National Institutes of Health

National Cancer Institute

NATIONAL CANCER ADVISORY BOARD

Summary of Meeting
May 16-18, 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*
May 16-18, 1983

The National Cancer Advisory Board (NCAB) convened its 46th regular meeting at 8:30 a.m., May 16, 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. Ed L. Calhoon
Dr. Tim Lee Carter
Dr. Maureen M. Henderson
Dr. Robert C. Hickey
Dr. Geza J. Jako
Dr. J. Gale Katterhagen
Ann Landers
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. Armand Hammer
Dr. William P. Longmire, Jr.
Dr. John A. Montgomery

Ex Officio Members

Dr. Hollis Boren, VA
Dr. William Farland, EPA
Dr. Elliott S. Harris, NIOSH
Dr. Allen Heim, FDA
Dr. Carl Leventhal, OSTP
Dr. F. Kash Mostofi, DOD
Dr. Peter W. Preuss, CPSC
Dr. David P. Rall, NIEHS
Dr. Ralph E. Yodaiken, LABOR

Absent

Dr. Roswell K. Boutwell
Dr. Victor Braren
Mrs. Rose Kushner

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*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

Mr. Alan 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. 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. William Dugan, President, Association of Community Cancer Centers, Indianapolis, Indiana, representing the Association of Community Cancer Centers.

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 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, a total of 25 registered members of the public attended the meeting.

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

Dr. Carter, Chairman, called the meeting of the National Cancer Advisory Board (NCAB) 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. John A. Montgomery, Senior Vice President and Director of Kettering-Meyer Laboratories, Southern Research Institute, and announced that Dr. Montgomery had recently been appointed to serve on the President's Cancer Panel. Dr. Carter also welcomed Mrs. Annette Bloch to the Board meeting and introduced the liaison representatives.

Procedures for the conduct of Board meetings were reviewed. Members of the public who wish 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. Future Board meeting dates were confirmed as follows: October 3-5 and November 28-30, 1983; January 30-February 1, May 14-16, October 1-3, and November 26-28, 1984.

The minutes of the NCAB Meeting of January 31-February 2, 1983, were unanimously approved by the Board.

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

Dr. DeVita welcomed Dr. Montgomery to the NCAB meeting and expressed appreciation to Dr. Harold Amos for his contributions during his 11 years of service as a member of the Board and of the President's Cancer Panel.

Announcements

(1) New ex officio members have been appointed to the Board. Drs. Carl Leventhal and Gordon Wallace have been appointed as alternates for the Office of Science and Technology Policy, Executive Office of the President. In addition, Dr. Ralph E. Yodaiken of the Occupational Safety and Health Administration, Department of Labor, has been appointed as an Ex Officio Member of the Board, replacing Dr. Denis J. Prager.

(2) Ms. Peggy Collins has been engaged to assist Dr. Carter. Ms. Collins was formerly with the University of Kentucky Diabetes Program.

(3) Ms. Iris Schneider has been named Director of Staff Operations in the Office of Director, NCI. Ms. Schneider formerly served as Special Assistant to the Administrator of the Health Resources Administration and Special Assistant to the Associate Director of Administrative Management, NCI.

(4) Dr. Susan Sieber has been appointed Deputy Director of the Division of Cancer Cause and Prevention (DCCP), NCI.

(5) Two NCI scientists have recently won awards. Dr. Lance A. Liotta received the Fleming Award and Dr. Michael Potter was awarded the 1983 Paul Ehrlich-Ludwig-Darmstaedter prize for his work on mouse plasma cell tumors.

(6) Dr. Gregory T. O'Conor has left his position as Associate Director for International Affairs to serve as liaison for NCI with the International Agency for Research on Cancer (IARC). Dr. Joseph F. Saunders has been named Acting Associate Director.

