within the Institute and across Divisions. DEA coordinates

and develops the initial review formats in accordance with concepts reviewed by the divisional Boards, and DEA staff meet regularly with grant and contract program managers in other NCI Divisions and in the Office of the Director to coordinate and discuss programmatic and management issues. The Division Director and Deputy Director represent NCI to NIH on the Review Policy Committee and on the Extramural Program Management Committee. DEA prepares materials and develops the agenda for NCAB meetings through its Committee Management Office.

Three other major activities carried out in the Division were described. The Research Analysis and Evaluation Branch serves as a central resource in responding to NCI, NIH, and outside inquiries for scientific information on all NCI-supported research projects and programs.

The formatting and publication of announcements of program initiatives are DEA responsibilities. Program Announcements and RFA's (Request for Applications), generated through concept review by divisional Boards, are coordinated through the Division's RFA Officer. The Division also works with program and review staff to develop peer review procedures for these programs. In FY 1982, ten RFA's and five Program Announcements were issued.

DEA also coordinates the Cooperative Minority Biomedical Program, which is designed to foster cancer research and training activities at minority institutions. NCI funds are funneled to special programs of the Division of Research Resources and the National Institute of General Medical Sciences through agreements with these agencies. Twenty-five institutions currently receive NCI support through this Program.

Budget

The total budget for DEA in FY 1982 was \$7,929,000; in FY 1983, the budget is estimated at \$8,222,000, a 3.7 percent increase. The three elements of the budget are: scientific review and evaluation grants (Chairman's Grants), which are used to support the review committees; review and approval, which covers support to resident NCI peer review groups, the extramural program, the Division Director's staff, and the management, administrative, and coordinating functions of the Division; and the minority biomedical support program.

Funding Plan Exceptions

In FY 1982, the NCI funded 39 grants totaling \$6.9 million as exceptions to the funding plan; 7 grants were skipped over in order to fund these programs. Funding exceptions are presented to the Executive Committee by Division Directors, and each grant is considered individually by the Committee. Exceptions over \$250,000 require approval of the NCAB Chairman or full Board. Major considerations of program administrators are to conserve high-quality scientific research, preserve program objectives, and prevent loss of investment in projects. Fewer than 5 percent of all approved applications are funded as exceptions by NCI.

Discussion

Several questions related to clarification of funding exceptions listed in the Program Review notebook as grants selected by NCI staff. It was

requested that, in the future, the notebook also include funding exceptions designated by the NCAB. While there are no written guidelines for program administrators in evaluating funding exceptions, expert opinions of study section reviewers and the NCAB provide scientific justification along with programmatic considerations.

IX. Division of Cancer Cause and Prevention Program Review--Dr. Richard H. Adamson

Mission, Organizational Structure, and DCCP Programs

The mission of DCCP is to plan and conduct NCI programs of coordinated research on the causes of cancer and basic research on cancer prevention. This research is conducted through intramural laboratories and through extramural research programs. DCCP scientists study the mechanisms of cancer induction at each step of the cellular process, from initiation and transformation of normal cells to the malignant state. The purpose of these studies is to prevent, reverse, or interrupt the cancer process prior to the development of clinical disease.

The Division has five major components: the Administrative Management Branch, the Office of the Scientific Coordinator for Environmental Cancer, the Carcinogenesis Intramural Program (which includes 13 laboratories), the Field Studies and Statistics Program (to be renamed the Epidemiology and Biometry Program), and the Carcinogenesis Extramural Program. The DCCP BSC works closely with the Office of the Director in administering and overseeing Division activities. The functions of each of these programs were described.

The Board of Scientific Counselors

The Board consists of 20 members, 11 of whom are newly appointed this year. The Chairman is Dr. Peter N. Magee, Director of the Fels Research Institute of the Temple University School of Medicine.

Major Initiatives in 1982

Major achievements in biological carcinogenesis include the isolation of transforming genes from human tumor cell lines and the generation of antibodies against Onc genes, the generation of monoclonal antibodies against human mammary tumor cells, and transforming growth factor studies. Significant achievements in chemical carcinogenesis include the development of antibodies against carcinogen-DNA adducts, studies on Z-DNA (left-handed DNA), growth of human epithelial cells in chemically defined serum-free medium, lymphotoxin studies, and phorbol ester receptor site studies.

