National Institutes of Health

National Cancer Institute

NATIONAL CANCER ADVISORY BOARD

Minutes of Meeting May 17-19, 1982 Building 31 Conference Room 6 NIH Campus Bethesda, Maryland

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

### Minutes of Meeting\* May 17-19, 1982

The National Cancer Advisory Board convened for its 42nd regular meeting at 8:30 a.m., May 17, 1982, in Conference Room 6, Building 31, National Institutes Health, Bethesda, Maryland. Dr. Henry C. Pitot, Chairman, presided.

### Board Members Present

#### Dr. Amos

Dr. Henderson

Dr. Hickey

Dr. Katterhagen

Mrs. Kushner

Ann Landers

Dr. Leffall

Dr. Pitot

Dr. Powers

Dr. Rowley

Mr. Samuels

Mr. Schrier

Dr. Seitz

Dr. Shubik

#### Board Members Absent

Dr. Ames

Dr. Selikoff

Dr. Wogan

### Liaison Representatives

Dr. Joseph F. Albright, Program Director, Cellular Physiology Program, National Science Foundation, Washington, D.C., representing Dr. Antonie Blackler.

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

### Ex Officio Members

Dr. Victor Alexander, Labor

Dr. Ken Bridbord, NIOSH

Dr. Richard Marland, EPA

Dr. Denis Prager, OSTP

Dr. David Rall, NIEHS

Representatives of the President's Cancer Panel

Dr. Amos

Dr. Fisher

Dr. Hammer

<sup>\*</sup> 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.

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

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

Dr. J. W. Thiessen, Acting Deputy Associate Director, Office of Health and Environmental Research, Department of Energy, Washington, D.C., representing Dr. Charles W. Edington.

#### Members, Executive Committee, National Cancer Institute

Dr. Vincent T. DeVita, Jr., Director, National Cancer Institute

Dr. Richard Adamson, Director, Division of Cancer Cause and Prevention

Mr. Philip D. Amoruso, Executive Officer, NCI

Mrs. Barbara Bynum, Director, Division of Extramural Activities

Dr. Bruce Chabner, Acting Director, Division of Cancer Treatment

Dr. Peter Fischinger, Associate Director, NCI

Dr. Peter Greenwald, Director, Division of Resources, Centers, and Community Activities

Dr. Jane Henney, Deputy Director, NCI

Dr. Alan S. Rabson, Director, Division of Cancer Biology and Diagnosis

In addition to staff, participants, and invited guests, 19 registered members of the public attended the meeting.

### I. Call to Order and Opening Remarks - Dr. Henry C. Pitot

Dr. Pitot called the meeting to order and welcomed members of the Board, the President's Cancer Panel (PCP), liaison representatives, guests, and observers. He welcomed Dr. Lorenzo Tomatis, Director of the International Agency for Research on Cancer who later addressed the Board; and Dr. Richard Marland who was sitting in for Dr. John Todhunter of the Environmental Protection Agency.

Dr. Pitot welcomed members of the public and announced that anyone wishing to comment on items discussed in open session could do so by submitting written statements to the Executive Secretary of the Board within ten days after the meeting. Statements by members of the public will receive careful consideration.

After briefly reviewing the procedure for the conduct of Board meetings, Dr. Pitot reminded Board members of the confirmed meeting dates of October 4-6, 1982, and November 29-December 1, 1982, and four proposed meeting dates of February 7-9, May 16-18, October 3-5, and November 28-30, 1983. No objection was made. Dr. Pitot then invited Dr. Armand Hammer, Chairman of the PCP, to give his report.

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

Dr. Hammer described the PCP meeting, which took place at the Harvard School of Public Health in Boston on March 29, 1982. This meeting was the first held outside the Washington/Bethesda complex. He also announced that the next PCP meeting will be held at the UCLA Jonsson Comprehensive Cancer Center in Los Angeles on June 22, 1982.

The Executive Secretary of the PCP, Dr. Elliott Stonehill, prepared a written account of the meeting for distribution to Board members and others. The Panel addressed peer review and the grants process. NCI has achieved a system that, in general, works to the benefit of the National Cancer Program (NCP) and its participants, although there is concern for difficulties faced by young investigators and research proposals that are "off the beaten track." The PCP shares the concern of the new NIH Director, Dr. Wyngaarden, over maintaining stability in support of investigator-initiated grants in the face of budget restrictions. Creative solutions must be found.

