D E P A R T M E N T O F H E A L T H A N D

H U M A N S E R V I C E S

National Institutes of Health
National Cancer Institute

NATIONAL CANCER ADVISORY BOARD

Minutes of Meeting
October 6-8, 1980

Place: Conference Room 10
Building 31C
National Institutes of Health
Bethesda, Maryland 20205

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

Minutes of Meeting[1]/
October 6-8, 1980

The National Cancer Advisory Board was convened for its 35th regular meeting at 8:30 a.m., October 6, 1980, in Conference Room 10, Building 31, National Institutes of Health, Bethesda, Maryland. Dr. Henry C. Pitot, Chairman, presided.

Board Members Present:

Dr. Bruce N. Ames
Dr. Harold Amos
Dr. Maureen M. Henderson
Dr. Robert C. Hickey
Dr. J. Gale Katterhagen
Mrs. Rose Kushner
Ann Landers
Dr. LaSalle D. Leffall
Dr. Henry C. Pitot
Dr. William E. Powers
Dr. Janet D. Rowley
Mr. Sheldon W. Samuels
Mr. Morris M. Schrier
Dr. Frederick Seitz
Dr. Irving J. Selikoff
Dr. Philippe Shubik
Dr. Gerald N. Wogan

Board Member Absent:

Mrs. Vincent Lombardi

Ex Officio Members:

Dr. Donald Fredrickson, Director, NIH
Dr. Marguerite T. Hays, represented Dr. Donald Custis, VA
Dr. Richard Marland, represented Mr. Douglas Costle, EPA
Dr. F. Kash Mostofi, represented Dr. John H. Moxley III, DOD
Dr. Denis J. Prager, represented Dr. Frank Press, OSTP

Representatives of the President's Cancer Panel:

Dr. Harold Amos

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

Liaison Representatives:

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

Mr. Alan C. Davis, Vice President for Governmental Relations, American Cancer Society.

Dr. Virgil Loeb, Jr., Professor of Clinical Medicine, Washington University, St. Louis, Missouri, representing the American Society of Clinical Oncology and the American Association for Cancer Research.

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

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

Speakers, Guests, and Observers:

Dr. Gilbert Beebe, Clinical Epidemiology Branch, NCI
Dr. Manning Feinleib, Epidemiology Branch, NHLBI
Mr. John Hartinger, Budget Officer, NCI
Mr. Richard Riseberg, Legal Advisor, NIH
Dr. Joseph Saunders, Office of International Affairs, NCI

Members, Executive Committee, National Cancer Institute:

Dr. Vincent T. DeVita, Director, National Cancer Program
Dr. Richard Adamson, Acting Director, Division of Cancer Cause and Prevention
Mr. Louis M. Carrese, Associate Director for Program Planning and Analysis, OD
Dr. Diane J. Fink, Associate Director for Medical Applications of Cancer Research, OD
Dr. Jane Henney, Special Assistant for Clinical Affairs, DCT
Dr. Bayard H. Morrison III, Assistant Director, NCI
Mr. Robert Namovicz, Acting Executive Officer, OD
Dr. Gregory O'Conor, Associate Director, Office of International Affairs, OD
Dr. Alan S. Rabson, Director, Division of Cancer Biology and Diagnosis
Dr. Saul Schepartz, Acting Director, Division of Cancer Treatment
Dr. William A. Terry, Acting Director, Division of Resources, Centers, and Community Activities
Dr. Richard E. Tjalma, Assistant Director, NCI
Dr. William A. Walter, Acting Director, Division of Extramural Activities
Mr. Paul Van Nevel, Associate Director for Cancer Communications

In addition to staff, participants, and invited guests, ten registered members of the public attended this meeting.

I. CALL TO ORDER AND OPENING REMARKS - Dr. Henry C. Pitot

Dr. Pitot called the meeting to order and welcomed Board members; members of the President's Cancer Panel; liaison representatives; guests; and observers. He announced that Dr. Harold Amos is now a member of the President's Cancer Panel. He introduced two new members of the Board -- Ann Landers, Journalist, Field Newspaper Syndicate, Chicago, Illinois, and Dr. LaSalle D. Leffall, Professor and Chairman, Department of Surgery, Howard University, Washington, D.C. He announced that Dr. Thomas King, formerly Executive Secretary of the Board, has left the National Cancer Institute to accept a position of Director of the Kennedy Institute of Ethics at Georgetown University. Dr. William A. Walter has been named Acting Director of the Division of Extramural Activities, and will also act as Executive Secretary of the Board.

