National Institutes of Health

National Cancer Institute

NATIONAL CANCER ADVISORY BOARD

Summary of Meeting
October 3-5, 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*
October 3-5, 1983

The National Cancer Advisory Board (NCAB) convened its 47th regular meeting at 8:30 a.m., October 3, 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
Dr. Roswell K. Boutwell
Mrs. Angel Bradley
Dr. Victor Braren
Dr. Ed L. Calhoon
Dr. Tim Lee Carter
Dr. Maureen M. Henderson
Dr. Robert C. Hickey
Dr. Geza J. Jako
Dr. J. Gale Katterhagen
Mrs. Rose Kushner
Ann Landers
Dr. LaSalle D. Leffall
Dr. William E. Powers
Dr. Janet D. Rowley
Mr. Sheldon W. Samuels
Mr. Morris M. Schrier

President's Cancer Panel

Dr. Armand Hammer
Dr. John A. Montgomery

Ex Officio Members

Dr. Hollis Boren, VA
Dr. Kenneth Bridbord, NIOSH
Dr. Allen Heim, FDA
Dr. Robert E. McGaughy, EPA
Dr. F. Kash Mostofi, DOD
Dr. David P. Rall, NIEHS
Dr. Ralph E. Yodaiken, LABOR

Absent

Dr. Irving J. Selikoff
Dr. William P. Longmire, Jr., President's Cancer Panel

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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

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

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

Dr. Raymond Lenhard, Jr., Associate Professor of Oncology and Medicine, Johns Hopkins Medical Institute, Baltimore, Maryland, representing the American Society of Clinical Oncology, Inc.

Dr. Wallace LeStourgeon, Associate Program Director, Cell Biology Program, National Science Foundation, Washington, D.C., representing the National Science Foundation.

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).

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 D. Amoruso, Executive Officer, 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 Resources, Centers, and Community Activities
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

In addition to NCI staff members, meeting participants, and guests, a total of 21 registered members of the public attended the meeting.

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

Dr. Carter, Chairman, called the 47th meeting of the National Cancer Advisory Board to order and welcomed members of the Board, the President's Cancer Panel, liaison representatives, National Cancer Institute (NCI) staff, guests, and members of the public. Dr. Carter announced that Dr. William Longmire, a member of the President's Cancer Panel, would be unable to attend because he is recuperating from surgery. Dr. Carter then 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: November 28-30, 1983; January 30-February 1, May 14-16, October 1-3, and November 26-28, 1984.

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

Dr. Hammer, Chairman, expressed his regrets that he was unable to attend the ceremony of October 2 dedicating the R. A. Bloch International Cancer Information Center. He congratulated all involved in this project, noting that the purchase of the building was made possible by grants from private citizens. He said he was looking forward to the benefits the Protocol Data Query (PDQ) System would provide for physicians and their cancer patients.

Dr. Hammer reported that, since the May NCAB meeting, the Panel had been planning for its meeting of October 12, 1983, to be held at the Memorial Sloan-Kettering Institute in New York City. Two issues on the agenda are:

- Stabilization of grant support at NIH.
- Peer review and funding of approved grants.

The Director of NCI will speak to the first of these issues at the October 12 meeting, to which all the members of the NCAB are invited. The issue involves measures that will provide stability in the present and growth in the future of biomedical research. The second issue concerns the regulations proposed by the Department of Health and Human Services for reimbursement by diagnosis-related groups (DRG).

Dr. Hammer reported on the dedication of the Armand Hammer Cancer Research Laboratory at the Stanford Medical Center, named in his honor. The laboratory will allow Dr. Ronald Levy and his colleagues to expand their cancer research, particularly their studies of hybridoma and in the use of monoclonal antibodies.

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

Dr. DeVita called the members' attention to a "brilliant" article written by Ann Landers concerning the use of animals in research.

Announcements

(1) Mrs. Pamela Temple has been engaged as Dr. DeVita's secretary.

(2) Dr. Joseph Saunders, Acting Associate Director for International Affairs, is retiring from the Government after 34 years of service.

(3) Dr. David Pistenmaa, Associate Director of Radiation Research, is also leaving the Institute.

(4) Dr. George Vande Woude, Chief, Laboratory of Molecular Oncology, has been selected by the Litton Company to be the Director of the research contract at the Frederick Cancer Research Facility.

(5) Dr. Bruce Wachholz has assumed responsibility for the Low-Level Radiation Branch.