Followup Items

(1) Dr. DeVita thanked Board members for responding to the mail ballot conducted to accelerate funding for research on Acquired Immune Deficiency Syndrome (AIDS). A new Request for Application (RFA) on AIDS has been issued in the area of virus isolation. The program will be jointly supported by NCI and the National Institute of Allergy and Infectious Diseases (NIAID). The NCI has formed an internal task force to mobilize intramural research efforts on AIDS. The task force is headed by Dr. Peter Fischinger; Dr. Robert C. Gallo is serving as Scientific Director and Dr. Samuel Broder, as Clinical Director. NCI project officers for extramural AIDS research will interact with the task force.

(2) A funding plan for the Community Clinical Oncology Program (CCOP) will be presented in the closed session of the Board. The funding plan takes into account the two bases for evaluating CCOP grant applications--priority scores and geographic spread. Dr. DeVita thanked the many physicians, NCI staff members, and others whose ideas and efforts contributed to the development of this program, which will bring practicing oncologists together with the clinical research effort and focus on patient care.

(3) Reports on the proposed Outstanding Investigator Grant program and the review of Program Project (P01) grant applications will be presented at the current meeting. Dr. DeVita reiterated that the purpose of the Board's consideration of P01 review procedures represented an effort to strengthen, not harm, this funding mechanism.

(4) Dr. DeVita referred Board members to their meeting notebooks for a followup report on the status of the contract to study effects of radiation fallout in Utah from atomic bomb testing and for a summary of NCI review of tumor marker research grants.

(5) An RFA on the Organ Systems Program has been issued and the deadline for applications is July 13. A funding plan for the program will be discussed in the closed session.

Budget

Dr. DeVita discussed the status of the NCI budget for fiscal years 1983, 1984, and 1985.

In FY 1983, the NCI is operating under a Continuing Resolution, which sets the budget level at $983 million. Some modifications have been made to the funding plan approved by the Board in October, which

was based on a funding level of $955 million. NCI will fund an additional 177 new and competing R01 and P01 grants in FY 1983, for a total of 812. Competing grants will be funded 15 percent below recommended levels instead of 20 percent, as originally planned. NCI will fund 31 percent of approved grants, rather than 24 percent as envisioned, and the priority score cutoff has been raised from 170 to 175-178.

The bypass budget for FY 1985 will be submitted to the Office of Management and Budget (OMB) in September. Planning assumptions for this budget have been developed and the NCAB Subcommittee on Planning and Budget will review the information and tables at their evening meeting and report to the Board on Wednesday.

The NCI has completed its testimony before the House and Senate appropriations subcommittees on the NCI budget for FY 1984. The Administration budget for NIH submitted in January was revised in March to permit NIH to meet its goal of funding 5,000 competing grants in FY 1984. Under the revised President's budget, NCI will receive $986,681,000, approximately $3 million less than in the original budget, and will be required to fund 817 new and competing grants. Modifications to the NCI budget necessitated by the revised budget include:

- Increase of $33.581 million to the competing grants pool, including funds obtained by reducing noncompeting grants by an additional 1 percent.
- Reduction of $19.8 million in the centers program.
- Reduction of $7.28 million for contracts.
- Other miscellaneous cuts.

In addition, the noncompeting centers pool would be reduced by 10 percent, and research project pool grants would be funded about 14.3 percent below average costs.

The Director emphasized that the budget is not final and still has to be acted upon by Congress. The NCI will not allow the centers program to bear the primary burden of these funding adjustments and that further modifications will have to be made to the budget as it stands now. It was suggested that the concept of stabilization, which often necessitates funding of grants below recommended levels, would be an appropriate topic for Board consideration at a later meeting.

New Items

(1) The Board's attention was called to the report in their notebooks, "Report on NCI Management Efforts and the Impact on Research," by Dr. Thomas E. Malone, Deputy Director, NIH, which summarizes changes in NCI since 1980 and was prepared as a followup report at the request of Congress.

