Department of Health and Human Services

Public Health Service

National Cancer Institute

National Cancer Advisory Board

Summary of Meeting
May 19-21, 1986
Building 31, Conference Room 6
National Institutes of Health
Bethesda, Maryland

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May 19-21, 1986

The National Cancer Advisory Board (NCAB) convened for its 58th regular meeting at 8:30 a.m., May 19, 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 Brinker
Mrs. Helene G. Brown
Dr. Ed L. Calhoon
Dr. John Durant
Dr. Gertrude B. Elion
Dr. Bernard Fisher
Dr. Phillip Frost
Dr. Geza J. Jako
Dr. David Korn
Dr. Enrico Mihich
Mrs. Irene Pollin
Mrs. Barbara Ingalls Shook
Dr. Louise C. Strong
Dr. Louis W. Sullivan

Absent

Dr. Tim Lee Carter
Dr. Armand Hammer

President's Cancer Panel

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

Ex Officio Members

Dr. Hollis Boren, VA
Dr. Jean French CDC/NIOSH
Dr. Robert McGaughy, EPA
Dr. David Rall, NIEHS
Dr. Andrew Ulsamer, CPSC
Captain Steven R. Veach, DOD
Dr. Ralph E. Yodaiken, DOL

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

Liaison Representatives

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

Dr. Raymond E. Lenhard, Jr., Associate Professor of Oncology and Medicine at the Johns Hopkins 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. Warren H. Pearse, Executive Director, American College of Obstetrics and Gynecologists, representing the American College of Obstetricians and Gynecologists.

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 and Assessment Division, U.S. Department of Energy, Washington, D.C., representing the U.S. Department of Energy.

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 13 registered members of the public attended the meeting.

I. Call to Order, Opening Remarks, and Consideration of February 3-5, 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.

Dr. Korn introduced the newly appointed members of NCAB--Mrs. Nancy Brinker, Founder and Chairman of the Board of the Susan G. Komen Foundation for Advancement of Cancer Research, Dallas, Texas; Dr. John Durant, President of the Fox Chase Cancer Center, and a member of the faculty of medicine at the University of Pennsylvania (both are located in Philadelphia, Pennsylvania); Dr. Bernard Fisher, Professor of Surgery at the University of Pittsburgh, Pittsburgh, Pennsylvania, former member of the PCP, and 1986 winner of the Lasker Award; Dr. Phillip Frost, Chairman of the Board of Key Pharmaceuticals, Miami, Florida; Mrs. Irene Pollin, psychiatric social worker, consultant, and Director of the Linda Pollin Institute, Chevy Chase, Maryland; and Mrs. Barbara Ingalls Shook, Chairman of the Board of the Barbara Shook Foundation, Birmingham, Alabama. He announced that the White House had approved the last new Board member, Dr. Louis Sullivan, a hematologist, who is current President of Morehouse School of Medicine, Atlanta, Georgia.

The minutes of the February 3-5, 1986, meeting were unanimously approved.

II. Future Board Meeting Dates

Future meeting dates were confirmed as follows: October 6-8, 1986; December 8-10, 1986; February 2-4, 1987; May 26-28, 1987; September 28-30, 1987; and December 16-18, 1987. Meeting dates for 1988 were proposed as follows: February 1-3, May 23-25, September 19-21, and December 5-7.

III. Report of the President's Cancer Panel--Dr. John A. Montgomery

In the absence of Dr. Hammer on the occasion of his 88th birthday celebration, Dr. Montgomery read Dr. Hammer's report of President's Cancer Panel activities. In his report, Dr. Hammer congratulated the new members on their appointment to the Board and expressed the willingness of Panel members to work closely with the Board to assure the viability and effectiveness of the National Cancer Program.

