

National Institutes of Health

National Cancer Institute

NATIONAL CANCER ADVISORY BOARD

Summary of Meeting
January 31-February 2, 1983
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

Summary of Meeting*
January 31-February 2, 1983

The National Cancer Advisory Board (NCAB) convened its 45th regular meeting at 8:30 a.m., January 31, 1983, 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. Roswell K. Boutwell
Dr. Ed L. Calhoon
Dr. Tim Lee Carter
Dr. Maureen M. Henderson
Dr. Robert C. Hickey
Dr. Geza Jako
Dr. Joseph G. Katterhagen
Mrs. Rose Kushner
Dr. LaSalle D. Leffall
Dr. William E. Powers
Dr. Janet D. Rowley
Mr. Sheldon W. Samuels
Mr. Morris M. Schrier
Dr. Irving J. Selikoff

President's Cancer Panel

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

Ex Officio Members

Dr. Robert Brandt, Labor
Dr. Ken Bridbord, NIOSH
Dr. Hollis Boren, VA
Dr. F. Kash Mostofi, DOD
Dr. David P. Rall, NIEHS

Absent

Ann Landers
Dr. Armand Hammer, Chairman, President's Cancer Panel

*For the record, it is noted that members absented themselves from the meeting when discussing applications (a) from their respective institutions or (b) in which conflict of interest might occur. This procedure does not apply to "en bloc" actions.

Liaison Representatives

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

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. Paul Sherlock, Chairman, Department of Medicine, Memorial Sloan-Kettering Cancer Center, New York, New York, representing the American Gastroenterological Association.

Dr. J. W. Thiessen, Acting Deputy Associate Director, Office of Health and Environmental Research, Office of Energy Research, Department of Energy, representing the Department of Energy (for Dr. Charles W. Edington).

Dr. Hugh R. K. Barber, Director, Department of Obstetrics and Gynecology, Lenox Hill Hospital, New York, New York, representing the Society of Gynecologic Oncologists.

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

Dr. Edwin A. Mirand, Associate Director of Administration, Roswell Park Memorial Institute, Buffalo, New York, representing the Association of the American Cancer Institutes.

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 Amoroso, 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, a total of 15 registered members of the public attended the meeting.

I. Call to Order and Opening Remarks--Dr. Tim Lee Carter

Dr. Carter, Chairman, called the 45th meeting to order and welcomed members of the Board and the President's Cancer Panel, liaison representatives, National Cancer Institute (NCI) staff, guests, and members of the public. He introduced Dr. Roswell K. Boutwell, Professor of Oncology with the McArdle Laboratory for Cancer Research at the University of Wisconsin, and announced that he had just been appointed to serve as a member of the Board. Dr. Carter also introduced the liaison representatives.

Members of the public who wanted to express their views on any matters discussed by the Board during the meeting were invited to submit their comments in writing to the Executive Secretary of the NCAB within 10 days after the meeting. Dr. Carter stated that comments from the public would receive careful consideration. Procedures for the conduct of Board meetings were reviewed and it was noted that a quorum of 12 was present.

Future Board meeting dates were confirmed as follows: May 16-18, October 3-5, and November 28-30, 1983; January 30-February 1, May 14-16, October 1-3, and November 26-28, 1984.

Dr. Carter noted that there would be no report from the President's Cancer Panel because of the absence of the Chairman, Dr. Armand Hammer.

II. Director's Report, National Cancer Program--Dr. Vincent T. DeVita, Jr.

Dr. DeVita welcomed Dr. Boutwell to the Board and expressed appreciation to Dr. Gerald N. Wogan, who has left the Board, for his contributions to NCI and NCAB activities.

Announcements

(1) Dr. F. Kash Mostofi of the Armed Forces Institute of Pathology, who serves as an alternate ex officio member of the Board, has received the Presidential Award for Distinguished Service.

