Department of Health and Human Services

Public Health Service

National Institutes of Health

National Cancer Institute

National Cancer Advisory Board

Summary of Meeting
September 24-26, 1984
James A. Shannon Building
(Bldg. 1)
Wilson Hall
National Institutes of Health
Bethesda, Maryland

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

Minutes of Meeting*
September 24-26, 1984

The National Cancer Advisory Board (NCAB) convened for its 51st regular meeting at 8:30 a.m., September 24, 1984, in Wilson Hall, Third Flood, James A. Shannon Building (Building 1), National Institutes of Health (NIH), Bethesda, Maryland. Dr. David Korn, Chairman, presided.

Board Members Present

Mr. Richard A. Bloch
Dr. Roswell K. Boutwell
Mrs. Angel Bradley
Dr. Victor Braren
Mrs. Helene G. Brown
Dr. Ed L. Calhoon
Dr. Tim Lee Carter
Dr. Gertrude B. Elion
Dr. Robert C. Hickey
Dr. Geza J. Jako
Dr. J. Gale Katterhagen
Dr. David Korn
Mrs. Rose Kushner
Ann Landers
Dr. LaSalle D. Leffall
Dr. Enrico Mihich
Dr. William E. Powers
Dr. Louise C. Strong

President's Cancer Panel

Dr. Armand Hammer
Dr. William P. Longmire, Jr.

Ex Officio Members

Dr. Bernadine Bulkley, OSTP
Dr. Allen Heim, FDA
Vice Admiral Lewis H. Seaton, DOD
Dr. Ralph E. Yodaiken, LABOR

Absent

Dr. John A. Montgomery, 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

Mr. John Madigan, Coordinator for Governmental Relations, American Cancer Society, New York, New York, representing the American Cancer Society.

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

Dr. James Robertson, Director, Human Health and Assessment Division, U.S. Department of Energy, Washington, D.C., representing the U.S. Department of Energy.

Ms. Kathleen M. Thaney, R.N., Oncology Nurse Coordinator, University of Maryland Cancer Center, Baltimore, Maryland, representing the Oncology Nursing Society.

Members, Executive Committee, National Cancer Institute

Dr. Vincent T. DeVita, Jr., Director, National Cancer Institute
Dr. Richard H. Adamson, Director, Division of Cancer Etiology
Mr. Philip D. Amoruso, Associate Director for Administrative Management, National Cancer Institute
Mrs. Barbara S. Bynum, Director, Division of Extramural Activities
Dr. Bruce A. Chabner, Director, Division of Cancer Treatment
Dr. Peter J. Fischinger, Associate Director, National Cancer Institute
Dr. Peter Greenwald, Director, Division of Cancer Prevention and Control
Dr. Jane E. Henney, Deputy Director, National Cancer Institute
Dr. Alan S. Rabson, Director, Division of Cancer Biology and Diagnosis
Ms. Iris Schneider, Director of Staff Operations, National Cancer Institute

In addition to NCI staff members, meeting participants, and guests, a total of 8 registered members of the public attended the meeting.

I. Call to Order--Dr. David Korn

Dr. Korn, Chairman, called the meeting to order and welcomed members of the Board, the President's Cancer Panel, liaison representatives, guests, staff of the National Cancer Institute (NCI), and members of the public. He introduced the new members of the Board and stated that he was deeply honored by his appointment as Chairman of the Board.

Procedures for the conduct of Board meetings were reviewed. Members of the public who wished 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. Korn emphasized the importance of having a quorum of 12 members present for each occasion when a vote is taken.

II. Future Board Meeting Dates

Future Board meeting dates were confirmed as follows: November 26-28, 1984; February 4-6, May 13-15, October 7-9, and December 2-4, 1985.

III. Consideration of NCAB Minutes of May 1984

The minutes of the May 1984 meeting of the National Cancer Advisory Board were approved without objection. A suggestion was made to mail the minutes to the members in advance of the meetings.

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

Dr. Hammer welcomed the new members of the Board and reported on the Panel's September meeting on cancer centers, held in San Francisco, which Dr. Korn, Mrs. Rose Kushner, and Mr. Richard Bloch attended. Problems faced in the San Francisco area include the size and diversity of the ethnic population, poor education of certain segments of these groups, and the lack of solid, accurate information about cancer in many of the communities judged to be most vulnerable to the risks of cancer. The major theme of the San Francisco meeting was the topic of the Consortium Center, which consists of a group of various institutions working on cancer in a particular area with one central administrative body. The Northern California Program Consortium coordinates the cancer-related activities of Stanford; the Universities of California at Berkeley, San Francisco, and Davis; and various hospitals, research institutions, and cancer agencies in the area. Speakers discussed their problems and their successes, thereby giving the Panel the opportunity to explore thoroughly the consortium theme.