The Panel held its second meeting of the year on April 11 at St. Jude Children's Research Hospital in Memphis, Tennessee, where members heard presentations on the molecular characterization of childhood cancers and its application to innovative approaches to cancer therapy. Subjects discussed included chromosome abnormalities in leukemia, the FMS oncogene and the CSF-1 receptor, and molecular biological and clinical evaluation of pleiotropic

drug resistance. Dr. Mark Israel, of the NCI, described his research on patterns of proto-oncogenic expression that identify homogeneous tumor groups. Dr. Hammer noted an exciting aspect of Dr. Israel's work is that molecular biology may, for the first time, be used as a treatment tool.

In line with the Panel's 1986 agenda, which is concentrating on innovations in cancer therapy, the meeting scheduled for June 9 at the Dana Farber Cancer Institute in Boston will be devoted to autologous bone marrow transplantation. NCAB members were invited to attend. The final Panel meeting for 1986 is expected to take place in Chicago in the fall.

Dr. Hammer expressed the Panel's concern that the restrictions imposed on NCI management in reprogramming funds, as reported by Dr. Vincent DeVita in Memphis, would affect NCI's ability to pursue and promote the most exciting new developments in cancer research in a timely manner. Ways of interceding should be investigated, on behalf of NCI, for relaxation of some of the stringent restrictions that now apply to reprogramming of funds, especially at this time when the funds themselves are being reduced.

Congratulations were extended to Dr. DeVita, recipient of the Richard and Hilda Rosenthal Foundation Award at the May meeting of the American Association of Cancer Research held in Los Angeles.

A Hammer Workshop at the Salk Institute in La Jolla on May 5 and 6 focused on immunological innovations in cancer research. The Workshop, planned by Dr. Renato DulBecco, Nobel Laureate at Salk, was attended by Dr. DeVita, Dr. Steven Rosenberg, and representatives of several of the six Centers chosen to repeat the LAK/IL-2 protocol, among others. Reports included an update by Dr. Rosenberg on work to further revise and improve his procedure. He stated that, as of the end of April, positive responses had been achieved in 21 of 55 patients, and 9 of 10 renal cell cancers treated showed tumor reduction of more than 50 percent. The Audie Murphy Veterans Administration Hospital in San Antonio, one of the six Centers repeating this study, reported an additional successful treatment of a renal cell cancer patient. On the basis of these reports and many others, Dr. Hammer affirmed his belief that the innovative and imaginative work being done by many cancer researchers promises success in the battle against cancer.

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

After welcoming the new Board members, Dr. DeVita expressed regret over the recent death of Mr. Louis M. Carrese, the Associate Director for Program Planning and Analysis and the Executive Secretary of the Subcommittee on Planning and Budget. A moment of silence was observed in memory of Mr. Carrese. Dr. DeVita announced that Dr. Elliott Stonehill would be serving as the Acting Associate Director for Program Planning and Analysis, and that Mr. John P. Hartinger would serve as the Acting Executive Secretary of the Subcommittee on Planning and Budget.

Dr. DeVita also announced that Dr. Korn had been reappointed as Chairman of NCAB for an additional 2 years, and that Dr. Montgomery had been reappointed to his second 3-year term as a member of the President's Cancer

Panel. He congratulated Dr. Mihich, who had been voted President-Elect of the American Association for Cancer Research (AACR) and had received an honorary degree from the University of Marseilles for his work in establishing pharmacology units in France; and then Mr. Bloch, who had been selected for the Spirit Award in Kansas City for organizing that city's annual Fight Cancer Rally.

Dr. DeVita announced the following staff changes:

- The retirement of Dr. Berge Hampar as General Manager at the Frederick Cancer Research Facility (FCRF), and the appointment of Dr. Cedric Long, formerly with the Biological Response Modifiers Program (BRMP), to that position

- The departure of Dr. Donald Iverson, Associate Director for the Cancer Control Science Program, Division of Cancer Prevention and Control (DCPC), to assume the position of Professor of Family Medicine at the University of Colorado

- The appointment of Dr. Paul Rambaut as Deputy Director and of Mr. Lawrence Ray as Administrative Officer of the Division of Extramural Activities (DEA).