Dr. Pitot also welcomed members of the public and announced that anyone wishing to express his or her views regarding any items being discussed during the open session could do so by submitting written statements to the Executive Secretary of the Board within ten days after the meeting. Any statements by members of the public will receive careful consideration.

II. CONSIDERATION OF MINUTES OF THE BOARD

The minutes of the meeting of May 19-21, 1980, were approved with the addition of the following paragraph. "Mrs. Kushner suggested that action be taken by NCI staff to see that payments are made to contractors earlier than they have been in the past."

III. FUTURE BOARD MEETING DATES

1980

November 17-19 (Program Review)

1981

February 2-4
May 18-20
October 5-7
November 30-December 2 (Program Review)

IV. REPORT, PRESIDENT'S CANCER PANEL - Dr. Harold Amos for Dr. Joshua Lederberg

In the absence of Dr. Joshua Lederberg, Chairman, Dr. Amos presented a brief report on the President's Cancer Panel. The Panel members have initiated individual efforts to formulate a concerted view of the role the Panel might play over the next two to three years. The first two

phases of the National Cancer Program, in which the Panel was chaired by Benno Schmidt, had their priorities set by the development of the Program. It is clear now that in the new phase, the Panel must, with the help of the Director and staff of NCI, attempt to balance the mission of the Institute. The Panel believes that there are several currents created by the public and the extramural community that call for a restatement of the primary goals of the National Cancer Program.

A meeting of the Panel was held at the NCI on August 29, and future meetings are scheduled for November 12 and December 9. At the August meeting, Dr. DeVita conducted the first of a series of briefings of the Panel on plans for program redirection and reorganization of the NCI leadership. It is now the Panel's intent to set the direction for themselves after an appropriate review by them with the help of the NCI staff, the National Cancer Advisory Board, and members of the extramural scientific community.

V. REPORT OF THE DIRECTOR, NCI - Dr. Vincent T. DeVita, Jr.

Dr. DeVita welcomed the two new members of the Board, Ann Landers and Dr. LaSalle Leffall, and reported on the following items:

NCI Staff Changes --

- Dr. Gregory T. O'Conor, who was Director of the Division of Cancer Cause and Prevention, has taken over his former position as Associate Director for International Affairs for the Institute, a program he built to distinction.

- Dr. Richard Adamson has assumed the position of Acting Director of DCCP. He was formerly Chief of the Laboratory of Chemical Pharmacology.

- Dr. John Bailar, who was Editor-in-Chief of the Journal of the National Cancer Institute has retired, and Dr. John Ziegler has assumed that position.

- Dr. Bruce Chabner has taken over Dr. Ziegler's old position as Associate Director of the Clinical Oncology Program and Deputy Clinical Director of the Division of Cancer Treatment.

- Dr. Robert Oldham, who is coming to the NCI from Vanderbilt University, will head the new Biological Response Modifiers Program in the DCT.

- Dr. William A. Walter, Jr., is the Acting Director of the Division of Extramural Activities in the place of Dr. Thomas King who is now at Georgetown University.

- Dr. Dennis Cain has been made Chief of the Grants Review Branch in DEA.

- Mr. Calvin Baldwin, former Executive Officer of NCI, has assumed the position of Associate Director of Administration of NIH, and Mr. Robert Namovicz is Acting Executive Officer.

NCI Staffing and Positions -- Of great concern is the NCI staffing situation. There are currently six Search Committees engaged in finding highly qualified people to fill the vacant high-level positions. At the end of fiscal year 1980, there were 1840 positions in the NCI which is 140 below the number at the beginning of the fiscal year. This was largely due to the hiring freeze. It creates a difficult situation at a time when new programs are being instituted, such as Biological Response Modifiers Program, the Diet and Nutrition Program, Smoking and Health, and Chemoprevention. An Institute-wide review of positions will be conducted in the near future in an attempt to find how positions can be reallocated with regard to priority of these new programs. Pressure is being placed on the NCI to curtail some of the work done by contract in favor of having it performed internally.

Dr. DeVita asked that the President's Cancer Panel and the Board be prepared to advise him on the identification of programs that might be subject to budget reduction in fiscal year 1981 and 1982 if the budget remains at the current level.

NCI Budget -- On October 1 the books were closed on fiscal year 1980, with 99.9 percent of the $1 billion budget obligated. During the year, $10 million of contract funds were redirected to the grants program. Dr. DeVita attended hearings with the Office of Management and Budget to discuss the 1982 budget, and it appears that the National Cancer Institute is getting proportionately smaller increases in budget than the other Institutes.