Dr. Hammer and Dr. DeVita recently participated in a session at Stanford University which marked 20 years of progress against Hodgkin's disease. Advances in this area, and in treating lymphoma-B with antibodies made under the hybridoma process are evidence of the NCP's success.

### III. Consideration of Minutes

The minutes of the February 1, 2, and 3, 1982, NCAB meeting were approved with no changes.

### IV. Report of the Director, National Cancer Institute -Dr. Vincent T. DeVita, Jr.

Staff Appointments. Dr. Wyngaarden was sworn in as NIH Director on April 30th. He has met with NCI staff to discuss budget proposals for FY 1984.

The NCI has completed the search for the Director of the Division of Cancer Treatment (DCT). Appointments within the Division of Resources, Centers, and Community Activities (DRCCA) include Dr. Jerome Yates, Associate Director, responsible for Centers and Community Activities; and Dr. Joseph Cullen, Deputy Director. Dr. Robert Freilich will be involved in the operation of the Community Cancer Oncology Program (CCOP). Dr. DeVita also introduced Dr. Mary Knipmeyer, who recently joined NCI as the Legislative Analyst.

#### Board Followup Items.

- (1) No further word concerning the selection of new Panel and Board members has been received.
- (2) The task force report on the NCI drug development process was submitted to the Assistant Secretary of Health; NCI has commented on it. Most recommendations had already been implemented. A new GAO investigation into informed consent and patient safety has been initiated by Senator Paula Hawkins.
- (3) NCI staff have met with practicing physicians in several workshops to discuss the CCOP Program. Some confusion persists about the types of projects to be funded; however, all questions about the program have now been raised.
- (4) The Director of NIH has announced the formation of the Frederick Cancer Research Facility Advisory Committee. The source evaluation group is reviewing the Frederick contract competition and expects to arrive at a slate of competitors this summer.
- (5) The National Cancer Institute, with contributions from the Departments of Defense and Energy, has signed a contract to analyze the effects of radiation fallout in Utah.
- (6) The November program review will follow the format used by Dr. Richard Adamson in the Division of Cancer Cause and Prevention (DCCP). Included in the review will be a discussion of funding grant exceptions below the payline.

#### New Items.

- (1) Secretary Schweiker discussed the NCP with the NCI Executive Committee on May 12. The cordial meeting focused on prevention, including the discovery of the human T-cell lymphoma virus, the reshaping of DRCCA's mission, the CCOPs, and new clinical research units.
- (2) New guidelines have been developed for review of NCI's intramural program. Some controversy has arisen over the demand that Branch Chiefs show their budgets to site visitors.
- (3) The National News Council characterized the <u>Washington Post</u> series on NCI as "marred by sensationalism" and the "20/20" series as "falling short in accuracy and responsibility."

Legislation. Dr. Mary Knipmeyer, NCI's new Legislative Analyst, gave an update on legislation affecting NCI. Authorization legislation, the Senate Bill, S-2311, was introduced by Senator Orrin Hatch on March 30, 1982, and reported out of committee in April. Floor action has not been scheduled. This Bill, which is supported by DHHS, calls for a 6 percent authorization over the 1982 level and has various provisions specific to NCI, including deletion of the payback requirement for National Research Service Awards and institution of an appeals mechanism for the grants process. Senator Moynihan may propose an amendment establishing the Organ Site Task Force as a non-governmental research institution. The line item for this program would be \$20,000,000 for FY 1983, \$20,100,000 for FY 1984, and \$21,100,000 for FY 1985.

The House Bill, introduced by Representative Henry Waxman, is now in full Committee workup; it may be divided into several separate bills. It proposes an NIH budget approximately 6 percent above the FY 1982 level. It includes several specifications directly relevant to the NCAB: members could be reappointed 2 years after their term expires, the NCI Director would make the reports previously made directly by the NCAB, and ex officio members would be given a vote. The bill would also establish an Office of Prevention in the Director's Office of each Institute, and create the position of Assistant Director for Prevention in the Office of the Director, NIH. NCAB review would be mandatory for all contracts over \$500,000.