Scientific highlights in the Epidemiology and Biometry Program include the publication of SEER data from 1973-77 as NCI Monograph No. 57 and an atlas showing geographic patterns of nonneoplastic diseases in the United States, radiation studies on low-level exposure, and studies on dysplastic nevus syndrome, HTLV, and Kaposi's sarcoma.

Managerial initiatives undertaken in 1982 include the consolidation of intramural laboratory facilities to on-campus sites, promotion reviews

for all Division personnel, implementation of a payback system for resources used in extramural research programs, development of a policy book and operating manuals, the formation of three ad hoc BSC subcommittees, the issuance of two new RFA's, and initiatives in the area of equal employment opportunity.

Intramural Site Visits

In 1982, the BSC conducted a site visit to the Experimental Oncology Section of the Laboratory of Cellular and Molecular Biology. Four site visits are scheduled for 1983, seven for 1984, and five in 1985.

Budget Presentation

The DCCP budget in FY 1983 is estimated at \$195,456,000, which is a 0.5 percent decrease from FY 1982. Approximately 60 percent of these funds are allocated to the Carcinogenesis Extramural Program, which has a budget of \$114.8 million in FY 1983. The Carcinogenesis Intramural Program and the Field Studies and Statistics Program have budgets of \$39 million and \$33.1 million, respectively. The budget of the Office of the Director will decrease 24.2 percent, to \$8.5 million. The preventive oncology program, which supports manpower training, is being moved to the Division of Resources, Centers, and Community Activities (DRCCA).

In 1983 four RFA's will be issued in the area of chemical carcinogenesis and two will be issued in epidemiology. Two cooperative agreements will be implemented, one with the International Agency for Research on Cancer and the other in cooperation with the Division of Cancer Treatment (DCT) for research on Acquired Immune Deficiency Syndrome (AIDS). In 1982, 55 project concepts totaling \$14.4 million were approved by the divisional BSC.

Board of Scientific Counselors Report--Dr. Peter N. Magee

The Board has held nine meetings since its initial meeting in October 1978; Dr. Magee has been chairman since that time and has been reappointed to serve a fifth year. Board members have backgrounds in biological and chemical carcinogenesis, genetics, biometry, and epidemiology. Three meetings are held each year to consider the Division budget, perform concept reviews, and review the intramural program and other programs.

In 1982, the Board reviewed studies on coffee consumption and cancer, heard a status report on the SEER Program, and site-visited the SEER registries. Recommendations made and implemented as a result of these visits will lead to a savings of \$776,800 annually in the program, which will be used to establish a new registry for minority populations. The Board also heard a review of current research with retinoids, implemented a payback system for resources, and reviewed 60 program concepts. The agenda for its February 1983 meeting will include concept review for a new RFA dealing with the epidemiology of childhood cancer, progress reports on previously approved concepts, and reviews of animal resources, chemical carcinogenesis studies relating to the use of human tissues, and the NCI's radiation research program.

In addition, in 1982, various Board members participated in Division workshops and site-visited a laboratory section. All DCCP intramural laboratories have been site-visited, and a new round of site visits will begin

in 1983. Because of the reprogramming of funds from contracts to high areas of scientific priority, some \$7.4 million has been added to the grants program, in addition to \$2.8 million added by DCCP.

Discussion

In response to questions concerning intramural laboratory support, Dr. Magee assured Board members that financial decisions regarding the intramural program are made only after careful consideration. The question of involvement of private industry, particularly pharmaceutical firms, in some NCI research was raised. NCI scientists work with pharmaceutical firms in the development of some drugs, and retinoic acid was cited as an example. Future areas of emphasis in DCCP include research with retinoids, somatic genetics, and DNA repair.

X. Division of Cancer Biology and Diagnosis Program Review--Dr. Alan Rabson

Mission, Organizational Structure, and Programs

The Division of Cancer Biology and Diagnosis (DCBD) supports research in the areas of tumor biology and immunology. The diagnosis program, which comprises the second part of the Division's mission, is concerned with applying principles of cell biology, immunology, and pathology as an approach to diagnosis.