Space -- Most of the space moves previously outlined are now completed. These include the transfer of one large laboratory to the Frederick Cancer Research Center; closing of some off-site laboratories in support of intramural scientists; redirection of some funds from resource contracts, and finding space for staff in Building 8; and moving staff who are doing extramural work or supporting the extramural programs out of laboratory space and into the Landow Building. All contract staff are now located in the Blair Building.

NCI Reorganization -- The reorganization of the National Cancer Institute is now official, and the Secretary's approval has been published in the Federal Register. The new Division of Resources, Centers, and Community Activities will be discussed in detail at the November meeting of the Board.

National Toxicology Program -- This was discussed at a previous Board meeting and the consensus was that one Institute should be responsible for the overall direction and management of the program. Also, it was agreed that the NCI portion of the merger (chemical testing) be transferred to the National Institute of Environmental Health Sciences. NCI has been working with NIEHS to effect the transfer which will include $47 million and 85 positions.

Legislative Update -- The Health Research Act, known as the Waxman Bill (HR 7036) passed the House the 28th of August. This bill provides for a three-year extension of the Authorization for the Cancer Institute at levels of $1.24 billion for 1981; $1.42 billion for 1982; and $1.6 billion for 1983. It provides for: a line item for cancer centers of approximately $100 million; the approval of contracts by the National Cancer Advisory Board; center grants of five-year duration; and, the authority of the Director of the Institute to approve grants of less than $50,000. It restricts the use of the 301 Authority, which is the authority to proceed with business without further authorization levels.

A companion bill, the Health Science Promotion Act or Kennedy Bill (S 988), also passed the Senate and there are significant differences between the two. The Senate bill leaves the 301 Authority intact; it has no time and dollar limits; it also gives a five-year duration to Center grants; and it offers the creation of the President's Council on Biomedical Research. There is still disagreement between the two committees of what the provisions will be.

Another bill, the Animal Cancer Research Bill, passed the House Agriculture Committee recently. It calls for a $25 million increase in the budget of the Department of Agriculture. Dr. DeVita expressed concern that this amount might be transferred from the NCI's budget to the Department of Agriculture.

There have also been hearings on the use of heroin for treatment of pain in terminal cancer patients. This was a very controversial hearing at which an NCI representative testified and expressed the NCI's opinion of the quality of the scientific data at the present time.

Laetrile -- In response to a request for an update on Laetrile, Dr. DeVita briefly outlined the progress to date. Trials with the drug are under way in four institutions. Patient accrual is now closed, and the patients will be followed to evaluate the results. It is hoped the information derived will be useful to the average American and average physicians who are faced with the issue of how to treat cancer in the future.

Conference on Cancer and Aging -- Dr. DeVita described a conference he attended which was co-sponsored by the National Retirement Research Foundation, Bankers Life and Casualty Company, the National Institute on Aging, and the NCI, at which 40 scientists from 7 countries presented their work. There is a plan to follow up the conference with workshops around the World which will expand on particular areas highlighted during the sessions. The proceedings will be published as a monograph of the Journal of the National Cancer Institute and as Proceedings of the House Select Committee on Aging.

Cancer Information -- The discussion centered briefly on distribution of the Cancer Clips and the observation that the incidence of cancer has increased to "epidemic" levels. Dr. DeVita pointed out that much of the data are based on the Third National Cancer Survey and the SEER Data Base. While these data are now somewhat "soft," it is hoped the NCI data will soon become firmer. This is an important activity of the Cancer Institute to collect data about expectations for the future of the population.

Community Program -- Dr. DeVita reported on the Community Hospital Oncology Program. Criticism has been received from the community about the small number of hospitals that have been funded under this program. However, after careful review of the requests, 23 institutions were eligible for funding and have been awarded a total of $13.1 million. In spite of the decrease in the Control budget, this program received high priority.

NCI Boards of Scientific Counselors -- Dr. DeVita related some significant issues from the meetings of the Divisional Boards of Scientific Counselors. The Board of the new Division of Cancer Resources, Centers, and Community Activities, under the Chairmanship of Dr. Stephen Carter, has taken on a special project for the revision of the Center Guidelines. It will make its final recommendations to Dr. Terry, the Acting Director of DRCCA. They have also established a subcommittee to look into the establishment of a Chemoprevention Program.

