DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health
National Cancer Institute

NATIONAL CANCER ADVISORY BOARD

Minutes of Meeting
November 17-19, 1980

Place: Conference Room 6
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 Meeting1/
November 17-19, 1980

The National Cancer Advisory Board was convened for its 36th regular meeting at 8:30 a.m., November 17-19, 1980, in Conference Room 6, Building 31, National Institutes of Health, Bethesda, Maryland. Dr. Henry C. Pitot, Chairman, presided.

Board Members Present:

Dr. Amos
Dr. Henderson
Dr. Hickey
Mrs. Kushner
Ann Landers
Dr. Leffall
Dr. Pitot
Dr. Powers
Dr. Rowley
Dr. Samuels
Mr. Schrier
Dr. Seitz
Dr. Selikoff
Dr. Shubik
Dr. Mostofi

Board Members Absent:

Dr. Ames
Dr. Katterhagen
Mrs. Lombardi
Dr. Wogan

Ex Officio Members:

Dr. Donald Fredrickson, Director, NIH
Dr. Denis J. Prager, represented Dr. Frank Press, OSTP
Dr. Marguerite T. Hays, represented Dr. Donald Custis, VA
Dr. Faye Calhoun, represented Dr. Anthony Robbins, NIEHS
Dr. Yasumura Selichi, represented Dr. David Rall, NIEHS

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 iterest might occur. This procedure does not apply to "en bloc" actions.

Liaison Representatives:

Dr. Stefano Vivona, Vice President for Research Grant Awards, 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.

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.

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, Divisionn 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, partcipants, and invited guests, ten registered members of the public attended this meeting.

I. Call to Order and Opening Remarks - Dr. Henry 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 then introduced Dr. Selichi Yasumura, representing Dr. David P. Rall, Director, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina; and Ms. Faye Calhoun, representing Dr. Anthony Robbins, Director, National Institute for Occupational Safety and Health, Rockville, Maryland.

Dr. Pitot pointed out that this was a program review meeting and no grants would be considered. Voting would be an informal voice vote; if not unanimous, the vote would be by show of hands.

II. Future Board Meeting Dates

Confirmed:

February 2-4, 1981
May 18-20, 1981
October 5-7, 1981
November 30-December 2, 1981

III. Report of the President's Cancer Panel - Dr. Harold Amos

Dr. Harold Amos, Panel member, reporting for Dr. Joshua Lederberg, Panel Chairman, indicated that the Panel is still in the process of discussing its role in relation to the National Cancer Program as it has developed since 1971 and to the mission of the NCI. To aid the Panel in setting new directions, Dr. DeVita is reviewing with them the major NCI programs and concerns as well as his long-range views of the National Cancer Program. The Panel met with Dr. DeVita at NCI on November 12 and will meet again in December. They will present their first formal report at a future NCAB meeting.

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

Dr. DeVita reported on the following items:

A. Boards of Scientific Counselors

At the request of the National Cancer Advisory Board, Dr. DeVita met with the Board of Scientific Counselors (BSC) of each Division to discuss ways in which the NCAB could become more involved in the BSC review of contracts, especially concept review. Several steps will be taken to aid in this involvement:

1. Minutes of the BSC meetings will be sent to NCAB members, and discussions of concept review will be highlighted.

2. Review of NCI programs, which are presented at the November NCAB meeting, will now include an overview of each Division's programs, a report by the chairman of the Board of Scientific Counselors on new initiatives, problems encountered by each Division, and perhaps a detailed report on one specific program.

B. Budget

1980: NCI has committed essentially the entire $1 billion appropriation for 1980.

1981: NCI is operating under a continuing resolution which expires December 15 and will probably be extended until next spring. The current level of funding is $1,001,330,000—only a fraction above the 1980 level. Dr. DeVita explained the restraints that NCI is forced to impose on the funding of grants, especially R01's, P01's, cancer center, and core grants. He asked the Board for suggestions on alternate ways to distribute funds in this tight budget situation.

1982: NCI is expecting the OMB markup soon.

C. NCI Staffing

Six search committees were formed several months ago to find highly qualified people to fill vacant high-level positions in NCI. The one for Executive Officer has completed its business. Dr. DeVita announced that he has interviewed all the candidates and made a decision which is awaiting Departmental approval.

D. Report on Radiation Research at NCI

Dr. Oddvar Nygaard and David Pistenma have completed a report based on the findings of an NCI group that has studied how to best organize radiation research at NCI, especially low-level radiation. Division directors are now considering several options. Areas covered include radiation research in treatment and diagnosis. NCAB members will soon receive the report and are invited to comment on it. The report is a result of NIH participation in a Department-wide effort to examine radiation research and its potential dangers.

