National Institutes of Health

National Cancer Institute

NATIONAL CANCER ADVISORY BOARD

Minutes of Meeting

February 2-4, 1981
Building 31
NIH Campus
Bethesda, Maryland

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

Minutes of Meeting*
February 2-4, 1981

The National Cancer Advisory Board was convened for its 37th regular meeting at 8:30 a.m., February 2, 1981, in Conference Room 6, Building 31C, National Institutes of Health, Bethesda, Maryland. Dr. Henry C. Pitot, Chairman, presided.

Board Members Present

Dr. Ames
Dr. Amos
Dr. Henderson
Dr. Hickey
Dr. Katterhagen
Mrs. Kushner
Ann Landers
Dr. Leffall
Dr. Pitot
Dr. Powers
Dr. Rowley
Mr. Samuels
Dr. Seitz
Dr. Selikoff

Ex Officio Members

Dr. Hollis Boren, VA
Dr. Robert Goyer, represented
Dr. David Rall, NIEHS
Dr. Richard E. Marland, EPA
Dr. F. Kash Mostofi, DOD
Dr. Denis J. Prager, OSTP
Dr. Anthony Robbins, NIOSH

Representatives of the
President's Cancer Panel

Dr. Amos
Dr. Fisher

Board Members Absent

Mrs. Lombardi
Mr. Schrier
Dr. Shubik
Dr. Wogan

Liaison Representatives

Mr. Alan 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 Association for Cancer Research and the American Society of Clinical Oncology, Inc.

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

Liaison Representatives (continued)

Dr. Paul Sherlock, Chairman, Department of Medicine, Memorial Sloan-Kettering Cancer Center, New York, New York, representing the American Gastroenterological Association.

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

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

Dr. Joseph Blair, representing Dr. William Burr, Director, Division of Biomedical and Environmental Research, Department of Energy, Washington, D.C.

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. Philip D. Amoruso, Executive Officer, NCI
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
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 D. 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, twelve 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 introduced two new ex officio members of the Board: Dr. Hollis Boren, representing the Veterans Administration, and Dr. Peter Preuss, representing the Consumer Product Safety Commission. He also introduced Mrs. Winifred Lumsden, the new NCAB recording secretary and NCI Committee Management Officer.

Dr. Pitot then welcomed members of the public and announced that anyone wishing to express his or her views regarding any items discussed during the open sessions could do so by submitting written statements to the Executive Secretary of the Board within 10 days after the meeting. Any statement by members of the public will receive careful consideration.

After briefly reviewing the procedure for conduct of the meetings, Dr. Pitot asked Board members to review the minutes of the previous meeting for eventual discussion and approval.

II. Report of the Director, NCI - Dr. Vincent T. DeVita, Jr.

Dr. DeVita first introduced Mr. Philip Amoruso, the new Executive Officer and Associate Director for NCI, and Ms. Barbara Harris, the new Legislative Liaison. He then reported on the following items:

Staffing. An EEO External Advisory Committee, chaired by Dr. Prince Rivers, is looking at NCI to see if it can help improve the Institute's EEO posture. A 100 percent review of the entire NCI personnel roster is being conducted to see if personnel resources can be reallocated to various programs. A follow-up will be given at the next Board meeting.

Reorganization. Plans for transferring the NCI Bioassay Program to the National Toxicology Program at the NIEHS have been turned over to the Department for approval. The program is expected to be transferred by the end of this year.

Biological Response Modifier Program. This program was submitted for approval for the fall. About 80 percent of all staff requirements involved were identified, and NCI is recruiting and filling positions for that program.

Potential Organizational Changes for Radiation Research Programs. Dr. DeVita reviewed the several options for the organization of a radiation research program to include efforts in diagnosis, therapy, and the effects of low-level radiation. NCI has begun to implement the option which involves creating new branches to deal with specific segments of radiation research, including diagnostic imaging research. Dr. DeVita invited comments concerning this program; he expects a more formal organizational change by the end of the year.

The Frederick Contract. As suggested by Board members and staff, the contract will be recompeted at 20 percent below the negotiated level. This reduction is in line with other cuts in the budget.

Interferon. NCI has filed an IND to the FDA and is waiting to hear whether the 30-day waiting period will be waived. All clinical trials for this interferon will begin in February. These trials will be conducted at three institutions supported by NCI (Memorial Sloan-Kettering, Stanford, and NIH Clinical Center) as well as at M.D. Anderson. All four institutions will test the same material, which is the only genetically pure interferon available. NCI is also working closely with Hoffman-LaRoche and genetically engineered clinical trials.