The Board of Scientific Counselors of the Division of Cancer Treatment has ended a three-year review of the Clinical Trials Program, and concluded that the main reason for the reduction in mortality has been the successful operation of this Program. The Board approved creation of a new mechanism of Regional Cooperative Groups to parallel the current Cooperative Group Program. Request for applications (RFA's) will be issued for support of institutions in this program.

Technology Transfer -- Dr. DeVita spoke briefly about technology transfer. He observed that although approximately 200,000 patients are receiving chemotherapy, only 40,000 of them are being treated optimally so as to maximize benefits.

He emphasized strongly that this issue must be faced and health care professionals trained to apply the best technology; and at the same time more patients should be put on studies so as to make tomorrow's technology available as broadly as possible.

Public Issues -- A suggestion was made by Dr. Amos that at each Board meeting, an hour be devoted for the Board to get a feeling for and to deal officially with matters the Public is concerned about as a result of what is happening in the National Cancer Program. This will be taken into consideration in planning future agendas.

Equal Employment Opportunity

There was a meeting September 30-October 1 of the newly appointed External EEO Advisory Committee. This Committee will oversee the functions of the personnel system of the NCI to be sure there is a balanced treatment of women and minorities in the program. Dr. DeVita anticipates progress will be made with the help of this committee. Much success was achieved with the Summer EEO Program. Two hundred and seventy-seven positions were filled by summer employees, 40 percent of whom were women and 20 percent minorities.

VI. BIOLOGICAL RESPONSE MODIFIERS PROGRAM - Dr. Saul Schepartz
Dr. John Macdonald

Dr. Saul Schepartz, Acting Director of the Division of Cancer Treatment, described the chronology of how the Biological Response Modifiers Program was organized and its present status. The DCT Board of Scientific Counselors agreed that a study of these agents would be worthwhile, and appointed Dr. Henry Mihich to chair a committee to review the state of the art and develop a program plan. The Committee held several workshops and presented a plan to implement the program. It was agreed that large quantities of the agent, interferon, would be needed, and proposals were solicited for the production of several types of the drug. RFP's were later issued for contracts to get the program started in 1980. During this year, about $4 million was spent for the purchase of interferon for clinical trials and a number of programs were established to evaluate biological response modifiers in Phase I and II clinical studies.

A formal Program has been set up under the direction of Dr. Oldham. It will be located at the Frederick Cancer Research Center where a large portion of the fermentation facility will be devoted to production of biological response modifiers. In addition, a clinical program will be established at one of the nearby hospitals where Dr. Oldham will carry out studies.

Dr. John Macdonald, Associate Director for Cancer Therapy Evaluation, DCT, presented an overview of the interferon investigation as it relates to clinical oncology, and a review of the clinical trials that have been completed and those now under way. He showed a series of slides of interferons that are of current interest, and on studies performed with the drug in various diseases.

Dr. Macdonald stated that there is an antitumor effect which may be nonspecific and antiproliferative, and some immunomodulation which may also have a role in antitumor effect. He pointed out that, to date, little is known about dose levels and schedules of interferon. The Division of Cancer Treatment plans to look more critically at dose and scheduling to try to develop rational regimens of treatment. Other unknown factors are (1) what are the most responsive diseases in which to use the material, and (2) what is the most appropriate stage of the disease to use it in. It is clear that with all these questions unanswered and with the exciting preliminary data that are available, there will be a lot of interesting work done in the next few years.

VII. REPORT ON CONTRACT ACTIVITIES - Dr. Vincent T. DeVita, Jr.

Dr. DeVita made the first of a series of presentations on the contract activities of NCI by stating he was giving this talk with specific purposes in mind, the first of which is to solve some of the problems in terms of how the NCAB can relate to the Divisional Boards of Scientific Counselors in their responsibility for the review of contracts. As was indicated earlier, the Waxman Bill calls for the NCAB's having responsibility for the review of contracts with a total cost of over $500,000. Dr. DeVita expressed the hope that some language would be inserted in the Bill that would provide for the primary review of contracts by the appropriate Divisional Boards of Scientific Counselors, with the secondary review by the NCAB.

There have been recent investigations into the contracting process by the Office of the Inspector General and the General Accounting Office. This will be discussed at a later Board meeting. There has also been increasing concern regarding the contract as an instrument for doing business by the Government, with strong recommendations for internalizing most activities now performed under contract. A paper is being prepared at the present time that will go into great detail on contracts, giving definitions, information on contracts and grants, requirements for dual review, etc. It will be made available to the Board by the time of the next meeting.

