Department of Health and Human Services

Public Health Service

National Cancer Institute

National Cancer Advisory Board

Summary of Meeting
October 6-8, 1986
Building 31, Conference Room 6
National Institutes of Health
Bethesda, Maryland

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October 6-8, 1986

The National Cancer Advisory Board (NCAB) convened for its 59th regular meeting at 8:30 a.m., October 6, 1986, in Building 31, 6th Floor, Conference Room 6, National Institutes of Health (NIH), Bethesda, Maryland. Dr. David Korn, Chairman, presided.

Board Members Present

Mr. Richard A. Bloch
Dr. Roswell K. Boutwell
Dr. Victor Braren
Mrs. Nancy G. Brinker
Mrs. Helene G. Brown
Dr. John R. Durant
Dr. Bernard Fisher
Dr. Phillip Frost
Dr. Geza J. Jako
Dr. David Korn
Dr. Enrico Mihich
Mrs. Barbara Ingalls Shook
Dr. Louise C. Strong
Dr. Louis W. Sullivan

President's Cancer Panel

Dr. Armand Hammer
Dr. William P. Longmire
Dr. John A. Montgomery

Ex Officio Members

Dr. Richard J. Greene, VA
Dr. James M. Melius, CDC/NIOSH
Dr. Lakshmi Mishra, CPSC
Dr. Peter W. Preuss, EPA
Dr. Robert Rabin, OSTP
Dr. David P. Rall, NIEHS
Captain Stephen R. Veach, DOD

Absent

Dr. Ed L. Calhoon
Dr. Tim Lee Carter
Dr. Gertrude B. Elion
Mrs. Irene S. Pollin

* 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

Ms. Susan Alderson, from Walter Reed Hospital, Washington, D.C., representing the Oncology Nursing Society.

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

Ms. Judy Fielding, representing the American College of Obstetricians and Gynecologists.

Dr. Raymond E. Lenhard, Jr., Associate Professor of Oncology and Medicine, Johns Hopkins University Hospital, Baltimore, Maryland, representing the American Society of Clinical Oncology.

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

Dr. Stanley Order, Director of Radiation Oncology, Johns Hopkins University, Baltimore, Maryland, representing the American Society of Therapeutic Radiologists.

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

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

Dr. Richard D. Williams, Professor and Chairman, Urology Department, University of Iowa, representing the Society of Urologic Oncology.

Dr. Sidney J. Winawer, Director, Division of Gastroenterology, Memorial Sloan-Kettering Cancer Center, New York, New York, representing the American Gastroenterological Association.

Members, Executive Committee, National Cancer Institute

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

In addition to NCI staff members, meeting participants, and guests, a total of 31 registered members of the public attended the meeting.

I. Call to Order, Opening Remarks, and Consideration of May 19-21, 1986, NCAB Meeting Minutes--Dr. David Korn

Dr. Korn, Chairman, called the meeting to order and welcomed members of the Board, the President's Cancer Panel (PCP), liaison representatives, guests, staff of the National Cancer Institute (NCI), and members of the public. Members of the public who wished to express views on items discussed during the meeting were invited to submit written comments to Mrs. Bynum, Executive Secretary of the National Cancer Advisory Board (NCAB), within 10 days after the meeting.

The minutes of the May 19-21, 1986, meeting were unanimously approved.

II. Future Board Meeting Dates

Future meeting dates were confirmed as follows: December 8-10, 1986; February 2-4, 1987; May 26-28, 1987; September 28-30, 1987; November 16-18, 1987; February 1-3, 1988; and December 5-7, 1988. Meeting dates were proposed as follows: May 16-18, 1988; and September 12-14, 1988.

Mrs. Bynum announced that a change (advancing the date about 10 days) was under consideration for the September 1987 meeting to provide Grants Management staff with more time to make awards following Board discussion of applications. Several members suggested that it would be helpful if the May 1987 meeting dates could be changed to coincide with NCI's 50th anniversary observances. Discussion of both changes was deferred pending further clarification. (See Section XI. below.)

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

Dr. Hammer reported that the President's Cancer Panel held its third meeting of the year on September 30 at the Dana Farber Cancer Institute in Boston. The Panel heard reports of some promising work involving autologous bone marrow transplantation, which appears to produce significant disease-free benefits. Presentations included Dr. Emil Frei's report on the intensification of chemotherapy in bone marrow transplants for solid tumors; an account by Dr. Lan Bo Chen of the definition of a new class of agents selectively toxic to carcinomas; and a report on experiments with monoclonal antibodies that are selectively active against solid tumors. Dr. Hammer stated that the presentations clearly illustrated the many new developments for cancer researchers to pursue and the fact that more progress is being made now than at any previous time in the fight against cancer.

Dr. Hammer expressed the Panel's regret that Dr. DeVita's recent surgery necessitated his first absence from a meeting since 1981, when the PCP started meeting at locations around the country. He thanked Dr. Fischinger on behalf of the Panel for representing Dr. DeVita.

Dr. Hammer then recounted for the Board his opening remarks in Boston concerning the nuclear accident on April 26 at Chernobyl in the Soviet Union. He described his intercessory role between Dr. Robert Gale, noted U.S. expert in bone marrow transplantation, and Soviet leader Mikhail Gorbachev, which led to acceptance of Dr. Gale's offer to help treat the victims of radiation exposure. Dr. Hammer arranged to send three more doctors with transplant expertise to assist Dr. Gale and medicine and equipment gathered from 12 countries over a period of 10 days. Dr. Gale operated on the 13 most seriously injured persons, who had been selected from among the 300 patients in a Moscow hospital, and succeeded in saving four lives. In addition, Dr. Gale set up a method for following the thousands of people in the Soviet Union who have been exposed to radiation and who are believed to be at considerable risk of suffering from cancer and other diseases in years to come. Drs. Hammer and Gale were invited back to the Soviet Union and were thanked by Mr. Gorbachev. They were flown by helicopter over Chernobyl to witness both the site of the accident and the surrounding 30-mile area that had been evacuated as a result. They also visited patients in hospitals in Kiev. Dr. Hammer stressed the need to learn the lessons implicit in this accident. To that end, he and Dr. Gale set up a worldwide institution of scientists with the hope of working with their Russian colleagues to gather follow-up information that would be of benefit, should a similar accident happen anywhere in the world. The initial meeting was held in July.

In closing, Dr. Hammer commended Dr. Steven Rosenberg for his continuing work with the LAK cells and IL-2 therapy for cancer and for new work with tumor infiltrating lymphocytes, the subject of an article recently published in Science. Dr. Jako noted that tumor infiltrating lymphocyte treatment is being tested in humans at Massachusetts General Hospital by Dr. Richard Creighton.

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

After welcoming Board Members to the meeting, Dr. DeVita congratulated Dr. Hammer for his success in fostering a better understanding and collaboration between the United States and the Soviet Union on behalf of the Chernobyl victims. The National Cancer Institute is meeting with Soviet scientists to discuss collaborative studies of the effects of radiation, among other areas of investigation, under the auspices of the existing bilateral agreement the NCI has with the USSR.

Dr. DeVita announced that Dr. Peter Greenwald, Associate Director of the Division of Cancer Prevention and Control, will be assuming additional responsibility as Associate Director for Prevention, NCI, in response to a requirement under the Health Research Extension Act.

Dr. DeVita also announced that Dr. John Donovan would serve as the new Chief of the Laboratory Animal Sciences Program, replacing Dr. Gene New who has left NCI to become the Executive Director of the American Association for Accreditation of Laboratory Animal Care (AAALAC). Other recent staff changes include the impending retirement of Dr. Berge Hampar and the appointment of Dr. Cedric Long to replace him as General Manager of the Frederick Cancer Research Facility (FCRF). Dr. Maryann Roper has left the Cancer Therapy

Evaluation Program in the Division of Cancer Treatment to join the Office of the Director, NCI, in the position of Special Assistant.