(2) Dr. R. Lee Clark, a former member of the President's Cancer Panel, and Dr. Gregory T. O'Connor, NCI's Associate Director for International Affairs, have received the Shield Award from the University of Cairo. Dr. Clark was honored for his contributions to the concept of cancer centers and Dr. O'Connor for his contributions to the development of the international program.

(3) The R. A. Bloch International Cancer Information Center, located adjacent to the NIH campus, has been donated to NIH and made available to the NCI. The building will house the International Cancer Research Data Bank (ICRDB) Program, the JNCI, Cancer Treatment Reports, and the NCI computer processing facility. Dr. DeVita thanked Mr. Bloch for his role in the acquisition of the building and noted that this is the first building donated to the NIH campus since 1942. The building will be dedicated this spring, and Board members are invited to attend the ceremonies.

(4) Dr. Robert Wittes, formerly with the Memorial Sloan-Kettering Institute for Cancer Research in New York City, has been appointed Associate Director for Cancer Therapy Evaluation, Division of Cancer Treatment.

Followup Items

(1) Applications for Community Clinical Oncology Program grants are being reviewed on schedule and should be ready for NCAB review at the May Board meeting.

(2) The subcommittee to evaluate NCI's new Outstanding Investigator Award, which is to be directed to researchers rather than projects, is to meet February 7. Dr. Harold Amos is Chairman of the subcommittee.

(3) The ad hoc Subcommittee on Program Project Grants, chaired by Dr. Maureen Henderson, has held one meeting and will meet again on February 2 and 3, following the Board meeting.

(4) The President's Cancer Panel has held one meeting since the November Board meeting. The Panel is currently meeting with grantees in various parts of the United States to discuss the review and approval of grants. The next meeting will take place in Houston, Texas, March 4, 1983.

(5) The Protocol Data Query (PDQ) system is making good progress. NCI staff members met recently with representatives from the American Medical Association (AMA) to discuss incorporation of PDQ into the AMA's TELENET system, which will give PDQ wider exposure. Dr. DeVita reiterated that the new system will result in no increase in cost or staff to NCI. The ICRDB program, which includes PDQ, will cost \$1.8 million less in 1983 than it did in 1982. Reasons cited were modifications to the CANCERLIT file and the donation of the new center.

(6) A director of contract-supported research at the Frederick Cancer Research Facility (FCRF) is being sought. NCI is hoping to locate an individual with excellent scientific credentials and a strong scientific background in an area of research supported at FCRF, such as oncogene research. Reasons for the recompetition of the Frederick contract were reviewed. One reason cited was the opportunity to reduce the costs of the intramural program by consolidating off-site laboratories on the Frederick campus. This has been accomplished at a cost of \$13.8 million. Operating costs for FCRF have dropped by 2 percent since 1980, from \$38.2 million in 1980 to \$37.3 million in 1983, including costs of intramural laboratories. Dr. DeVita praised NCI staff members for their handling of the recompetition process.

Budget

Dr. DeVita reviewed the major steps in the NCI budget process, which involves consideration of three budget years concurrently--the current fiscal year and the two succeeding fiscal years. In the current fiscal year, NCI is operating under a Continuing Resolution passed by the last Congress. NCI's budget for FY 1983 is \$983,576,000, an increase of 4 percent over

FY 1982. Because the funding plan approved by the NCAB in October 1982 was based on the FY 1982 level of \$943 million, a revised funding plan is being proposed for the Board's approval. Under the revised plan, NCI proposes to add \$12.5 million into the R01 grant program, restoring a portion of the reductions made in these grants under the original plan; and to fund an additional 77 R01 and P01 grants. Competing R01 grants would be reduced 10 percent below the levels recommended by the study sections instead of 20 percent, as in the original plan. This would result in a 23 percent increase over the current level of R01 grants. P01 grants would retain the 20 percent reduction specified in the original plan, which results in an 8 percent increase over their current level. Other aspects of the original plan would be retained. That is, no competing renewal grant recommended for an increase would receive less than its current level; grant dollars would be allocated by program; and Program Directors, with the concurrence of the Division Directors, could approve a 10 percent variance on funding levels for individual grants. The revised plan also would retain the 5 percent reduction in research and support contracts, limit intramural research to a 4 percent growth over the 1982 base and modify the review of P01 grants. The alternative to this revised plan is to retain the original funding plan as approved by the Board in October and use the additional funds to support more grants. After some discussion, the Board deferred a decision on the revised funding plan until a later session.