Dr. DeVita gave a broad overview of the history of contracts at NCI. Although the Institute was created in 1937, the use of contracts came out of the efforts of the Government to become involved with industry

in World War II. The Drug Development Program was the first NCI program to use contracts for activities other than straight procurement of supplies and services.

Dr. DeVita showed a series of slides illustrating some of the problems the NCI faces concerning allocation of resources; the differences between basic and fundamental research; and a continuum of the funding mechanism as it relates to Government involvement. He spoke briefly about the various funding instruments for support of research--grants, contracts, and the newest instrument, cooperative agreements. In a cooperative agreement, which is reviewed by the regular study sections in the peer review system, there is substantial involvement on the part of the Government, which is spelled out clearly. There are two types of contracts; the research contract and the resource contract. The resource contract is strictly a procurement instrument to support the production of resources for the scientist.

Dr. DeVita stressed the importance of reviewing contracts at the concept level. He explained the difference in the review of contracts and grants. In a grant, the reviewers see the whole project. Contract review is different in that there is a review at the level of the program concept and another review at the merit level. It was decided at NIH that this dual review would be separate and that the body that performs the concept review would be a different group of reviewers from those that perform the merit review. Concept review is deemed the most important, and Dr. DeVita said the Boards of Scientific Counselors should be given the responsibility for the total review for a particular program, including budget, so they can make decisions about the concept of a new program. Every Board would see all the proposals supported by contract in a particular Division and have the opportunity to weigh their value. They would look at the basic purpose of the program, the scope, the objectives, whether or not it is proper for an institution in a program to be doing a particular kind of work, and, if it is proper, whether it should be done under grant or contract.

Because each contract reviewed at the concept level must be discussed individually, Dr. DeVita expressed concern that the NCAB may not be the appropriate body to conduct the reviews for the whole Cancer Institute, and he believes that the initial review should be up to the individual Boards of Scientific Counselors.

To satisfy the requirement for review by the National Cancer Advisory Board, he suggested some alternatives: (1) have the RFP's reviewed by the Board, but this would create a delay in letting the contracts; (2) furnish the Board a list of the existing contracts; (3) at the program review meeting of the Board in November, have the programs supported by contract pulled out and identified and reviewed in context to the Institute Budget; and, (4) have all minutes of the Boards of Scientific

Counselors supplied to the Board members and a special document prepared on each concept review, listing the action taken.

Dr. DeVita described an approach used by one Board that provides the members with complete information needed to make decisions for approval or disapproval. A booklet is provided in which each group of contracts in an area are listed with dates, past history of the contract, current funding, and a one-page description of what the program does. Such a booklet could be provided for the NCAB if they desire.

Because the Board is to have more responsibility for work performed under contract, Dr. DeVita will devote some time at the next few Board meetings for further discussion of this subject. There was general agreement that there should be more interaction between the NCAB and the Boards of Scientific Counselors through attendance at each others' meetings and exchange of minutes. A suggestion was made that Board concurrence with the review of contracts could be made by means of a mail ballot. Dr. DeVita agreed that this is possible.

VIII. NCI BUDGET FY 1981 - Dr. Vincent T. DeVita, Jr.
Mr. John Hartinger

The Director reviewed for the Board the status of the 1980 and 1981 budgets, and spoke briefly on the proposed 1982 budget.

The amounts are as follows:

1980	1981 Amended President's Budget	1981 House Allowance	1982 NCI By-pass Budget
$1,000,000,000	$ 965,105,000	$1,001,330,000	$1,192,000,000

When the President submitted his budget for 1980, NCI was faced with a rescission of approximately $17 million. When this rescission budget did not pass, other decisions were made on the redistribution of some of the funds identified for rescission among various NCI programs. A chart was distributed to the Board members which showed a breakdown of these funds.

Along with the budget discussion, Mr. Samuels expressed his opinion that the states and other local agencies are not contributing a fair share for the support of cancer centers. He felt there should be some way to get them to carry a greater share of the costs. There was agreement that the recipients of the grants are the appropriate ones to put pressure on their local agencies.

Dr. DeVita concluded his presentation by reiterating his previous statement that if the budgets for 1981 and 1982 continue to be flat, we are going to face the issue of which programs will have to be cut. This will be discussed further at the November Board meeting.

IX. REPORT OF THE DIRECTOR, NIH - Dr. Donald S. Fredrickson
Mr. Richard Riseberg

Dr. Fredrickson reported on the new debarment regulation which will appear shortly in the Federal Register which deals with the problem of individuals who appear to misuse Government funds provided for biomedical research or who violate the code of ethics in medicine. He asked Mr. Richard Riseberg, the General Counsel's representative at NIH, to explain the regulations.