(2) As previously reported, an amendment to the Orphan Drug Bill, proposed by Senator Orrin Hatch, requires the development of radioepidemiologic tables to assess attributable risks to persons exposed to radiation. In accordance with this amendment, NCI has been directed by DHHS to plan for research on thyroid cancer risks from radiation exposure. The tables are being developed by an NIH committee chaired by Dr. Joseph E. Rall, Acting Deputy Director for Science, NIH, and will be reviewed by an oversight committee prior to being presented at hearings conducted by the Senator next January.

(3) An announcement was made that Senator Hatch and members of his committee will visit NIH on May 23.

(4) OMB has established a ceiling on the number of government experts, and NCI's allotment of 150 experts may be reduced. Dr. Armand Hammer, Chairman of the President's Cancer Panel, has requested DHHS Secretary Margaret Heckler to look into the possibility of developing other mechanisms to provide positions.

(5) Guidelines for core grants have been modified to provide flexibility to center directors in filling vacated positions supported through core grants (subject to the 25 percent cap on staff salaries paid by the grant) and to allow for inclusion of an Associate Director for Cancer Control in the core grant program. Announcement of these revisions will be sent to center directors.

(6) Dr. DeVita spoke of fruitful discussions resulting from meetings conducted by the President's Cancer Panel with investigators at major centers; the concept of an outstanding investigator grant originated from these discussions. Among other ideas is the suggestion that core grant review include an administrative component, with scientists serving in a consultant role.

(7) A meeting on Cancer and Minorities, held recently in Memphis, Tennessee, was attended by several members of the NCI staff, including a presentation for NCI by Dr. Jane Henney. Dr. LaSalle D. Leffall of the NCAB and Dr. Amos also attended.

(8) The General Accounting Office has completed its report on the conduct of clinical trials by NCI and the Food and Drug Administration, a review requested by Senator Paula Hawkins. The conclusions of the report are favorable to NCI.

(9) The delay in approving the drug cis-platinum has resulted in the company marketing the drug, Bristol Laboratories, requesting an extension of its license. NCI will report its recommendations to the Department. Although other companies wish to market the drug, two issues are involved; one concerns the cost of the drug and the other concerns the willingness of firms to make the necessary investment in a drug that is of relatively limited use.

(10) Japan has requested NCI's assistance in developing a cancer program modeled after the National Cancer Program. Dr. DeVita is meeting with the

Japanese Minister of Health and with other delegations. Cancer is the leading cause of death in Japan, but the incidence of stomach cancer, the most common malignancy in that country, is declining, while the incidence of breast and colon cancers is rising.

Legislative Update--Dr. Mary Knipmeyer

Dr. Knipmeyer introduced Ann Houser, Legislative Analyst with NIH, who works with Dr. Knipmeyer. She reviewed the status of legislation pertaining to NCI reauthorization, AIDS, radiation exposure, animal welfare, and cigarette labeling.

Both House and Senate reauthorization bills for NIH are similar to legislation introduced last year. Both bills include provisions for a separate Institute for arthritis, animal welfare legislation, and a National Academy of Sciences study on the organization of NIH. Special provisions relating to NCI in the House bill include a "line item" for cancer centers, support of clinical cancer education programs for students, elimination of the NCAB biennial report to the NIH Director, and a $35,000 limit on grants and cooperative agreements that can be awarded without NCAB approval (the Senate bill establishes a $50,000 limit). The Senate bill includes provisions for the continuing care of cancer patients and their families and for the establishment of an appeals process at NIH for grant and cooperative agreement applications. Both bills call for a 3- to 5-year extension on funding for cancer research and demonstration centers. The House bill authorizes $1.3 billion for NCI, and the Senate bill authorizes $1.006 billion. Both bills have been reported out of committee, but not yet acted upon by the full House or Senate.