Most Division activities are carried out through the Extramural Research Program, which has two Branches--the Cancer Biology Branch and the Diagnosis Branch. The Intramural Research Program is carried out in 11 laboratories, including those in the Immunology Intramural Research Program. The total intramural research budget is \$38 million. Dr. Rabson described the research being performed in each of these laboratories. Other components of the Division are the Planning and Analysis Branch and the divisional BSC.

The Board of Scientific Counselors

The BSC, which started with 6 members, has grown to 15 members. Dr. David Korn of Stanford University, who has served as Chairman for 6 years, is stepping down and will be replaced by Dr. Nelson Fausto of Brown University. The Board is composed of experts in the fields of cancer biology, tumor biology, biochemistry, dermatology, and immunology. In addition to reviewing the intramural program, the Board also oversees concept review for intramural and extramural support contracts.

Major Initiatives in 1982

Managerial initiatives accomplished in 1982 include the creation of two new laboratories, the Laboratory of Tumor Immunology and Biology and the Laboratory of Genetics; preparations for the movement of the Laboratory of Immunobiology to FCRF; the implementation of Delegated Procurement Procedures; and improvement and standardization of intramural site visit procedures. Promotion reviews also were carried out for all Division personnel. DCBD is vacating its laboratory facilities in Building 8 due to NIH renovation activities. An additional change will take place in 1983 when the Breast Cancer

Program Coordinating Branch, including Breast Cancer Task Force activities, is transferred to DRCCA.

Intramural Site Visits

Site visits were made to three intramural laboratories in 1982: the Laboratory of Pathology, in January; the Laboratory of Cell Biology and Macromolecular Biology Section, in October; and the Laboratory of Mathematical Biology, in May. Site visits are scheduled for the Laboratory of Molecular Biology in January 1983 and the Dermatology Branch in June 1983.

Budget Presentations

The estimated budget in FY 1983 of \$171,343,000 represents a 0.93 percent decrease from FY 1982. The largest decrease will be in epidemiology, reflecting the transfer of the breast cancer program. The largest program area in DCBD is tumor biology, followed by immunology. DCBD plans to increase support for programs in diagnostic research in 1983. Extramural research will account for an estimated \$131.7 million in FY 1983, and the budget for intramural research will rise by 3.7 percent. The Director's budget is \$1.3 million. Most extramural research is supported through R01 and P01 grants, with R01 grants accounting for the major portion.

Thirty concept reviews were presented to the BSC at its October 1981 meeting and one at its May 1982 meeting. Twenty-three were approved, representing \$20.8 million. Of these, nine were in diagnosis, seven in breast cancer, five in intramural resource support, and two in tumor biology.

Board of Scientific Counselors Report--Dr. David Korn

At its October 1981 meeting, the Board reviewed the sputum cytology contract program. At the request of the NCAB, all project sites were visited and detailed reviews conducted. The BSC also discussed issues related to research with human monoclonal antibodies. As a result, a workshop on this subject was conducted in May. It was recommended that research in this field should be stimulated through Program Announcements rather than by targeted funds. Another unresolved issue relating to monoclonal antibodies concerns the extent of NCI's involvement in banking programs. It was suggested that all banking programs supported by NCI and NIH be reviewed.

Highlights of the October 1982 meeting of the Board were a review of DCBD budget projections and all intramural programs and a site visit to the Laboratory of Cell Biology. Dr. Korn made a strong plea for continued NCAB support of basic biomedical research, stating that NCI's role in basic research is paramount and must be maintained despite tightened resources.

Discussion

In response to a question relating to areas of future research emphasis, Dr. Korn cited genetic chemistry and immunogenetics as fields of great possibility. A question was raised on the status of the three contract-supported sputum cytology studies. Screening activities will be completed this year, and followup data are being collected and analyzed. Sputum cytology as a diagnostic technique does not appear to reflect a decrease in lung cancer

mortality. NCI stresses the need for continued accurate followup of study participants for at least one year. Research with monoclonal antibodies was discussed. It was considered important that an effort be made to distinguish antibodies, particularly those used for diagnosis. A number of labs in DCBD are working on monoclonals to melanoma and workshops are being held. Mammary monoclonal antibodies are ready for clinical testing. Several Board members echoed Dr. Korn's concerns for continued support of basic research.