Mr. Riseberg described the procedures for debarment. If an individual is debarred, he will be rendered ineligible for grant support during the period of debarment. The regulations set up a formal procedure to accomplish this, which serves two purposes. First, it provides a regularized process for determining whether an individual or institution should be debarred. At the same time, it provides procedures that will protect the right of that individual. When a decision is made that a person should be considered for debarment, he will be provided with a notice giving the grounds, and offered an opportunity for a hearing before a hearing officer. After the hearing, he would have a right to be represented by counsel and the Government has the responsibility of proving that the grounds for debarment exist.

If the Government prevails, he would be debarred, but if the Government fails to prove its case, then in future situations any information that led to consideration of debarment could not be taken into account in dealing with future applications. If an individual is dissatisfied with the decision by the hearing examiner, he has an opportunity to appeal to the Secretary herself. She would then have to render a decision according to the regulations simply on the evidence provided at the hearing. If the individual is still not satisfied, he has a right to go to court. These regulations provide regular procedures for dealing with the very small number of cases where improper activity has been discovered and the Government feels it can prove that some serious activity has occurred.

In response to questions on types of violations, Mr. Riseberg gave the examples of where there has been a conviction of a fiscal-type crime; violation of the antitrust laws; defrauding the Government on a contract; and also if a person has been debarred by another agency, it would be grounds for considering debarment by DHHS. A particular incident was cited in which there was falsification of data.

Dr. DeVita asked what happens to the support for these people while the debarment proceedings are in process. Dr. Fredrickson responded that NIH will look to Boards for their instruction and guidance in these situations. Procedures will probably be developed that will not leave

matters unresolved for long periods of time. He pointed out that debarment is very rare, and these regulations protect the individuals as well as the Government.

Dr. Fredrickson next reported briefly on the 1982 budget which is in the process of formulation. In response to a question about why the NCI is receiving a proportionately smaller budget increase than the other NIH Institutes, Dr. Fredrickson explained the tremendous competition for dollars under a small ceiling. NIH is seeking funds to renovate the six oldest buildings on the NIH campus. Continued effort is needed on the part of bodies like the NCAB to carry the message to Congress on issues like the need for biohazard containment and animal facilities for the grantees throughout the nation. He added that the Office of Science and Technology was holding a meeting that day to discuss the need of institutions for that kind of support.

X. REPORT OF THE SUBCOMMITTEE ON CENTERS AND CONSTRUCTION - Dr. Maureen M. Henderson

Dr. Henderson, Chairman, directed the Board's attention to a report of the Subcommittee and a statement of the policies concerning the Cancer Center Support (Core) guidelines which had been distributed to the Board members. She pointed out that when the Subcommittee met in August, they realized the Director had appointed a Board of Scientific Counselors for the Division of Resources, Centers, and Community Activities. The report discusses the separation of duties of the new Board of Scientific Counselors and the NCAB Subcommittee on Centers and Construction.

Dr. Henderson outlined the general policies the Subcommittee would like the Board to endorse concerning centers:

- The NCI should continue to support multidisciplinary programs.
- There should be diverse organizations and different categories of centers.
- Organizational and programmatic flexibility is desirable and should be preserved by permitting centers to change their category and program emphasis.
- Cancer Center core grants should serve as a support mechanism for the research activities of cancer centers.

She also listed specific policies that relate to the purpose and general provisions of core support:

- Support should be provided for those activities that consolidate and focus cancer-related research efforts in a single programmatic and administrative structure in order to promote stability and development of centers and to facilitate administrative and programmatic control.

- Funds should be provided for salaries of selected cancer center staff.
- There should be a provision of funds for the operation of centralized shared resources and services.
- Funds should be provided for the administration of centers.
- There should be a requirement that support for all other cancer center activities should depend upon other Federal and non-Federal funding mechanisms.

The second group of specific policies relate to the qualifying criteria used to decide whether or not a center should receive core support:

- There should be an existing base of established programs of high quality in laboratory and/or clinical cancer research as a precondition for CCSG eligibility. There should be peer-reviewed support from sources other than the NCI.
- Interdisciplinary coordination should be an essential and reviewable attribute. The Subcommittee recognized that there is a difference between interdisciplinary and multidisciplinary research.
- The organizational capability and facilities should be appropriate and adequate for the conduct of a center's activities and to facilitate collaboration among its constituent programs.
- There should be a qualified director with adequate authority. He should serve the center on a full-time basis without prohibiting another concurrent academic commitment, providing such a commitment is in another institutional unit whose major activities bear a direct relation to the activities of the center.
- There should be a clear commitment of the institution to the center.