New Items

- (1) Dr. Armand Hammer has presented his first award in cancer research to Dr. Ronald Levy of Stanford University and Dr. George Stevenson of Great Britain. The two scientists will share the \$100,000 prize, which was awarded in recognition of their work with monoclonal antibodies in the treatment of lymphoma.
- (2) Dr. Hammer and the Leukemia Research Fund of Great Britain co-sponsored the Second World Summit Conference on Leukemia and Lymphoma, recently held in the Virgin Islands.
- (3) Through the Hammer Foundation, Dr. Hammer sponsored the Second Monoclonal Antibody Conference, held recently at the Salk Institute in California, which Dr. Peter Fischinger attended on behalf of NCI.
- (4) A meeting of the Third United States/People's Republic of China Joint Health Committee was held recently at NCI. Dr. DeVita is cancer coordinator of this committee. NCI is exploring the possibility of cooperating with the People's Republic of China in chemoprevention studies.
- (5) The first meeting of the Directors' Advisory Committee was held with Dr. James B. Wyngaarden, Director of NIH. Dr. Carter represented the NCAB. Topics of discussion included the continued use of the "stabilization" approach by NIH, which refers to an assigned number of grants to be funded by each Institute, and a study of the organizational structure of NIH, recently initiated by the National Academy of Sciences.

(6) A preview of Dr. DeVita's upcoming testimony to Congress on the National Cancer Program was presented. NCI efforts in technology transfer and the application of the results of basic research on the clinical level will be highlighted along with promising areas of basic research, including oncogenes, biochemical epidemiology, and research on the human T-cell leukemia virus. The Director also will discuss the new PDQ system, chemoprevention intervention studies, the cancer control science program, and clinical trials in chemoprevention, biologicals, and breast cancer.

(7) Dr. Jane Henney recently attended a meeting on pain control, sponsored by the AMA and the Public Health Service. A new publication on this topic has been prepared by NCI and is being printed and distributed by the American Cancer Society.

(8) NCI has studied data on changes in cancer incidence and mortality rates in the past decade in persons between 20 and 44 years of age to determine whether declines in mortality for some types of cancers can be attributed to treatment or prevention. For six types of cancer--testicular, ovarian, premenopausal breast, bone, Hodgkin's disease, and non-Hodgkin's lymphoma--mortality rates fell while the incidence rate rose or remained level, indicating that improved survival is due to improvements in treatment. Both incidence and mortality rates for lung, cervical, and stomach cancers decreased in this age group in the 10-year period. These changes were attributed to earlier diagnosis (for cervical cancer), a decline in smoking among young men (for lung cancer), and changes in eating patterns (for stomach cancer).

(9) Dr. DeVita noted the recent deaths from cancer of Dr. Sol Spiegelman, a former member of the NCAB, and Dr. Charles Heidelberger, Director for Basic Research and Distinguished Professor of Biochemistry and Pathology at the University of Southern California. He praised the contributions of these scientists to the cancer research effort.

III. Legislative Report--Dr. Mary Knipmeyer

Legislation related to the reauthorization of NCI and Institute appropriations was not passed during the last session of Congress. NCI is currently operating under a Continuing Resolution, as authorized under the Public Health Service Act, which provides for a budget of \$983,576,000 in FY 1983. Reauthorization bills similar to those proposed last year are expected to be reintroduced in the House and Senate during the current session. The Senate reauthorization bill may contain amendments dealing with fetal research and the use of animals in scientific research.