E. News Coverage

No major stories appeared over the last few months. However, coverage has been generally favorable and has included stories about accomplishments of the National Cancer Program.

F. Review of the Division of Resources, Centers, and Community Activities (DRCCA)

Dr. DeVita explained that the DRCCA was approved this past summer and will be discussed in detail during the rest of the meeting. The Division was organized to make more efficient use of funds by eliminating overlapping programs and to give NCI a focal point for applied efforts in cancer prevention. The Division is presently understaffed and must deal with a number of problems with no immediate solutions. It is appropriate for the Board to examine the Division at this early stage in order to suggest changes in organization and solution of problems.

V. Statement of Relationship between the National Cancer Advisory Board and the Boards of Scientific Counselors - Dr. Henry C. Pitot

Dr. Pitot asked Board members to comment on a statement of the relationship between the NCAB and the Boards of Scientific Counselors (BSC), which they had received earlier. The statement was prompted by the requirements of pending legislation for the NCAB to assume greater responsibility for review of contracts, now handled in great part by the BSC's. Dr. Pitot pointed out that the new Division of Resources, Centers, and Community Activities is establishing its own BSC that will be responsible for the concept review of contracts for many programs, including those on Organ Site and Centers. It is, therefore, important that the NCAB define its relationship with the BSC in order to be informed of contract matters and take action as needed.

In the discussion that followed, several points were emphasized:

1. The Boards of Scientific Counselors were established to meet the demands of a growing contract program as NCI began its rapid expansion in 1972.

2. The BSC plays an advisory role to the NCI Director with one exception: their decisions about concept review of programs are binding. On rare occasions, the NCAB or the NCI Director, in consultation with the NCAB, may take issue with a BSC decision and override it.

3. A standing invitation should be issued to members of the NCAB to attend meetings of the BSC's.

4. The statement of the relationship between the NCAB and the BSC is an effort to open the channels of communication. It does not diminish the authority of either group.

The statement, incorporating changes suggested by Board members, was unanimously approved by the Board. It reads as follows:

> In order to facilitate interchange between the National Cancer Advisory Board and the Boards of Scientific Counselors of the Divisions of the National Cancer Institute and to enhance the capabilities of the NCAB to carry out its mandated responsibility of monitoring programs and recommending policy of the National Cancer Plan to the Director of the NCI, the following recommendations are presented to the Director for formulation beginning in 1981.
>
> (1) Chairpersons of the Boards of Scientific Counselors (BSC) or their designates are invited to attend all meetings of the NCAB and its Subcommittees and shall attend the November meeting of the NCAB and participate in the Program reviews at that time. At this meeting, each chairperson will report on the year's activities of his/her BSC.
>
> (2) Copies of the minutes of each BSC meeting and those of their Subcommittees shall be forwarded to all members of the NCAB as soon as they have been drafted. The activities and policy recommendations of the BSC's should be clearly delineated in such minutes. These will be given the most serious consideration by the NCAB in decisions on policy and program. A standing invitation for members of the NCAB to attend the meetings of the BSC's has been given by the Director.

VI. <u>Ten Year Report on the National Cancer Program</u> - <u>Mr. Paul Van Nevel</u>

Mr. Paul Van Nevel, Associate Director for Cancer Communications, NCI, described the contents of the ten year report on the National Cancer Program, which documents the major accomplishments since the National Cancer Program was legislated in 1971, and indicates future research needs. The report, in the final stages of publication, is entitled, <u>Decade of Discovery: Advances in Cancer Research, 1970-1980</u>, It is geared toward a lay audience, and is divided into three sections.

The first section deals with treatment, and features accomplishments in childhood cancers and breast cancer. The second deals with prevention, and examines chemicals, lifestyle, and the environment. It includes studies of populations such as migrants and those at high risk to cancer; and testing for carcinogens. The third section highlights the latest developments in areas of basic research such as immunology, hybridomas, viruses, and DNA cloning.

Board members asked to receive a copy in order to suggest changes before final publication.

VII. Review of the Division of Resources, Centers, and Community Activities - Dr. William Terry, Acting Director, and Staff

Dr. Terry described the origin of the Division of Resources, Centers, and Community Activities (DRCCA) as part of the major reorganization of NCI initiated by Dr. Arthur Upton, former Director, to separate program review from program management. The Division serves as a focal point for the applied aspects of cancer prevention.

The organization of DRCCA was approved in August and the structure presented to the Board is a proposed one and has not been officially accepted. It consists of newly proposed programs as well as many from the former Division of Cancer Control and Rehabilitation and Division of Cancer Research Resources and Centers.

Dr. Terry pointed out that the new Division will have two budgets to contend with—cancer control legislated as a line item and other budget items. A discussion followed of the difficulty in defining cancer control in order to identify the projects that should be supported by control dollars.