Budget. NCI is developing its FY 1984 budget with NIH. The FY 1983 budget represents a 1.3 percent increase over the 1982 budget after the 4 percent cut was made. The 1982 budget, as proposed by the President, was \$1,260,000,000; this was an increase from \$989,000,000 but was reduced to \$986,000,000 after the 4 percent cut. At the \$1,260,000,000 level, the competing grants pool was \$99,000,000, which would have allowed NIH to fund 4,700 new grants. An NIHwide decision cut 4 percent from the non-competing grants pool, leaving it with a budget of \$258,000,000, while the budget for competing grants was first cut to \$88,205,000, then raised to \$98,475,000. Again at the \$1,260,000,000 level, the line item for contracts was \$160,637,000, down from \$238,000,000 in 1980. However, after the 4 percent cut, this figure was reduced to \$147,000,000. The budget for intramural programs at the original level was \$127,000,000; NCI took a 1 percent cut in supplies and a 3 percent cut in salary to accommodate the 4 percent cut. The actual intramural budget is \$119,000,000, down 6.1 percent. The research community has expressed concern over the NCI budget figures, but this is often a result of distortions created by the shifting budget levels. To counteract the confusion, the Office of the Director may send a communique to grantees, explaining the budget situation.

At the projected 1983 level of increase, NIH will only be able to fund 4,100 grants. At its February retreat, the NCI staff decided to raise the grant pool allotment by 5.5 percent, and hold the increase in intramural funds to no more than 4 percent. The non-competing grant pool in the President's budget is \$252,519,000; under these assumptions, it will increase to \$258,165,000. The competing pool will increase to \$115,470,000 from \$107,564,000, and the intramural funding increased from \$132,510,000 to \$124,636,000. The contract pool will be \$136,808,000. It should be noted that the average recommended increase in research project grants, including ROIs and POIs, was 44 percent.

NIH has switched to raw priority scores, which are approximately 30 points lower than normalized scores. NCI is currently funding to a raw score of 180 (normalized score 210). It was decided to pay non-competing grants at the 4 percent reduced level, pay competing renewals at the previous year's level plus an 8 percent cost of living increase, and fund new grant applications at the recommended level minus 4 percent. This created distortions and drew complaints; the NCI Executive Committee is considering requests for exceptions totaling some \$8,000,000, of which \$2,000,000 have been paid. NCI decided to stretch available money over as many grants as possible, rather than simply pay until the money runs out.

Questions and Answers: The NCAB was asked to decide whether some \$5,000,000 available for the grant pool should be used to pay exceptions or to change the payline from 180 to 185. After considerable discussion, Dr. Seitz's motion in favor of paying exceptions was defeated; a motion by Dr. Powers to use existing monies on a sliding scale within the existing payline to augment reduced grants died without a second; and a motion by Dr. Henderson to extend the payline was carried 10-3.

# V. Report on the International Agency for Research on Cancer Activities (IARC): Objectives and Functions - Dr. Lorenzo Tomatis

With a current staff of 128 and situated in Lyon, France, the IARC was created in 1965 by the World Health Organization (WHO); it currently has 12 member countries with an annual budget of approximately \$8,000,000. General policy is controlled by a Governing Council comprising one representative from each member country and one from WHO; the scientific program is reviewed by a 12-member Scientific Council.

The IARC's primary focus is on environmental carcinogenesis and the search for etiological clues; its main objective is to generate and disseminate information. Studies are international in scope and significance, and follow four main directions: 1) collection, critical analysis, and dissemination of information useful for cancer control and prevention; 2) epidemiological studies on cancer etiology; 3) laboratory work concentrated on experimental test development and studies aimed at determining the significance of experimental results to the assessment of human risk; and 4) an educational program for cancer research. Under the first group activities, IARC publishes the series "Cancer Incidence in Five Continents"; the fourth volume will appear in the summer of 1982. The Agency also gathers, evaluates, and selects methods to detect and analyze carcinogens in the human environment, and publishes the IARC Monograph Series, which critically reviews carcinogenicity of chemicals; NCI currently shares the cost of producing this series. Chemicals are grouped according to whether they are carcinogenic to humans, are probably carcinogenic, or could not be classified. Under the second group of activities, IARC studied nasopharyngeal carcinoma, concluding that poor diet and opium use, rather than carcinogens, alcohol, or tobacco, were contributing factors, and Burkitt's lymphoma, which explores the roles of Epstein-Barr Virus and/or cytogenic changes. second group of activities also covered studies of occupational risks and the long-term effects of therapeutic radiation. The third activity group, covering laboratory work, has concentrated on developing a network of collaborating national laboratories testing environmental chemicals, developing criteria to

assess experimental carcinogenicity data from humans, and developing methods for monitoring human subjects for endogenous formation of carcinogens, especially  $\underline{N}$ -nitroso compounds. The educational activities include fellowships, courses, and scientific communication. Priorities for the future include developing programs on the role of nutritional factors in carcinogenesis, creating a network of national centers to test hypotheses internationally, and reviewing collections of human biological specimens.