Community Hospital Oncology Programs. Of 23 programs, 14 have been funded and 9 have not; however, these should be funded by the end of February.

Drug Development Program. The flow of new drugs through this program has accelerated, with 17 new drugs on the horizon (8-10 are a normal year's output). There is some problem in finding money for clinical trials for 10 or so of these drugs. An FDA member recently criticized NCI for its conversion to a new toxicology protocol: NCI now relies primarily on rodents for testing chemotherapy drugs (formerly, rodents, dogs, and monkeys were used). The new protocol was supposed to reduce costs from about $180,000 to about $80,000 a year while remaining equally safe. Unfortunately, after the protocol was widely discussed, advertised by FDA in the Federal Register, commented on by outside scientists, reviewed and approved by an FDA advisory committee, and implemented, the cost of the revised protocol had risen to about $200,000 a year, mostly due to inflation. (Had NCI not revised its protocol, the cost would have been approximately $350,000 a year for the same toxicology.) Consequently, NCI does not have the increased capacity expected as a result of the protocol revision; there are more new drugs to test than capacity to run them through the protocol.

Hearings and Legislation. In meetings with the NIH Forward Plan Review, the following were discussed: the impact of stabilization of NIH research projects; whether training ought to be stabilized in a similar fashion; NCI's progress report on the Biologic Response Modifier Program; and other items, including the future of our Biologic Response Modifier Program and NCI's proportionate share of the NIH budget. The Senate Appropriations Committee, with 8 new members out of 29 and a Republican majority, will begin hearings February 18 under the chairmanship of Senator Harrison Schmidt. The Senate Health Subcommittee was abolished, with health problems now being handled by the Committee as a whole, chaired by Senator Orrin B. Hatch. Dr. DeVita reported that Senator Hatch had requested and been sent conflict of interest statements from all NIH Board and Council members. A new Subcommittee on Oversight and Investigations is chaired by Senator Paula Hawkins. NCI may be subject to investigation; Dr. DeVita welcomed this, saying the National Cancer Program is in a good position to defend itself.

Cancer Mortality. The report prepared by Drs. Myers and Henke titled "Cancer Patients' Survival Experience" was presented by Dr. DeVita. Data show in graphic form the differences in five-year survival between 1960-1963 and 1970-1973. Cancer mortality continues to decrease in persons under age 45. It was mentioned that cancer data are criticized for being old, but Dr. DeVita pointed out that there is no way to get five-year survival data without waiting five years.

Odds and Ends. The use of THC has been well received; NCI has applied to FDA to allow THC use with radiotherapy to prevent nausea and vomiting. NCI was assessed $496,000 of $950,000 needed to conduct a study to follow up Love Canal victims to see if removal from exposure caused changes to subside. This amount was reduced to $413,000 after NCI voiced strong objections.

Press Coverage. Press coverage of NCI has been generally accurate and good. Dr. DeVita mentioned samples, including:

- a series of articles on the influence of cholesterol and heart disease in cancer;
- articles on the Surgeon General's report that shifting to low-tar cigarettes resulted in a noticeable difference in mortality from lung cancer (Dr. DeVita emphasized that reduction was not nearly as significant as discontinuing smoking);
- a series of articles on the Delaney Clause (Mr. Schweiker has commented on the possibility of doing away with this clause);
- an article on the study of infectious etiology of Hodgkin's disease; and
- an article on the potential carcinogenicity of Valium.

This last article engendered a lengthy discussion among Board members. Dr. DeVita reported that there is no evidence that Valium is a carcinogen; Board members raised the question of how to study and test for cancer promoters.

Robert Wood Johnson Foundation. Dr. DeVita reported that this Foundation has added new directions to its grant program, some of which correspond to cancer control initiatives. Anyone interested in applying for a grant should contact Dr. Cluff or Mrs. Schuster at Robert Wood Johnson.

III. General Discussion

Dr. Seitz commented that he believes more publicity should be given to the symptoms of testicular cancer. Dr. DeVita agreed, pointing out that testicular cancer accounts for 1 percent of male cancers and is especially common between the ages of 20 and 30; in the last five years it has become curable in more than 80 percent of all cases. Mr. Van Nevel reported that informational materials being produced are being gathered and should be publicized more widely in the future.

NIH's tardiness in paying bills and its effects on patient care and delivery of new drugs was questioned. Dr. DeVita said he doubted the Board could do more than express concern, although many Board members agreed this was a definite problem. Mr. Amoruso informed the Board that NIH is working to computerize and thus speed up payments.

IV. Report of the President's Cancer Panel

Dr. Lederberg could not attend, and no report was given.