Dr. DeVita then announced that Dr. Robert Gallo had received the Clinical Research Lasker Award, in conjunction with Dr. Max Essex from Harvard University and Dr. Luc Montagnier from the Pasteur Institute. Dr. Gallo was also the recipient of the Basic Science Lasker Award in recent years. This most recent award was bestowed upon the three scientists in recognition of their work resulting in the discovery of the AIDS virus.

A final announcement was about the recent appointment of Dr. Maxine Singer, Chief of the Laboratory of Biochemistry, to the Pontifical Academy of Sciences.

Follow-up Items

Journal of the National Cancer Institute Monograph

Dr. DeVita referred to a Journal of the National Cancer Institute monograph, "Cancer Control Objectives for the Nation 1985-2000," which had been distributed to Board members. He pointed out that this document, which was prepared by Dr. Greenwald and Dr. Edward Sondik, would serve as a blueprint for the implementation of the Year 2000 goals and would be most helpful to the Subcommittee on Cancer Control.

Correspondence with Drs. Cairns and Bailar

Referring to earlier discussion of letters sent by Dr. Cairns and Dr. Bailar, Dr. DeVita corrected his statement that Dr. Bailar had not responded to Dr. Greenwald's letter about the article that subsequently appeared in the New England Journal of Medicine. In fact, Dr. Bailar had written in response to Dr. Greenwald's comments.

AIDS Research

The beneficial effects of azidothymidine (AZT), first published by Dr. Samuel Broder, have been confirmed in a controlled clinical trial. The drug is being administered to increased numbers of patients around the nation. Another drug, dideoxycytidine, also developed under the auspices of the NCI's cancer drug development program, has also shown exciting results. The FDA recently approved the clinical protocol for dideoxycytidine, and the first patients are being treated in the Clinical Center. The NCI is about to announce a competition among pharmaceutical houses for an exclusive license on production of dideoxycytidine. Dr. DeVita credited Dr. Samuel Broder with developing and testing these drugs in record time.

The joint National Institute of Allergy and Infectious Diseases (NIAID)/ NCI anti-AIDS drug development effort is about to be split. The NIAID will be responsible for the clinical aspects of the program, while the NCI will continue the preclinical research effort.

Dr. DeVita noted that other compounds, as yet unpublicized, have been much more active in vitro than the compounds now in clinical trials and seem very promising for development of new AIDS therapies.

In response to a question from Dr. Braren about the development of an AIDS vaccine, Dr. DeVita stated that there are a number of candidate vaccines. Some have already been injected into chimpanzees. (See discussion in Section VI. below).

LAK Cell Therapy

The LAK cell extramural trials have been temporarily closed due to contamination of the sera with hepatitis A virus. The results observed in 90 patients before cessation of the trials were comparable to Dr. Rosenberg's findings in the melanoma cases but less promising in kidney cancer. Dr. DeVita noted that the response rate appears to be related to tumor volume since in Dr. Rosenberg's patients the primary tumor had been removed, while it was not removed in the extramural trial patients.

Dr. Rosenberg has begun testing a new protocol using tumor infiltrating lymphocytes and IL-2. These cells are 50- to 100-fold more potent than the cells obtained from the peripheral blood. Greater killing capacity is achieved with smaller quantities of IL-2 than are required in the LAK cell and IL-2 protocol, resulting in a significant reduction in toxicity.

Cancer Centers

The emergency supplemental appropriation passed by Congress has allowed NCI to restore funding in the amount of $6 million to the Cancer Center Program. Non-competing and competing grants with good scores were given priority. Five additional grants were funded, including four to previously funded institutions--University of Vermont, Fels Institute, Ohio State University and Georgetown University--and one to a new grantee, the University of Kentucky.

Community Clinical Oncology Program (CCOP)

A Request for Applications (RFA) for recompetition of the CCOPs was announced in July. The applications, which were due in October 1986, will be presented to the NCAB for review in May 1987 and funding of the programs is expected to take place in June 1987. Approximately 130 letters of intent were received in response to the RFA. The RFA was modified to include responsibilities for cancer control research. Under the new structure, community hospitals will be able to use state and local health departments as a research base.

Community Group Outreach Programs (CGOPs)

Responsibility for the CGOPs has been transferred to the Division of Cancer Treatment (DCT), which has overall responsibility for the Clinical Trials Program. The programs will be recompeted at current levels in FY 1987, and the DCT will provide funding out of its own divisional budget.

Dr. DeVita added that the reorganization of the Clinical Cooperative Groups initiated by the DCT Cancer Therapy Evaluation Program was going smoothly and is expected to result in many more intergroup studies with larger numbers of patients.

Organ Systems

The NCI recommends that the Organ Systems Headquarters grant not be recompeted in FY 1987. Dr. DeVita then requested, and received from the NCAB, their approval to extend the grant, which was originally approved for five years, for the final two years.

A review of the Organ Systems Program by the Board is planned for the fall 1987 meeting of the NCAB, at which time the impact of the new organizational structure of the program will be better understood.

Outstanding Investigator Grants (OIGs and MERIT Awards)

Dr. DeVita reminded the Board of the differences between the OIGs and the MERIT Awards. The OIGs are awarded for a period of seven years on the basis of the applicant's past record and potential continued productivity. The application is not based on a proposal for a specific project, allowing novel and riskier research. By contrast, Institute staff select MERIT Award recipients among investigators with good priority scores for the purpose of extending their projects. The two types of awards also differ in the review process: MERIT Awards are reviewed like R01s and P01s while the OIGs are sent through the mail and reviewed independently by individual reviewers. For each OIG application, a panel of about 12 reviewers is selected from a larger panel of more than 300 expert consultants.

Dr. DeVita noted that this departure from the regular review mechanism has been criticized by some NIH staff. The process is still considered to be an experiment and subject to future modifications. He emphasized his personal support for the concept of individual review conducted in private by experts, adding that an assessment of this mechanism should be conducted by the NCAB in the future.

Frederick Cancer Research Facility (FCRF) Recompetition

The FCRF contract is in the process of being recompeted. In anticipation of the discussion to be held in the closed session, Dr. DeVita presented a brief history of the contract which is the largest contract in the Department of Health and Human Services. Initiated in 1972 as a single award, it was recompeted in 1981 as five different contracts. The management of the contract was restructured, with the appointment of an Associate Director for the FCRF operating out of the Office of the Director, NCI, and of a General Manager for on-site duties. In 1982, a new NCI/FCRF Advisory Committee, analogous to the intramural Boards of Scientific Counselors, was established with the responsibility of reviewing contractor research conducted at the FCRF. In 1985, that Committee approved the concept of the recompetition. The new contracts are expected to be awarded in September 1987. In order to provide stability, NCI plans to recompete these contracts for a period of performance of seven years

instead of five, with the added option of extending them for three more years.

New Items

Dr. DeVita announced that the decision was made at the annual NCI Director's retreat in July to begin exploring the concept of establishing an intramural program in nutritional biochemistry in the Division of Cancer Prevention and Control (DCPC). Dr. Greenwald has appointed a subcommittee of the DCPC Board of Scientific Counselors to study the feasibility. Their report will be presented to the BSC DCPC in May 1987 and brought to the NCAB in September.