In addition to the budget, the Division faces other problems. One has been the difficulty in deciding on the expertise needed for the 16-member Board of Scientific Counselors in order to satisfy the broad range of disciplines covered by the DRCCA programs. Dr. Terry asked Board members for their suggestions. Another has been understaffing, both in top-level management and scientific expertise, with the added difficulty of a hiring freeze. A third is poor condition of the work area.

Following Dr. Terry's introductory remarks, heads of the programs and branches of the Division reviewed the status of their areas and pointed out their individual problems and needs. The highlights of each of these presentations follow.

VII. A. Education Programs

1. Education Research and Evaluation Branch—Dr. Arlene Barro, Acting Associate Director for the Education Program; Acting Chief of the Educational Research and Evaluation Branch.

2. Mr. Thomas Kean, Special Assistant in the Office of Cancer Communications. Dr. Barro explained that, in addition to her Branch, the Program consists of the long-established Research Manpower and Clinical Manpower Branches. The Education Program serves to centralize the major NCI education programs.

The Educational Research and Evaluation Branch is now in the process of being established. Its purpose is "to test and evaluate specific approaches to cancer education in order to improve the quality of professional and health education in cancer." She briefly mentioned the Cancer Communications Network, which combines both professional and public education and serves as a resource for the comprehensive cancer centers; Mr. Kean later gave more details (see below).

To aid in future program planning, Branch members are now evaluating past and present NCI education programs throughout the Division.

Major topics of discussion raised by the Board included appropriate criteria to use for evaluation, the value of evaluation, avoiding duplication of past efforts by NCI and other organizations such as the American Cancer Society, education programs in cancer centers, and pay back policy for continuing education.

Mr. Thomas Kean described in detail the structure and function of the contract-supported Cancer Communications Network (CCN), initiated in 1975 as part of the National Cancer Program. It consists of individual offices located in each of the 21 comprehensive cancer centers to meet the public's need for cancer information and education. Combined service includes 28 states and the District of Columbia, covering about 70 percent of the U.S. population.

Mr. Kean explained the nationwide and community-oriented services and projects supported by the CCN, including the toll-free telephone Cancer Information Service. Periodic local users surveys indicate that the public is highly satisfied with the CCN, which now responds to almost 11,000 inquiries each month. He described the major problems now facing the CCN--first the need for a national evaluation in order to obtain ongoing management information and determine the national impact of the CCN. He noted that funds have been awarded by the Department

the progress of a special task force that is developing a technical plan for conducting it. There is also need for quality control of the information provided by the CCN; Mr. Kean described the steps taken so far to determine if the information is adequate and up-to-date.

Subsequent discussion by the Board covered restriction of the CCN offices to the comprehensive cancer centers, how to reach the 30 percent of the U.S. population not covered by the CCN, and ways to alleviate costs.

2. Research Manpower Branch - Dr. Barney Lepovetsky, Chief

Dr. Lepovetsky explained the broadly based, multidisciplinary nature of programs funded by grants from the Research Manpower Branch, as well as requirements for cancer-related activities under these programs. He then reviewed briefly the history of training awards at NIH, including passage of the National Research Service Awards Act of 1974, now the major support mechanism for training programs.

The programs include basic or applied, clinical or nonclinical research training in cancer cause and prevention, cancer detection and diagnosis, cancer treatment and rehabilitation, and cancer biology, and they support individuals at various stages of their career. Other programs, not covered by the National Research Service Awards Act, include Research Career Development, Research Career, and Veterinary Pathology Training.

Dr. Lepovetsky explained the pay-back provision of the National Research Service Awards. NCI has been involved in the liberalization of these terms, and data on awardees involved in pay-back. He explained the need for long-term stability of the training programs and how the pay-back provision may discourage M.D. trainees. The Branch now plans to establish a discrete training program in nutrition, an area in need of more research.

The Board's comments and questions pertained primarily to successful NCI-supported training of epidemiologists and radiation oncologists, possible over-training of medical oncologists, the limited number of physicians in clinical research, and the veterinary pathology program.

3. Clinical Manpower Branch - Dr. Margaret Edwards, Chief

Dr. Edwards explained that the Branch reviews and manages Clinical Cancer Education grants awarded to medical and dental schools and teaching hospitals to improve the quality and broaden the scope of coordinated, multidisciplinary cancer teaching efforts. She gave examples of some of the activities supported by these grants, reviewed the historical background of this long-established program, and explained how individuals qualify to receive support.

Dr. Edwards discussed the way in which Clinical Cancer Education grants are reviewed and evaluated by the program's own review committee. She described a series of workshops initiated in 1975 to review in depth various aspects of cancer education; and told of two contracts awarded for studies to help guide the program more effectively.