The Radiogenic Cancer Compensation Act of 1983, introduced by Senator Hatch, would establish the radioepidemiologic tables mandated by the Orphan Drug Act as standard for determining compensation claims. Eight bills relating to AIDS have been introduced in Congress. Several would establish special, expedited review procedures for grants, contracts, and cooperative agreements in research areas designated as public health emergencies; other bills call for the establishment of an emergency fund at NIH to support such research and supplementary funds for the Centers for Disease Control for the conduct of epidemiological and medical research on AIDS and related opportunistic infections. Both reauthorization bills contain provisions for expediting review procedures in public health emergencies as determined by the Secretary of DHHS. Three bills relating to cigarette labeling have been introduced, two deal with labeling and one with advertising. Dr. Henney has testified before Congress on this issue, along with Dr. Edward N. Brandt, Jr., Assistant Secretary for Health.

A number of bills have been introduced concerning the use of animals in research, in addition to those included in reauthorization legislation for NIH. In general, the bills call for the development of alternative methods of research and testing, less painful procedures, and oversight procedures to ensure humane care and treatment. The Animal Welfare in

Research Study Act of 1983, part of the Senate reauthorization bill, provides for a National Academy of Sciences study.

The freshman class in the House has not yet acted to implement its project on cancer research. Dr. Knipmeyer is in contact with a staff representative of Congressman Sherwood Boehlert, who is coordinating the activity. Dr. DeVita testified on the role of epidemiology in cancer risk assessment before the House Agricultural Subcommittee on Department Operations, Research, and Foreign Agriculture. He will testify at the Senate hearings on food safety in June.

Protocol Data Query (PDQ) System

The R.A. Bloch International Cancer Information Center will be dedicated on October 2, and all Board members are invited to attend the ceremony. PDQ-1 now contains 917 protocols, 293 of which have been added since October (187 have been dropped). PDQ-2 is about a month behind schedule. Capsule statements are completed, and all but six state-of-the-art statements have been drafted; 250 consultants have been involved in the development of these protocols. In addition, 245 non-NCI-supported protocols have been submitted of which 61 have been reviewed. All statements will be reviewed by center directors. Presentations on PDQ are being made to major medical organizations, some of which have assisted with the development of files for the system.

Several issues related to PDQ were raised for Board consideration. One issue, to limit the system to physicians, has been resolved by the Board. Another, to establish actual goals for PDQ, including the identification of national targets for specific disease areas, was proposed for discussion at the October meeting. The third issue, how to promote PDQ, was presented for NCAB discussion. Three alternative methods of promotion to direct users of PDQ and to those who need to be aware of the system were reviewed.

- Promotion to vendors only.
- Promotion to target audiences in conjunction with vendors.
- Promotion to target audiences in conjunction with vendors and the general public.

The first method was cited as cost-free, however, one over which NCI would have little control.

Mr. Bloch spoke for the third method of promotion. This approach would best serve the primary purpose of PDQ, which is to make up-to-date cancer care available to every cancer patient in the country. After some discussion of this issue, the Board passed the following resolution, which was introduced by Dr. William E. Powers and seconded by Dr. Irving Selikoff:

That the question of promotion and distribution of PDQ be brought to the Subcommittee on Cancer Control and the

Community and that the subcommittee report back to the Board its recommendations for developing guidelines and for implementation.

III. Report of the President's Cancer Panel--Dr. Armand Hammer

Dr. Hammer, Chairman, formally welcomed Dr. Montgomery to the Panel and presented him with his official commission signed by the President and the Secretary of State. Dr. Montgomery is appointed for a 3-year term, ending in February 1986. The Chairman noted Dr. Amos' long years of service as a model member of the Board and Panel and thanked him for his "help, dedication, and hard work." Dr. Hammer emphasized good relations between the Panel and the NCAB in carrying out their responsibilities effectively.