Another issue discussed at the July retreat was the need for an assessment of several issues regarding the review of P01 grants. Dr. Rambaut has formed a Working Group to study this issue. He will present the Working Group's conclusions to the NCAB at the February 1987 meeting.

The centralization of the animal facilities was completed in July in response to the NIH initiative to obtain AAALAC accreditation for all the laboratories in the intramural program. Personnel changes will be completed by December 1986.

Dr. DeVita noted that the demand for laboratory animals for the drug screening programs will soon be reduced due to NCI's decision to discontinue the P388 screen in favor of an in vitro screen using human cell lines. Animals will still be required in the post screen. Dr. DeVita reported that the initial results of the in vitro screen have been impressive and suggested that Dr. Michael Boyd be invited to make a presentation to the NCAB on the new program within the next year.

Next, Dr. DeVita commented on a new development in the issue of apportionment of the budget. Senator Orrin Hatch has introduced some technical amendments to the Act that reauthorized the National Cancer Institute which would require that the Office of Management and Budget (OMB) apportion the NCI budget directly to the Institute rather than pooling it at the NIH. The amendment has passed the Senate Committee and still has to go to the full Senate.

Dr. DeVita reported that Dr. Fischinger had attended the 14th International Cancer Congress in Budapest in his behalf. He expressed his appreciation for Dr. Fischinger's assistance and noted that Dr. Fischinger's presentation had been extremely well received.

In summer 1986, the Subcommittee on Oversight and Investigation of the Committee on Energy and Commerce held a hearing on the formaldehyde study conducted by the NCI in conjunction with the Formaldehyde Institute. Dr. DeVita noted that NCI had anticipated that collaboration with industry might raise questions. He reported that the hearing went very well and commended Dr. Aaron E. Blair, Division of Cancer Etiology, for having produced an outstanding study on the carcinogenicity of formaldehyde.

Dr. DeVita then briefly described the purpose and format of the annual program review regularly conducted at the December meeting of the NCAB. Each NCI Division Director, jointly with the Chairman of the Divisional Board of Scientific Counselors, is invited to present the work accomplished in that particular Division during the preceding year. Dr. DeVita then proposed that the next meeting be targeted to a review of the entire Centers Program and presented a plan to hold the meeting at Memorial Sloan-Kettering Cancer Center in New York City. He reported that the Center had agreed to host the NCAB meeting and organize a visit of the facilities. Dr. DeVita suggested that the first day be devoted to the usual program review followed by a presentation on the Centers Program.

Dr. DeVita concluded this part of his report by announcing that Dr. Marc Lippman, Head of the Medical Breast Cancer Section in the Clinical Oncology Program/Medicine Branch would receive an award at the Susan Komen Foundation annual awards luncheon on October 29.

Budget Presentation

Dr. DeVita began his budget report by emphasizing the complexity of the budget situation. He pointed out that NCI was currently looking at several different budget levels for FY 1987, including the original FY 1987 President's Budget, a revised FY 1987 President's Budget for funding transfer related to AIDS (August 1986), another revised FY 1987 President's Budget related to a transfer for drug abuse (September 1986), House and Senate markups of the budget request, and the potential August Gramm-Rudman impact on the budget.

Dr. DeVita began to illustrate the chronology of events that affected the FY 1986 budget. The FY 1985 actual budget, shown for comparison, was $1.190 billion, and the estimated FY 1986 budget with the AIDS reimbursement was $1.228 billion. The initial appropriation of $1.258 billion was augmented by two funding carryover actions from 1985, one for the St. George, Utah, Diagnostic Center and the other for grants, then reduced by several other actions, the largest one being the sequestration of funds resulting from the Gramm-Rudman legislation. Reimbursement of funds for AIDS research from the Office of the Director, NIH, and an emergency supplemental appropriation for the Centers Program resulted in a final budget level of $1.228 billion.

In comparing the FY 1986 budget to FY 1985, Dr. DeVita stated that basic research remains the highest priority. The largest increases shown in the FY 1986 budget estimate are for research project grants (8.0%) and for Cancer Centers (3.9%). The intramural research program increased by 1.0 percent and all other areas were reduced, including 3.1 percent for the Cooperative Clinical Research Groups and 13.0% in research and development contracts. Obligations directed towards AIDS research show an overall increase of 3.2 percent over the FY 1985 actual budget.

Turning to the FY 1987 budget, Dr. DeVita illustrated the various requests presented in January, August, and September 1986. From an initial $1.158 billion request, August and September revisions to the President's Budget resulted in a $1.127 billion level as a result of requirements for

AIDS research and the drug abuse program. Dr. DeVita noted that, in the meantime, the House and Senate have passed substantially higher amounts for the NCI budget, at $1.246 billion in the House version and $1.397 billion in the Senate.

Dr. DeVita described how the two initiatives for AIDS and the drug abuse program mandated transfers and absorption of expenditures that would result in reductions in awards to the research project grants, the Cancer Centers and the National Research Service Awards program. He noted that if the $1.127 budget request were enacted, the 1986 supplemental appropriation for the Centers would in fact be negated and some reductions in the Centers Program would have to be made. The number of competing research project grants estimated to be 874 in the original FY 1987 President's Budget would drop to 697.

Dr. DeVita illustrated the proposed Congressional increases by program area. In both versions, by far the largest increase would be in the research project grant pool. The seemingly large increase for research and development contracts includes about a $20 million increase for clinical trials; although the funds were included in contracts, they will be redistributed to the most appropriate mechanism.

Dr. DeVita then provided information on the number of competing research project grants funded in FY 1986 which was 951, compared to 1,017 in FY 1985. The priority score cutoff of 173 in 1985 allowed funding of 36 percent of approved applications. In FY 1986 the percentage of funded applications was close (34%) but the priority score was a more stringent 164.

In closing, Dr. DeVita briefly pointed out FY 1987 budget levels in the various components of the NCI program in a comparison table displaying the January and September President's Budgets and the House and Senate allowances. He then showed the increases in the budget for AIDS, from actual expenditures of $26.9 million in FY 1985 to $45 million in 1986 and the $61.7 million budgeted for FY 1987. It still is not known whether the AIDS funds will be in a central fund or the NCI budget. Funds for the Small Business Innovative Research (SBIR) program increased from $9.1 million in FY 1985 to $11.3 million in FY 1986. Dr. DeVita also pointed out that the quality of the SBIR proposals had improved considerably since the beginning of the program.

Lastly, Dr. DeVita directed the Board members' attention to a document containing the FY 1988 by-pass budget that had been distributed to the Board before the meeting and indicated that this budget had been sent to the OMB in mid-September.

Legislative Report--Dr. Mary Knipmeyer

Dr. Knipmeyer gave a report on recent legislative activities and hearings of interest to NCI staff. In addition to the formaldehyde hearing, there were AIDS hearings throughout the 99th Congress and a hearing on skin cancer and its prevention, particularly among the elderly. Dr. Knipmeyer

also reported that Dr. Joseph Cullen, Deputy Director, Division of Cancer Prevention and Control was about to testify before the State legislature in California to discuss NCI policies and priorities.

Elaborating on Dr. DeVita's earlier comments on the apportionment issue, Dr. Knipmeyer pointed out that the proposed technical amendment is in fact a restoration of authority that had been changed when the National Cancer Act was reauthorized in November 1985. The new legislation would clarify that the NIH Institute Directors can establish peer review committees, with NCAB and NIH Director approval, and appoint members under their own authority. It would also add a new ex officio member to the NCAB from the Department of Energy, clarify that the NCAB ex officio members are non-voting members, and eliminate confusion about the NCI Boards of Scientific Counselors intramural review function. In other provisions of the bill, cancer control would become an authorized activity for the Cancer Center Core Grant Program.

