

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL CANCER INSTITUTE
113th NATIONAL CANCER ADVISORY BOARD**

**Summary of Meeting
February 16, 2000**

**Building 31C, Conference Room 10
National Institutes of Health
Bethesda, Maryland**

NATIONAL CANCER ADVISORY BOARD

BETHESDA, MARYLAND

Summary of Meeting

February 16, 2000

The National Cancer Advisory Board (NCAB) convened for its 113th regular meeting at 9:45 a.m. in Conference Room 10, C Wing, Building 31, National Institutes of Health. The brief meeting was conducted via teleconference.

NCAB Members

Dr. J. Michael Bishop (Chairperson)
Dr. Richard J. Boxer (absent)
Dr. Kay Dickersin
Dr. Alfred L. Goldson
Dr. Elmer E. Huerta
Dr. Frederick P. Li
Dr. Susan Love
The Honorable James E. McGreevey
Dr. Sandra Millon-Underwood
Dr. Arthur W. Nienhuis (absent)
Dr. Larry Norton
Dr. Amelie G. Ramirez
Dr. Ivor Royston
Dr. Philip S. Schein
Dr. Phillip A. Sharp (absent)
Ms. Ellen L. Stovall
Dr. Vainutis K. Vaitkevicius

President's Cancer Panel

Dr. Harold Freeman (Chairperson) (absent)
Dr. Paul Calabresi
Ms. Frances Visco (absent)

Alternate Ex Officio NCAB Members

Dr. Rachel Levinson, OSTP
Dr. Hugh W. McKinnon, EPA (absent)
Dr. Alison Martin, FDA
Dr. Eugene Schwartz, DOL, OSHA
Dr. T.G. Patel, DVA
Dr. Michael V. Viola, DOE
Dr. Steven K. Akiyama, NIEHS

Members, Executive Committee, National Cancer Institute, NIH

Dr. Richard Klausner, Director, National Cancer Institute
Dr. Alan Rabson, Deputy Director, National Cancer Institute
Ms. MaryAnn Guerra, Deputy Director for Management
Dr. Robert Wittes, Deputy Director for Extramural Science; Director, Division of Cancer Treatment and Diagnosis
Dr. Dinah Singer, Director, Division of Cancer Biology
Dr. Joseph Fraumeni, Director, Division of Cancer Epidemiology and Genetics
Dr. Peter Greenwald, Director, Division of Cancer Prevention
Dr. Marvin Kalt, Director, Division of Extramural Activities
Dr. Edison Liu, Director, Division of Clinical Sciences
Dr. Barbara Rimer, Director, Division of Cancer Control and Population Sciences
Dr. Joseph Harford, Associate Director for Special Projects
Ms. Sandy Koeneman, Executive Secretary, NCI Executive Committee

Liaison Representatives

Dr. John Currie, American Association for Cancer Education, Inc.
Dr. Ronald B. Herberman, Association of American Cancer Institutes
Ms. Barbara Duffy Steward, Association of American Cancer Institutes
Dr. Margaret Foti, American Association for Cancer Research
Dr. Marc E. Lippmann, American Association for Cancer Research
Dr. Robert Martuza, American Association of Neurological Surgeons
Dr. Robert W. Frelick, Association of Community Cancer Centers
Ms. Kerrie B. Wilson, American Cancer Society
Dr. John Stevens, American Cancer Society
Dr. Stanley Zinberg, The American College of Obstetricians and Gynecologists
Dr. Bernard Levin, American Gastroenterological Association
Dr. Edward P. Gelmann, American Society of Clinical Oncology
Dr. Ross Abrams, American Society of Therapeutic Radiology and Oncology
Ms. Nancy Riese Daly, American Society of Therapeutic Radiology and Oncology
Ms. Ruth Hoffman, Candlelighters Childhood Cancer Foundation
Dr. Lovell A. Jones, Intercultural Cancer Council
Dr. Armin D. Weinberg, Intercultural Cancer Council
Ms. Katharine R. Boyce, Intercultural Cancer Council
Ms. Martha M. Kendrick, Intercultural Cancer Council
Ms. Jean Ard, Leukemia Society of America, Inc.
Ms. Carolyn Aldige, National Coalition for Cancer Research
Ms. Dorothy Lamont, National Cancer Institute of Canada
Dr. Robert A. Phillips, National Cancer Institute of Canada