The Panel meetings of November 8, 1982, March 4, 1983, and April 18, 1983, were described. The November meeting, held at NIH, was concerned primarily with the discussion of support for construction, diet and nutrition research, and gene research. Concern was expressed about the funding level for construction, which was termed "unrealistic." The Panel will advise the President of the need for more funds for construction; suggestions from the Board on this issue are welcome. Diet and nutrition and gene research were described as exciting, promising research areas that should be vigorously pursued.

The meetings in March and April, held at the University of Texas and at Northwestern University in Chicago, were continuations of the Panel's meetings with investigators throughout the country, which have included discussions on peer review committees, priority scores, and methods of rebuttal. Dr. Hammer noted the possibility of the development of an appeals system at NIH and suggested that the Panel meetings would be an effective means of making the scientific community aware of the new system. The Panel intends to continue these regional meetings, but may focus on more specific topics. He asked for suggestions from the Board.

IV. Diet and Nutrition and Cancer Chemoprevention Plans--Dr. William DeWys

Dr. DeWys, Assistant Director for Cancer Prevention, Division of Resources, Centers, and Community Activities (DRCCA), reported on the status of NCI's implementation of recommendations of the NCAB ad hoc Subcommittee on Nutrition and Cancer. His report covered activities in DRCCA, DCCP, and the Office of Program Planning and Analysis.

NCI has developed two programs; one focuses on diet, nutrition, and cancer prevention research and the other on chemoprevention research. Details of the planning process and of the research flow in laboratory, epidemiologic, and human intervention research were described for both programs. The principles underlying planning are the relative role of diet

and nutrition in cancer etiology, the need for a multidisciplinary approach, and the need to aim for a balance between investigator-initiated research and research according to a preconceived strategy. The current funding level for diet and nutrition and chemoprevention research is $37 million, but will rise to $50 million in FY 1984 and $60.7 million in FY 1985. In terms of resource allocation, the current emphasis is on laboratory research, with secondary emphasis on epidemiology. Human intervention trials in chemoprevention have begun and trials will be implemented in 1984-85 in the diet and nutrition program and will be expanded as the programs progress.

V. Outstanding Investigator Grant--Dr. Harold Amos

Dr. Amos, Chairman of the Panel's ad hoc Working Group to Consider the Parameters of an Outstanding Investigator Award, presented a final draft of the working group's report for the Board's review and discussion.

Dr. Amos noted first that the name of the program had been changed to "Outstanding Investigator Grant." He reviewed the aims and objectives of the proposed grant program, which are: to provide eligible investigators with a stable source of financial support and flexibility over a definite period of time, to encourage research on long-term projects in areas of unusual or novel potential, and to recognize an investigator on the basis of his or her established research preeminence and productivity. The draft report included the working group's recommendations regarding eligibility requirements, application and review procedures, award size and duration, and other conditions relating to the grant. The working group proposed that a panel of 150-200 internationally recognized scientists assist with the review of applications. It is anticipated that the program will begin with 20 grants, with 50 grants being funded in 5 years. During the discussion, it was suggested that the Board review the draft guidelines prepared by the working group and that NCI seek input from the scientific community. The Board will consider details of the Outstanding Investigator Grant at a later session.

VI. Subcommittee Structure--Mrs. Barbara Bynum

The following six questions relating to the Board's charter and the structure and operations of NCAB subcommittees were presented for Board consideration:

1. What subcommittees of the Board are needed?

2. What factors are important in subcommittee structure? (Quality, size, overlap, non-NCAB members)

3. Should they be standing or ad hoc?

4. Should their mission overlap with the divisional Boards of Scientific Counselors?

5. Should interested observers who are NCAB members but not subcommittee members be compensated?

6. What records of subcommittee meetings should be kept?

The Board took the following actions, passed in the form of resolutions, with regard to these questions:

- That the NCAB charter language be retained; that those subcommittees that are chartered remain chartered and those that are ad hoc remain ad hoc.

- That the subcommittee structure of the NCAB be retained and that the membership and term of the subcommittees be the prerogative of the Chairman of the NCAB with advice from NCAB members.