Dr. Hammer reported that the Panel has benefited from traveling around for 3 years, because it has given the members the opportunity to meet personally with those on the front line of cancer research in many parts of the country.

The Panel's next meeting is scheduled for Hawaii in November.

Dr. Hammer announced that CDP Associates of Rockville, Maryland, has been selected as the contractor to prepare the study of the construction needs of the Nation's cancer research community, a study sponsored jointly by Dr. Hammer and the American Cancer Society.

Dr. Hammer reported on the work of the Bone Marrow Graft Department at UCLA, headed by Dr. Robert P. Gale, and stated that he was able to fund a program in Israel that is working in the same area, using monoclonal antibodies to destroy cancer cells in bone marrow before transplanting it.

V. Director's Report, National Cancer Institute—Dr. Vincent T. DeVita, Jr.

Dr. DeVita welcomed the new members of the Board and thanked the members who have left the Board for their hard work over the years. He briefly reviewed the format of the Board's first two meetings of the fiscal year, with the first or current meeting emphasizing information on the closing out of the budget for fiscal year 1984 and on the budget for fiscal year 1985. The November meeting will be devoted to program review, with the Division Directors and the Chairmen of the Boards of Scientific Counselors presenting the work that has taken place during the past year at the boards and in the divisions, as well as plans for this year. The November meeting also includes scientific presentations.

Announcements

(1) Dr. Lucius F. Sinks from Tufts University has been named Chief of the Cancer Centers Branch, Division of Cancer Prevention and Control (DCPC).

(2) Dr. Donald C. Iverson from the Denver Colorado Emergency Hospital has become Associate Director for Cancer Control Science Program, DCPC.

(3) Mr. Mark F. Kochevar has been appointed Administrative Officer for the Division of Cancer Etiology (DCE).

(4) Ms. Susan M. Hubbard will serve as Director of the International Cancer Information Center, Office of the Director (OD).

(5) Dr. Daniel R. Masys has been named Chief of the International Cancer Research Data Bank Branch, Office of the Director (OD).

(6) Ms. Mary C. Stram has been selected as the Chief of the Computer Communications Branch, Office of the Director (OD).

Budget

Dr. DeVita discussed the status of the NCI budget for fiscal years 1984, 1985, and 1986.

The fiscal year 1984 budget of $1.081 billion includes a $4.2 million supplemental, which was divided into two portions: $2.2 million for a pay raise and approximately $2 million for AIDS research.

Funding projections and current end-of-year estimates for fiscal year 1984 were reviewed. Of the 5,000 grants in the NIH competing pool, NCI had projected funding 923 grants and actually funded 961 grants, an increase of 38 grants for a total of $155.9 million, up $4.4 million from the original projection of $151.5. Funding of grants amounted to 38 percent of approved applications, a level the Institute is comfortable with.

The research project pool, estimated at 2,833 grants for the fiscal year 1984 congressional budget, increased to 2,839 grants, with the dollar amount decreasing by approximately $8 million. This $8 million was transferred to research and development contracts, representing a distribution of funds into epidemiology, nutrition and carcinogenesis, AIDS research, and some renovation at the research laboratory.

NCI funds approximately 38 to 40 percent of NIH research on AIDS, with $16.5 million estimated for fiscal year 1984 and nearly $27 million for fiscal year 1985. A subcommittee of the Division of Cancer Treatment Board has been formed to consider the development of a vaccine to the retroviruses; the subcommittee's latest report has been distributed to the Board. Currently, five companies have been licensed to receive the cell line that supports the HTLV3 virus and to develop a diagnostic test.

Dr. DeVita explained the three-phase funding structure of the Small Business Innovation Research Grants Program and reported that the difficulties the Institute has had funding these grants result largely from the lack of appropriate applications. If applications are submitted in fiscal year 1985 at the same rate as in fiscal year 1984, the Institute will have to return to the Treasury most of the money set aside in the budget for this program. Board members can help the Institute's efforts to alert the scientific community about this program.

The fiscal year 1985 budget increase is expected to fall between 8.6 and 9.8 percent, resulting in a budget in the range of $1.175 billion to $1.187 billion--the largest increase since the late 1970's. Areas of concern are the cancer control budget, the construction budget, and the training budget, which are all flat for fiscal year 1985. Major features include an increase in competing research projects to approximately 1,100, increased funding for cancer centers from $78 million to $85.9 million, and, in the Senate bill, $13.1 million for construction, with $4.5 million set aside for the construction of a center in West Virginia.