Dr. Knipmeyer then indicated that both AIDS and tobacco legislation would continue in the 100th Congress. Legislation was recently introduced in the House and the Senate to ban smoking in Government buildings. The 16-cent per package tax became law in April; attempts to raise that tax to 24 cents failed in this Congress.

The Cancer Center Reimbursement Reform Act of 1986 was introduced by Senator Moynihan in the 99th Congress but was not passed. This would allow establishment of separate accounting and reimbursement systems for Clinical and Comprehensive Cancer Centers.

A resolution passed to express the sense of Congress that there should be no job discrimination on the basis of current or past cancer history.

The Small Business Innovation Research Act will continue, with a new, prospective termination date of 1993.

Concern over animal rights will continue to generate discussion of animal welfare issues in Congress.

Following the Director's Report and Legislative Update, Dr. Korn referred Board members to a document on the authority of the Director of the NCI to appoint members to review and advisory groups. He explained that in the language of the reauthorization legislation, the Director's authority to establish advisory groups must be exercised with the approval of the NCAB. Dr. Korn read the proposal distributed to Board members and moved that it be approved. He commented that this action would give back to the NCI the authority it always had and added that if the Hatch bill were enacted, this procedural step would no longer be necessary. The motion was seconded and unanimously approved (See Attachment A).

V. NIH Centennial and NCI 50th Anniversary Celebrations--Dr. Alan Rabson and Dr. John R. Durant

Dr. Rabson, substituting for Dr. Elliott Stonehill, opened his report with slides of the official NIH Centennial logo and a copy of the joint

Congressional resolution (S.J. Res. 395) that designated the period October 1, 1986, to September 30, 1987, as "National Institutes of Health Centennial Year." In addition to the NIH-wide schedule of observances, each Bureau, Institute, and Division is assigned a month to conduct Centennial-related activities; NCI has the month of May. An Office of Centennial Activities has been set up in Dr. Wyngaarden's office to handle inquiries.

The closing days of the Centennial celebration (October 15-18, 1987) will feature an alumni reunion and a series of scientific symposia held at the NIH campus on the following topics:

1) Oncogenes--chaired by Drs. Rabson and Rosenberg. Presenters will include Dr. Harold Varmus, a GM award winner and discoverer of oncogenes, from the University of California at San Francisco (oncogenes); Dr. Robert Gallo of NCI (viral etiology of cancer); Dr. Lance Liotta of NCI (invasion and metastases); Dr. DeVita (chemotherapy); Dr. Rosenberg (immunotherapy); and Dr. Peter Greenwald of NCI (prevention).

2) The Relationship between NIH and the Extramural Research Community--planned by the extramural program of NIH and opened by Dr. David Korn

3) Genetics--chaired by Dr. Maxine Singer of NCI

4) Molecular Biology--chaired by Dr. Ira Pastan of NCI

5) Immunology--chaired by Dr. Tom Waldmann of NCI.

NCI's Centennial observance plans include a 50th anniversary commemorative book, prepared under the leadership of Mr. J. Paul Van Nevel in the Office of Cancer Communications; a 50th anniversary issue of the Journal of the National Cancer Institute; and a reunion of NCI alumni, special friends, and current staff.

Finally, Dr. Rabson related a brief history of NCI as he heard it from his early mentor, Dr. Harold Stewart, and as he experienced it since he joined the staff in 1955. He noted the efforts of the first leader of the USPHS cancer program, Dr. Joseph Schereschevsky, and all the NCI directors from Dr. Carl Voegtlin, the first director, to Dr. DeVita.

National Coalition for Cancer Research Centennial Plans--
Dr. John R. Durant

Dr. Durant briefly outlined the history of the National Coalition for Cancer Research, an extramural organization of cancer professionals and concerned lay groups. The Coalition, organized primarily by Dr. John Ultmann and Dr. Durant, evolved from the recognition that, while individual societies disseminate information about their own specialties, there was no joint effort to inform the public about issues of common importance. During the first year, this effort was directed at publicizing the value of NCI programs

and the need for reauthorization of the National Cancer Act. The Coalition is currently making plans to celebrate the anniversaries with a variety of activities that will focus on the future direction of the National Cancer Program, as well as its major contributions to basic biomedical science and to the reduction of cancer morbidity and mortality.

In discussion, the following points were made:

- The Coalition has recruited help from experts in information dissemination
- The information program must be clearly identified as an activity of the extramural community to assure maximum freedom and flexibility
- Two aspects of the activity are 1) informing the public, and 2) informing Congress with help from the public
- Dr. Alan Sartorelli, President of the American Association of Cancer Research, has strongly endorsed the Coalition's activities from the basic science standpoint as well.

VI. Update on AIDS Vaccine Development--Dr. Peter Fischinger

Dr. Fischinger provided an extemporaneous update on AIDS vaccine development. NCI became involved in AIDS research because of the Institute's significant expertise in viral oncology. Dr. Gallo identified the AIDS virus, HTLV-III*, and in May 1984 an Institute AIDS Task Force was established. A follow-up Committee known as AVIS, AIDS Vaccines and Intervention Strategies, was subsequently established. Experts in retroviruses and prevention and intervention examined various approaches to vaccine development. Some common approaches, such as using inactivated virus, killed virus, or genetically engineered changed virus, were not useful with the AIDS virus, which integrates into the cell's DNA and potentially can trigger oncogenes. The simplest approach was considered the development of a subunit-type vaccine using various permutations as genetically engineered products in various systems. Dr. Fischinger noted that a number of intramural and extramural groups have worked together on this effort.

The vaccine development strategy is based on the fact that in every retrovirus, only the major external viral glycoprotein affords protection. Therefore, efforts focused on the isolation of the protein product GP120, which when tested in mice, rabbits, goats, and rhesus monkeys, produced strong neutralizing antibody. Dr. Fischinger said that while the antibody was probably as strong as anything produced with any retroviral component in any model system, it must be recognized that a number of very different virus isolates of the disease are known today. However, these results led to consideration of testing GP120 in chimpanzees, the only animals that can be readily infected with the virus. Such a test will occur in the next few months, and, if successful, other agents related to the HTLV-IIIb prototype may be considered.

*The name human immunodeficiency virus (HIV) has been proposed for these viruses (Science 1986: 232:697).

Dr. Fischinger said a meeting was held at Cold Spring Harbor to discuss various vaccine preparations. NCI's vaccine preparation induces neutralizing antibody to a much greater degree than the other preparations, including the infectious recombinant viruses. Some genetic engineering preparations induce neutralizing antibody to lesser degrees and may offer good alternatives. NCI investigators, in collaboration with a genetic engineering group, have found stretches of the envelope gene which code for surface determinants and can induce a neutralizing antibody. These genetic sequences can be readily propagated in bacteria. Dr. Fischinger suggested these might be used in the next level of testing in the chimpanzee.

Points raised in discussion included the following:

- The purpose of the vaccine is to induce protection against disease from a primary exposure to the virus
- There are indications (e.g., persons entering the Army) that the disease is spreading beyond the known high risk populations
- An estimated 270,000 people have been exposed to the AIDS virus in the United States in the past 5 years
- Any vaccine developed would be a preventive measure, not a cure, for AIDS.

VII. Mapping the Human Genome: Importance for Cancer Research--Dr. James Watson

Dr. Watson prefaced his remarks with a plea to encourage an increase in the number of people entering science, so as to maintain the momentum in cancer research.

Dr. Watson stated that the philosophical reason for mapping the human genome is that finding out about ourselves is the real frontier in science. Insight could be gained about the process of human evolution. However, knowledge of the complete human gene sequence per se may not transform cancer research as, Dr. Watson suggested, had occurred with the discovery of recombinant DNA.