- That a mechanism be continued and funded to provide support for secretarial and administrative assistance to the Chairman of the NCAB and for Board-related activities of NCAB members.

- That prior approval and authorization by the Chairman of the NCAB for attendance or participation be the basis for reimbursement for travel, per diem, and consultant fee.

All of these motions were proposed by Dr. Powers. For the record, it is noted that Dr. Carter relinquished the Chair to Dr. Ed L. Calhoon during consideration of the third motion.

Another motion, relating to the establishment of a mechanism or contact for NCAB members for requesting and obtaining information from NCI staff on budgets, administration, or programs, was withdrawn after it was noted that such a mechanism had been established. A motion relating to attendance of NCAB members at meetings of divisional Boards of Scientific Counselors was deferred for consideration at the November program review meeting.

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

Mr. Samuels presented, for the Board's review, the draft report developed by the subcommittee. The subcommittee was convened to gather information and views for development of a policy on quantitative risk assessment to be adopted by NCAB. The report included discussions of the steps involved in quantitative risk assessment, uses of quantitative risk assessment, institutional responsibilities with regard to quantitative risk assessment, application and validity of research models, and NCI activities relating to risk assessment and studies in environmental carcinogenesis. Mr. Samuels highlighted issues concerning the role of animal bioassay studies, uses of quantitative risk assessment, and institutional responsibilities. The subcommittee recommends that the risk assessment process be separate from the regulatory process and that a formal mechanism be established to deal with challenges in risk assessment. Mr. Samuels thanked Dr. Richard H. Adamson, Director of DCCP, and his staff for their support to the subcommittee, and

he particularly cited Dr. Robert Tardiff of the National Academy of Sciences and Dr. William Nicholson of the Mt. Sinai School of Medicine for their assistance.

Dr. Adamson described current and planned NCI activities in the areas of biochemical epidemiology and environmental carcinogenesis, highlighting NCI's new programs in biochemical and molecular epidemiology and their potential application in risk assessment. It was proposed that the final report of the subcommittee be mailed to NCAB members and that a telephone or mail poll be conducted to determine Board approval.

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

Dr. Henderson, Chairperson, reported on the deliberations of the subcommittee, which was formed in October to examine questions relating to the review of P01 grant applications and to develop recommendations for improving the quality, consistency, and discriminatory capacity of P01 review. The subcommittee, which was composed of experienced basic science and clinical science program project review experts, held three meetings.

Dr. Henderson's report included a review of the history of the P01 grant mechanism; the definition of a program project grant; the grant's current role in the NCI research effort; statistics on the spread of P01's in NCI programs and divisions; a discussion of P01 review, including site visit review; the composition of review committees and procedures employed by these bodies (for both P01 and R01 grants); and a discussion of factors involved in developing priority scores for P01 grants.

Dr. Henderson submitted guidelines for P01 applicants developed by NCI and revised by the subcommittee. She requested the Board's approval of these guidelines for immediate distribution and implementation by NCI. The subcommittee also recommended a study of factors involved in assessing the merit of both individual projects and the program as a whole in developing a priority score for P01 applications. The subcommittee has designed such a study and requests suggestions from the Board and from the Boards of Scientific Counselors. Dr. Henderson asked the NCAB Chairman to appoint two or three NCAB members with P01 experience to meet with representatives from the subcommittee and the Boards of Scientific Counselors to consider all of the recommendations in detail and to agree on specific action recommendations to the Board. It was proposed that Board members review the draft guidelines and vote on acceptance at the next day's session.