Dr. DeVita discussed the 1986 bypass budget assumptions and principles, as well as the estimated increases in dollar amounts and percentages. Basic research continues as the Institute's first priority; other funds in fiscal year 1986 will provide for five additional cancer centers, for doubling the capacity of Clinical Cooperative Groups, and for the expansion of prevention and community efforts within cancer control. The total fiscal year 1986 bypass budget amounts to $1.460 billion, an increase of 22.9 percent over

the fiscal year 1985 Senate bill level of $1.187 billion. The total budget for 1990 is estimated at $2.044 billion, a 72-percent increase over the fiscal year 1985 estimated level.

Followup Items

(1) The first annual review of Community Cancer Oncology Programs (CCOP's) has been completed, and the overall results show that they are functioning well, although a few did not accrue sufficient patients to continue.

(2) The Organ Systems Program Coordinating Center Grant has been funded at Roswell Park Memorial Institute, as the Board recommended, for 3 years.

(3) The Outstanding Investigator Grant Award has been very well received. The Institute has received 103 applications, and approximately 200 reviewers have agreed to do the mail ballot reviews, which will probably be brought before the Board between January and May, 1985.

(4) The Institute has licensed BRS Colleague to vend PDQ, which is improving daily. The Institute is working with the American Medical Association to resolve its difficulties with PDQ, as expressed by the Board of Trustees in response to the Association's House of Delegates' resolution 78 voicing opposition to the development by an agency of the Federal Government of a list of physicians with "special expertise" in cancer care. Two points should be made clear: NCI is not compiling a list of specialists but a list of directories of organizations where physicians spend the majority of time caring for cancer patients, and second, this is not a public list but a system devoted to physicians.

(5) Cancer centers have been undergoing management review, have been discussed by the President's Cancer Panel in terms of geographic clusters, and are the subject of a study now being prepared by a subcommittee of the Division of Cancer Prevention and Control and the Board of Scientific Counselors on how the centers' programs can be improved to help meet the goals set for the year 2000.

(6) The Executive Committee of NCI and the executive staff of the American Cancer Society have established a schedule of meetings to go over potential problem areas, so that resources will be used wisely.

(7) The Mary Lasker Center for Health Research and Education, located on the NIH campus, was dedicated on September 21, 1984.

(8) Regarding two recent newspaper articles questioning NCI's survival statistics, the Institute remains confident in its source, which is the SEER data base.

Legislative Update—Dr. Mary Knipmeyer

Hearings of interest since May 1984 included House committee and subcommittee hearings on medical quackery, oncogenes, breast cancer, and AIDS

and a Senate committee hearing on liability for radiation injury and probability tables.

Preparations for a House and Senate conference on the NIH/NCI reauthorization bill began during the week of September 17, 1984. The House bill contains numerous and extensive changes for NIH.

The Compassionate Pain Relief Act, which would have authorized making heroin available for treating intractable cancer pain, failed to pass the House.

The National Cancer Screening Act of 1984, introduced in the Senate in June, would require the Secretary of Health and Human Services to make grants for planning and implementing model programs to develop an economical model for early detection of cancer. To date, no hearings have occurred.

On August 6, 1984, the House passed the Cigarette Safety Act of 1984; the bill is pending in the Senate. The provision that NCI serve on the proposed study committee and interagency task force has been changed, and the bill now calls for an NIH representative.

On September 10, 1984, the House passed the Comprehensive Smoking Education Act, which would establish a national program to increase the availability of information on the health consequences of smoking and to amend earlier legislation on cigarette labeling requirements, replacing the current health warning statement with more specific warnings. A Senate bill on the same topic is awaiting floor action.

The Office of Technology Assessment, an arm of Congress, is reviewing the recent and proposed activities of the Public Health Service in response to AIDS; the study is expected to conclude by the end of 1984.

Organ transplantation legislation is awaiting a Senate and House conference. The Department of Health and Human Services and NCI support the provision of the Senate bill establishing an interagency task force on organ procurement and transplantation to assess current activities and develop a plan for a coordinated organ donation and procurement system.

Congressional visits included Ms. Joy Silver of Senator Frank Lautenberg's staff, who followed up on an earlier visit by representatives from the New Jersey State Commission on Cancer Research, and House Speaker Tip O'Neill, who spoke at the Mary Lasker Day ceremony. Mr. Steve Bongard, staff assistant to the Senate Appropriations Committee, plans to visit NIH in October 1984.