For the benefit of the new Board members, Dr. DeVita then reviewed the format that he follows in his reports to the Board, including the following components: general comments (as above), status of the budget, followup on items previously discussed at Board meetings, new items, and comments on newsworthy subjects in the cancer clips. He noted that although a report by Dr. Mary Knipmeyer, the NCI Legislative Liaison, usually follows his report, there would be no report by Dr. Knipmeyer at this Board meeting.

Dr. DeVita then reviewed the role of NCAB in the management of the Institute, noting the dual mandate of the National Cancer Act to NCI to support both basic research and the application of the results of basic research. He explained that NCI is the only Institute within NIH that has the PCP, which reports to the President. All meetings of the four Boards of Scientific Counselors (BSC) of the operating divisions and of the NCAB are open to the public. NCAB members were encouraged to attend one or more BSC meetings, as well as a meeting of an initial review group, arrangements to be made through DEA. The legal responsibility of the Board was reviewed, as well as the Board's previous involvement in general policy issues, such as the first recompetition of the contracts supporting the FCRF, the development of the goals for the year 2000, initiation of the Outstanding Investigator Grants, decisions on the Organ Site Program, and issues involved in AIDS research.

Apportionment was described as one of the most serious issues facing NCI, reducing flexibility to redirect resources to new areas of scientific opportunity. Touching on new items, Dr. DeVita referred to a "palpable excitement" in the scientific community over the issue of molecular characterization of tumors and the identification of genetic loci that are

associated with specific tumors. He noted that in a recent letter to Science, Dr. Renato DulBecco had suggested sequencing the entire human genome as a national effort, and that this had been discussed among several Government Agencies and by various groups of scientists.

Dr. DeVita began his budget report by providing a brief background of the evolution of the NCI budget since the mid-1970s. After the passage of the National Cancer Act in 1971, the funding for the Institute increased rapidly from about $200 million in 1972 to about $800 million in 1976, when inflation began to rise and effected a flattening of the increases up through 1987, which has actually decreased NCI's purchasing power in terms of constant dollars. Over the recent years in marking up the NIH budget, both the Congress and OMB have been dealing with setting an absolute number of research project grants and debating how much money should be given to NIH in terms of numbers of competing grants. This system, in effect, tends to exclude other funding categories within NCI, such as clinical cooperative groups, cancer control, and contracts, while smaller Institutes, which support mainly intramural research and research project grants, receive a bigger percentage increase than does NCI.

Dr. DeVita stressed that the Institute's number one priority to support basic research is reflected in the fact that the research project pool (i.e., R01 and P01 grants) has received the largest percentage funding increase since 1980. He drew the Board's attention to the illustrations of funding for the Cancer Centers Program, the Cancer Control Program, and the Cooperative Group Program. One-third of the budget of the Cancer Centers Program provides core resources for research projects, and the Cancer Control funding fulfills NCI's mandate to apply research results. Fifty-five percent of the Cancer Control budget is currently devoted to a prevention program.

Turning to the 1986 budget, Dr. DeVita described the effects of three events on the 1986 budget appropriation. First, the Gramm-Rudman-Hollings Act required a 4.3 percent reduction to each budget category within the Institute, or a $53.8 million reduction to the total NCI budget. In addition, the President proposed a $6.8 million rescission in the budget, which was recently rejected by Congress. The third issue is the apportionment process, the current control imposed on all NIH that reduces program flexibility. The apportionment process requires the Institute Director to obtain approval of the NIH Director (or above) before any shifting of resources amongst mechanisms takes place. This lack of flexibility to reallocate funding may impede the Institute from rapidly adjusting resources to accommodate current requirements. Despite the increasing mandate fully to support emerging research such as AIDS, LAK/IL-2, and other areas, NCI has been reduced by about 300 full-time equivalent positions (FTEs) since 1984.