Ms. Paula Bowen, NCI Director’s Consumer Liaison Group
Dr. Eve I. Barak, National Science Foundation
Ms. Pearl Moore, Oncology Nursing Society
Ms. Roberta Strohl, Oncology Nursing Society
Dr. W. Marston Linehan, The Society of Urologic Oncology

CONTENTS

I. Call to Order, Opening Remarks, and Consideration of Minutes of Previous Meeting—Dr. J. Michael Bishop 1

II. Future Meeting Dates—Dr. J. Michael Bishop 1

III. Report of the Director, NCI—Dr. Richard Klausner 1
Questions and Answers 2

IV. Annual Delegations of Authority—Dr. Marvin Kalt 2

V. New Subcommittees/New Business—Dr. J. Michael Bishop 3

VI. Response to DHHS Confidentiality Regulations—Dr. J. Michael Bishop,
Dr. Frederick Li, Ms. Mary McCabe 4

VII. Competing Continuation Program Project Budget Caps—Dr. Marvin Kalt 5

VIII. NCAB Subcommittee on Minority Coding Report—Dr. Frederick Li,
Dr. Susan Sieber 6

IX. Adjournment of Open Session 7

I. CALL TO ORDER, OPENING REMARKS, AND CONSIDERATION OF MINUTES OF PREVIOUS MEETING—DR. J. MICHAEL BISHOP

Dr. J. Michael Bishop called to order the 113th meeting of the National Cancer Advisory Board (NCAB), which was conducted via teleconference. The roll was called to ascertain that a quorum was online. Dr. Bishop welcomed members of the public and press and invited them to submit in writing, within 10 days, any comments regarding items discussed during the meeting. A motion was requested and made to approve the minutes of the December 1999 meeting. They were approved by the Board unanimously.

Dr. Bishop announced that the current meeting would be his last, and he expressed gratitude at having had the opportunity to work with the Board and NCI staff in helping to advance the National Cancer Program. He commended the work of the NCI, its staff, the Director, and his immediate colleagues.

II. FUTURE BOARD MEETING DATES—DR. J. MICHAEL BISHOP

Dr. Bishop called attention to the proposed 2002 meeting dates and asked the Board to report potential conflicts to the office of the Director, Division of Extramural Activities (DEA). Because of the need to compress the February meeting, the likelihood was discussed that the June NCAB meeting would require 3 days, and members were presented with two scenarios for accomplishing this. A survey of Board preferences will be conducted by fax, and the final June date will be announced on the NCI Web Site.

III. REPORT OF THE DIRECTOR, NCI—DR. RICHARD KLAUSNER

Dr. Richard Klausner, Director, NCI, briefly summarized information and emphases made the previous day in his testimony before the House Subcommittee on Labor—Health and Human Services (HHS)—Education Appropriations. He noted that cancer statistics were presented to demonstrate dramatic decreases in cancer incidence, particularly breast and prostate cancer. These statistics soon will be released in the annual report published jointly with the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS), and American Cancer Society (ACS). Dr. Klausner indicated that this year's report would emphasize colorectal cancer, and that more details on changing patterns in this disease would be presented at the June meeting. Two questions posed most often to the NCI by members of Congress concerned the allocation of the FY2000 budget increase, and how the additional increases envisioned beyond FY2001 would be utilized. In responding to the former, Dr. Klausner emphasized the level of concordance reached in the FY2000 budget distribution among NCI planning, priority setting, and budget distribution processes. It was noted that approximately 84 percent of the \$420M new dollars received by the NCI in FY2000

was aligned with either the extraordinary opportunities or the Director's Challenge section of the Bypass Budget. Budget distribution details will be published on the NCI Web Site together with explanations of NCI's planning, priority setting, and budget distribution processes, which heavily engage the research community. To demonstrate how the NCI would use the additional increases, Dr. Klausner discussed how Bypass Budget-linked requests for applications (RFAs) have generated such response and interest in the research community that there is a significant disparity between the set-aside approved for these major initiatives by the Board of Scientific Advisors (BSA) and the dollar amount requested. He announced that peer review results for the large number of applications received in response to the RFAs initiating these high-priority programs will be presented to the Board in greater detail at the June meeting. In conclusion, Dr. Klausner emphasized that cancer research support from the House committee remained strong and enthusiastic during this set of hearings. He reminded members that Representative Porter is retiring as Chair of the House Subcommittee for Labor, DHHS, and Education, and he acknowledged Mr. Porter's support not only for the level of NCI funding but also for his support of NCI values and operating standards.