XI. Announcement--Dr. Harold Amos

At the request of Dr. William Farland, ex-officio representative for the Environmental Protection Agency, Dr. Amos read the following statement into the official record of the NCAB meeting:

"I wish to acknowledge the excellent working relationship in environmental carcinogenesis that has been developed over the last several years with Dr. Adamson and Dr. Kraybill. This collaboration and the pass-through funding that partially supports it illustrates an important cooperative effort between the research community and the regulatory scientists."

XII. Division of Resources, Centers, and Community Activities Program Review--
Dr. Peter Greenwald

Mission, Organizational Structure, and Programs

The Division of Resources, Centers, and Community Activities (DRCCA) supports programs in cancer control research and application, applied prevention, and a national system of cancer centers and community oncology programs. The Division is in transition, and many of the staff and programs are new. New initiatives have been undertaken in chemoprevention, diet and cancer, education, and community oncology programs, and 50 of the Division's 107 staff members joined the Division or NCI in the past year.

The Division is organized into three major program components: Cancer Control Applications, Centers and Community Oncology, and Prevention. The Division also includes a Biometrics and Operations Research Branch and an Administrative Office. The Biometrics and Operations Research Branch is new and will be responsible for tracking progress against cancer and for developing models and strategies that might best affect mortality rates from the disease.

The Cancer Control Applications component supports programs in cancer control science, behavioral medicine, education, cancer training, and career development.

The Centers and Community Oncology Program supports cancer centers, community oncology and rehabilitation programs, the Organ System Program, and the Research Facilities Program. Forty-five percent of the total Division budget covers core support for cancer centers, including 22 Comprehensive Cancer Centers and 24 clinical and 15 nonclinical centers. A major priority in the program this year will be developing the Community Clinical Oncology Program (CCOP).

The prevention component supports studies in chemoprevention, diet and cancer, occupational cancer and worker education, and cancer detection, including programs in lung and breast cancer screening. The emphasis is on applied prevention techniques.

The Board of Scientific Counselors

The BSC has 21 members; the Chairman is Dr. Lester Breslow, Professor, School of Public Health, University of California's Center for Health Sciences. The Board includes individuals with backgrounds in medical and surgical oncology, oncology nursing, sociology, epidemiology, behavioral science, cancer control, and continuing care.

Major Initiatives in 1982

All current programs in diet and cancer, cancer screening, occupational cancer, education, behavioral medicine, and the Centralized Cancer Patient Data System were reviewed by the divisional BSC. Studies in chemoprevention, diet and cancer, and smoking and health were initiated or expanded along with the CCOP, Cancer Control Research Unit, and Cancer Control Science programs. Management initiatives also included the addition of new staff members (including the Director and Deputy Director, Associate Directors, and Branch Chiefs) and the initiation of phased cancer control research. It also has been proposed that the name of the Division be changed to Division of Cancer Control and Prevention.

Budget Presentation

The total budget for DRCCA in FY 1983 is estimated at \$171,191,000, of which \$54,079,000 represents cancer control funds. The estimated budget is \$4.3 million higher than the FY 1982 level. Almost one-third of the Division budget is a line-item allocation for cancer control activities. The largest budget item is cancer center core support (\$76.9 million), the second largest is the cancer control budget, and the third largest segment covers education and training activities (approximately \$35 million). Of the \$54 million in cancer control funds, 31 percent is in centers and community outreach programs.

Eighteen new concepts were reviewed by the Division's BSC in 1982: 15 approved, 1 disapproved, 1 deferred, and 1 phased out. All concepts presented to the Board are discussed by Division and NCI Executive Committees and refined before being presented.

Presentation of the Board of Scientific Counselors--Dr. Lester Breslow

He defined cancer control as "the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to their broad systematic application."

Cancer control research focuses on the prevention and management of cancer. We now have the knowledge to reduce morbidity and mortality from cancer and even to prevent the disease in some instances. The mission of cancer control is to foster the application of this knowledge. He suggested that the 1980's should be the decade for the control of cancer and cited

specific objectives that could be established: to increase the ratio of in situ versus invasive cancers from 3:1 to 6:1; to reduce the percentage of adult smokers from 33 percent to 25 percent; to eliminate new cases of asbestosis; and to increase the number of persons aware of cancer's warning signals from 60 percent to 80 percent.