Presenting the actual budget figures, Dr. DeVita illustrated that the original 1986 appropriation, adjusted for comparability purposes for the proposed transfer of AIDS resources to the Office of the Assistant Secretary of Health, was $1.230 billion. After Gramm-Rudman-Hollings, with the rescission added back in, the 1986 budget is $1.177 billion. Thus, a decrease is shown from the 1986 appropriation level in the 1987 President's Budget. When the Gramm-Rudman-Hollings legislation took effect, NCI had to reduce all budget

categories by 4.3 percent even though Congressional increases in 1986 were principally for research projects. In effect, the 4.3 percent reduction left the research grants funding with a 9.7 percent increase over the 1985 level, while other mechanisms reflect a decrease from 1985.

In summary, looking at the period 1985 to 1987 and taking into account Gramm-Rudman-Hollings and other distortions, NCI has had a 5.8 percent increase in the research project pool, and a decrease in all other areas, including the overall Institute budget, of 0.5 percent. The Cancer Centers Program received $85 million in 1985, and as a result of Gramm-Rudman-Hollings was reduced to about $82 million for 1986 and 1987. In 1985, a total of 2,981 grants (including 1,017 new grants) were funded. The average priority score cutoff of 172 allowed funding of 36 percent of approved applications. In 1986, the estimated cutoff will be about 162, allowing funding of 33 percent of approved applications.

The actual NCI budget for AIDS in 1985 was $26.9 million, of which about $9 million came from supplemental appropriations or amendments. In 1986, the NIH Director was appropriated $67 million to distribute for AIDS research. Of that amount, approximately $15 million has been identified for NCI. Other funds will support the AIDS Evaluation Units to test drugs, and Clinical Evaluation Units, managed jointly by NCI and the National Institute for Allergy and Infectious Diseases.

The President has proposed that, effective in 1987, all AIDS funds be transferred to the Office of the Assistant Secretary for Health; therefore, the NCI budget has been adjusted and the number of grants removed from the tables. Thus, for 1987 the NCI estimates about 820 competing grants will be funded with a priority score of about 160, allowing funding of about 27 percent of approved applications.

The following points were raised in discussion of the budget process:

- Whereas the reduction in flexibility caused by apportionment was emphasized in the Director's report, the overriding issue is the decrease in funding.

- The percentage of approved grants funded within other Institutes is similar to NCI's 36, 33, and 27 percent figures for the years 1985, 1986, and 1987, respectively.

Follow-up Items

Clinical Education Program

The Board had previously objected to a proposal that the Clinical Education Program be phased out to allow redirection of funds to other priorities. Based on this advice, the Program, with a new structure and new guidelines, is being maintained at a level of $1 million in 1987.

LAK/IL-2 Studies

Six centers have entered 29 patients with renal cell cancer to the trial in less than one month. Accrual of patients with other types of cancer will begin soon.

Organ Systems Program

The grant for the Organ Systems Program headquarters will be discussed during the October Board meeting. This grant, on the advice of the Board, was awarded for 3 of the 5 years for which it was approved and the Board will now have to decide whether to extend it for the additional 2 years or take other action. Dr. DeVita met with the Working Groups on April 16 to discuss the current operation of the Program. The Program has developed seven RFAs, which are being submitted to the Boards of Scientific Counselors.

Summer Program for Students

As announced at the February 1986 Board meeting, the Summer Program has been discontinued at NIH, and NCI is utilizing private donations to support summer students through the Gift Fund as it did last year. A donation of $10,000 has been received from the Lymphoma Foundation of New York.

Community Clinical Oncology Program (CCOP)

A followup on this Program was presented after Dr. DeVita's report (see Section V).

Grants to the City of Hope

On May 2, Dr. James Wyngaarden, Director of NIH, lifted the NIH restriction on grants to the City of Hope supporting research involving animals. Repeat site visits showed that the institution's animal facilities are now in compliance with the Public Health Service guidelines.

Screening Clinic in St. George, Utah

As mandated by an act of Congress, a contract was signed for $3 million to be spent over a period of time not to exceed 6 years to study the St. George, Utah, population exposed to radiation fallout during the 1950s, when atomic bomb testing took place in that region.