(6) Dr. John Minna, Chief, Medical Oncology Branch, has been selected as the delegation leader for the 1984 Lung Cancer Project with the Peoples Republic of China.

(7) Dr. Robert Gallo has recently become the recipient of the Griffwell Prize, given by the Association for Cancer Research in France.

(8) Dr. Frank Schabel passed away while attending the International Cancer Congress in Vienna.

Budget

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

Since the last meeting, the FY 1983 budget of $983,576,000 was increased to $987,142,000 by two supplemental appropriations: one for a pay raise ($1 million), the second related to the issue of Acquired Immune Deficiency Syndrome (AIDS) ($3.3 million).

The funding plans and actual operating policies for FY 1983 were reviewed. Grants were reduced 15 percent from recommended levels for all competing grants, with no grant to receive less than the current level without Executive Committee approval. Grant dollars were allocated by general program areas. Research and support contracts were reduced by 5 percent, and the growth of the Intramural Program was limited to 4 percent. The year-end number of competing grants is estimated at 888, an increase of 98 grants over the original projection of 790, at an additional cost of $3.3 million. The ability to fund this extra number is due largely to the Institute's use of a funding plan. In the Intramural Program, the overall increase was held to 3.3 percent, or $131 million compared with $127 million in FY 1982.

Congress passed a large supplement for NIH research on AIDS. NCI received $3.3 million, of which $2.8 million went to grants, and $0.5 million went to an intramural task force coordinating the resources for this program, which is headed by Dr. Peter Fischinger. The $3.3 million brings the 1983

NCI total for AIDS research up to $9.8 million. In response to the Small Business Innovative Research Act (SBIR), the Institute approved 47 of the 98 applications received, and funded 28 applications or 60 percent of those approved.

For fiscal year 1984, the Institute is operating on a continuing resolution. The House has before it a reauthorization bill that would increase the Institute's budget to $1.067 billion. The Senate bill has passed the full Committee at a level of $1.084 billion. Most of this $81 million increase is taken up by fixed obligations, including restoration of research grants and restoration of funds reduced from the President's original budget. As 1984 progresses, and the full Senate acts on the budget, the issue of the Institute's developing a funding plan will become more clear.

The bypass budget for FY 1985 was sent to the Office of Management and Budget (OMB) on September 15.

Organizational Changes

(1) The Office of International Affairs (OIA) has been reorganized and Dr. Ihor Masnyk will serve as Acting Associate Director for International Affairs. The OIA now consists of its central office on the NIH campus, in Building 31A, and the rest of its operation in the Bloch Building. Also in the Bloch Center are the Scientific Information Branch from the Division of Cancer Treatment (DCT), together with its Literature Research Section, the journals Cancer Treatment Reports and the Journal of the National Cancer Institute, and the International Cancer Research Data Bank. In addition, the Computer Communication Branch, headed by Dr. Robert Esterhay, will be located in the Bloch Building.

(2) Most of the Biometry Branch and all of the Surveillance, Epidemiology, and End Results Program (SEER) has been transferred to the Division of Resources, Centers, and Community Activities (DRCCA) from the Division of Cancer Cause and Prevention (DCCP).

Followup Items

(1) As a result of the report on the PO1 grants presented by Dr. Maureen Henderson, a new set of guidelines has been issued and will be mailed to Board members.

(2) Four additional grants in the Community Clinical Oncology Program have been awarded. The recipients are North Mississippi, Fort Worth, Green Mountain Oncology Group, and one in the San Joaquin Valley.

(3) Eight thousand bulletins outlining the Outstanding Investigator Grant have been sent to all grantees, contractors, and institutions. Response was modest, and in January the Board will probably be requested to approve the final set of options developed by the Executive Committee.

(4) The Institute has exceeded its commitment in terms of dollar amounts devoted to the Organ Systems Program. Three excellent applications for organ systems headquarters have been received and will be reviewed by a special review committee.

New Items

(1) Five hearings have been held since the last meeting: the Drug Development Program, food safety, smoking, AIDS, and cancer in fish.

(2) Visitors to NIH included Senator Orrin Hatch and Secretary Margaret Heckler. The freshman class in this Congress has selected cancer as its theme for the year and held a breakfast at which Dr. DeVita, Dr. John Ultman, Dr. Timothy Talbot, and others spoke. As a result, staff members of about 25 Congressmen visited NIH, and on October 18, some Congressmen themselves are scheduled to visit NIH.