To estimate the cost of mapping the genome, Dr. Watson pointed out that the human haploid genome contains 3 billion base pairs. The cost of mapping is about $1 per base pair, and a good scientist could map approximately 100,000 base pairs per year. The cost of maintaining one scientist is about $100,000 per year. Dr. Watson said the cost has decreased over the past 5 years and could be expected to continue to decrease, although the rate of decrease is unknown.

Dr. Watson suggested that money be spent on instrumentation development so that the mapping can be done by machines, without diverting scientists away from cancer and other basic research. A consortium in Japan is proposing a machine that could map one million base pairs a day at a cost of $5 million.

If the instrumentation problem could be solved, it should be possible to have the whole sequence by the year 2000.

Potential difficulties in mapping involve the magnitude of the effort. The smallest human chromosome, which constitutes about 1 percent of the genome, has about 1×10^7 base pairs. To separate the chromosomes, DNA must be purified, and while this is being done at Livermore and Los Alamos by cell sorters, the chromosomes get somewhat broken up in the process. The mapping can be done by cutting the DNA with restriction enzymes and lining up the fragments or by pulse field electrophoresis, which allows separation of bigger pieces of DNA on a gel. Dr. Watson said the map itself is not especially useful; rather, what is needed is a series of overlapping cloned fragments of the genome, e.g., as cloned cosmids, which are about 50 kilobase pairs. A group at Cambridge (Sidney Brenner) is working on a method to order cloned cosmids of a small worm, which has about 50 times less DNA than a human. Successively larger pieces of DNA have been sequenced and the information stored in computers. Another method, being used in Heidelberg (Hans Larich), involves two cuts by restriction enzymes and the use of computers to look for terminal similarities among regions of the cosmids and to link them all together.

There is also the question, assuming it is possible to get overlapping cosmids for a human chromosome, of whether to sequence the entire chromosome. Dr. Watson suggested it would cost more to show that some regions of DNA are junk than to sequence all of it. To selectively sequence DNA would require knowing which sequences are transcribed.

Another problem is arranging the restriction fragment-linked polymorphisms (RFLP) into an ordered map. Humans are extremely polymorphic, and the same gene in two individuals may be different. In many cases, the differences are in nonessential sequences, but there may be changes in a base pair that change the potentiality for a restriction enzyme cut, thereby resulting in cutting the genetic region of interest in two different ways for two individuals.

Dr. Watson stated that approximately 1,000 polymorphisms have been isolated and some mapped, with the principal work being done at the University of Utah Medical School and at the Howard Hughes Institute by Ray White. Success in using maps to locate genes of particular interest has been achieved for Duchenne's muscular dystrophy and cystic fibrosis. Identification of specific genes and their location can be useful in both diagnosis and treatment of diseases and definition of susceptibility to disease. Dr. Watson said there was consensus among the scientific community that the mapping of polymorphic markers should be speeded up. In comparing two approaches--sequencing a single human male genome or study of many genomes based on RFLPs--Dr. Watson said the latter approach was likely to yield more immediate benefits.

The James McDonald Foundation of St. Louis has given money to the National Academy of Sciences to fund a committee to examine how best to approach the problem of mapping the human gene sequence. Dr. Watson suggested that a coordinated national plan of action should be developed to approach the problem.

The following points were raised in discussion:

- As technology develops in the next few years, faster ways of mapping and sequencing will be available and the costs may decrease.

- Writing in Science, Dr. Joseph Gall stated that the cost is likely to far exceed $3 billion and will divert money from other worthy projects. He also questioned whether it would be worthwhile to sequence the entire human genome, as most DNA does not code for proteins and may have no sequence-dependent function.

- The "junk" DNA may offer insights into evolutionary decisions.

- An international consortium might be an appropriate mechanism for funding this research, which may have many applications.

- NCI spends about $220 million a year (40 percent of the basic research budget) on molecular biology research, and a large number of the researchers are working on the human genome.

- Most researchers are focusing on specific regions, genes, or diseases, not actually on mapping the genome as an explicit goal.

- While many consider mapping projects to be very valuable, a fear is that human or financial resources may be diverted from other important areas of biomedical investigation.

- Mapping and sequencing research should be identified as a special initiative in NCI's by-pass budget.

- It is important that some of this research be supported by public money so that the probes for mapping are generally available.

- Any special research initiative should be delineated so as not to divert funds from other research.

In conclusion, Dr. DeVita noted Dr. Watson's elucidation of the structure of DNA as the seminal contribution to this area of research.

VIII. Cancer Communication--Mr. Paul Van Nevel

Mr. Van Nevel introduced the speakers to discuss the Cancer Communication System and the Cancer Prevention Awareness Program for Black Americans. While these two programs may appear to be quite different, Mr. Van Nevel said they are, in fact, closely intertwined and mutually nurturing. The speakers were Ms. Judith Stein, Project Officer for the Cancer Communications System Program, Office of Cancer Communications (OCC); Ms. Rose Mary Romano, Chief of the Information Projects Branch, OCC; Dr. Lee Monroe, Senior

Advisor to the Governor of North Carolina and Chairperson of the Advisory Group for the Cancer Prevention Awareness Program for Black Americans; and Ms. Jane Hoey, Coordinator of the Cancer Communications System Office at the Meyer L. Prentis Comprehensive Cancer Center of Metropolitan Detroit.

Cancer Communications System Program--Ms. Judith Stein

Ms. Stein described the creation of the Cancer Communication System (CCS) in 1975 in response to the National Cancer Act's mandate to provide a program to disseminate information on cancer to the general public, cancer patients and their families, and health professionals. This is a nationwide program with regional field offices that 1) engage in information and education activities (e.g., serve on local advisory groups and provide speakers for community meetings); 2) develop and maintain resource directories (e.g., stopsmoking clinics, cancer detection clinics, etc.); and 3) establish and operate the Cancer Information Service (CIS), the most visible part of the program.

The Cancer Information Service is a telephone information service designed to provide accurate, current information on a one-to-one basis by health educators and in some offices, trained volunteers. No attempt is ever made to diagnose a patient or propose treatment. NCI provides information to answer questions on nearly a daily basis. Each office is accessed by the toll-free number, 1-800-4-CANCER. Currently there are 24 regional offices, serving about 80 percent of the U.S. population, and a national office in Bethesda, serving the rest of the population. NCI funds 16 contracts for the Cancer Communications System. An additional eight offices are independently funded, although they are treated exactly the same as the NCI-funded offices.

Ms. Stein described the ongoing evaluation that has been part of the program since 1983. Quality control derives from a nationally developed staff training program, with participation required of every staff member. In addition, there is a test call system which compares responses to a common set of standards.

Another aspect of the evaluation is the development of a common data set of information on every call to the CIS, including type of caller, reason for the call, cancer site in question, behavioral suggestions, and other items. The data set now contains information on over one million calls. Ms. Stein noted the following information about CIS:

- The CIS has responded to over 2 million inquiries since 1976
- The number of calls per year has increased from almost 60,000 calls in 1976 to almost 400,000 calls in 1985
- The current rate is approximately 33,000 calls each month, or more than 1,600 inquiries daily
- From 1983 to 1985, almost half the callers were from the general public, perhaps reflecting the recent interest in cancer prevention

- Approximately 39 percent of all calls concern a specific cancer site, the most common being breast, colon and rectum, and lung

- Risk factors are the subject of inquiry for about 23 percent of all calls, and 80 percent of these concern tobacco use.