Questions and Answers. A letter from Congressman David Obey had suggested that NCI might have interfered with the publication of the IARC monograph on benzene or raised questions on how to accumulate the data. Dr. Tomatis and Dr. DeVita stated that NCI's questions were confined to the feasibility and appropriateness of making quantitative risk assessments. The Committee on Environmental Carcinogenesis was charged with looking into the issue and reporting on the most up-to-date methodology of quantitative risk assessment in the human. The Committee will not consider Mr. Obey's comments.

### VI. NCAB Annual Report - Mr. Paul Van Nevel

The Activities and Agenda Subcommittee has recommended that the Annual Report be made more interesting and readable by devoting two-thirds to three-quarters of it to a topic of high interest, with better typeface and illustrations, while covering the routine report of NCAB activities in the remaining portion. Possible topics are cancer and minorities, nutrition, prevention, and control. The NCAB was asked to decide whether to change the format and, if so, what topic to address.

Questions and Answers. The cost of adding a new section would be minimal; funds would not be taken from the grant pool. After discussing the scope of a new section, the Board voted to change the format for the 1982 report, with the special section devoted to projections of what activities will be most significant, and to issue a report focused on one subject in 1983. The experimental version will be given to the NCAB at its November meeting.

# VII. Resolution Concerning Mrs. Marie Lombardi - Ms. Ann Landers

The following resolution was passed unanimously by the Board:

Mrs. Marie Lombardi, wife of the late Vincent Lombardi, died at her home in Florida on April 17, 1982. When Vincent developed cancer, he was treated at Georgetown University Hospital. In recognition of his great courage the Cancer Center at Georgetown was named for him.

Marie Lombardi served as an advisor for cancer control activities at Georgetown and in Florida.

Following his illness, Marie served as a member of the National Cancer Advisory Board, to which she was appointed on August 11, 1976, by the President.

Therefore, the members of this Board wish to express gratitude to the family of Marie Lombardi for her contributions over the years.

# VIII. Report of the ad hoc Subcommittee on Nutrition - Dr. Maureen Henderson

The ad hoc Subcommittee presented its report at the February NCAB meeting. Implicit in the recommendations of that report was that one person at NCI be responsible for managing the overall nutrition program. It is now crucial that NCI achieve vigorous scientific results in this area, especially since unproven information is being given to the public.

Questions and Answers. The Task Force proposed in the report should have representation and collaboration with the NIH Central Committee on Nutrition. The National Academy of Sciences (NAS) will deliver its recommendations for research programs in June; the report is based on published literature only and does not include ongoing research. The second phase of the report, due in June 1983, will make further recommendations. There is little overlap between NAS's work and that of the proposed Task Force. Accepting the report constitutes endorsement of a funding request and of establishing the Task Force. The NCAB voted 12-0, with one abstention, to accept the report.

IX. Report on the Division of Extramural Activities (DEA) Review Process and the Division of Research Grants (DRG) Panel Discussion - Mrs. Barbara Bynum, Dr. Stephen Schiaffino, and Dr. Louis Angelone

The DRG does not make awards, only receives applications, conducts scientific review, and makes recommendations. At the DRG, an application is first read thoroughly by a Referral Officer, all of whom are experienced Executive Secretaries, who assigns the application to the appropriate Study Section. The Executive Secretary of each Study Section checks that the application is appropriate for his Study Section, and, if necessary, consults with the investigator and brings in ad hoc members if additional expertise is needed. Study Section members are chosen by the Executive Secretary, and DRG maintains records of competency areas for all Study Section members. Executive Secretaries screen members to ensure that no conflicts of scientific opinion exist between a reviewer and a particular applicant. A referral handbook for Study Section members is constantly updated.

Questions and Answers. The review process is not adversarial. DRG is attempting to get Study Sections to increase the time of award, or justify any decreases, to approve more innovative projects, to increase the number of clinical projects approved, and to formalize appeals procedures. Applications that address the transition of laboratory research to clinical research are reviewed by Study Sections comprising both laboratory and clinical researchers. DRG has a Statistics and Analysis Branch which can generate data on a wide variety of topics related to applications.