The functions of the Board are to develop and review concepts, oversee the budget, and advise on management and relations with other elements in the public and private sectors relevant to the Division's mission. Accomplishments in the past year include the issuance of RFA's on Cancer Control Research Units and Cancer Control Science Programs. Other major emphases include concept review for chemoprevention activities, initiation of CCOP, the development of new guidelines for core support of cancer centers, and systematic review of the Division budget and programs.

Discussion

Dr. Greenwald noted that while no specific initiative is planned in an effort to promote testicular self-examination, similar to the breast cancer self-examination, the Division is investigating possible screening efforts, site by site, to determine potential benefits. The necessity of increased interaction with other Government agencies, as well as with institutions and groups outside of the Government and traditional cancer community, with regard to cancer control, education, and other aspects of cancer care (i.e., economic, sociological) was noted. In the general discussion that followed, opportunities for strengthening relationships with institutions and agencies were suggested.

XIII. Division of Cancer Treatment Program Review--Dr. Bruce Chabner

Mission, Organizational Structure, and Programs

The research mission of the Division of Cancer Treatment (DCT) is to discover, develop, and clinically evaluate new treatments for cancer. The Division's research activities encompass all modes of therapy--chemotherapy, radiotherapy, immunotherapy, biologics, and surgery--and include both pre-clinical and clinical research.

DCT has five program components representing the treatment modalities: the Developmental Therapeutics Program, the Cancer Therapy Evaluation Program, the Radiation Research Program, the Biological Response Modifiers Program, and the Clinical Oncology Program. In addition, the Office of the Director includes an Advisory Committee composed of the five program directors and the Board of Scientific Counselors. The functions of these programs were described.

The Board of Scientific Counselors

Board members represent all major fields in cancer treatment, radiotherapy and radiology, clinical oncology, pharmacology, molecular biology, biochemistry, surgery, immunology, pediatric oncology, and cell biology. Dr. Samuel Hellman serves as chairman.

Major Initiatives in 1982

The Office of the Director implemented a number of management initiatives during the year, including the expansion of the BSC to 18 members to incorporate newer areas of research activity in the Division, such as radiology; transition of the Baltimore Cancer Research Program from an intramural program to a grant-supported cancer center; establishment of a budget ad hoc working group of BSC; and refinement of procedures for intramural site visits, including the development of a book describing the intramural program. A thorough review was conducted of P01 grants, which constitute the major portion of DCT extramural research support.

The Developmental Therapeutics Program brought seven new drugs to clinical trial in 1982. Other scientific highlights were the discovery of a new anti-purine agent, pyrazofurin, which will enter clinical trials in 1983, and work on the T-cell lymphoma virus. In addition, the program refined toxicity protocols for testing new drugs prior to entry in clinical trials. The procedure involves simplified testing in mice and dogs to determine a safe starting dose and target organ toxicity. Pharmacology laboratories were consolidated, resulting in cost savings, and a new laboratory--the Laboratory of Experimental Therapeutics and Metabolism--was created to strengthen the Division's science base in toxicology.

Initiatives in the Cancer Therapy Evaluation Program include the reorganization of the Investigational Drug Branch and the identification of two new promising agents: AZQ, which is active against brain tumors, and Mitozantrone, a derivative of ballpoint ink. With the assistance of BSC, the monitoring system for the clinical trials program was expanded; all studies using experimental drugs will be monitored once every 3 years. Cooperative arrangements have been made with drug firms to assume distribution costs for Group C drugs that are awaiting FDA approval for marketing, which will save NCI an estimated \$750,000 next year. A number of research clinical trials programs have been converted to cooperative agreements and an RFA to support research on AIDS was issued in conjunction with DCCP.

Important developments in the Clinical Oncology Program included the publication of results from studies of adjuvant therapy for soft-tissue sarcoma and histiocytic lymphoma, the reorganization of the Pediatric Oncology Branch, the transfer of the Medical Oncology Branch from the VA facility to the Naval Medical Center near NIH, and the opening of the Radiation Oncology Facility on the NIH campus. In addition, the Radiation Research Program was established as a separate entity within DCT and the Biological Response Modifiers Program completed phase 1 of a clinical trial with recombinant interferon. The Laboratory of Immunodiagnosis was transferred from DCBD, along with funds and positions, which saved the Division \$500,000.