Turning next to another aspect of the NCI budget, Dr. Klausner reported that the dollars being requested in applications received during the second and third round of grants have continued to increase; for example, about a 10 percent increase in the third round for regular program grants (R01s) and about 40 percent for program projects (P01s). A more detailed report will be presented at the June meeting on NCI plans for addressing the shortfall in the research project grant (RPG) budget line that is projected as a result of these dramatically changing numbers and the unexpected stress they could exert on available funds. A variety of funding approaches will be considered to ensure that the agreed-to payline and fiscal policy are maintained.

Questions and Answers

In discussion, it was decided that a resolution of gratitude and commendation would be sent to Representative Porter in recognition of his support of the National Cancer Program. A working group of the Board will be convened to draft and circulate such a resolution either for action at the June meeting or to be subject to a mail ballot in the interim.

IV. ANNUAL DELEGATIONS OF AUTHORITY—DR. MARVIN KALT

Dr. Marvin Kalt, Director, DEA, briefly reviewed the delegations of authority to be requested annually from the NCAB, as stated in the Public Health Service Act. He explained that the agreement with the Board in regard to these delegations permit the NCI to accomplish the administrative tasks needed to make sure that there are timely awards and processing of administrative requests. Delegation A allows the Director, NCI, to obtain the services of up to 151 experts or consultants who have scientific or professional qualifications to assist in accomplishing the mission of the Institute.

Delegation B grants authority to the Director to appoint one or more advisory committees to cope with individual issues that arise.

Dr. Kalt explained that the second part of the annual delegations of authority was embodied in the Statement of Understanding with the NCI Staff on Operating Principles in Extramural Awards. The Statement addresses (1) extramural awards that the NCI is empowered to make without concurrence of the NCAB (e.g., scored applications with recommended direct costs of \$50,000), (2) provisions for decreasing the number of summary statements included in the Board books (e.g., removal of applications scoring over the 50th percentile, with notable exceptions); (3) principles for conducting a process of expedited concurrence for R01 and R21/33 applications (excluding those from foreign organizations) that fall within NCI paylines for those mechanisms and have no concerns noted that would represent an administrative bar to award; and (4) permission to allow NCI staff to negotiate appropriate adjustments in dollars or other terms and conditions of grant and cooperative agreement awards recommended by the Board.

A motion was made to approve Delegations A and B as stated in the Public Health Service Act and the operating principles relating to extramural awards that are included in the statement of the understanding. The motion was seconded and unanimously approved. In discussion, it was suggested that the Board, at the June meeting, should discuss the possibility of recommending that the ceiling be raised for scored applications that the Institute could award without NCAB concurrence. A motion by the Board to that effect would provide a basis for requesting administrative relief at the necessary level of government toward the goal of expediting small awards.

V. NEW SUBCOMMITTEES/NEW BUSINESS—DR. J. MICHAEL BISHOP

As background for the vote to create two new working groups, Dr. Bishop reminded members that the proposal for creating an Ad Hoc Subcommittee on Communications emerged from discussions at the fall retreat and December meeting of the Board. As proposed, the committee would be charged with providing advice on issues relating to cancer information and communication of that information to the constituencies of the NCI, including the public, physicians, health care professionals, researchers, advocacy and professional organizations, the media, and Congress. The committee would also provide advice and oversight of the organizational units within the NCI that provide these services, products, and functions. A motion was made to accept the proposed functional statement of the Ad Hoc Subcommittee on Communication, with the current subcommittee composition to include Dr. Susan Love as Chair, Dr. Amelie Ramirez, Dr. Richard Boxer, Mr. James McGreevey, and Dr. Elmer Huerta, with additional members to be added from the new appointees to the Board. The motion was seconded and unanimously approved.