# X. Resolution Concerning Restricted Authorizations - Dr. Maureen Henderson

The following resolution was unanimously adopted by the Board:

The National Cancer Advisory Board reiterates its objection to any introduction of authorization for appropriations within the budget of the National Cancer Institute restricted to the support of individual programs. This procedure limits the flexibility that is essential for sound fiscal and scientific management.

# XI. Report on the Organ Site Program: Recommendations of the National Organ Site Programs Subcommittee and NCI Staff--Dr. William Powers

The report of the Subcommittee on National Organ Site Programs review was accepted, though not endorsed, at the February NCAB meeting. The Subcommittee has since prepared a recommendation which includes the recommendations made at that meeting. Outside leadership of the program should be retained, and be consolidated to focus on the four current sites and to identify new ones. There should be open competition for the organizing body, which coordinates clinical and laboratory segments; this unit should have two Divisions: Gastro-intestinal and Genitourinary. Basic laboratory research in epidemiology should be reviewed and funded as RO1s and PO1s, with NIH and NCI deciding whether the review falls within the purview of DEA or DRG. Clinical trials research should be reviewed and funded by mechanisms devised by the Director and staff, but current applications should be reviewed and funded by existing mechanisms. If these recommendations are approved, the program will be called the Organ Systems Program. The staff was asked to recommend to the current Subcommittee any procedural and operational changes to achieve the goals of the new Program.

Questions and Answers. Dr. William Raub has agreed to classify Organ Site applications as ROls and POls. Approximately half of the current 88 grants, worth \$10,000,000, will come up for review in 1983, the remainder in 1984. The NCI staff would prefer that the organizing body be in-house; otherwise it is in general agreement with the recommendation. After considerable discussion, an amendment by Dr. Henderson that the organizing body be in-house was defeated, and the original recommendation was endorsed.

# XII. Followup Report on the Community Clinical Oncology Program (CCOP) -- Dr. Joseph Gale Katterhagen

The Subcommittee on Cancer Control and the Community met May 16 to discuss the document "Program Description: Community Clinical Oncology Program" and approved the 20 recommendations made. The prototype CCOP could be a consortium of hospitals, or a large institution or clinic, with patient management guidelines and a local cancer data system already in place. Funds will support clinical research at the community level. Each CCOP must contribute at least 50 patients; the CCOPs will thus add new patients with early-stage disease to protocols.

Questions and Answers. Dr. Rowley suggested that existing mechanisms for providing services at the community level should be extended, rather than have NCI set up a new, and possibly competitive, program at a time of reduced funding for grants. Although high-quality clinical research is expected from this program, the level of care might not compare to that given at centers. The response was that the CCOP complements current programs, since cancer control should involve bringing the results of grant-supported research to the community, where 80 percent of the patients are still treated. The funds for the CCOP could not be transferred to the grant pool in any case. The NCAB discussed the results which could be expected. The CCOP would probably not change mortality rates significantly, but could impact on morbidity. It would allow for both clinical trials and testing of the diffusion hypotheses. At present, existing therapy is not evenly distributed throughout the country;

therefore, priority would be given to establishing CCOPs in areas with low survival rates. Communities would be able to point out their needs to the national program. However, people may overestimate what the CCOP can achieve.

Dr. David Johnson, President of the Association of Community Cancer Centers, expressed his organization's support for the program. Hospitals do not currently have money to expand services on their own. It was again expressed that the CCOP's primary objective is to collect information on use of protocols in delivering patient care, not to set up a patient care system. Dr. Virgil Loeb of the American Society of Clinical Oncologists (ASCO) also supported the program, noting that ASCO has some reservations about the current RFA. The NCAB voted to accept the report.

### XIII. Report of the Planning and Budget Subcommittee--Mr. Lou Carrese

Procedures for formulating the FY 1984 bypass budget included development and discussion of basic categories by the NCI staff at the January Planning and Budget Subcommittee meeting, review of these categories by the Planning and Budget Subcommittee and the NCAB at the February meeting, and a mail ballot to establish priorities. The results of the ballot were reviewed by the Subcommittee on May 17, with the proposed budget based on these results.