Dr. Edwards summarized the accomplishments of the program as follows: (1) support of clinical manpower areas of need; (2) increased exposure of undergraduates to cancer education; (3) development of integrated, coordinated approaches to cancer teaching; (4) strengthening of cancer education in neglected areas, especially nutrition, epidemiology, and prevention; and (5) introduction of concepts of program evaluation. She also described plans for future activities such as workshops in radiation oncology, pathology, and cancer rehabilitation, and activities directed toward nutrition education in medical shools.

Dr. DeVita stated that a Board of Scientific Counselors may compare grant programs from the Clinical Manpower Branch with the National Research Service Awards, under the Research Manpower Branch, in order to eliminate duplication of effort in the training area. He emphasized that this is necessary because of stringent budget requirements and enumerated the options available for dealing with the Clinical Cancer Education Program: (1) reduce the budget by 30 percent by dropping support of trainees while still maintaining the major strong point of the program—development of curricula; (2) phase out the entire program; (3) leave the program intact; or (4) fund the program with cancer control money and free research funds. Discussion followed on the value of the Clinical Cancer Education grants and benefit derived from them.

VII. B. Community Oncology Program

1. Cancer Centers Branch - Dr. Donald Pitcairn, Chief

Dr. Pitcairn spoke about the primary objectives of the Centers Program and types of centers which include laboratory cancer research, clinical cancer research, and comprehensive center. He explained that the NCI provides 77 percent and other NIH institutes 11 percent of funds for cancer centers.

Dr. Pitcairn described the principal activities of the Centers Branch. The first is management of core grants, an important mechanism of NCI center support that applies to major equipment and shared resources and services. He outlined the budget history of core grants and other types of support for centers, the application procedure, and how core applications are reviewed.

To preserve the primary purposes of the core grant, efforts have been made since 1978 to revise the 1976 guidelines. Both the NCAB Subcommittee on Centers and Construction and the new DRCCA Board of Scientific Counselors are reviewing this problem.

The second major activity of the Centers Branch is grant support of the Centralized Cancer Patient Data System (CCPDS), used to register individuals with operable malignancies who are patients in the 21 comprehensive centers. Data from the CCPDS are processed and evaluated by the contract-supported Statistical Analysis and Quality Control Center (SAQCC) in Seattle, Washington. Dr. Pitcairn discussed some of the studies being done with the data.

The third important responsibility for the Branch is the grant-supported Centers Outreach Program. Dr. Pitcairn detailed the purpose and fiscal history of this program, designed to enable centers to share their expertise and to cooperate with professional personnel and facilities in a community. Issues dealing with problems of the Outreach Program are now being reviewed by the Working Group on Cancer Control of the Board of Scientific Counselors.

Dr. Terry emphasized the importance of defining the goals of cancer control in order to clarify the role of centers, the community, and other organizations, and thereby enable the Outreach Program to fulfill its potential. He also commented on the early problems and present status of the CCPDS, indicating that the value of this system is still to be determined.

2. Research Facilities Branch - Dr. Donald Fox, Chief

Dr. Fox explained the purpose, authorization, and eligibility criteria for the NCI Construction Program. He also detailed the peer review of construction grants for safety and engineering factors, merit of the science, and need for the facility, explaining that all these criteria must be satisfied in order for a construction grant to be awarded. The NCAB Subcommittee on Centers and Construction then evaluates the grants and the full Board reviews them. With the establishment of the new Division, the Board of Scientific Counselors will also have a chance to evaluate construction grants after they have been considered by the NCAB. Dr. DeVita pointed out that this is an area where the roles of the NCAB and the BSC will have to be clearly defined, but that the NCAB remains the final authority for approval of grants.

Dr. Fox presented a funding and budget history of the Construction Program. He explained a survey taken two years ago by NCI staff, at the Board's request, to identify the national need for facilities for cancer research and presented data on the budgeting needs based on this survey.

To obtain construction funds from NCI, the applicant institution must match at least 50 percent of the money. Dr. Fox showed that the $11 million budget for fiscal year 1980 was distributed among nine institutions, whereas only $1 million is budgeted for FY 1981. NCI will make an appeal to OMB for more funds.

Some members thought the Board should make an official statement of their concern regarding the budget for construction, and personnel shortage of the new Division. Dr. DeVita explained that NCI's new executive officer will review personnel matters in terms of reallocation of slots.