V. Report on Contract Activities - Dr. Vincent T. DeVita, Jr.

Dr. DeVita presented the second of a series of presentations on NCI contract activities. All Board members received a copy of "NCI Contracting Process," which summarized the material presented.

It was reiterated that, unlike grant review, the contracting procedure is divided into concept review and merit review. Concept review is now being handled by the divisional boards of scientific counselors. Proposed organizational changes to make the merit review system more comparable to the grant review system were presented.

A series of slides was shown to illustrate various issues. The grant mechanism differs from the contract mechanism in that the degree of government involvement is greater in contracts than in grants. A new instrument, cooperative agreements, falls somewhere in between the two: the government has substantial involvement, but initiative can come from the investigator. Generally, grants and cooperative agreements are used to assist and stimulate research, while contracts are used to procure a specified service or a defined end product.

The first presentation of contracts was reviewed, which led up to a proposal to transfer merit review of all contracts to the Division of Extramural Activities. In 1974-1979 there was mandatory peer review of the technical merit of research and development contracts, while resource contracts were reviewed by NCI staff. This led to a definitional problem, since some contracts could be and were classified as either research or resource, depending on how much review a program would be required to have. In 1978 the programs were transferred to the divisions, and the review groups for the research contracts were transferred to DEA. However, relatively few contracts are classified as research, so a small number are being reviewed by DEA and a large number by the various divisions. The proposed organizational change will transfer the review of all contracts--both research and resource--to DEA. This would allow more scrutiny of contract review, in addition to making the system more uniform with grant review.

The tentative plan is as follows: After redefining research and resource contracts, the merit review of research contracts will be handled within DEA by committees composed of outside investigators, while the merit review of resource contracts will be handled within DEA by separate committees, again composed of outside investigators.

Merit review of intramural support contracts will be handled by a separate committee composed of intramural scientists. In the past, concept review of contracts has been handled separately by boards of scientific counselors, and merit review has been handled primarily by the branch that would receive the services of the contract. However, the Department has been emphasizing the need for maximum competition for funds. It is hoped that a committee of NIH scientists, with rotating memberships, will deal effectively with this issue.

To review all other contracts (about 2,500 project reviews are anticipated within the next three years) within DEA, it will be necessary to refurbish the four existing committees and establish four new committees. Since a Contract Review Branch was established recently, the administrative structure exists to

handle making the necessary changes. The major needs are staffing and space. Since staffing may be obtained by transferring people who now do this job in other divisions to DEA, it is not known if costs for staffing will be higher.

Dr. DeVita invited discussion of this system, saying that it would provide a uniform way of controlling development of contract programs and determining whether a particular program should continue--in other words, a uniform method of concept review. Merit review will be handled uniformly by a group of individuals whose job it is to handle contracts, working side by side with the people who handle grants. To provide communication between concept and merit review committees, the chairmen of the merit review committees will attend meetings of the appropriate boards of scientific counselors as ad hoc members.

The question was asked whether the boards of scientific counselors get feedback on what contracts are eventually selected. In response, Dr. DeVita described the contracting process. After a concept is developed by staff and reviewed by the boards, an RFP is published in the Commerce Business Daily. When proposals are received, they are evaluated by the peer review committee, which determines the competitive range. Organizations or individuals with competitive proposals are allowed a chance to amend their proposals before a decision is made. The final decision on the award of a contract is made by staff, although attention is paid to the evaluations of the peer review committee. After negotiation, a contract is awarded. During this final review, an award decision can be held up to obtain additional information, if necessary, on exactly why the contract is necessary. That is, information may be requested on what was decided during the original concept review. The problem is that divisional board members have four-year terms, so that, if a contract is recompeted less often, it may be necessary to educate new board members on the original decisions of the concept review. However, through this process there is feedback to the boards on which contracts are being awarded.

Dr. Pitot asked if the names of individuals who responded to the RFP are available after the contract is awarded. The reply was that there is a list of companies or institutions--not individuals--that responded and that the information would be made available if it was in the desired format.

The only other issue concerned concept review for the Office of the Director by the NCAB or a subcommittee of the NCAB. This would relate to contracts such as the Office of Cancer Communications and the International Cancer Research Data Bank. Dr. Pitot suggested that the idea was for the NCAB to act as a board of scientific counselors for OD. Dr. DeVita replied that this was already the case; concept review of these contracts would be an added function for which a system could be worked out.

Members were concerned about the time delay involved in the reviews and inquired whether the new system would add to the delay. Dr. DeVita replied that handling matters in a more uniform way might in fact speed up the process but that it would take time to implement the changes and get the system to function efficiently.