The issue of animal welfare has support from both sides of the Congress. The main provisions of the bills considered in the last Congress concerned the development of research and testing approaches that do not require animals or that reduce the need for animals and accreditation requirements for laboratories using research animals. As noted, an animal welfare provision may be attached to the Senate reauthorization bill.

The Orphan Drug Act (P.L. 97-414) was signed into law on January 4. The law provides for Government subsidies in the form of tax credits to private companies for the development of drugs or other medical products used to treat rare diseases. One provision of the Act concerns the development of methods to assess exposure to I¹³¹ from nuclear testing and fallout and the development of radioepidemiological tables to provide estimates on the probability of cancers caused by radiation exposures. NCI's role in the implementation of the Orphan Drug Act has not yet been determined by the Department of Health and Human Services (DHHS).

Legislation concerning compensation for persons exposed to radiation from atomic bomb testing in the Southwest is expected to be reintroduced into both the House and Senate during this session. Senator Orrin Hatch will sponsor the legislation in the Senate.

DHHS may propose legislation to repeal the NCI's bypass budget. NIH appealed this decision, but was not successful.

The incoming group of new Representatives in Congress has chosen the subject of cancer research as their "freshman class project." NCI will cooperate in this project through presentations, workshops, and other activities. As a representative of the public, the NCAB also will take an active role, apart from NCI, in support of this project.

At the request of the NCAB, as part of the regular legislative report, the Board will be informed on procedures and processes relating to the writing of regulations stemming from new legislation.

IV. Resolution in Support of the House of Representatives Freshman Class Project on Cancer Research--Mr. Sheldon W. Samuels

Mr. Samuels introduced the following resolution:

"That the National Cancer Advisory Board sponsor a joint meeting with Freshman Representatives on the Hill who have shown interest in the progress of cancer research."

The motion was seconded by Mrs. Rose Kushner and passed unanimously. Dr. Carter was designated as Dr. Knipmeyer's liaison on the Board in arranging the meeting.

V. Cancer Care Costs--Dr. Thomas Hodgson

Dr. Hodgson of the National Center for Health Statistics (NCHS) reported to the Board on the economic burden of cancer in the United States, including costs of medical care and indirect costs (e.g., lost wages, earnings, work-time, productivity) associated with cancer morbidity and mortality.

VI. Role of the NCAB--Mrs. Barbara Bynum

Mrs. Bynum reviewed the structure and functions of the National Cancer Advisory Board, with special emphasis on the responsibility of the NCAB and its individual members in the National Cancer Program, the structure of NCAB subcommittees, and the Board's role in the dual review of grant applications.

Board Structure

In introducing the topic of NCAB structure and how it can best serve the activities of the Board, Mrs. Bynum reviewed the NCAB Charter, authorizing legislation, the current subcommittee structure in relation to the divisional Boards of Scientific Counselors, and the activities of the Board, including those mandated by the National Cancer Act and those dictated by practice.

The current Charter of the Board, approved by the Secretary of HHS on July 21, 1982, specifies seven standing subcommittees composed entirely of Board members. Ten issues relating to the nature, structure, membership, and functions of these subcommittees were presented for the Board's consideration.

1. Which of the present Board subcommittees should be retained or abolished in view of present or projected activities of the National Cancer Program?
2. Is there a need to charter new subcommittees, or is new language needed for the next NCAB Charter?
3. Could some of the activities carried out by the Board be conducted through "ad hoc" versus "standing" (chartered) subcommittees?
4. To what extent is there overlapping between Board subcommittees and BSC working groups, and if so, should this overlapping exist?
5. Should the number of subcommittees to which a Board member may belong be restricted in any way?
6. Should the size of subcommittees be limited?
7. Should the current practice of restricting subcommittee membership to NCAB members be continued?
8. Should Board members be compensated for attendance at meetings of subcommittees of which they are not officially members?
9. What records should be kept of subcommittee proceedings?
10. What is the status or influence of the subcommittee in relation to Board actions and recommendations?