The bypass budget includes a 7 percent cost-of-living increase over FY 1983, plus an additional 5 percent for modest program growth. It also includes payment of grants at full recommended levels, including NRSAs at full institutional allowances. Under this budget, research would increase from \$783,000,000 in FY 1983 to \$864,000,000 in FY 1984, resource development would grow from \$115,000,000 to \$149,000,000, and cancer control would increase from \$55,000,000 to \$60,000,000. The total budget would rise from \$955,000,000 to \$1,274,000,000--a 12.4 percent increase.

The Subcommittee also approved the 5-year projections of the NCI budget (FY 1983 to FY 1988), and agreed that a new career investigator award would be desirable. It was recommended that the NCAB discuss this at its fall meeting. The Board approved the report unanimously.

# XIV. Proposal to Reopen Competition for Geographic Cooperative Groups -- Dr. Robert Hickey

Dr. Hickey requested that the RFA for Geographical Cooperative Groups be reopened. Dr. DeVita explained that this program was reviewed by the Board of Scientific Counselors (BSC) of the Division of Cancer Treatment (DCT), and that \$1,500,000 were made available. There is currently no money to support new grants, although the BSC is debating whether to open the Cooperative Group budget to competition for Geographic Groups. A motion by Dr. Hickey to have the BSC reconsider opening the competition was passed unanimously.

# XV. Report on the Significance and Use of Relative Cancer Survival Rates -- Dr. Earl Pollock

The data for calender years 1973-1979 are now becoming available from the Surveillance Epidemiology End Results (SEER) Program. SEER, which began in

1973, now covers 10 areas and 10 percent of the U.S. population. It measures the incidence of cancer and the 5-year survival rate, and is operated by NCI's Biometry Branch. The 5-year relative survival rate for whites during 1973-1979 was shown to be 46 percent, which represents a ratio of patients to persons in the general population of the same age, sex, and race each year. Summary data from SEER will be published in 3 to 4 months, and a comprehensive monograph will be produced in early 1983. Statistics are kept by cancer site. Since there is no precursor directly comparable to SEER, it is difficult to judge the extent of improvements.

Questions and Answers. NCI expects to receive relative survival rates on an annual basis. The Atlas of Cancer Incidence, which will be produced in late 1982, is not based on SEER data. It was noted that overall data on survival are influenced by any increase in a particular form of cancer; thus, it is difficult to assess the general effectiveness of new cancer therapies. Since Blacks and Hispanics are at present under represented in SEER, another registry may be added to remedy this. It was suggested that SEER include occupational data; this would be expensive, and NCI cannot solicit funds from the American Cancer Society to add this information. SEER is not subject to the Privacy Act but it does not contain personal names. Some concern was expressed over the ability of SEER to register deaths of patients who moved from a SEER area, as some of these individuals might not be included or might be registered twice. However, every effort is made to cross-check among states and with the National Death Index. Addition of the Social Security number as a data element could As the SEER system continues, it will be able to give the relative survival rates over longer intervals.

### XVI. Report on Misconduct in Science -- Dr. William Raub

Among the 20,000 grants funded by NCI in the last 3 years, only nine cases of misconduct occurred. These were defined as plagiarism or misrepresentation, falsification, or falsification of data. Other practices not included in this definition, but being studied by NCI, are misappropriation of funds and failure to protect humans or animals. When misconduct is demonstrated, NCI suspends or terminates awards and disqualifies the recipient from future funding for a specified time. Currently, NCI is in the process of systematizing its practices for dealing with misconduct and is developing written guidelines for awardees and applicants.

Questions and Answers. It was noted that the incidence of misconduct is so low that this should be publicized. There may be a problem connected with retention of data. Many scientists do not retain their records for a long period of time after an experiment is completed, yet investigations could occur as much as 5 years later. NIH will not prescribe procedures in this area, but encourage scientists to follow their normal procedures for storing and verifying data. Even Congress does not advocate set requirements or surprise inspections. It was asked whether NCI was involved in a recent incident involving alleged cruelty to animals at a Silver Spring research site. NCI has invalidated the Institution's assurances in this area and is at present caring for the monkeys. The facility had passed a U.S.D.A. inspection; NCI might institute a system of site visits to ensure compliance with high standards. However, the American Association for Accreditation of Laboratory Animal Care conducts independent animal welfare inspections, so this might be another option.

# XVII. Adjournment

The meeting was adjourned at 11:45 a.m.

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