VI. Cancer in Black Americans - Dr. LaSalle D. Leffall

Dr. Leffall first noted that his presentation would actually concern cancer in minorities--Black Americans, Hispanic Americans, Asian Americans, and American Indians. The subcommittee that studied this issue consisted of himself, Dr. Selikoff, and Dr. Amos.

The purpose of the study was to find out what NCI and the American Cancer Society could do to address the issue of increasing awareness of cancer among minorities. He pointed out that any program developed must apply to a specific minority group, since what would be effective in a Black community, for instance, would not necessarily be effective in a Hispanic community.

The objectives of the program are to emphasize the importance of early detection of cancer, the availability of better treatment options in the health care system, and the growing evidence of a need for preventive measures in the workplace and in social life patterns.

In 1979 the American Cancer Society sponsored a conference on Cancer in Black Americans. As a result of this conference, local divisions and units of the ACS have instituted programs to provide professional and public education and information. Also as a result of the conference, the ACS formed the National Advisory Committee on Cancer in Minorities (Dr. Leffall is chairman), which is developing a five-year action plan focused on Hispanic and Black Americans.

Some people have reservations about data presented in the ACS conference, e.g., that every major cancer, with the exception of skin cancer, is more common in Blacks than in whites. Therefore, the NCI is being asked to assist in determining what information is needed and in acquiring and presenting that information.

Dr. Leffall presented six ways the National Cancer Institute could assist in this effort. They are: (1) to establish a reliable data base for providing facts about cancer incidence, treatment, and prognosis for minorities; (2) to assist the American Cancer Society in expanding ways to present the data; (3) to encourage training of minority oncologists; (4) to utilize control program funds to determine how minorities in selected communities are handled and should be handled by the cancer diagnostic and treatment modalities; (5) to initiate a specific program to bring minority patients into the practice field of comprehensive cancer centers; and (6) to contribute--not necessarily a large amount of funding but reorientation and closer cooperation--to the American Cancer Society's efforts.

Dr. Leffall said also that immediate action should be taken to commission two basic documents or monographs: one a statistical review and analysis of the morbidity and mortality data among minorities and the other a geographical distribution of cancer among Blacks and Hispanics.

Dr. Selikoff pointed out the importance of the statistical data base on which the current concern exists, e.g., the ratio of cancer in Blacks to whites was 1.04 in 1950 and 1.32 in 1977. He mentioned that the American Cancer Society had calculated there would be 160 fewer cancer deaths among Blacks each week if cancer mortality rates for Blacks were the same as for whites. He added that there are virtually no data concerning cancer rates in Hispanic people.

Dr. Hickey responded to this last statement, saying that the Texas Comprehensive Cancer Center has data covering about two decades and comparing three ethnic groups from El Paso, Laredo, and San Antonio. The data concur with cancer and survival rates in Spanish-American, Black, and white populations.

Among the reasons considered by the committee for the greater increase in Blacks were fewer educational efforts among minorities concerning early recognition; poorer screening; delayed therapy, for either economic or social reasons; greater occupational risks; early exposure to farming chemicals; the problem of nutrition and difference in diets; alcohol; poor follow-up; delayed diagnosis; stress, either socioeconomic or behavioral; and difficulties in entering the health care system.

An Office of Cancer Communication study on breast cancer attitudes in Hispanic and Black women found that while white women get most of their information on breast cancer from the written press, most minority women get information from television, indicating there must be more research on how to reach minority populations with the necessary information.

The Board voted to accept Dr. Leffall's report, thus authorizing the Board to cooperate in some official way with the American Cancer Society. Dr. Pitot asked that the committee members look into ways to begin to implement some of the suggestions made in the report.

VII. Report of the Nutrition Subcommittee - Dr. Maureen M. Henderson

The ad hoc subcommittee on nutrition, consisting of Dr. Ames, Dr. Wogan, Dr. Amos, and Dr. Pitot as well as Dr. Henderson, was formed at the preceding Board meeting after a presentation by Dr. Diane Fink, coordinator of nutrition studies. Since the subcommittee had met only once, Dr. Henderson was able to report only that it will be a few months before the subcommittee can bring recommendations back to the Board.

VIII. Report of the Organ Site Subcommittee - Dr. William E. Powers

Dr. Powers reported that funding for the Organ Site Program is now decreasing and the subcommittee is looking into the question of what to do about phasing out or modifying the monies of the program in a period of tight budgets. Dr. Pitot added that the subcommittee would do everything possible to come up with a recommendation to the Board in the May meeting.