The third aspect of the evaluation was a survey of a sample of CIS users to determine their perception of the services they received and their health actions in response to their contact with the CIS offices. Some results of the CIS user survey of over 7,600 callers are summarized below:

- Respondents felt the information provided by the CIS staff was useful, clear, and easy to understand

- Respondents perceived the CIS staff as knowledgeable, courteous, friendly, and sympathetic

- Almost 98 percent said they would call again if they had questions, and over 50 percent said they had recommended CIS to others

- Over 93 percent reported taking some health-related action following their call and 91 percent said the contact with the CIS was important to their decision to take action

- By extrapolating from respondents who said they shared information with others, it was estimated that CIS information reached about 1.2 million people in 1985.

Ms. Stein said that a variety of approaches is used to promote NCI materials to specific audiences, such as people over 50, Blacks, smokers, and cancer patients and their families. NCI also works with other agencies and organizations on promotion campaigns, illustrated by three public service announcements prepared with the Office of Smoking and Health. One featured the Surgeon General, Dr. C. Everett Koop; the others were titled "Chained Smoker" and "Reaching Smokers." Ms. Stein reported that the number of calls to the CIS about smoking increased dramatically following each promotion (e.g., from 500 calls a month on smoking to over 12,000 the month after the Surgeon General's announcement was released).

NCI also promotes awareness of the toll-free phone number through the national print media. CIS recently served as a major resource to NCI and the public during major news events, such as the public announcement that President Reagan had colon cancer and the interleukin-2 clinical trials. Ms. Stein pointed out that CIS offices have become major users of the PDQ data base, which has led to an increase in the number of CIS referrals to cancer centers and clinical trials. In addition, the CCS regional offices serve as the primary intermediaries for NCI's Cancer Prevention Awareness Program.

Ms. Stein identified the following recent innovations and current projects:

- "Advanced 800" telecommunications to route people who only want publications to a central ordering office and those with questions to regional CIS offices
- Electronic mail to link all offices with each other and with NCI
- A book and several journal articles in preparation using CIS data.

CCS provides assistance to organizations (e.g., the National Arthritis Foundation) and other countries that want to set up similar operations.

The following points were raised in discussion:

- The Privacy Act prohibits collecting information on callers other than their names and addresses, which are recorded only if the person wants publications
- The CCS is integrated with the American Cancer Society (ACS) to the extent that one office is funded by ACS and all offices are instructed to involve ACS in their activities whenever possible
- NCI cannot pay for public service announcements, so their airing depends on the good will of public service directors
- Other means of publicity are feature articles, clip sheets, interviews, NCI publications, Kellogg's cereal boxes and commercials, and phone books
- NCI sets minimal standards for physician referrals but the local institutions essentially establish their own policies.

Cancer Prevention Awareness Program for Black Americans--
Ms. Rose Mary Romano

Ms. Romano said NCI initiated the Cancer Prevention Awareness Program in March 1984 as part of its Year 2000 cancer control goals. The Institute has developed messages and materials to inform the public that cancer is a preventable disease and that changes in behavior can reduce one's risk of cancer. The first phase of the Program focused on creating awareness among the general public of the cancer prevention messages. This involved working closely with broadcast and print media and developing a network of interested health professionals around the country, called Partners in Prevention.

In January 1985, efforts were initiated to reach groups at greater than average risk of developing cancer. Ms. Romano said that because of the disproportionately high rates of cancer among Blacks and the existence of numerous misconceptions within this population in relation to cancer, NCI's first target effort has been aimed at reaching Black Americans. Dr. DeVita announced the Cancer Prevention Awareness Program for Black Americans at a

media briefing in Detroit in May 1985. Leaders of the Black community were invited to join NCI as Partners in Prevention.

Ms. Romano noted several efforts that were undertaken before the Program was initiated: 1) review of successful health education programs; 2) meetings with communication and health education experts experienced in communicating messages to Blacks; 3) market research, including formation of focus groups; 4) surveys to test cancer prevention messages and obtain information on the public's perceptions; and 5) formation of a committee of experts to develop a long-range plan and an advisory committee to serve on an ongoing basis. To reach Black Americans, the Cancer Prevention Program uses three approaches: the media, organizations, and the community.

The media approach in 1985 included 450 television public service announcements featuring Aretha Franklin; 1300 radio public service announcements featuring CBS recording artists; 750 print media kits to major daily newspapers, Black publications, consumer magazines, and health and science reporters; press releases to 885 Black newspapers and publications, 520 radio stations, and 160 television stations. A second wave of television public service announcements was developed in 1986 and distributed by local CIS offices. These and earlier messages encourage viewers and listeners to call the toll-free CIS number and request the free booklet, "What Black Americans Should Know About Cancer." Currently, a follow-up media kit is being distributed to encourage continued coverage of cancer prevention issues for Black Americans. (The television public service announcements were shown to the Board.)

The Program's second approach, the Joint Health Venture, is a network of national and regional leaders of civic, religious, and professional groups working with NCI to disseminate cancer prevention information to members of the Black community. Ms. Romano cited cooperative projects with the National Medical Association, the Black Shriners, the National Black Nurses Association, the National Council of Negro Women, the National Football League, and the National Association of Retired Persons, among others. For example, the National Medical Association is asking member physicians not to smoke at its meetings, to query patients about their eating habits, and to institute screening programs in community settings such as churches.

Ms. Romano described the Program's third approach as outreach to the local community. NCI plans to target about five or six communities and tailor each effort specifically to the community. To date, programs have been initiated in Detroit, the state of North Carolina, Atlanta, and Washington, D.C. In most cases, a number of organizations have joined forces to increase local sources of information, education, intervention, and social support related to cancer. NCI's role is to provide technical support in the form of materials, speeches, exhibits, and consultation. Other initiatives include working with historical Black colleges, which often play a key leadership role in their respective communities; supporting community information and education programs designed by school staff and targeted to nearby populations (a collaborative effort of the Division of Extramural Affairs and the Office of Cancer Communications); and involving the clergy of Black churches. Ms. Romano said NCI hopes to be able to document successful community interventions and share these with other communities interested in undertaking similar efforts.

Although the Program is quite diverse and complex, Ms. Romano said NCI is trying to incorporate some systematic evaluation of the process. NCI hopes to be able to quantify the extent to which the message is reaching the Black audience and to determine how Blacks are responding to the messages. Research methods being used include media monitoring, case studies of Black organizational efforts, community surveys and user project surveys, and focus groups with Black health professionals.

Ms. Romano stated that in the coming years NCI's Cancer Prevention Awareness Program will focus its education effort more systematically on the problem of tobacco use among Blacks. Addressing the cancer control needs of minorities is critical to achieving the Year 2000 goals. In conclusion, Ms. Romano recognized the efforts of Dr. Joan Houghton in designing and developing the Program for Black Americans.

The following points were raised in discussion:

- Efforts are being made to involve other major sports organizations, such as the National Basketball Association, in the Program

- The message may not be getting through in some communities, where groups are initiating efforts that may duplicate NCI and American Cancer Society efforts.

Cancer Prevention Awareness Program for Black Americans--Dr. Lee Monroe

Addressing the question of identifying local persons to carry the message to the community, Dr. Monroe cited various organizations, e.g., Shriners, Eastern Star, Daughters of Isis, etc. in North Carolina, which are involved in the effort. A spokesperson from each organization is trained to take the message to the community. The same process was used on the national level to identify approximately 88 organizations that were thought to be instrumental in the Black community.