3. Organ Sites Branch - Dr. Andrew Chiarodo, Chief

Dr. Gilbert Friedell - Director of the National Bladder Cancer Project
St. Vincent Hospital, Boston, Massachusetts (Headquarters)

Dr. Chiarodo presented an overview of the disease-oriented National Organ Site Program, initiated in 1972 to stimulate research activity and recruit new investigators into fields with exciting research leads not yet exploited. He explained the duties of the personnel in charge of an organ site program, including a project director, headquarters staff, and working cadre of scientists.

He then presented fiscal and programmatic analyses of the National Bladder Cancer Project, National Prostate Cancer Project, National Large Bowel Cancer Project, and the National Pancreatic Cancer Project. He discussed the areas of investigation, including therapy, diagnosis and detection, and cause and prevention.

Dr. Friedell first described some basic aspects of bladder carcinogenesis and pathogenesis, and discussed the importance of urologists in the management of cancer patients and the significant role they have played in development of the National Bladder Cancer Project (NBCP).

He outlined the history and development of the NBCP, which was initiated to encourage both laboratory and clinical research scientists in various disciplines to focus on the course of the disease and to integrate their efforts. He described the specific functions of the NBCP working cadre, headquarters staff, project director, and deputy project director, and emphasized their success in facilitating and encouraging communication between investigators in many different fields.

A lengthy discussion followed on how to reduce the cost of the National Organ Site Program. Board members suggested having the grants reviewed through the regular study sections instead of the working cadres; eliminating headquarters components; eliminating an organ site project after it had developed a sound research base; and cutting funds for the projects that do not depend heavily on the National Organ Site Program for support. Dr. Friedell expressed concern that some of these suggestions would jeopardize the communication and coordination that are essential to the continued success of the Bladder Cancer Project. Dr. Pitot asked that the Board Subcommittee on the National Organ Site Program review these issues and report at the next NCAB meeting.

4. Community Outreach and Rehabilitation Branch - Dr. William Terry, Acting Chief

Dr. Terry reviewed the status of the programs in this Branch, which are supported by contract and initiated in the former Division of Cancer Control and Rehabilitation. The first of these is the Outreach Program, which provides contract support for clinical cooperative groups to upgrade cancer therapy and rehabilitation in the communities. In some cases, these contracts have helped increase the flow of patients into cooperative group studies. However, it is difficult to measure the effect this program has had on the overall quality of care. The Division must decide if this type of activity should continue and if it could be taken over by other groups, such as the cancer centers. Dr. DeVita pointed out that this raises the problem of overlap in many of the areas supported by the Centers and Commmunity Oncology Program.

Dr. Terry next discussed the status of the Community Oncology Program (COP), designed to upgrade the quality of staging disease, treatment, and rehabilitation of cancer patients in the community, and the Community Hospital Oncology Program (CHOP), created to establish multidisciplinary oncology programs. Discussion centered on the value of keeping cancer patients in their community-based hospitals, and the value of sending patients with certain types of cancer to large research-oriented hospitals. Also discussed were how patient expenses are paid, and the Board of Scientific Counselors' suggestion for a bartering arrangement, whereby community hospitals receive support in exchange for participation in research studies.

The third program was one in which community-based contracts were set up in six different parts of the country to coordinate and integrate cancer activities among communities. Dr. Terry explained that at the midpoint of these five-year contracts, a group of reviewers suggested termination of three and reduced funding of the others. In May, the NCAB suggested that all six contracts continue for another 12 to 24 months with support only for projects of merit. Because it has been difficult for NCI staff to comply with the Board's request, Dr. Terry urged a restatement of the Board's wishes based on negotiations thus far. Board members, in turn, requested a detailed status report at the next meeting, and several recommended that the three contracts be terminated.

VIII. C. Prevention Program

1. Preventive Medicine Branch - Dr. Richard Costlow, Chief

Dr. Costlow reviewed the status of the projects managed by the Preventive Medicine Branch, which involve demonstrations of screening procedures, populations at risk, promoting proven techniques, and human carcinogens. They are supported mainly by contracts, but there are a number of grants and a few interagency agreements.

The largest of the screening and diagnosis projects is the Breast Cancer Detection Demonstration Project (BCDDP), initiated in 1974 and cosponsored by the American Cancer Society. Dr. Costlow presented preliminary findings from the BCDDP, which is currently being phased out, and discussed related ongoing studies, including assessment of risk factors, long-term follow-up of BCDDP participants, predictive value of Wolfe classification mammogram patterns, and pathology of breast cancer.

Dr. Costlow then reviewed the projects on female pelvic cancer detection, including the Cervical Cancer Screening Project, also being phased out; endometrial cancer detection; and effects of DES exposure during pregnancy.

Projects are also being supported in cancer prevention education. The largest segment of the latter category involves the establishment of six centers for radiological physics that deal with matters such as accuracy of radiation treatment machinery and the proper function of radiology diagnosis equipment in order to minimize exposure and improve image quality.