Intramural Visits

In March 1982, the Radiation Oncology Branch under the direction of Dr. Eli Glatstein was site-visited by BSC. A site visit was also conducted in August 1981 to the Medicine Branch, which is headed by Dr. Robert Young.

Budget Presentation

The estimated budget for DCT in FY 1983 is \$279,134,000, a 2 percent increase over FY 1982. The Cancer Therapy Evaluation Program will have a funding level of \$90.9 million and the Developmental Therapeutics Program will be funded at a level of \$82.3 million. The budgets for the Clinical Oncology Program and the Biological Response Modifiers Program will increase by 1 percent and 3 percent respectively.

Sixty-three project concepts were presented to BSC in FY 1982; of these 58 were approved, totaling \$32.3 million. These included 29 projects in the Developmental Therapeutics Program, 13 in the Cancer Therapy Evaluation Program, 12 in radiation research, and 4 in the biologics program.

Board of Scientific Counselors Report--Dr. Samuel Hellman

The BSC provides scientific, administrative, and fiscal advice to DCT and conducts concept reviews for contracts. Scientific and administrative advisory functions include intramural site visits; initiation termination, and alteration of DCT scientific activities; evaluation of new scientific leads proposed by the scientific community and intramural scientists; and approval of new funding initiatives, including RFA's. In 1982, the BSC also sponsored a workshop to develop areas of research appropriate to surgical oncology, assisted with the development of a system to monitor clinical trials, and reviewed the impact of CCOP on the Division. The DCT budget is considered at regular meetings of the full BSC, and a three-member ad hoc working group of the BSC meets twice a year to review budgetary matters.

Discussion

The value of P01 grants as a funding mechanism was discussed. Dr. Hellman noted that these grants have a unique position in DCT activities in their ability to link laboratory and clinical research, allowing for the rapid transfer of knowledge from basic to clinical research and providing a mechanism for interaction between basic and clinical researchers. New review procedures being developed for these grants will aid in strengthening and streamlining the P01 program. Concern was expressed about the need for training programs in radiopathology to assess effects on normal tissue. It was noted that many pathologists were deficient in this area. Dr. Jako commented that surgery will continue to play a key role in cancer treatment for the next 10 years and encouraged research to develop more precise, less invasive surgical procedures that could be combined with other treatment modalities being developed. Several Board members supported Dr. Jako's comments.

XIV. The Acquired Immune Deficiency Syndrome (AIDS)--Dr. Bruce Chabner and Dr. James Curran, Center for Disease Control (CDC)

The report by Dr. Chabner and Dr. Curran concerned the epidemiology and clinical aspects of AIDS, a disease that is occurring in epidemic proportions in the male homosexual population of the United States. The disease is associated with a marked deficiency of helper T-cells and is clinically manifested as pneumocystis carinii pneumonia, other opportunistic infections, and several

unusual forms of cancer, primarily Kaposi's sarcoma. AIDS was first reported in July 1981, and the incidence is rising rapidly. The current mortality rate of 40 percent is projected to rise as high as 90 percent, as more patients live through the course of their disease. Seventy-five percent of the patients are homosexual or bisexual men, most of them from New York City, San Francisco, and Los Angeles. Other groups that have been identified include i.v. drug users, recent emigrants from Haiti, male hemophiliacs, and a few recipients of blood products.

NCI is supporting research on AIDS, including workshops with the CDC, grant supplements to institutions treating AIDS patients, and intramural studies. An RFA to conduct etiologic, epidemiologic, and treatment research on the disease has been issued, which will be supported jointly by DCCP and DCT. The budget for this RFA is \$1,250,000, and awards are expected in 2 months.

XV. Adjournment--The 44th meeting of the NCAB was adjourned at 12:40 p.m., December 1, 1982.

Tim L. Carter, M.D.
Chairman
National Cancer Advisory Board

NATIONAL CANCER ADVISORY BOARD

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