(3) All members are invited to the October 24-26 Consensus Development Conference on Precursors to Malignant Melanoma.

Themes and Special Problems

During this fiscal year items of particular concern for the Institute will include:

(1) The complex issue of grant stabilization will be addressed in detail at the October 12 meeting of the President's Cancer Panel in New York.

(2) NIH has commissioned the Institute of Medicine of the National Academy of Sciences to prepare a study and make recommendations on the organizational structure of NIH. Board members will be kept apprised of developments and sent materials that could provide background for expressing their views, should they have the opportunity to testify.

(3) The revision of the Cancer Center Guidelines has begun with a presentation of some of the issues to a subcommittee of DRCCA's Board of Scientific Counselors. Board members will be kept informed as this issue proceeds to the full Board of Scientific Counselors.

(4) The Institute's links to Japan's cancer initiative are expected to continue and improve during the coming year. The Japanese have based their initiative on the National Cancer Program in the United States.

Legislative Update--Dr. Mary Knipmeyer

A detailed analysis of the House and Senate reauthorization bills was presented at the May NCAB meeting.

The Waxman bill, HR2350, reached the floor of the House for a one-hour discussion, with an indication that a simpler substitute bill, at the same funding level, will be offered by Representatives James T. Broyhill and Edward R. Madigan.

The Senate bill passed the full committee and is ready to come to the floor of the Senate; currently it is "on hold" because of issues related to animal welfare and fetal research.

Several bills are at various stages in both chambers of Congress regarding legislative action on AIDS. Some relate to appropriations and others to

the issue of the Federal Government's ability to respond quickly to an emergency or epidemic situation. The Public Health Emergency Fund was enacted in July to provide funds for responding to public health emergencies. The Government Operations Subcommittee on Intergovernmental Relations held a hearing on August 1 and 2 to describe comprehensively the Federal Government's response, particularly to the AIDS situation.

Bills on cigarette labeling and animal welfare are at various stages in both chambers of Congress.

IV. AIDS Update--Dr. Peter J. Fischinger

Dr. Fischinger, Associate Director, NCI, presented an update on AIDS in terms of what has been happening, the prospective for the future, and what NCI is doing regarding AIDS.

Epidemiological data for 1982-1983 show a precipitous rise in the number of AIDS cases, reaching 2,374 in 1983. At risk are homosexual or bisexual males with a high degree of sexual activity, intravenous drug abusers, hemophiliacs (particularly those who have been receiving the antihemophilic Factor 8, which is a composite of several thousands of pooled sera), Haitians, and others including sexual partners of intravenous drug abusers, persons receiving blood transfusions from suspicious blood donors, health care personnel, and patients with Kaposi's sarcoma.

Reported cases of AIDS show that pneumocystis carinii infection occurs in over half the cases, Kaposi's sarcoma without pneumocystis in approximately one-fourth of the cases, and total Kaposi's sarcoma involvement in about 30 percent. Other opportunistic infections in AIDS include significant infections of the colon and of the eyes (causing blindness), hepatitis, candida infection of the mouth and esophagus, and cryptococcal infection. The death rate ranges between 80 and 100 percent. Malignant diseases besides classical Kaposi's sarcoma encountered in AIDS patients include various kinds of B-cell lymphomas and squamous cell carcinoma.

The major problem in AIDS is a reduction in the absolute numbers of lymphocytes because of a net decrease of the T-helper cell population. Human T-cell Leukemia Virus (HTLV) is seen as a possible causative agent of AIDS because this virus attacks the T-helper lymphocyte population. Future investigation is needed to explore the manner in which HTLV might be a causative agent, and to establish the evidence needed to confirm this hypothesis.

V. Tumor Cell Invasion--Dr. Lance Liotta

Dr. Liotta, of the Laboratory of Pathophysiology, Division of Cancer Biology and Diagnosis (DCBD), described advances in the understanding of the biochemical mechanisms of tumor invasion and metastasis. Identifying the biochemical factors which contribute to tumor aggressiveness and invasiveness may lead to better diagnosis and possibly new strategies for cancer therapy. Cell transformation, the ability for unrestricted growth and the production of a tumor, is the first step in malignancy. The transformed cells must be able to invade and destroy surrounding tissue and metastasize. Research has

demonstrated that profound differences exist between benign and invasive human breast carcinoma cells with regard to their interactions with surrounding tissue. Tumor cell invasion is an active process that requires synthesis of proteins, enzymes, and receptors to facilitate invasion.