Discussion centered on the publication of Branch-supported monographs dealing with carcinogenic agents. Board members expressed concern that the monographs duplicate data published by other government agencies. Dr. Costlow pointed out that the NCI monographs on vinyl chloride, asbestos, and DES deal with prevention aspects of the agents and thus do not duplicate other documents. Care is being take to evaluate the needs and avoid duplication.

2. Behavioral Medicine Branch - Dr. Sandra Levy, Acting Chief

Dr. Levy presented the historical development of behavioral medicine and pointed out that it has been a formally recognized area of research at NIH since 1977. She described the current position in her Branch and the program scope, giving examples of projects supported by grant or contract. In the area of prevention/detection, one project deals with motivating breast self-examination and another with prevention of smoking in adolescents. In the area of treatment, there is a study of anticipatory nausea and vomiting in patients receiving chemotherapy and one on the value of peer help for discharged patients. Research projects being carried out within the Branch include staff stress in a hospice environment and survival time in metastatic breast cancer patients.

In addressing future progam activities, Dr. Levy described a Request for Grant Application (RFA) concerned with patient compliance with therapeutic regimens. She explained that emphasis will be placed on prevention and health maintenance research—modifying addictive behavior, changing dietary habits, altering worker behavior in the face of carcinogen exposure, developing effective counseling and intervention techniques, and the natural history of behavior problems related to disease.

Dr. Levy explained that initial peer review of grants is by either the Cancer Control Grant Review Committee, which is understaffed in behavioral scientists, or the Behavioral Medicine Study Section, understaffed in scientists with expertise in cancer. She indicated that this is an issue which must be resolved. The Board discussed the pros and cons of supporting a program in behavioral medicine in light of the limited budget, the mission of NCI, and the success of such research in controlling other diseases.

3. Occupational Medicine Branch - Dr. Margaret Sloan, Acting Chief

Dr. Sloan described the role of NCI in the field of occupational medicine, taking into account the other government agencies responsible for various aspects of occupational and environmental health, including cancer. She highlighted

the ongoing programs initiated in the former Division of Cancer Control and Rehabilitation. These included the education of workers about occupational cancer hazards through interagency agreement with the Occupational Safety and Health Administration (OSHA): education of health professionals through a series of conferences; development of a form for use by physicians to take better occupational and environmental histories; and a large asbestos program to educate health professionals, workers, and the public about the health hazards of asbestos and to help solve the problems of asbestos in school buildings.

Dr. Sloan expressed the opinion that the Branch should continue to interact with other government agencies and private organizations and should serve as an information resource for the other DRCCA branches, for all Divisions of NCI, and the other Institutes of NIH. Some areas being considered for support include refinement of data on cancer risk; joint efforts with the National Institute of Occupational Safety and Health and OSHA; development of educational materials for health professionals and workers; and field trials of chemopreventive agents.

Dr. Sloan briefly mentioned two areas of concern--the need to assure appropriate review of grants and contracts, and the possibility that NCI may need to pay for examinations of individuals at high risk who participate in medical surveillance programs and have no other source of funds.

VII. D. Smoking, Cancer, and Health Program

1. Overview - Dr. Diane Fink, Coordinator

Dr. Fink explained that the NCI-wide Smoking, Cancer, and Health Program is now coordinated in the Office of the Director and is being considered for inclusion in the new Division of Resources, Centers, and Community Activities (DRCCA). She presented a history of the NCI smoking research program, initiated in 1968, and highlights of the program activities during fiscal year 1980.

The Division of Cancer Cause and Prevention has a prime contract which provides support and management of their Smoking and Health Program through use of subcontracts. These are now being phased out, and a program announcement has been issued in an effort to emphasize investigator-initiated, grant-supported research in this area.

A Department-wide effort was initiated in 1979 to coordinate all smoking programs in about 12 different agencies including NIH. Dr. Fink described some of the interagency coordinated activities designed to deal with potential overlaps, and the budget for smoking and health projects throughout NCI.

2. Smoking Programs of the Division of Cancer Cause and Prevention (DCCP) - Dr. Donald Luecke, Chief, Special Programs Branch

Dr. Luecke presented details of the prime contract let in 1968 to administer the DCCP Smoking and Health Program, and explained the role of the Tobacco Working Group, established as an advisory body. Three major objectives of the Program were the production of a less hazardous cigarette, identification of persons at increased risk of tobacco-related disease, and pharmaceutical intervention of controlling smoking behavior.

Development of a less hazardous cigarette was given the highest priority until 1978, but is no longer a goal of the program. During the past two years, epidemiological and pharmacological approaches have been emphasized. Dr. Luecke summarized the studies now being funded in these areas, supported by various contracts and four interagency agreements.