VI. National Science and Technology Policy (NSTP) Act of 1976--Dr. Bernadine Bulkley

Dr. Bulkley, Deputy Director of the Office of Science and Technology Policy (OSTP), reviewed the Federal science policy as outlined in the NSTP Act of 1976. The Act recognizes that science and technology are vital to the general welfare of the Nation and that scientific knowledge needs to be

incorporated into the national decisionmaking processes. The Act states that Federal funding for science and technology and funding for training scientific manpower represents an investment in the future.

The Act outlines nine national priority goals for which science is a key factor, including improved health care for all citizens; the Act also delineates the principles for a national policy for science and technology and procedures for its implementation.

Dr. Bulkley described the functions of the OSTP and discussed six areas of OSTP's involvement:

- Developing model policies for the protection of human subjects in research.
- Studying health in the universities, a study that addresses policy issues and fundamental questions regarding the relationship of the Federal Government with universities and the private sector doing basic research.
- Chairing the Cabinet Council Working Group on Biotechnology, which is looking at the regulatory environment in biotechnology.
- Playing an advisory role to OMB regarding regulatory activities.
- Maintaining liaison with Federal agencies involved in the life sciences.
- Interacting with Congress on scientific issues.

Dr. Bulkley discussed OSTP's role in the development of the President's budget and the ambiguity that arises in the review by OMB of the NCI budget.

VII. New NCI Mechanisms Update—Mrs. Barbara Bynum

Mrs. Bynum, Director, Division of Extramural Activities, NCI, and Executive Secretary of the NCAB, discussed the new funding mechanisms developed by NCI during the past year to supplement the 23 traditional funding mechanisms currently used by NCI. New support mechanisms include:

- The Cancer Control Small Grants Program (R03), which grew out of a need to provide seed money to attract experienced investigators from a variety of academic disciplines to cancer control intervention research.
- The Small Business Innovation Research Grants, Phase I (R43), which are intended to establish the technical merit and feasibility of proposed research and development efforts by small businesses that may lead to commercial products and services. Phase II grants (R44) fund the continuation of efforts initiated in Phase I.

- Predoctoral Fellowships for Oncology Nurses (F31), which provide predoctoral training support for nurses who wish to develop their research skills in any scientific area related to cancer and oncology treatment and care.

- Physician or Clinical Investigator Awards (K08), which are intended to encourage recently trained physicians in the clinical sciences to undertake careers in cancer research.

- Cooperative agreements in two forms: cooperative clinical agreements (U10), awarded to support research activities using patient volunteers in the clinical evaluation of various methods of cancer treatment, and the cooperative agreement designated U01, a new assistance mechanism that includes substantial NCI program staff involvement with the recipient during the performance of the anticipated project.

- The Organ Systems Coordinating Center (U26) Grant, which is a cooperative agreement that funds a single center located at Roswell Park Memorial Institute.

- The Minority Investigator Supplement (MIS), which provides supplementary funds to active NCI grantees to support a minority investigator in the grantee's cancer research project.

- The Outstanding Investigator Grant (R35), which provides long-term support to experienced investigators with outstanding records of research productivity.

VIII. NIH Peer Review Appeals System--Dr. William Raub

Dr. Raub, NIH Deputy Director for Extramural Research and Training, presented highlights of the proposed NIH appeals system for peer review of grant applications and cooperative agreement requests.

The formal appeals system was developed to resolve disputes associated with real or apparent mistakes in the peer review system, thereby reducing inequities. The proposed system involves two steps. The first step maintains and reinforces the practices already in place in each Institute for dealing with unhappy applicants for research grants. The second step, based in Dr. Raub's office, is highly formal in character, and is intended to guarantee objectivity and a fresh look at appeals. The second stage appeals process requires a written report to the relevant Institute's national advisory council or board, thereby reinforcing the traditional practice and legal responsibilities of the Institute's council in acting as the final forum for funding. Dr. Raub discussed the principles that will serve as guidelines for responding to appeals.

The number of appeals is expected to reach 5 percent or 1,000 of the 20,000 grant applications received by NIH each year; of these, an estimated 5 percent or 50 a year may not be resolvable by interactions between the Institutes and study sections and would be directed to Dr. Raub's office for review.