During the Board's discussion of these issues, the following motion was introduced by Dr. Braren:

"That any Board member wishing to attend other subcommittee meetings will submit a request to the Chairman, who will approve the request with assistance from Dr. DeVita or an appropriate staff member as determined by him."

The motion was seconded by Dr. Powers and passed in a voice vote.

Because of the importance of the issues involved and because of time constraints, the Board elected to continue the discussion at another time. It was suggested that the subject be rescheduled for discussion in a more expanded format at an open session of the Subcommittee on Activities and Agenda.

Review of Research Grant Applications

Mrs. Bynum reviewed the rationale and principles underlying the concept of dual review of research grant applications at NIH. The issue to be determined by the Board is how it can best carry out its mandated review of 1,500 to 2,000 grant applications per round in an effective, legal, and informed manner.

Board members are currently sent all summary statements for review, but they discuss in detail only those cited by staff or Board members, those which involve a sensitive issue, or those for which the principal investigator has written a rebuttal. For all other applications, the Board tacitly accepts the recommendations of the study sections through an "en bloc" vote. This procedure is within legislative, Departmental, and NIH guidelines. It has been suggested that the Board may wish to modify this system or consider optional procedures. Review procedures of other Institutes were described, along with a system formerly used by the NCAB in which one specific program area was reviewed in detail at each meeting. A poll of NCAB members in the fall of 1982 showed that the majority of members responding wished to receive all of the summary statements; 7 of the 16 respondents indicated that, in addition, grants should be assigned for review. One optional approach is to assign some grants to NCAB members for indepth review to ensure that all areas are covered. Dr. Janet Rowley moderated the Board discussion, which focused on two issues: how to carry out grant review and whether to reinstate the program review system or develop other procedures for the review of grants.

Most of the Board's discussion focused on the issue of assigned or selected review of summary statements. The discussion was summarized by Dr. Rowley as follows: Board members should continue to receive all summary statements; they can read as many of these statements as they choose, but will be responsible for the careful review of a certain fraction; each summary statement will be assigned to an individual so that it will receive an appropriate review. If a member chooses, he or she can review all of the summary statements in detail. It was suggested that the discussion be continued during the Special Actions Subcommittee meeting, scheduled for the next day. It was agreed that the proposed system would receive a trial run at the May 1983 meeting.

VII. Revolution in Diagnostic Imaging and Its Potential Impact on the Diagnosis of Cancer--Dr. David Pistenmaa, Dr. Paul Capp, and Dr. William Hendee

Dr. Pistenmaa, Associate Director of the Radiation Research Program in the Division of Cancer Treatment, described the diagnostic imaging research carried out in the NCI program. The Diagnostic Imaging Research Branch supports research in x-ray imaging, nuclear medicine, and non-ionizing radiation imaging.

Dr. Capp, Professor of Radiology at the University of Arizona, and Dr. Hendee, Professor of Radiology at the University of Colorado, gave a scientific presentation on nuclear magnetic resonance (NMR) and other new imaging techniques and their potential impact on cancer diagnosis. Diagnostic imaging has significantly contributed to the earlier detection of many diseases and, in addition, has proved a valuable tool in tests to determine the presence or absence of cancer. In recent years, the emphasis in diagnostic imaging has focused on the development of techniques that are less hazardous and less costly. NMR is one of several emerging technologies in diagnostic imaging. Other new imaging techniques were described, including emission computerized axial tomography (ECAT), ultrasound, computerized tomography with ultrasound, rapid CT scanning, and digital radiology, a computerized imaging technique.