Cancer Clinical Cooperative Groups

The Division of Cancer Treatment (DCT) is reanalyzing the Cooperative Group Program, which was last reviewed in 1979. Any restructuring of the Groups will be undertaken only with full input and agreement from the Groups. The peer review system for the Groups continues to evaluate applications based on their scientific content, independent of consideration of possible future restructuring of the Cancer Therapy Evaluation Program.

AIDS

Dr. DeVita announced that he had written a memo to Dr. Wyngaarden and Dr. Anthony Fauci, who chairs the NIH AIDS Executive Committee, pointing out that NCI has strained FTE requirements in the Drug Development Program by attempting to operate the drug development programs for both cancer and AIDS. The requirement for greater numbers of FTEs for this effort needs to be recognized.

Frederick Cancer Research Facility (FCRF) Supercomputer

Dr. DeVita expressed enthusiasm for the Supercomputer development and operation. The Board visited the facility during the Monday afternoon session of the meeting.

Reauthorization Act for the Cancer Program

As an addition to the discussion of the reauthorization of the Cancer Program at the February 1986 Board meeting, Dr. DeVita noted that ex officio Board members are now afforded voting rights. To maintain a quorum, 12 of the 18 appointed members must be present.

New Items

Dr. DeVita described briefly the new MERIT Awards which will allow Advisory Councils, with staff recommendations, to extend 3-year grants of particularly high quality to 5 years without their having to undergo additional peer review. (During the closed session of the meeting, 25 R01 grants were proposed and approved for MERIT Awards.)

Dr. DeVita announced that Mr. Leonard Abramson from Philadelphia has donated $1 million per year for 5 years to the NCI Director's Gift Fund for research in the area of breast cancer, the first $1 million of which has been received. Dr. Marc Lippman is heading a consortium of investigators to be involved in this research.

Dr. DeVita also noted two examples of industry's cooperation in the Cancer Program. Mr. Manly Molpus, President of the American Meat Institute, wrote to Dr. DeVita about his industry's progress toward marketing leaner meats, pointing out that the Kroger Company has started a "trim program" which will result in 13 million pounds of fat not reaching the marketplace each year. Also, the Coors Brewing Company is sponsoring a mammography campaign, with the entertainer Cher as spokesperson.

Dr. DeVita announced the upcoming hearing on skin cancer by the House Select Committee on Aging, to be attended by Dr. Steven Katz, Chief of the Dermatology Branch. Dr. DeVita also noted that he had attended the recent ACCC meeting where the CCOP evaluation was discussed and where Mr. Richard Nixon was honored for his role in the passage of the National Cancer Act and for opening up relations with China. The NCI benefits from this diplomatic initiative as it collaborates on etiology and prevention research in China.

Dr. Peter Fischinger attended the meeting of the governing council of the International Association for Research on Cancer on behalf of Dr. DeVita.

In his closing comments, Dr. DeVita discussed Dr. John Bailar's recent article entitled "Progress Against Cancer?" in The New England Journal of Medicine (NEJM). The following criticisms of the article were raised:

- For many cancers, data were used that measured events in diagnosis and treatment between 1972 and 1975.
- Age-adjusted mortality was the single yardstick used to measure the multidimensional Cancer Program; no benefit from prolongation of life, which is estimated at some 65,000 person-years of life prolonged each year, was considered.
- Survival statistics were not mentioned although they may be a better measure of the impact of prolongation of life in non-curative therapies than are mortality statistics.
- NCI research initiatives and progress made in the prevention field, which Dr. Greenwald had detailed in a review of an earlier manuscript, were not acknowledged.
- The significant decrease in mortality in cancer patients under age 50 and progress against breast cancer were not mentioned.

Dr. DeVita concluded by emphasizing the underestimation of the substantial advances resulting from investment in basic research, which is unmeasured by the analysis that Dr. Bailar's article presents.