Dr. Henderson said the Subcommittee had identified several issues of concern to be referred to the DRCCA Board of Scientific Counselors for its consideration. The first of these was the problem of multiple core grants. The subcommittee favors flexibility on this issue and would ask the BSC to identify circumstances in which multiple core grants would be permissible. The second issue was that of supplemental applications. The present position is not to accept them. The next issue was that of salary support for staff investigators. The committee endorsed the proposal that there should be a ceiling on staff investigator salary support.

A discussion of these and other issues in the report followed. Dr. Pitot said the DRCCA Board of Scientific Counselors will draft a set of guidelines for core support and present it at the May meeting of the Board for review.

He and Dr. Henderson will attend the meeting of the BSC.

Dr. Rowley raised the issue of abolishing staff salary support from the core grant and including it in the R01 and P01 grants.

The Board accepted unanimously the report of the Subcommittee on Centers and Construction.

XI. REPORT OF THE SUBCOMMITTEE ON ORGAN SITE PROGRAMS - Dr. William Powers

Dr. Powers reported on the Subcommittee on Organ Site Programs. He pointed out that this program has a modest budget with total funding for all four of the programs--Bladder, Large Bowel, Pancreas, and Prostate --of $17.6 million. As part of a systematic review being conducted of the existing programs, the Subcommittee met on October 5 to discuss the Prostate Program. Dr. Gerald Murphy reported on the current status of this project which supports epidemiologic, laboratory, and clinical studies encompassing the areas of etiology and prevention, detection and diagnosis, and treatment. An effective multidisciplinary research plan with work designs and well-defined priorities has been developed. A number of resources have been developed and have been made available to the research community, and a successful preclinical and clinical treatment program has been instituted. To date, the Project's cooperative group has accessioned over 1500 patients to 13 protocols among ten institutions. Many publications have appeared in medical journals, and workshops have been held which have effectively communicated information on the studies to the biomedical community.

Dr. DeVita said he would be interested in knowing when the Task Force considers its job finished. Dr. Powers responded that Dr. Murphy does not see an end to the Task Force's duties at the present time. Past reviews of the Organ Site Programs have found them to be effective in attracting new investigators and stimulating new research. Dr. Powers urged that the programs not be phased out, adding that such a move would be premature and would result in a decrease in the number of investigators studying these diseases. The Subcommittee recommended that adequate funds be made available to keep this successful program going and recommended further that the continued surveillance of the Organ Site Programs be done by the NCAB Subcommittee.

The Board voted acceptance of the report of the NCAB Subcommittee on Organ Site Programs.

XII. REPORT OF THE NCAB SUBCOMMITTEE ON ACTIVITIES AND AGENDAS - Dr. Harold Amos

Dr. Amos presented a brief report, stating that the aim of the Committee is to assist the Director in establishing priorities of subjects to present at Board meetings and to maximize for the Board members the

informational value of these meetings. The major portion of the November meeting will be a discussion of the newly formed Division of Cancer Resources, Centers, and Community Activities. It will include presentations on the Diet and Nutrition and Smoking and Health Programs. Dr. Pitot suggested that at the November meeting a discussion also be held of the relationship of the Boards of Scientific Counselors to the NCAB.

The Board unanimously approved the report of the Subcommittee.

XIII. FREDERICK CANCER RESEARCH CENTER - Mr. Sheldon W. Samuels

As part of the May NCAB meeting, the Board made a site visit to the Frederick Facility, and an ad hoc subcommittee consisting of Mr. Samuels, Mr. Schrier, Dr. Amos, and Dr. Rowley, was formed to look into the contract. This committee met in August and reviewed the proposal made by the NCI for the recompetition of the contract.

Mr. Samuels reported that the Subcommittee had no strong feelings one way or another for commercial versus Government supervision of the Program, or for single versus multiple contracts. They felt the operation is on the right track, and recommended that the contract to run the Frederick Center be continued. They also recommended that a permanent subcommittee of the Board should be formed under the chairmanship of someone with managerial experience to oversee the Frederick contract in general.

Dr. DeVita advised the Board that because the Litton Contract at Frederick will run out in 1982, some decisions that affect the contract have already been made by the NCI, i.e., some NCI laboratories have been moved from the NIH campus to Frederick. After the visit by the Board, everyone was satisfied that the quality of the work there was good and the staff recommended to the Board subcommittee that the contract be recompeted but at a 20 percent reduction. The recompeted contract should be in two parts--one for research and one for resources and services. The new contract will be in force for five years.