Dr. Liotta summarized some potential applications of these findings to clinical medicine. Antibodies to components of the basement membrane can be used to differentiate between benign and malignant breast carcinoma tissue. Measurement of laminin receptors may allow prediction of the aggressiveness of an individual tumor. Using antibodies to antigens on invading tumor cells may make possible the detection of occult metastases. Finally, by understanding the biochemical mechanisms of invasion, it may be possible to develop strategies for inhibiting the process in patients at high risk for developing invasive carcinomas.

VI. Cancer Control and the Community Subcommittee Report: DRG's and PDQ--Dr. J. Gale Katterhagen

Dr. Katterhagen's report consisted of two topics, DRG's and PDQ.

DRG's, or diagnosis-related groups, refer to a method of prospective reimbursement for hospitalized Medicare patients. Hospitals will be paid a specified amount for diagnosis and treatment of a particular disease based on the patient's diagnosis on admission and discharge. Those investigators involved in clinical research are concerned that there will not be enough money allowed within a specific DRG to permit clinical studies. The Health Care Financing Administration has proposed certain exemptions for cancer patients provided that the hospital is recognized as a comprehensive clinical cancer center, that the entire organization is oriented towards cancer research and treatment, and that 80 percent of all discharge diagnoses are neoplasms.

After a discussion of the implications of DRG's on clinical cancer research, the Board decided to table the portion of the Subcommittee Report dealing with DRG's.

Dr. Katterhagen then presented the recommendation of the Subcommittee of Cancer Control and the Community with regard to PDQ promotion. The recommendation consisted of three parts:

- That NCI promote PDQ to physicians in conjunction with the vendors.
- That PDQ would not be promoted directly to the public.
- That NCI would continue promoting the availability of accurate, up-to-date cancer information through the Cancer Information Service without direct reference to PDQ.

After discussing the composition of the list of doctors provided by PDQ, and whether these lists would be available to the public, the Board accepted the recommendation, with amendments, that NCI would not make available to the vendors specific lists of physicians other than those physicians who are directly related to NCI-approved protocols or physicians who are listed with specialty societies related to cancer. Further information could be obtained from local medical societies.

VII. Respiratory Cancer State of the Art--Dr. John Minna

Dr. Minna, DCT, presented a state-of-the-art review of respiratory cancers. Although only modest progress has been made in developing successful treatments for lung cancer, there have been dramatic advances in the basic understanding of lung cancer at the cellular and molecular levels.

The death rate from lung cancer is rising, especially for women. Histologically, several distinct types of lung cancer respond differently to the various treatment methods. Even so, there is only a 10 percent chance of curing lung cancer patients. Recent results seem to indicate that combination chemotherapy may be beneficial for some non-small cell lung cancer. Radiotherapy is useful in relieving symptoms of obstruction or pain.

Significant understanding of lung cancer cell biology has resulted from research conducted during the past decade. Dr. Minna predicted that within the next 5 years pathologists will be able to use immune histochemical techniques to help diagnose cancer.

Recently, dramatic strides have been made in understanding the fundamental nature of what causes lung cancer. A great deal of effort is contributing to the understanding of the function of oncogenes and how the changes they induce might be reversed.

VIII. NCI Support of Respiratory Cancer--Dr. Andrew Chiarodo

Dr. Chiarodo, DRCCA, presented a brief overview of NCI support for lung cancer research, how this support is distributed among the NCI Divisions, and the scope of research activity supported through the Divisions.

During fiscal year 1982, approximately $25 million were expended for lung cancer research support. About one-third supported investigator-initiated research in epidemiology and laboratory and clinical studies. Twenty-three percent was spent on contracts for studies in epidemiology, carcinogenesis, early detection and diagnosis, and adjuvant therapy trials. Clinical Cooperative Group trials accounted for about 20 percent. Intramural research in carcinogenesis, tumor biology, field studies, and clinical trials accounted for approximately 14 percent. The Cancer Centers Program and cancer control activities accounted for the remainder. Dr. Chiarodo provided details of how the money for research was allocated among the five NCI Divisions and described the areas of research responsibilities for each Division. In summary, lung cancer has received a significant level of research dollars, supporting a wide range of studies encompassing epidemiologic, laboratory, and clinical approaches to studying the etiology, biology, detection, diagnosis, treatment, control, and ultimately the prevention of this disease.