IX. Report of the Environmental Carcinogenesis Subcommittee

In Dr. Wogan's absence, Dr. Pitot outlined the history and recent functions of this subcommittee. He related that the subcommittee was first appointed in 1974-1975 and charged with the task of defining cancer or neoplasia. The subcommittee did define neoplasia, but deferred on defining a carcinogen. Later the subcommittee was given the task of reporting on the relationship of human risk to compounds tested in the bioassay system. While the subcommittee was deliberating, the "ILRG" group came out with a document on this subject; it was decided that it was not appropriate to continue working on the matter.

Since then, the subcommittee has had no major function. However, in view of the fact that environmental carcinogenesis is still a subject of interest, Dr. Pitot felt that the Board would decide upon an appropriate task for this subcommittee in the future.

X. Report of the Subcommittee on Activities and Agenda - Dr. Harold Amos

Dr. Amos reported that this subcommittee is charged primarily with the continuous review of issues raised in various sectors of NCI, especially those requiring periodic examination in order to plan possible programs for Board meetings. The subcommittee tries to sort out a year or so in advance what matters to bring up in these meetings. The subcommittee feels it should be responsive to the biomedical research community, both clinical and basic science, the public at large, and the community activity, or control, segment. Congress is a factor in determining whether questions of professional education and training come before the Board; the Director and NCI staff generate most material. One of the most important items that determines agendas is how the material must be initially presented to the Board: a good deal of work goes into preparing the necessary materials for the presentation. High-priority issues must be brought before the Board immediately.

Dr. Pitot added that this subcommittee also assists in preparing the Annual Report of the Board and that he hoped there would be a rough draft of this document by the April meeting.

XI. Report of the Subcommittee on Centers and Construction - Dr. Maureen M. Henderson and Dr. William A. Walter

Dr. Henderson first asked Dr. Walter to give a historical perspective about the centers and construction subcommittee. He reported that the subcommittee originated shortly after the passage of the National Cancer Act, in 1971, which authorized the Director of NCI to create 15 new centers that would deal in clinical research, training, education, diagnosis, and treatment of cancer. The Board decided these centers would be "comprehensive centers," dealing with the total realm of cancer from basic and clinical research to diagnosis and control over cancer. The Board then directed the staff to come up with characteristics to describe these comprehensive cancer centers. The staff came up with nine characteristics, and the Board added a tenth. The Centers Subcommittee was charged in 1973 with identifying and recognizing centers conforming to these characteristics. Although there was no organized method for setting up site visits or an organized review of cancer centers, the 10 characteristics were published and promulgated; the subcommittee then reviewed applications from institutions wishing to be recognized as cancer centers and made recommendations to the Board. The Board then advised the Director on which centers conformed to the characteristics. Over the next two years, the Board was concerned primarily with the implementation of these characteristics and with recognition of the comprehensive cancer centers. Three centers immediately met the characteristics: Roswell Park, Sloan-Kettering, and M.D. Anderson. After 15 centers were identified, the subcommittee took on the tasks of reviewing all the special actions related to centers and developing better procedures for recognizing additional centers that wished to be designated "comprehensive." Around 1976 it was decided that the existing comprehensive centers needed a thorough review. The earlier ones had been recognized without any real site

visit or review by members of the Board or subcommittee. At that time, the 10 characteristics were reviewed and revamped, and a number of questions were developed and submitted to those institutions that had been recognized as comprehensive. In 1977-1978 the subcommittee sponsored site visits to each of these cancer centers. Reports of each of the centers were compiled and this information was sent to both the NCI Director and the directors of the individual cancer centers involved. Most centers were deemed to have met the characteristics; some needed further review; and some were found to have certain deficiencies.

Early in the existence of this subcommittee, it was recognized that very little time was being spent on matters relating to construction. Thus, around 1974-1975, the Construction Subcommittee became a separate entity. This subcommittee was primarily responsible for reviewing construction grants recommended for approval and making recommendations to the Board. Subsequently, the subcommittee on construction also undertook various surveys on the status of construction, the types of construction being done, the biohazard situation, and the needs for animal facilities in cancer institutions around the country. The subcommittee has also looked at the need for additional funding for cancer construction. The construction subcommittee was recently merged into the Subcommittee on Centers and Construction due to a small construction budget.

Dr. Walter pointed out that the Subcommittee on Centers had no role in developing guidelines for support of cancer centers. The subcommittee became involved in guidelines only after the Board was brought into the issue to attempt to revise the guidelines for core grants (in 1977).