IX. Report of the Subcommittee on Cancer Control and the Community--Dr. J. Gale Katterhagen

Dr. Katterhagen reported on the Subcommittee's concern about the prospective payment system and its effect regarding cancer patients in clinical trials, and presented to the Board for its action the following resolution: "To remove the disincentive against clinical trials research produced by the prospective payment system, the National Cancer Advisory Board urges that a cost-based reimbursement mechanism be implemented for National Institutes of Health approved trials." Dr. Katterhagen explained that the intent of the resolution is to call to the attention of the Secretary of DHHS, other administrative leaders, members of Congress, and the citizens the danger that exists and will increase the disparity of patients who are placed on clinical trials and the losses that can occur to the institution that hospitalizes that patient.

The Board decided to have the resolution reworded, and at the Wednesday meeting the Board unanimously accepted the following statement:

> "National Institutes of Health approved clinical trials are an important mechanism whereby the latest advances in biomedical research can be evaluated for their applicability to direct patient care. The trials, based at major medical centers and community hospitals, are of critical importance as part of the Year 2000 Goals of the National Cancer Institute.
>
> "The relationship of these clinical trials to the DRG reimbursement system is of vital concern to the NCAB. The DRG system may have an unintended, harmful effect on clinical trials. We understand that studies identifying all relevant cost factors and issues are now being undertaken. Until completion of these necessary studies, which may indicate that adjustments are in order, it may be prudent to continue to fund these patients on a cost reimbursement basis.
>
> "The NCAB recommends this proposal to the Secretary, HHS, and urges its consideration by the Health Care Financing Administration (HCFA)."

X. Report of the Subcommittee on Innovations in Surgical Oncology--Dr. Ed L. Calhoon

Dr. Calhoon reported that the subcommittee met in Houston, Texas, in August and discussed and clarified their position on the issue of increasing the number of surgical oncologists, primarily in community practice. The group's proposal is to train postgraduate physicians, in part through the K08 grant mechanism, for perhaps 2 years. Additional support, similar to the K08 mechanism, was proposed.

This training in surgical techniques would include many other allied courses, such as oncological imaging techniques, molecular biology, immunology, chemotherapy, and biostatistics. The subcommittee's intent is to have this training culminate in a certificate of special qualification in surgical oncology issued by the American Board of Surgery.

XI. Subcommittee Structure--Dr. David Korn

Dr. Korn presented to the Board his plan for restructuring the subcommittees, including a new Subcommittee on Cancer Control for the Year 2000. The new subcommittee, formed in response to the need to facilitate information and technology transfer to maximize control efforts among underserved populations, would combine the previous Subcommittee on Cancer Control and the Community and the Subcommittee on Cancer in Minorities. A mission statement for the new subcommittee and a roster of members for each subcommittee were distributed to the Board.

To maximize efficiency, Dr. Korn emphasized that the subcommittees should all remain small; they should meet, when possible, during the regular NCAB meetings in Bethesda; and members should be able to rotate periodically among subcommittees.

Because an advisory committee for the Frederick Cancer Research Facility (FCRF) was formally established and chartered by NCI in March 1984, a subcommittee of the Board on this facility seems superfluous. The FCRF advisory committee is equivalent to a board of scientific counselors and will make a presentation to the Board at the November program review meeting, along with the other boards of scientific counselors. Dr. Korn suggested that the Subcommittee on Activities and Agenda become a subcommittee of the whole, with a regularly scheduled place on the Board's agenda.

XII. New Business--Dr. David Korn

As the major item of new business, Dr. Korn proposed to begin immediately the practice of asking, at this point in each NCAB meeting, that Board members indicate those items they would like to have on the agenda of future meetings. Suggested topics were:

- The consequences and implications of the NIH commitment or requirement to fund 5,000 research grants.
- Production of the AIDS virus.
- Computerized informational systems, including the Cancer Information Service (CIS), the possibility of an independent evaluation of the CIS, and the Protocol Data Query (PDQ) system.
- Clinical epidemiology studies, including smoking-related cancers.
- Intramural research activity.
- Extramural support.
- Imaging techniques.
- Photobiology and the research aspects relating to cancer.

- The role of cell membranes in cancer research and treatment.
- Industrial carcinogenesis.
- The use of computers in cancer research and treatment.
- The cost of cancer and the impact that accomplishing the year 2000 objectives will have on health care costs.
- Cancer patient survival.
- NCI's drug development program.
- Research methodology and clinical research methodology.
- The SEER program--the study methodology and the utility of the materials that are collected.
- Cancer Center Guidelines for Consortium Grants.
- Cancer Education Program--the R25 grant-supported program in clinical education.

XIII. Adjournment--Dr. David Korn

The 51st meeting of the NCAB was adjourned at 10:20 a.m., on Wednesday, September 26, 1984.

Date

David Korn, M.D.
Chairman
National Cancer Advisory Board