Dr. Monroe said the Program was developed on the basis of a linking model in which research organizations are linked to the community through consultants and conveyors. In the conceptualization, the resource system (NCI) was connected to the client system (the citizens) through the conveyor (the CIS). Target areas having CIS offices were identified. An Advisory Committee serves as consultants to help link NCI and the community. Dr. Monroe reviewed recent recommendations of the Advisory Committee:

- Churches should dedicate one Sunday to discussion of cancer prevention awareness

- A "summit" meeting should be convened, perhaps at an historical Black college with a medical program, to focus once again the attention of the community on the issue

- The Black insurance companies, which still collect money by going to individual homes, and the Black banks should be involved

- Audiovisual messages should be emphasized because of high illiteracy rates in some Black communities.

Dr. Monroe said that in North Carolina, when the Program is kicked off, the Governor will declare a cancer prevention awareness month and the Department of Human Resources has committed some money to the Shriners and Masons for their involvement. Dr. Monroe emphasized the importance of NCI's role at the local level, not necessarily as a Federal presence but as a Federal catalyst to see that this important issue is addressed.

In discussion, the point was raised that economic and political considerations may serve to directly counteract the Cancer Prevention Awareness Program. This makes efforts to promote the Program and involve as many organizations and groups as possible all the more important. Efforts should continue to expand the group of local Black leaders involved in the Program.

Community Link--Ms. Jane Hoey

As background, Ms. Hoey stated that the city of Detroit is 63 percent Black and the Michigan Cancer Foundation is one of the original participants in the NCI's Surveillance, Epidemiology, and End Results (SEER) program. The Michigan SEER data constitute nearly 90 percent of the information on Blacks. Detroit's Black population has been recognized as a primary target audience for cancer prevention messages and outreach activities.

When the Comprehensive Cancer Center of Metropolitan Detroit became part of the Cancer Communication Network, Ms. Hoey started working with Ms. Romano to establish networks in the community to secure focus groups for pretesting health messages. Ms. Hoey identified that activity as the beginning of community linkage. A local radio station was able to arrange for Aretha Franklin to appear in public service announcements, which NCI decided were relevant to the Black population nationally and could be used for the National Cancer Prevention Awareness Program for Black Americans. Detroit was selected to host the national kickoff for the Program in May 1985.

Ms. Hoey reviewed activities that occurred before the kickoff to get Black leadership involved in the activity. With the help of Mr. Ofield Dukes, an NCI consultant, Black leaders from organizations, such as the NAACP, the Detroit Urban League, Detroit Inner Greek Council, Detroit Medical Society, and Detroit Association of Business Organizations, agreed to form the Detroit Steering Committee. NCI served as a consultant and catalyst to link Detroit to the Institute's activities and the Year 2000 goals. Among the activities that have occurred in Detroit are a Cancer Alert Sunday in churches, the formation of subcommittees to plan how to get the message into the school curriculum, and investigation of worksite programs. Key leaders, including lawyers, business people, and health professionals, have made public service announcements.

Ms. Hoey also mentioned that the Michigan Cancer Foundation was recently awarded a contract (as a cooperative effort) to study avoidable mortality for cancers in Black populations. Seven cancer control interventions will be designed, tested, and implemented over the next 5 years. The Detroit Steering Committee will serve as the advisory committee for that contract. Ms. Hoey concluded by emphasizing the many mutual benefits that have accrued through collaborative efforts with NCI.

In discussion of all the Cancer Communication presentations, the following points were raised:

- The Board's attention was called to a flyer detailing the spectrum of NCI's activities to reach Black populations
- Smoking can be considered a form of substance abuse and should be brought to the attention of the sponsors of the national "Just Say No" Program to fight drug abuse
- Means of working with drug abuse programs should be investigated
- Black business leaders should be approached about eliminating practices such as allowing exhibits at conferences that are paid for by tobacco companies
- Some NCI brochures now include information inviting private corporations to contribute money to support the dissemination of NCI information
- The feasibility of holding a conference for major corporate leaders with special interest in minority communities should be investigated.

IX. Closed Session

The second day of the meeting was closed to the public as it was devoted to the Board's review of grant applications. The applications reviewed numbered 1,147, requesting support in the amount of $162,359,511. Of these, 985 were recommended for funding at a total cost of $112,931,711. The Board recommended 19 MERIT Awards for funding by NCI.

X. Subcommittee Reports

Subcommittee on Planning and Budget--Dr. Louise Strong

The minutes of the October 6, 1986, meeting of the Subcommittee were distributed, and Dr. Strong reviewed three major issues. The Subcommittee discussed the requirement of the current apportionment process that NIH and, in some cases, OMB approve redistribution of funds among mechanisms. Subcommittee members expressed a willingness to be involved in the determination of proposed redistributions amongst mechanisms. It was suggested that NCAB

members be contacted by mail or conference call and, when appropriate, that Dr. DeVita could work with Dr. Korn to ascertain the consensus of the Board.

All Subcommittee members agreed that the funds requested for the special initiative for mapping and sequencing the human genome should be kept separate from the core NCI budget. It was emphasized that while this project is important and worthy of pursuit, it should not be accomplished at the expense of other promising areas of research. Dr. Chabner proposed that SBIR awards be targeted to this research and used to stimulate research in methods development.

Members of the Subcommittee expressed concern that the number of scientific trainees continues to decline, principally because of budgetary constraints. The future of scientific research could be jeopardized if the rate of attrition exceeds that of new investigators entering the field. The Subcommittee urged that current levels of training be stabilized or increased.

The report of the Subcommittee on Planning and Budget was accepted.

Subcommittee on Organ Systems--Dr. Bernard Fisher

Dr. Fisher presented the summary of the October 5, 1986, Subcommittee meeting. Subcommittee members do not believe there are serious problems with the Organ Systems Program at this time. The main area of interest was considered to be investigation of the nature and quality of the research being done as a result of the Program. In addition, the aims and objectives of the Program should be re-examined to determine whether they are still applicable. As there will be a presentation reviewing the accomplishments of the Organ Systems Program at the next NCAB meeting, the Subcommittee agreed to meet after that presentation.

The report of the Subcommittee on Organ Systems was accepted.

Subcommittee on Innovations in Surgical Oncology--Dr. Victor Braren

Dr. Braren presented the summary of the October 6, 1986, Subcommittee meeting. He noted the input and historical reflections of Drs. Fisher and Longmire. Dr. Braren highlighted the following items of discussion:

- The Subcommittee recognized the many positive efforts that NCI has used to stimulate surgical oncology research
- There is no broadly accepted definition of surgical oncology and no specialty Board certification
- There has been an encouraging response (12 surgical T32 applications) to the ongoing training grant application initiative
- Preliminary data presented by Dr. Avis showed that the number of applications submitted and grants awarded in surgery has gone down between FY 1980 and FY 1985 compared to other disciplines, especially medicine

- NCI has brought about 14 separate initiatives in surgical oncology, with the Planning Grant mechanism being one of the most successful.

Dr. Braren then presented possible solutions and areas of stimulation discussed by the Subcommittee:

- The surgical community bears responsibility for promoting surgical oncology research.

- The Subcommittee and the NCAB should continue to stimulate NCI to pursue areas of surgical oncology research. Subcommittee members were asked to come to the next meeting with at least one specific research suggestion.

- Training should be expanded.

- There should be more dissemination of information from NCI to the surgical oncology research community.

- The Subcommittee proposed to work with Dr. DeVita to develop additional specific plans for the promotion of surgical oncology research.

In discussion of the report, it was noted that although the number of surgical oncology grants has decreased, the approval rate was the same for surgical and medical grants. It was suggested that the problem might be one of restimulating the surgical oncology research community, which during the past few years viewed NIH as not encouraging such research. Participation in the training programs should be followed to see whether the number of grant applications increases. The preliminary data presented were on grants that originated from departments of surgery compared to grants that originated from departments of medicine.