VIII. Problems of Marker Research--Dr. K. Robert McIntire

The presentation by Dr. McIntire, Chief of the Diagnosis Branch, Division of Cancer Biology and Diagnosis, included a review of the discovery and development of cancer markers, their role in the diagnosis and treatment of cancer, possible future applications, characteristics and types of markers, problems associated with markers, and recommendations for future research.

Dr. McIntire cited eight recommendations for the NCI's marker research program: (1) conduct studies to select batteries of appropriate markers for specific types of cancer; (2) conduct studies during active therapy to identify markers that correlate with change in tumor size; (3) increase the availability of tumor marker assays in cancer centers; (4) evaluate monoclonal antibodies in tumor marker research; (5) conduct studies of markers in cell culture lines and transplanted tumors in nude mice; (6) conduct studies of marker metabolism; (7) increase the availability of serum for the testing of new markers; and (8) conduct studies to improve the evaluation of markers.

IX. Resolution Concerning Tumor Marker Research--Mrs. Rose Kushner

The following resolution was proposed by Mrs. Kushner:

"That the National Cancer Advisory Board ask National Cancer Institute staff to consider ways of studying markers and approaching and focusing on marker research, including the possibility of a special study section but not exclusively that, and report back to the full Board."

The motion was seconded by Dr. Braren and passed unanimously by the Board.

X. Consideration of the Minutes of the November NCAB Meeting--
Dr. Tim Lee Carter

Dr. Braren moved that the minutes of the November Program Review be approved as amended by the Board. The motion was passed unanimously.

XI. Resolution Concerning Minutes of NCAB Meetings--Dr. Maureen Henderson

The following motion was introduced by Dr. Henderson:

"That the minutes of NCAB meetings record the actions and recommendations of the Board and that a transcript of the proceedings be made available to Board members if they want to review the details of discussion."

The motion was seconded and passed. The vote on the motion was eight "For" and five "Against."

XII. Report of the Subcommittee on Activities and Agenda

As the subcommittee had not yet met, there was no report. A meeting will be scheduled prior to the May Board meeting.

XIII. Report of the Subcommittee on the Organ Systems Program--
Dr. William E. Powers

Dr. Powers, Chairman, presented for the Board's approval the subcommittee's recommendations regarding the Organ Systems Program. The subcommittee recommended that NCI maintain and operate a strong, multidisciplinary Organ Systems Program and that the NCAB subcommittee be continued and report to the Board on the progress of the program. Other recommendations were related to the organization, implementation, and funding of the program, as well as to the review of Organ Systems Program grant applications and the roles of the NCI, NCAB, and the Organ Systems Coordinating Center and working groups.

The report was approved as amended by the Board.

XIV. Resolution Concerning the National Cancer Institute--Dr. Victor Braren

Dr. Braren proposed the following resolution:

"Whereas the National Cancer Institute is the largest and most complex of the Institutes within the National Institutes of Health and whereas the Institute has been run in a cost-effective and superbly scientific fashion and whereas preparations by the staff for National Cancer Advisory Board meetings are tedious and demanding, be it hereby resolved that the National Cancer Advisory Board lauds and commends

Dr. Vincent T. DeVita, Jr., Mrs. Barbara Bynum, and the NCI staff on the preparations for this and all National Cancer Advisory Board meetings and further lauds and commends Dr. DeVita and NCI staff on running the National Cancer Institute and the National Cancer Program."

The motion was seconded and passed unanimously by the Board.

XV. Report of the Subcommittee on Planning and Budget--Mr. Louis Carrese

In the absence of Dr. LaSalle Leffall, Mr. Carrese presented the report of the subcommittee. The report covered four topics: the 1985 NCI Bypass Budget, modifications to the 1983 funding plan, monitoring procedures for clinical trials, and an update on the subcommittee's effort to obtain information about third-party payments to the Clinical Center. The 1985 budget will include inflationary and mandatory increases, as well as funds for selective high priority programs. These actions are expected to result in a budget increase of 10 to 14 percent over the FY 1984 level. The revised 1983 funding plan presented to the Board at Monday's session was modified so that both R01 and P01 grants would reflect the same percentage reduction, an estimated 12 to 15 percent, from recommended levels. The plan proposed by NCI would have reduced R01 grants 10 percent below recommended levels and retained the 20 percent reduction for P01 grants.