Dr. DeVita said that because the management of the contract and the relationship between NCI staff and the Frederick contractors could be improved, he plans to have a person in his office whose main responsibility would be the management of the contract. He anticipates that very shortly there will be improved relationship between NCI and LBI--more NCI people will be working at Frederick, and although the contract will be smaller, the high quality of the research there will be preserved.

Dr. DeVita expressed pleasure with the result of the Board site visit and the Subcommittee's report, and thanked them for their assistance. The Board approved the Subcommittee's report.

XIV. POTENTIAL NCI MONETARY CONTRIBUTION TO THE MORTALITY FOLLOW-UP STUDY OF A REPRESENTATIVE SAMPLE OF THE 1980 CENSUS - Dr. Robert Miller and Dr. Manning Feinleib

Dr. DeVita introduced this subject by stating that NCI has been asked to contribute support to a follow-up study of the National Death Index, and before making a decision on this he wanted the Board's advice and recommendation.

Dr. Robert Miller, Chief of the Clinical Epidemiology Branch, NCI, gave the background on the establishment of the National Death Index. He felt that use of the index would be a tremendous aid in follow-up in epidemiological studies, and an inexpensive way to follow large series of patients.

Dr. Manning Feinleib, of the National Heart, Lung, and Blood Institute, described a proposed study which would be a long-term follow-up on a large, random sample of individuals in the United States who completed the long form in the 1980 census. It would provide annual trends in mortality by age, sex, race, and cause of death. It would also provide mortality rates by occupation, industry, and other factors. He showed a series of slides giving further information and data, and also pointing out problems in implementing such a study.

There is a proposal by the NHLBI to conduct a pilot study, and if the results of the study are positive, NCI will be asked to contribute to a full-scale, NIH-wide, initiative.

This issue was discussed at length by the Board and it was agreed that no recommendation will be made until the results of the pilot study are received.

XV. INTERNATIONAL ACTIVITIES - Dr. Gregory T. O'Conor

The Office of International Activities of the NCI serves as an informational and coordinating focus for the Institute for activities in which NCI participates with other countries. Dr. O'Conor illustrated his presentation with a series of slides showing the functions of the office. These are categorized as: support of cancer research through grants and contracts to non-American scientists outside the United States; cooperative research under bilateral agreements; maintenance of liaison in research collaboration with international agencies; support of and hospitality to foreign scientists in the United States; and support of work assignments of Americans to other countries for research purposes. The International Activities area is also responsible for the management and operation of the International Cancer Research Data Bank Program. He described in detail these various functions and distributed a folder containing summaries on the activities under the ICRDB program. This program disseminates research information, but it is not itself a research program.

Dr. O'Conor spoke briefly on the budget. During 1979 there were 44 grants of $2.4 million and 78 contracts totaling $8.8 million which provided support to scientists in 21 different countries.

XVI. OTHER BUSINESS

Mrs. Kushner brought up for discussion the following resolution passed by the Planning and Budget Subcommittee at the May Board meeting:

> "The Subcommittee on Planning and Budget recommends that the NCI should be able to maintain the maximum amount of flexibility regarding the process of budget formulation to best be able to reflect current scientific economic conditions. Therefore, the Subcommittee expressed its opposition to the identification of specific line items in the budget."

There was general agreement that the resolution should be sent to the Congress from the Board, and that if individual members desired to do so, they could contact their Congressmen as private citizens.

XVII. CLOSED SESSION (RESEARCH GRANT REVIEW)

The Special Actions Subcommittee convened in closed session for the consideration of applications that had been selected for special review by staff action. Their recommendations were presented to the full Board for their review and approval. Individual applications brought up for discussion by Board members were also considered. The Board concurred en bloc with the recommendations made by the initial review groups.

XVIII. ADJOURNMENT

The meeting of the Board was adjourned at 12:40 p.m., October 8, 1980.

October 6, 8:30 a.m. - 5:00 p.m.
October 7, 8:30 a.m. - 5:00 p.m.
October 8, 9:00 a.m. - 1:00 p.m.

I certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

Date

Henry C. Pitot, M.D., Ph.D.
Chairman
National Cancer Advisory Board

Prepared by:

Mrs. Jeannette Steinbraker
Recording Secretary
National Cancer Advisory Board

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January, 1981

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