The discussion following Dr. DeVita's report focused on Dr. Bailar's article. It was suggested that any response should emphasize positive aspects of the Cancer Program and the numerous prevention activities within the context of a public information effort. For example, it was suggested that an annual symposium on advances in cancer research be jointly sponsored by NCI and the American Cancer Society, perhaps funded in part by private sources. A letter to NEJM, which was drafted by Dr. DeVita, was distributed to the Board members for review. The Board unanimously agreed to consider joining in the signing of a letter. Further discussion of the letter was deferred until the Wednesday morning continuation of the Board meeting.

V. Community Clinical Oncology Program (CCOP) and Other Community Oncology Evaluations and Program Plans--Drs. Jerome W. Yates and Leslie Ford

As previously requested by the Board, Dr. Yates reviewed the main points of the CCOP concept and described the RFA to be issued. He explained that the CCOP is part of the Cancer Control Program because participation in clinical trials activities, as required by the current RFA, should help to provide a standard of practice for diffusion through the community hospitals.

The original CCOP RFA, issued in 1982, required that the participating organizations maintain a patient log and accrue at least 50 patients per year

to clinical trials activities. There was no formal requirement or financial support for groups to participate in cancer control.

Dr. Yates also defined two other programs that had preceded the CCOP:

- The Community Hospital Oncology Program (CHOP), which included 17 directly funded institutions, was developed so that institutions would establish guidelines for patient management within their hospitals, thereby influencing the level of care in those institutions. This program was completed in 1984.

- The Cooperative Group Outreach Program (CGOP) was started in 1977 to involve community physicians in research protocols. CGOP is still in operation, and the funding is made available to the community through the Cooperative Groups.

There are currently 59 CCOPs throughout the United States funded by Cooperative Agreement. Mrs. Bynum commented that in May 1982 she had prepared an information package on the CCOP development and that she would provide a package to Board members interested in further information on the history of the Program.

Dr. Leslie Ford presented a summary of the evaluation of the Program which was funded concurrently with the CCOP RFA. This evaluation has been conducted under contract to the Statistical Analysis and Quality Control Center of the Fred Hutchinson Cancer Center, Seattle. Dr. Ford defined two levels of intervention within the CCOP: participation of community physicians in clinical research and direct funding of community programs for clinical research.

The parameters of the evaluation included measurement of any increase in clinical trials research, consequent changes in patient care, and any other changes in the health care delivery system, as well as the characteristics of a successful program. Data were collected from the CCOPs and 15 controls (chosen from institutions approved but not funded for CCOP) to measure patterns of care for breast, small cell lung, and colorectal cancers, from before and after initiation of the Program. In-depth studies and physicians' surveys were conducted in eight of the programs and four control sites. The analysis of the data from the CCOPs and controls was stratified by size of the program, proximity to a medical school or university, and previous experience in clinical research.

The results of the analysis showed increased participation in clinical trials, from accrual of approximately 2,000 patients to studies during the year before the Program began, to almost 4,000 in year 1, and then to 4,300 in year 2 (not including referrals to Cancer Centers). Two-thirds of the patients were accrued to late Phase II and Phase III trials, with investigational drugs being used in about 40 percent of the protocols. Only 25 percent of registrations were to studies of adjuvant therapy, while 70 percent of the registrations were accounted for by four cancers--breast, lung, gastrointestinal, and leukemias. Analysis of changes from year 1 to year 2 of the CCOP demonstrated increases in the numbers of protocols used, the numbers of

patient registrations, and the numbers of physicians participating. The majority of registrations were to multidisease and to specialty Cooperative Group studies, with only 7 percent of total registrations to Cancer Center protocols.

The data demonstrated better patterns of care among CCOP physicians but no changes over time. There was a wide variability within and among CCOPs on patterns of care. The vast majority of CCOPs participated in and initiated physician education programs. Few surgeons participated in the CCOP. The defined determinants of a successful program included previous accrual to NCI-supported protocols, established stable relationships with a research base and among the participating physicians, and a sufficient patient population for accrual to clinical trials.