The subcommittee's report was approved unanimously by the Board.

XVI. Report of the Subcommittee on Cancer Control and the Community--
Dr. Joseph Gale Katterhagen

The Subcommittee on Cancer Control and the Community reviewed changes in reimbursement mechanisms stemming from the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 that may adversely affect clinical research programs supported by NCI. The subcommittee recommended that NCI staff discuss Board concerns with the Health Care Financing Administration (HCFA) and other agency officials and seek exemption from TEFRA regulations for patients enrolled in clinical research studies in university and community settings. The subcommittee also recommended that the Chairman of the NCAB or his designee communicate with HCFA on deficiencies in draft regulations pertaining to the care of patients in hospice programs, which are also covered under TEFRA. The subcommittee asked that results from both discussions with HCFA be reported to the Board at its next meeting. The subcommittee also commended Mr. Richard A. Bloch for his outstanding contribution to the National Cancer Program through his sponsorship of the PDQ concept and his assistance in the development of the project.

The subcommittee's report was accepted unanimously by the Board.

XVII. Report of the Subcommittee for Review of Contracts and Budget of the Office of the Director--Dr. Robert C. Hickey

Dr. Hickey described the activities of various offices within the NCI's Office of the Director. The subcommittee provides concept review for contracts supported through the Office of the Director and, since May 1981, has reviewed and approved 21 contracts, totaling \$28.3 million. A review of these contract concepts was presented to the Board.

The subcommittee's report was approved unanimously by the Board.

XVIII. Report of the Subcommittee on Environmental Carcinogenesis--Mr. Sheldon Samuels

Mr. Samuels presented an interim report for the Board's approval; a final report is awaiting incorporation of information from Dr. Paul F. Deisler, Jr., and Dr. Roy Albert, whose comments were received after the last meeting of the subcommittee on November 15, 1982. Mr. Samuels alerted the Board Chairman and the Subcommittee on Activities and Agenda that the subcommittee's final report will require time for a full technical presentation of the issues and a detailed explanation of the subcommittee's recommendations and the reasons for these recommendations. Dr. Boutwell was appointed to the subcommittee by Dr. Carter.

The interim report was accepted unanimously by the Board.

XIX. Report of the ad hoc Subcommittee on Program Project Grants--Dr. Maureen Henderson

Dr. Henderson summarized the subcommittee's initial activities for the Board's information. The subcommittee is composed of Dr. Henderson, Dr. Carter, current and immediate past chairmen of the Basic Science and Clinical PO1 Review Committees, a member of the present Therapeutic PO1 Review Committee, the immediate past chairman of the NCAB, and a member who has served as chairman of several PO1 review committees. Mrs. Bynum, Dr. Dennis Cain, and the Executive Secretaries of the three chartered NCI review groups serve as consultants to the subcommittee. The subcommittee will examine the role and unique contributions of the PO1 grants to the cancer research effort and specific aspects of PO1 review, as well as the broad review picture. The subcommittee will consider options for improvements in the review process and will develop recommendations.

XX. Adjournment--Dr. Tim Lee Carter

Dr. Carter announced that the President's Cancer Panel will hold regional meetings with NCI grantees in Houston, Texas, on March 4, 1983, and Chicago, Illinois, on April 8, 1983. Another meeting will be held in Bethesda in late spring.

The 45th meeting of the NCAB was adjourned at 12:20 p.m. on Wednesday, February 2.

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

January 28, 1983

NATIONAL CANCER ADVISORY BOARD

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PAGE 2 - NATIONAL CANCER ADVISORY BOARD

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