Dr Luecke also explained the effort to seek investigator-initiated grants in the area of smoking and health by issuance of a program announcement in January, cited the research areas in need of attention, and summarized the grants received by the Special Programs Branch during fiscal year 1980 and 1981.

Board members subsequently presented their views, on the now disbanded Tobacco Working Group, which included members of the tobacco industry. Mr. John Pinney, Director, Office of Smoking and Health, then explained that the NCI decision to stop supporting the development of a less hazardous cigarette was based on a decision by the Secretary of DHEW and the Surgeon General to stop such efforts and concentrate on "understanding the actual effects those cigarettes have had on disease." The Government is negotiating with cigarette companies for a confidential disclosure of cigarette additives.

3. Smoking Programs of the DRCCA - Dr. Sandra Levy, Acting Chief, Behavioral Medicine Branch

Dr. Levy explained that the need exists for research on the process of becoming a smoker and maintenance of smoking behavior in order to develop more effective intervention techniques. She reviewed the history of support for such research and showed a series of slides describing the DRCCA grants and contracts dealing with smoking behavior, and indicated future program emphasis.

4. Smoking Activities in the Office of Cancer Communications (OCC) - Mr. Robert Denniston, Chief, Information Projects Branch

Mr. Denniston described various OCC projects designed to help smokers who want to quit. The major ones include three kits developed in conjunction with other organizations for physicians, dentists, and voluntary community groups to inform individuals on how to stop smoking; a booklet entitled Smoking Programs for Youth; a smoking and health bibliography; information on smoking policies in the work place and development of stop-smoking programs; activities directed at smoking and minorities; and assistance to the press and other organizations.

5. The Changing Cigarette - Dr. John Holbrook, Assistant Professor of Medicine, University of Utah Medical School

Dr. Holbrook reported on the status of the changing cigarette and the populations who are smoking. He summarized the Surgeon General's reports of 1964, 1979, and 1980, which include topics such as the relation between smoking and certain diseases, the alarming increase in lung cancer incidence in women, and the effects of passive smoking in nonsmokers.

He then discussed a conference held in 1980 to deal with two major questions: (1) the relative health risk associated with smoking cigarettes of various nicotine, tar, and carbon monoxide content; and (2) the health risk of cigarettes that contain additives. The conference was held as a result of the 1978 Health Services and Centers Act, requiring the Secretary of Health, Education, and Welfare to conduct or arrange for studies of these two questions.

Discussion centered on the alarming rise in lung cancer incidence in women despite the development of low tar and nicotine cigarettes. It was pointed out that there are problems in comparing data from low tar and nicotine cigarettes of the 60's with those of today because the cigarettes are now made differently; that the sharp increase in women smoking began about 1955; that data we have now are based on populations that began smoking before 1960; and that there is a great need for more up-to-date studies.

VII. E. Diet, Cancer, and Nutrition Program

1. Dr. Diane Fink - Coordinator

Dr. Fink briefly described the history of nutrition research at NCI from its official designation as a program in 1974, when it was administered by the Division of Cancer Cause and Prevention, to its development into an NCI-wide program coordinated in the NCI Director's Office. Along with the Smoking, Cancer, and Health Program, it is being considered for incorporation into the new Division.

She then reviewed the budget of the Diet, Nutrition, and Cancer Program (DNCP), pointing out that support has increased for grants but decreased for contracts. The Research Analysis and Evaluation Branch analyzes all grants and contracts to determine the percentage of nutrition research in each project.

2. Diet, Nutrition, and Cancer Treatment - Dr. William DeWys, Head, Nutrition Section and Acting Chief, Clinical Investigations Branch, Division of Cancer Treatment

Dr. DeWys explained that Division of Cancer Treatment (DCT) grant-supported research in nutrition began in 1978, when staff developed specific referral guidelines. The three areas being supported by grants are pathophysiology, nutritional assessment, and intervention. He then described two of the projects in detail--one dealing with the Cori cycle in cancer patients and the other with anorexia in cancer patients receiving chemotherapy in relation to learned aversions. He described the history and development of the contract program initiated in 1976, and also projects in the three areas supported by grants. Dr. DeWys then described some of the intramural nutrition projects. He noted the multidisciplinary nature of nutrition research and the challenge to bring these disciplines together in meaningful collaboration.

3. Diet and Nutrition in the National Organ Sites Program - Dr. Andrew Chiarodo, Chief, Organ Sites Branch

Dr. Chiarodo presented a breakout of grant-supported research in each of the four organ site projects. The National Large Bowel Cancer Project supports studies in the areas of epidemiology, diet and flora, dietary inhibitors, fecal sterols and bile acids, mutagens, and carcinogenesis. The National Bladder Cancer Project, involves studies in epidemiology and carcinogenesis, and the Pancreatic and Prostate Cancer Projects, epidemiology. Dr. Chiarodo closed by saying that multidisciplinary cooperation has been achieved in these studies.