Under the new RFA expected to be issued in mid-July 1986, participating CCOPs will be required to enter patients onto NCI-approved research protocols (both treatment and cancer control) through one or more NCI-funded research bases (Cooperative Groups or Cancer Centers). Accrual of approximately 50 patients to clinical trials per year will still be required and accrual to cancer control studies will be phased in. The review criteria for cancer control will be whether the CCOPs can provide adequate numbers of patients and whether the research base can perform multidimensional studies. Dr. Yates provided a list of examples of cancer control research, such as studies to evaluate tumor markers for early detection, premalignant lesions, and long-acting morphine substances in cancer pain management. A protocol review committee within DCPC will probably evaluate these cancer control protocols, in an integrated program with DCT, and with extramural participation.

The RFA will be released in mid-July, with the letters of intent due in early September. The application receipt date is late October. Awards will be made following the May 1987 NCAB meeting.

The following points were raised in discussion:

- There will be no automatic renewal of CCOP agreements; the new RFA will be open to current CCOPs as well as to any new applicant institutions.

- It was originally estimated that 200 CCOPs would be needed for sufficient nationwide accrual; however, there are only 59 CCOPs at present. The concern was raised that adding cancer control activities to the RFA without additional financial support would discourage applicants.

- The projected budget for the program is $9 million per year. The funding is used mainly for local data management, data management of the research base, and statistical support; no patient care funding is included.

- It was suggested that required accrual be based on available patient population rather than a requirement of 50 patients per year regardless of differences in population size. Dr. Yates pointed out that

the current CCOPs enter almost uniformly an approximate 20 percent of their populations onto studies.

- The likelihood of individual CCOPs mounting effective cancer control activities was discussed. The leadership of the research bases is expected to be vital in this area. Support will be provided to the research bases for cancer control committees to establish travel and consultant funding, and developmental monies for pilot projects for cancer control activities.

VI. 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 1,447, requesting support in the amount of $196,223,298. Of these, 1,166 were recommended for funding at a total cost of $125,764,075. The new MERIT Award mechanism was utilized by the NCI-NCAB for the first time. This award is intended to provide long-term grant support to investigators whose research competence and productivity are distinctly superior and who are highly likely to continue to perform in an outstanding manner. The Board recommended 25 MERIT Awards for funding by NCI.

VII. Subcommittee Reports

Subcommittee on Planning and Budget--Dr. Gertrude Elion

The minutes of the May 19, 1986, meeting of the Subcommittee were distributed and the highlights discussed by Dr. Elion. The 1988 bypass budget and the assumptions on which it is based were the main subjects of the meeting. The budget incorporates $50 million for special initiatives to provide flexibility to take advantage of the latest scientific advances, possibly for participation in early plans for mapping and sequencing of the human genome.

Dr. Elion pointed out that although it appears that the 1988 bypass budget represents a large increase over the 1987 President's Budget, the present budget request is probably not the final 1987 budget, so it is likely that the percent increase will be smaller. Amounts in constant dollars have decreased. The 1988 budget reflects the assumption that the proposal to transfer all AIDS-related activities to the Office of the Assistant Secretary for Health will not be accepted. It was suggested that levels of intramural funding be increased and funding for extramural instrumentation be added.

Dr. Elion then discussed the impact of the apportionment process on NCI operations (a handout was provided). The Subcommittee recognized that apportionment reduces the Institute's flexibility to respond rapidly to cancer research opportunities and move funds to where they are most needed. The following points were raised in discussion:

- The launching of the IL-2 program was accomplished under apportionment by redirecting funds within the Clinical Cooperative Groups.

- The Institute would prefer to have OMB directly apportion the NCI appropriation.

- Three centers (Fels, Vermont, and Ohio State) could not be funded because the apportionment process would not allow additional money to be added to the Centers' budget from other parts of the NCI appropriation.

- Reprogramming requests can be made to NIH, HHS, and, if necessary, Congress.

Dr. Korn distributed information from the Ad Hoc Group for Medical Research Funding that reiterated the need for funds for basic biomedical research.