It was asked whether a center can be a comprehensive center if it does not receive Federal funding. Dr. Walter replied that from the standpoint of NCI, a center is an institution that receives a core grant. Dr. Terry explained that the rationale was that NCI comprehensive centers should represent centers that are funded through a recognized mechanism that has undergone peer review and that NCI should not become an accrediting agency for centers. Therefore, although there are more centers than there are core grants, NCI centers are those that have core grants.

There was a concern that people were only being referred to centers receiving Federal funding, but Dr. DeVita said that this was not the case: people can be referred to any center supported by NCI, not just those with core grants.

Dr. DeVita brought up two points: First, he believes that NCI-designated centers are different from other centers because the core grant generates a base for an institutional commitment that does not change as Federal support changes. Second, he asked if there was a way to determine the correct number and distribution of comprehensive cancer centers. Should the number of centers be based on geography? Or, should the number be based on research opportunities? He added that this might be a good issue for the DRCCA Board of Scientific Counselors to address.

Dr. Seitz felt that, since money for core grants is shrinking, if a community pulls together funds and creates a center with attributes of a comprehensive cancer center, it should be designated a comprehensive cancer center. This might add to local prestige and strengthen local budgets as well as fulfilling a need.

Dr. Henderson mentioned some thoughts on what the subcommittee should consider in the future, if it is decided that it should continue to exist. One was that there should be a way of monitoring these earmarked funds so that, when necessary, the Board can provide detailed reports to Congress on exactly which programs are successful. Dr. Henderson was also worried that, since the comprehensive centers get proportionally little funding from core grants, as the centers enter into broader relationships to obtain funding, the goals of the centers may become different from those of the NCI; she thought there should be a way to ensure that NCI's goals are being met. Dr. DeVita thought the staff of the Board's new division should be given a chance to work out solutions to these and other problems.

XII. Report on the Clinical Manpower Meetings - Dr. Margaret Edwards

Dr. Edwards stated that this report is a follow-up to discussions within board meetings of the Clinical Cancer Education Program, which defines the need to support the training of clinical oncologists in certain specialties.

In the 1950s and 1960s a group of radiation therapists presented data on manpower needs in their specialty to the National Advisory Cancer Council, and this led to the development of a special program to train additional clinical radiation therapists. NCI never supported a study of manpower needs in clinical specialties until 1975, when the Clinical Manpower Branch initiated a study to provide information to guide the Clinical Cancer Education Program in its support of four other clinical oncologic specialties: pediatric hematology, medical oncology, GYN oncology, and surgical oncology. These specialties were selected because they represented the largest numbers of graduate students for whom support was being requested by applications for clinical cancer education grants and because no good data were then available on the numbers of such specialists needed.

The study was performed under contract by Geomet, Inc. The numbers of specialists projected as needed in each discipline were those required to treat all patients with the types of cancer most appropriate for that specialty. For example, pediatric hematology oncologists would be expected to treat all leukemias, lymphomas, and solid tumors in children up to age 15. A panel of experts for each specialty assisted in developing prototype specifications for the study. Future manpower needs were projected to accommodate various proportions of time devoted to direct patient care. Estimates of the current supply of specialists in each field were obtained by reviewing the numbers of positions certified by the boards in those disciplines and by membership lists in pertinent professional societies. Since there is no board in surgical oncology, the data for that subspecialty are open to question.

The results indicated that in 1977 there were adequate numbers of pediatric hematology oncologists but shortages in the other specialties. It was estimated that by 1985 the supply of medical oncologists would be 86 percent of those needed; projected needs for GYN oncologists and surgical oncologists

also would not be met. However, there was expected to be an oversupply of pediatric oncologists. Pediatric oncologists were the only ones to offer strongly dissenting comments: they stated that the proportion of time devoted to patient care should be much less than was calculated for the study. The surgical oncologists disagreed with estimates of their current numbers but found the lower estimate more favorable.

Dr. Edwards pointed out that the study was done on a low budget within a two-year period; it was done as simply as possible with as few variables as possible to yield the maximum numbers of specialists that might be needed under the assumptions. She compared the results of this study with a study conducted by the Graduate Medical Education National Advisory Committee (GEMENAC), supported by DHHS, although comparison was possible only in the pediatric hematology subspecialty. The GEMENAC study projected a need for a much larger number of such specialists than did the Geomet study.

Dr. Edwards concluded by saying that manpower needs studies are very difficult to perform in health service professions because of the great variability of demand and the unequal distribution of positions, as well as the total openness of the health service market.