4. Diet, Nutrition, and Biology and Diagnosis - Dr. Elizabeth Anderson, Chief, Epidemiology Projects Section, Breast Cancer Program Coordinating Branch, Division of Cancer Biology and Diagnosis

Dr. Anderson reviewed nutrition studies in the Division of Cancer Biology and Diagnosis (DCBD). She described intramural research projects that deal with the study of Vitamin A and retinoids, dietary lipids, and cachexia. She then gave a broad overview of the extramural research with emphasis on nutrition, supported by two branches of DCBD. The Breast Cancer Program Coordinating Branch supports, primarily by contract, the Breast Cancer Prgram, which includes studies in epidemiology and experimental biology. The Cancer Biology Branch encompasses two grant-supported programs that include research in nutrition—the Tumor Biology Program and the Immunology Program.

Dr. Anderson announced that the Epidemiology Working Group of the Breast Cancer Task Force, in conjunction with the DNCP, will hold a workshop to hear reports from the earliest studies on the relation between breast cancer and diet. She expressed the need for studies in the area of benign breast disease in relation to diet and potential for progression to cancer.

Discussion followed on the possibility of examining, for breast cancer incidence, several groups of Europeans who survived World War II, some of whom have already been studied for occurence of heart disease.

5. Diet, Nutrition, and Cancer Cause and Prevention - Dr. Appasaheb Patel, Program Director for Diet and Nutrition, Division of Cancer Cause and Prevention

Dr. Patel summarized some of the extramural nutrition-related activities. He also described the two clinical nutrition research units, which are supported jointly by NCI, the National Institute of Arthritis, Metabolism and Digestive Diseases, and the National Institute on Aging.

Dr. Patel explained that only 18 percent of nutrition and carcinogenesis grants are being funded because of poor proposal design. He therefore held a meeting of experts in each field to discuss the significance of diet in carcinogenesis and determine ways in which such proposals can be improved. Proposed new areas of research include natural carcinogenic products on food and improved techniques for detection and characterization of these carcinogens.

6. Dr. Regina Ziegler - Nutritionist Environmental Epidemiology Branch, DCCP

Dr. Ziegler highlighted some of the recently initiated efforts in the Field Studies and Statistics Program of DCCP. She reviewed the studies designed to test in human populations hypotheses generated by animal experiments or by other epidemiological studies, to explain unusual geographical patterns of cancer risk pointed out by U.S. cancer maps, studies that develop and utilize national data resources, and studies on migrants and their changes in environment, lifestyle, and cancer risk.

A discussion followed on validity of results of the NCI study on saccharin in relation to bladder cancer, and the problems involved in nutritional epidemiologic studies. Some Board members pointed out the need for a workshop to determine the most fruitful research approach to the question of dietary fats, fecal mutagens, nitrosamines, and bile acids in relation to the development of cancer.

In her closing remarks, Dr. Fink indicated that one of the major aims of the DNCP is to hold about six workshops this year similar to one held in 1980 to discuss fats and cancer. She reviewed the grant support of nutrition and cancer research for 1979 and 1980, pointing out the need to attract more qualified investigators to the field. Dr. Fink presented three possible ways to meet this need, all dealing with ways to educate and train clinicians and research scientists.

Dr. Edwards and Dr. Lepovestky commented on the role of the Clinical Manpower and Research Manpower Programs in these efforts. Dr. DeVita suggested that three or four Board members meet with Dr. Fink to deal with some of the issues in the DNCP and perhaps form a Board subcommittee.

VIII. Closing Remarks

Dr. Shubik made a few remarks in behalf of the Tobacco Working Group to clarify any misconceptions that may have developed from critical discussions the day before and suggested that the Board consider the valuable resources in industry in the future. Dr. Pitot asked Dr. Shubik to put his comments in writing for the record. Dr. DeVita pointed out that the NCI has very strong links with industry, especially the drug industry.

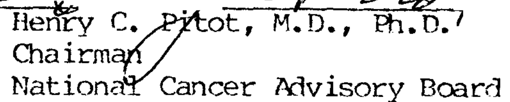
Dr. DeVita thanked NCI staff for their presentations and asked the Board for their suggestions on the new Division of Resources, Centers, and Community Activities. Dr. Pitot closed the meeting by thanking Dr. Terry and other speakers on the agenda.

IX. ADJOURNMENT

The meeting of the Board was adjourned at 11:30 a.m., February 4, 1981.

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:

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