IX. Studies of Human T Cell Lymphoma--Dr. Robert C. Gallo

Dr. Gallo, Chief of the Laboratory of Tumor Biology, Division of Cancer Treatment, spoke on the human T-cell leukemia-lymphoma virus (HTLV), which has been associated with certain adult T-cell malignancies in various parts

of the world and, recently, with AIDS. His presentation included a description of the structure of the virus, the history of the isolation of the virus in animals and its discovery in humans in the late 1970's, what is known about its mechanism of action in cells, its biologic activity, the successful molecular cloning of HTLV, the isolation of T-cell growth factor, and the epidemiology and other characteristics of the virus. Dr. Gallo said that HTLV is widespread in nature and is the most common known cause of leukemia and lymphoma in animals. The virus has been found in three categories of disease in adult humans, adult T-cell leukemia, peripheral T-cell lymphoma, and mycosis fungoides. So far HTLV has only been found in adults. A feature of the virus is its tight clustering, and clusters have been found in Japan, the Caribbean, the southeastern United States, South and Central America, and Africa. Dr. Gallo also discussed its recent discovery in some patients with AIDS.

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

Dr. Powers presented, for NCAB approval, the subcommittee's recommendations on the Organ Systems Program. The subcommittee's first recommendation was that NCI maintain and operate a strong, multidisciplinary Organ Systems Program. Other recommendations concerned the organization and implementation of the program, review of grant applications, program funding, and the role of the Organ Systems Program subcommittee. The subcommittee's recommendations were unanimously approved by the Board.

XI. Small Business Innovative Research--Mrs. Lily Engstrom

Mrs. Engstrom, Coordinator of the Small Business Innovation Research (SBIR) Program at NIH; presented an overview of this program, mandated by the Small Business Innovation Development Act of 1982. The specific purposes of this new program are to: stimulate technological innovation, use small businesses to meet Federal research and development needs, increase private sector commercialization of innovations derived from research and development efforts of the Federal Government, and foster and encourage participation by minority and disadvantaged persons in technological innovation.

The program is government wide and will affect almost all extramural research components at NIH. Under the program, a certain percentage of an agency's extramural research and development budget must be set aside for small business awards. The percentage to be set aside rises from 0.2 percent in the first year to 1.25 percent in the sixth, and final, year of the program. NIH will set aside $6.07 million this year for SBIR grants. The program will consist of three phases, with phase I to be implemented this fiscal year. It was estimated that NIH has received about 700 applications during its first solicitation, which closed May 1, and expects to fund between 100-125 SBIR awards this year. Grant applications will be reviewed and awarded within a 5- to 6-month period, and special study sections will be

formed for these grants. Review criteria for SBIR grants were described. Board members will be sent summary statements of applications within NCI's aegis for mail approval so that approved grants can be funded this fiscal year.

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

Mr. Carrese, Associate Director for Program Planning and Analysis, presented the subcommittee's report on the 1985 bypass budget for Dr. Henderson, Acting Chairperson. The minutes of the subcommittee's meeting on May 16 were read, which included a discussion of the assumptions underlying the development of the budget; key features of the budget; and tables showing budget allocations by major activities, research programs, groups (i.e., investigator-initiated, co-initiated, etc.), and funding mechanisms. The proposed budget for FY 1985 is approximately 20 percent higher than the FY 1984 budget submitted by the Administration and includes increases for construction, cancer control, research in chemical and physical carcinogenesis, nutrition, centers, and clinical and drug research. Board members were asked to submit any changes or suggestions to the narrative accompanying the tables to NCI by the end of May. The budget will be submitted to OMB in the fall.

The report was approved unanimously by the Board.

XIII. Consideration of the Report of the ad hoc Subcommittee on Program Project Grants--Dr. Tim Lee Carter

The NCAB voted unanimously to accept the subcommittee's report presented in Monday's session and approved unanimously in closed session on Tuesday, May 17. The motion was restated by Dr. Powers and seconded by Dr. Hickey.

XIV. Adjournment--Dr. Tim Lee Carter

The 46th meeting of the NCAB was adjourned at 11:00 a.m. on Wednesday, May 18.

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

April 11, 1983

NATIONAL CANCER ADVISORY BOARD

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