XIII. Report on the Community-Based Cancer Control Programs - Dr. William D. Terry

Dr. Terry reported that as a consequence of the position taken by the Board, DRCCA has proceeded with negotiations of the final period of these contracts and, with the exception of one of the contracts, is close to reasonable and equitable agreements. The overall consequence will be a savings, over the entire course of the program, of about $11 million. Of this, an estimated $4 million has been saved since May 1980.

A question was raised as to what would happen to these programs when their funding is cut off. Dr. Terry explained that some have already made arrangements to obtain state funding; all the programs are seeking funding from other sources for the most important portions of their work.

Dr. DeVita asked about differences in the phase-out of these programs. Dr. Terry said that the timing, as recommended by the Board, is such that each contract will run its full five years from the initiation of the contract. There has really been no change in phase-out time; the change is only in the level of support during the terminal period of the contract. Since the contracts are in different phases, the level of funding differs for each. It is anticipated that there will be requests for extensions from some groups as they approach their termination dates; the staff position is that the ordered phase-down should accomplish the process and that there should be no further extensions.

XIV. Report on the Use of Priority Scores in the Grant Review Process - Dr. Dennis Cain

The single most important factor in the decision whether a grant application coming to NCI will be funded or not is the priority score received by the application during peer review. There have been recent changes in the way these numbers are calculated and used in the funding system.

The grant applications receive their initial review for scientific merit in one of 110 NIH review committees. About 75 of these committees, referred to as "study sections," are within the Division of Research Grants. The study sections review the regular research grant applications, the new investigator awards, and the fellowship applications for all institutes. The other 35 committees are located in various institutes and divisions, and they review primarily large grant instruments or grant instruments peculiar to the missions of the specific institutes. NCI has six committees in the Grants Review Branch.

Each review committee has 15-20 members; each of the 75 initial review groups in DRG reviews 60-100 grant applications in each review cycle. Each reviewer develops a priority score to reflect his or her assessment of the scientific merit of every approved application. The combined average of these numbers is the raw priority score. A value of 100 is the highest priority score, while a value of 500 is the lowest.

A study of voting practices in the NIH study sections demonstrated that the mean priority score of grants awarded was 250. It was observed that the average priority score voted by different study sections varied significantly from this mean, and certain study sections characteristically voted better priority scores than others.

In earlier times, the role of the study section was to separate good research from bad. As the number of applications multiplied and competition became keen, the number of grants in the borderline area increased and funding decisions became more difficult. The Division of Research Grants developed a normalization procedure based on the premise that the average quality of the grant application coming to each review committee was approximately the same. Better or poorer priority scores related to the characteristic behavior of the particular group of reviewers. The normalization process was designed to transform the raw priority spectrum of each review committee to a standard distribution; this resulted in a normalized priority score. A line was drawn and applications with normalized priority scores above the mean were funded, with certain exceptions based on programmatic considerations. Up until October, every application that came to NCI had both the raw and the normalized priority score.

The normalization process was not universally accepted at NIH; half continued to use raw scores for funding decisions. The Grants Peer Review study team looked at the problem and recommended developing a single priority score system. Dr. Frederickson analyzed recommendations developed by a staff committee and directed that the normalization process be scrapped. He recommended that the raw priority score should be the NIH-wide convention for representing scientific merit. He believed that the normalization process did not adequately substitute for actual values voted by study sections but that each institute should determine how to relate the findings of one review committee to another. This decision was implemented in the last review cycle.

Program directors are again concerned with difficulties associated with trying to interdigitate raw priority scores from different committees. At present, no decision has been made concerning general NCI policy on this issue. During the current review cycle, program directors will receive computer printouts of approved applications; this may help them assess which mechanism provides a

better discrimination between better and poorer applications. Dr. DeVita and the division directors will eventually have to make a choice. It may be possible to use a combination of both systems and provide for individual program decisions for applications that fall into the gap between the systems.

Dr. DeVita indicated that currently NCI is using raw scores and a large dose of judgment by program directors over a range of 20-30 priority score points. After some discussion, it seemed the consensus of the Board was to continue this procedure.

XV. Discussion of a Proposal to Assess Leukemia and Thyroid Disease in Relation to Radiation Fallout in Utah

The Board was asked to act as a committee of the whole to provide concept review of a sole-source contract under consideration within the Office of the Director to study radiation fallout victims in Utah and surrounding states. Later there will be a prospective contractor's formal application which will be reviewed for scientific merit. The task of the Board was to review the proposed study for relevance to the mission of the NCI and for scientific need from the point of view of NCI.