IX. Overview of NCI Smoking, Tobacco, and Cancer Program--Dr. Joseph Cullen

Dr. Cullen, Deputy Director, DRCCA, stated that the primary emphasis of the Smoking, Tobacco, and Cancer Program (STCP) is intervention research with the ultimate aim of smoking prevention and cessation, thereby reducing the incidence of lung cancer. It is a coordinated effort by DRCCA, DCCP, and the

Office of Cancer Communications (OCC). The role of DRCCA will be to implement intervention studies, to coordinate the program for the Institute, and to provide liaison with other Federal and non-Federal agencies and organizations.

After reviewing smoking statistics, Dr. Cullen described the five basic steps in developing a cancer control intervention: defining the idea, testing the idea, carrying out a controlled study, intervention in a defined population and, finally, a demonstration project. Many smoking cessation programs have been studied, but their success over long periods of time has not been quantified. Programs must be cost-effective and socially acceptable. Current initiatives and coordination in the STCP program include RFA's dealing with longitudinal studies of school-based prevention programs, self-help intervention strategies, the use of physicians and dentists as intervening agents, and looking at the media for opportunities to get people to stop or not start smoking. Dr. Cullen stressed the importance of prevention programs for smoking in children and adolescents and the need for smoking statistics for the black population, and also for people of hispanic/Mexican surname. Coordination activities under way with both Federal and non-Federal agencies were described as well as proposed budget projections for the next 5 years. By 1988, $17 million will be targeted for intervention research.

X. Small Business Innovative Research Act: Update--Mrs. Barbara Bynum

The SBIR Act, a result of Public Law 97-219, required a set-aside of a certain percentage of funds of NIH, the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), and several health-related agencies to support grant applications submitted by small and disadvantaged businesses to allow them access to health-related and research and development activities.

The program has two phases. The first phase awards did not exceed $50,000 and were not to exceed a 6-month period. NCI funded 29 grants in the first phase. In the second or current phase, awards may be up to 2 years in duration and may be up to $500,000 each. Phase two awards are expected to be made in April 1984.

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

The report of the Subcommittee on Environmental Carcinogenesis was approved unanimously in a mail ballot of Board members conducted in August. Mr. Samuels reported on dissemination efforts and on his request that NCI issue a press announcement on this report.

After some discussion, the Board voted unanimously to have NCI issue a press release on the Subcommittee's report.

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

Dr. Powers indicated that the report of the Subcommittee on Organ Systems Program had been distributed to the members. The Subcommittee expects that more information will be available by the November meeting on the number of applications, dollars, and grants that are approved, as well as the assignments, principals, and procedures.

The Subcommittee recommends that the Board endorse the concept of a strong Organ Systems Program, and that the Board urge and recommend expeditious review of applicants for the Organ Systems Coordinating Center.

The Board unanimously accepted the report and recommendations of the Subcommittee on the Organ Systems Program.

XIII. Report of the Subcommittee on Planning and Budget--Mrs. Rose Kushner

Mrs. Kushner summarized the meeting of the Subcommittee on Planning and Budget which focused on:

- The increases in NCI spending level for fiscal year 1983 by the addition of $3.3 million for AIDS, $1 million for the October pay raise, and $1.1 million for the Organ Systems Program.

- Fiscal year 1984 congressional action, with increases for NCI ranging from 8.4 percent in the House to 10.2 percent in the Senate, levels which aligned closely with the NCAB 1984 bypass budget.

- Fiscal year 1985 bypass budget which shows an increase in nutrition research and diagnostic research.

The Subcommittee discussed the impact of House and Senate language concerning the funding of grants for fiscal year 1984, and voted unanimously to assist NCI in clarifying the situation for the scientific community, and to recommend that the NCAB assist the Institute in the same way. The Board voted unanimously to accept the Subcommittee's report and its recommendations.

XIV. New Business

After some discussion on the topic of surgical oncology, Dr. Carter established an ad hoc Subcommittee on Innovations in Surgical Oncology. Its function is to initiate workshops, hold hearings, and make recommendations to the Board of Scientific Counselors, DCT. He appointed Dr. Ed L. Calhoon chairman of the subcommittee and called for interested Board members to volunteer to serve on the subcommittee.

XV. Adjournment--Dr. Tim Lee Carter

The 47th meeting of the NCAB was adjourned at 11:30 a.m., on Wednesday, October 5, 1983.

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

September 27, 1983

NATIONAL CANCER ADVISORY BOARD

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