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

VIII. New Business

Reports

Dr. Korn noted a change in reporting requirements under the new authorization: a single biennial report, to which advisory councils may contribute, is prepared by the Office of the NIH Director. Each council also has the option of preparing additional reports as it determines appropriate. (A report of the National Heart, Lung, and Blood Advisory Council was distributed.) Dr. Korn asked the Board to consider whether a report should be prepared for public information purposes. In discussion, it was emphasized that such a report would be a report of the NCAB, not the NCI, although some funds would likely come from the Institute, in addition to private sources.

A motion was made and seconded that the Subcommittee on Cancer Information be charged with developing a plan for the preparation of an NCAB report as part of an overall public information effort. The Subcommittee will report back to the Board in October. The motion was unanimously approved.

In regard to the Director's contribution to the NIH biennial report, Dr. DeVita said that the information for the first such report was due shortly, unless the Secretary gives an extension. If the tight schedule remains in place, there will be little opportunity for the Board to be involved, although such involvement can be incorporated into future planning.

Summary Statement Review Assignments

Mrs. Bynum described the NCAB's mandated function to give the Director of NCI the authority to award grants and the consequent need for Board members to review the documents on which judgments of concurrence or nonconcurrence must be based. Various mechanisms to accomplish this review have

been instituted, with the most recent permutation being to distribute truncated summary statements to all Board members, with full text documents being sent only to assigned NCAB reviewers, but available to other members upon request. Full text documents on individual grants will be sent in response to phone calls to Mrs. Bynum or Mrs. Pelham.

Board members were asked to indicate areas for which they would like to have partial or full copies of documents before Board meetings. A master list of review assignments will be generated on the basis of preferences indicated. The possibility of providing the full text on microfiche and obtaining microfiche readers will be investigated.

In response to a question about the role of ex officio members, it was noted that the National Cancer Act had specifically excluded ex officio members from voting, probably to prevent the size of the Board from being unwieldy. The reauthorization describes the role of the ex officio members not specifically in relation to the NCAB, and voting is not mentioned. Therefore, the Committee Practices Act takes precedence and ex officio members can now vote. The original issue of increasing the voting membership from 18 to 29 remains a subject for consideration, although there is no intention to change the involvement of the ex officio members in terms of distributing review materials.

Subcommittee Assignments

Dr. Korn distributed the listing of subcommittee assignments for the next 2 years. Efforts were made to assign Board members to the subcommittees of their choice. In light of the decision to undertake a public information effort, Mrs. Brinker was added to the Subcommittee on Cancer Information. It was suggested that the Subcommittee meet on the Sunday (October 5) preceding the next Board meeting to enable the attendance of as many members as possible.

As there is no construction money in the President's FY87 budget, the ad hoc Subcommittee on Construction may have little to do. However, it was pointed out that the Subcommittee could address itself to the need for construction money.

Response to The New England Journal of Medicine

The Board considered various options as response to the article by Dr. Bailar in The New England Journal of Medicine. Dr. Wyngaarden had asked Dr. DeVita to send a letter of response. A draft of Dr. DeVita's letter revised by Mrs. Brown was distributed. The Board supported Dr. DeVita's initiative to respond to the article.

Announcement of Change of Hotel Accommodations

In light of the dissatisfaction with the present hotel accommodations expressed by the Board, Mrs. Bynum announced that hotel accommodations for the October meeting would be changed, probably to the Bethesda Hyatt.

Future Agenda Items

The following topics were suggested as future agenda items:

- Clarification of the role of the NCI within the NIH in the light of the National Cancer Act
- Followup on delivery of cancer information and treatment within the poverty sectors in the country
- Linkage of Year 2000 goals with budget forecasts
- Follow-up report on the black awareness campaign
- Molecular characterization of tumors as basis for selecting therapy
- Sequencing and mapping of genomes
- Development of a national tumor registry
- Review and update on the Organ Systems Program
- NCI prevention programs.

IX. Adjournment

The 58th meeting of the NCAB was adjourned at 10:31 a.m. on Wednesday, May 21, 1986.

SEP 17 1986

Date

David Korn, M.D.