Dr. Nygaard presented a case for the study. First, leukemia has a relatively low natural incidence, and this study should clearly demonstrate radiation-induced leukemia. Second, there is a significant likelihood of thyroid abnormalities resulting from radiation exposure. Dr. Nygaard expressed the belief that, at best, a study in this area could establish that there are indeed health defects of a certain magnitude resulting from fallout in the test areas. Two questions were posed to the Board: Is this study relevant to the function of NCI? Should the NCI proceed toward a contract?

In the discussion that followed, most Board members agreed that the concept was within the domain of the NCI and that information the study proposes to obtain could be useful. However, members expressed reservations about whether the proposed work was based on sound scientific procedures and whether the work could be done within the funding limit of $1 million over five years. Various people expressed fears that additional funding would be required over time and that the research, if done poorly, would be a bad reflection on the Institute. There were suggestions that perhaps this work should be opened to competition.

Finally, a motion was made and seconded to approve the concept of the study, recognizing the importance of the subject matter and the difficulty in passing it as a sole-source contract, conditional upon a limitation of funds, a peer review group with government employees barred from participation to avoid future charges of conflict of interest, and a review by the Board of the peer review material. The motion carried by a vote of 6 to 4.

XVI. Consideration of Minutes of the Board

The minutes of the previous Board meeting were approved without discussion.

XVII. Report of the Subcommittee on Centers and Construction - Dr. Maureen M. Henderson

The subcommittee met and carried out two items of business. The first was the review of the recommendations of the working group of the DRCCA Board of Scientific Counselors on the guidelines for grants for cancer centers. Dr. Henderson presented a draft of these guidelines, pointed out the major issues that had been considered, and asked for the Board's approval of the report. The Board approved, expressing appreciation to the staff, the Board of Scientific Counselors, Dr. Henderson, and other members who had worked on this task.

The second item of business carried out by the subcommittee was to review the status of the Colorado center and to agree that this center no longer meets the criteria for comprehensiveness. The report of the subcommittee was approved.

XVIII. Report of Subcommittee on Planning and Budget - Mr. Louis Carrese

In the absence of Dr. Frederick Seitz, this report was given by Mr. Carrese.

The 1982 Carter budget was reviewed and highlights presented. The 1981 budget had been passed in several versions, finally ending up at $996,347,000, including proposed pay supplements. The proposed NCI budget for 1982 is $1,041,761,000. Over the 1981 period, NIH extracted a 4.8 percent increase in budget, while NCI experienced a 0.2 percent decrease. During the 1980-1982 period, NCI will experience a 4.4 percent increase, compared to NIH's 12 percent increase in budget. NCI's share of the total NIH budget has been decreasing for the past few years: in 1980, NCI's share was 41.1 percent; in 1981, 27.7 percent; and in 1982, it will be 27.1 percent.

Some highlights for the 1982 NCI budget include: overall research increases from $823.4 million to $859 million (4.4 percent); Cause and Prevention, increase from $289.5 million to $294.7 million (1.8 percent); Detection and Diagnosis, increase from $57.7 million to $61.9 million (7.5 percent); Treatment, increase to $327 million (3.9 percent). These increases show a slow downtrend over a period of four or five years. Cancer Biology increased from $168 million to $175 million, an 8.9 percent increase, a change which reflects responses from the scientific community which will increase the bill for the funds for these strict projects, and also response for the RFAs. Cancer Control increased $55.9 million to $58.2 million, a 4.0 percent change, which will provide a base for restructuring program activities toward applied prevention in the new division.

The NIH policy of stabilizing R01s and P01s at a fixed number of 5,000 projects commands a large amount of funds off the top and in periods of decreasing budgets forces NCI to set priorities behind the stabilization of R01s and P01s. Some programs may not get funded at recommended budgets. NCI's position on the stabilization concept has not changed; we are in favor of the concept, but a percent increase rather than a fixed number of projects is preferred. In view of the decreasing budget, the Subcommittee recommended NCI consider conversion of P01s to R01s and re-establishment of a policy of not encouraging P01s to be used as add-ons to R01 projects. It was noted that this subject would be a major agenda item in a senior staff meeting planned for April 1981. Hearings on the 1982 budget requests are scheduled to start February 19 in the Senate; the House schedule is still uncertain.

In addition to the proposed recisions of the 1981 budget, there is one other tap on NCI resources: the assessment of $950,000 to continue the studies of health consequences to former residents of the Love Canal area. The Centers for Disease Control is submitting a proposal to Congress for the funds to complete the Love Canal Study, but until it is approved, NIH is contributing toward the study. Of the $950,000 NIH tap, NCI's share is $413,000, a disproportionate share.

XIX. Adjournment

The meeting was adjourned at 11:25 a.m., February 4, 1981.

Date

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