The report of the Subcommittee on Innovations in Surgical Oncology was accepted.

Subcommittee on Cancer Information

Mr. Bloch presented the minutes of the October 5, 1986, Subcommittee meeting, which were distributed to the Board. In considering whether the Board should sponsor a major new report similar to the Decade of Discovery report, the Subcommittee unanimously approved the following recommendation to the full Board:

> That NCI staff work with the Board to develop a major attractively packaged report describing progress in the cancer program, particularly within the last 15 years, but emphasizing recent advances. This report would be distributed to the more professional and interested segment of the population. A much shorter and simpler companion piece would be developed for mass distribution. NCI and Board members should explore the ways of printing this

publication without cost to the Government. The target publication date should be May 1987 to coincide with NCI's 50th anniversary celebration.

A second recommendation offered by the Subcommittee related to a suggestion by Mrs. Brinker that interested NCAB members serve as active ambassadors for the National Cancer Program, carrying information about research progress, as well as health educational messages to the public. The Subcommittee approved the following recommendation to the Board:

> That Mrs. Brinker work with Paul Van Nevel, soliciting the help of outside experts as necessary, to develop a proposal to use NCAB members and other national Program leaders as spokespersons to inform and educate the public about progress in cancer research. This proposal would be presented to the full Board at its December meeting.

Mrs. Brown suggested that the Board members conduct public hearings in various places to establish two-way communication.

The following points were raised in discussion of the proposed Ambassador Program:

- Board members participating in such a program would do so in their capacity as NCAB members, not as representatives of institutions with which they may be associated
- Board members acting as ambassadors should go outside their own communities
- The Program might be especially appropriate for the lay members of the Board to communicate with the public and receive feedback
- Such a program could serve to make science and research more "touchable"
- Much staff work is required to support such a program
- Person-to-Person from the National Cancer Institute was suggested as the name for the Program.

The report of the Subcommittee on Cancer Information and the two recommendations presented were accepted.

Subcommittee on Cancer Control for the Year 2000--Mrs. Helene Brown

Mrs. Brown presented the report of the October 7, 1986, meeting of the Subcommittee. The Subcommittee formulated the following charge for Board approval with the report:

That the Committee is to provide the link between the NCAB and the various publics, for example, business leaders, consumers, governmental representatives, providers, etc., relative to the initiatives that will aid in achieving the Year 2000 goals. Such initiatives will include building awareness and consensus necessary to achieve those goals, describing the resources necessary, and seeking those resources.

The Subcommittee noted the importance of the total NCI budget to this effort and emphasized the need to continue to build all the research thrusts, including cancer prevention and control, rather than shifting support between priority programs. Activities discussed by the Subcommittee included sponsorship of a conference of business leaders, development of information and materials describing milestones and progress, annual projections of achievements related to resources available, and identification of existing barriers.

The post office poster warning people about unauthorized cancer treatments was presented for the Board's review. The posters are to be displayed around the country, and official letters of approval from the cooperating agencies will be obtained.

The report of the Subcommittee on Cancer Control was accepted.

Subcommittee for the Review of Contracts and Budget of the Office of the Director--Dr. Roswell Boutwell (for Dr. Phillip Frost)

Dr. Boutwell presented the report of the October 7, 1986, Subcommittee meeting for Dr. Frost. He stated that the Subcommittee reviews concepts for contracts through the Office of the Director.

The Subcommittee considered ten projects (five for recompetition, three that are new, one interagency agreement, and one sole source) for concept approval and approved all of them. Dr. Boutwell noted that the budgets for these contracts have been reduced from last year to comply with the Gramm-Rudman-Hollings Deficit Reduction Act. Dr. DeVita explained that this Subcommittee was established because the Office of the Director does not have a Board of Scientific Counselors to approve concepts for contracts.

The report of the Subcommittee for the Review of Contracts and Budget was accepted.

XI. New Business

December 8-10, 1986, NCAB Meeting

The proposal to hold the December 8-10, 1986, NCAB meeting at Memorial Sloan-Kettering Cancer Center in New York was discussed. It was agreed to try to have the meeting in New York with the caveat that one day would be devoted to regular Board business, including the Divisional reports, the Organ Systems Program report, and the Subcommittee reports. A second day

could be devoted to clinical and scientific presentations by Memorial Sloan-Kettering and a tour of the facilities. NCI will investigate the feasibility of this plan and notify Board members as soon as possible of the arrangements.

May 26-28, 1987, NCAB Meeting

The Board discussed whether schedule changes could be made so that the May NCAB meeting could coincide with NCI's 50th anniversary celebration. NCI will investigate the various possibilities--changing the date of the symposium or changing the date of the NCAB meeting--to determine if suitable changes can be made. It was suggested that the Board consider sponsoring some kind of public awareness event during the time of the May meeting as part of the activities associated with NCI month.

Mail Ballots

Mrs. Bynum explained that the use of the mail ballot is tied to two considerations: 1) the need to obtain NCAB concurrence with every initial review group recommendation before a grant is awarded and to do so in time for the Grants Administration Branch to complete pre-award negotiations in a given fiscal year; and 2) the need for the Board to be able to discuss fully any grant application before voting its approval or IRG concurrence. Last year, when the Division of Research Grants transferred to the Institute responsibility for review of all applications responsive to Requests for Applications (RFAs), mail ballots had to be used to ensure funding within FY 1986.

Mrs. Bynum asked the Board's consideration of the following proposals: 1) to allow the Institute to use the mail ballot following the May Board meeting for FY 1987 funding of RFAs already released; and 2) to consider moving the October NCAB meeting back to September to allow time for discussion of applications and awards by the end of the fiscal year. In discussion, the point was raised that mail ballots are used only when absolutely necessary. If funds are allocated for an initiative within a particular fiscal year, they must be spent within that year or they will be lost.

It was agreed that the dates of next fall's meeting will remain as September 28-30, 1987, and mail ballots will be used as necessary. Board members will have the opportunity to remove applications from the mail ballots for full Board review.

It was also agreed that an effort be made to tighten up the Board meetings to minimize the amount of time required. Subcommittee meetings should be scheduled after full Board meetings and in the evenings rather than on Sunday afternoons.

Dr. Jako offered a statement urging recognition of need for improvements in surgical oncology, as well as in chemotherapy, biological therapy, and radiation therapy, to achieve progress in the combined or adjuvant modality of treatment. New concepts and methods are needed for improved detection of cancer cells and their destruction and removal.

Future Agenda Items

The following topics were suggested as future agenda items:

- Enhancing the effectiveness of the by-pass budget (next year)
- Scientific presentations on R01 grants
- Update on the Institutional Prior Approval Test Program
- Nerve-saving radical prostatectomy (by Dr. Pat Welsh)
- Human cell lines in vitro drug screening (by Dr. Dan Longo)
- Update on the low fat breast cancer trials
- Relationship of oncogene expression to therapeutic outcome (by Dr. Mark Israel)
- Update on AIDS and interactions with industry.

XII. Adjournment

The 59th meeting of the NCAB was adjourned at 9:55 a.m. on Wednesday, October 8, 1986.

NOV 24 1986

Date

David Korn, M.D.

ATTACHMENT A

DELEGATIONS OF AUTHORITY

In accordance with stated policies of the Public Health Service and the National Institutes of Health, the Director of the National Cancer Institute may:

(1) appoint not more than 151 special experts; and

(2) establish, and appoint members to, technical and scientific peer review groups.

(Received unanimous approval at the October 6-8, 1986, NCAB Meeting)