Dr. Bishop presented the proposed functional statement for the Ad Hoc Subcommittee on

Confidentiality of Patient Data for Board approval. The Subcommittee would provide advice and oversight of the proactive NCI efforts to establish best practices to ensure patient confidentiality in cancer research settings. The subcommittee, insofar as is practical and as time permits, would recommend and comment on provisions of draft regulations issued by the DHHS in response to the Health Insurance Portability and Accountability Act of 1966 (HIPAA) while those are still in the comment period. Particular attention would be given to recommendations distinguishing the impact of such regulations and practices in patient-oriented research settings as opposed to those settings that are limited solely to the delivery of care; and the possible adverse impact on the conduct of clinical and epidemiological research and accrual of subjects. The subcommittee also could focus on recommendations that illuminate the impact and consequences of regulations on participation of community-based health care professionals in research, since maintaining participation of these groups is crucial to expanding access of subjects to clinical trials. The subcommittee also would consider recommendations to balance or mitigate the burden of regulations on research subjects who have already made clear their intent and strong desire to participate in protocols through a valid informed consent. A motion was made to accept this charge, with the current composition to include Dr. Frederick Li and Dr. Kay Dickersin as co-chairs, and Ms. Ellen Stovall, Dr. Arthur Nienhuis, and Dr. Ivor Royston. The motion was seconded and approved unanimously. In discussion, Dr. Dickersin noted that as the June meeting would be her last, the person identified to succeed her as co-chair should also occupy a public advocacy slot on the Board to maintain adequate representation of patient interests.

New Business. Dr. Bishop asked members to identify items of business that should be addressed at the June meeting and received the following requests:

- C An information item on how the NCI organizes intellectual property and property rights, both intramurally and extramurally, and what has been happening with respect to actual issues currently on the horizon. It was suggested that the presentation include an update on the deliberations of the NIH committee addressing intellectual property issues and a presentation by a representative of the National Cancer Policy Board (NCPB) of the Institute of Medicine (IOM). The need for further action by the Board could then be assessed and addressed.

- C An update on the use of tamoxifen as a preventive agent in breast cancer, including a

clarification of the intended population.

**VI. RESPONSE TO DHHS CONFIDENTIALITY REGULATIONS—
DR. J. MICHAEL BISHOP, DR. FREDERICK LI, AND MS. MARY MCCABE**

Dr. Bishop presented for Board action a draft letter indicating support of concerns identified by the NCI in its response to the DHHS proposed rule entitled “Standards for Privacy of Individually Identifiable Health Information.” Because the comment period was scheduled to end the following day, immediate action was required. Dr. Bishop noted, however, that the Board would have opportunity for further discussion as the newly established Subcommittee on Confidentiality of Patient Data began to function. Through the subcommittee, the Board would work with the NCI on continued oversight of the consequences of these regulations on the National Cancer Program. As background, Ms. Mary McCabe, Director, Office of Clinical Research Promotion, NCI, reminded members that the DHHS had been mandated to draft confidentiality regulations when Congress failed to enact national privacy legislation as required under HIPAA. She noted that NCI’s response to the proposed regulations, a copy of which had been circulated to Board members and discussed at the previous NCAB meeting, reflect the discussion of more than 120 participants in a December 1999 meeting, convened by the NCI to discuss the issue of “best practices” for maintaining data confidentiality. The participants included researchers in the areas of genetics, clinical trials, tissue banks, epidemiology, surveillance, and large databases. Areas highlighted by the researchers were those considered to have the potential to impede the conduct of research without adding protection in the area of confidentiality.

After a brief discussion, Ms. Stovall moved that the Board approve the draft letter of support for the concerns outlined in the NCI comments to the proposed rule drafted by the DHHS. The motion was seconded and approved unanimously. In conclusion, Dr. Bishop noted that the letter would be sent to the DHHS in time to comply the February 17 deadline, and the position of the Board also would be stated as a resolution of support for the Institute’s response.

**VII. COMPETING CONTINUATION PROGRAM PROJECT BUDGET CAPS—
DR. MARVIN KALT**

Dr. Kalt presented for Board action a proposed revision to NCI P01 policy that would limit budget requests for direct costs for NCI-supported competing continuation (type 2) P01s to an increase of 20 percent over direct costs awarded in the last noncompeting (type 5) year. If approved, the revised policy would be implemented beginning with the June 1, 2000, receipt date. As rationale for the proposed policy revision, Dr. Kalt referred to Dr. Klausner’s earlier report of dramatic increases in both the number of P01 applications received and direct costs requested (e.g., 40 percent over the last noncompeting year award for that individual). He explained that the policy revision was an attempt to bring budgetary increases for P01 awards into closer alignment with the overall NCI

extramural budget. Dr. Kalt pointed out that provisions for greater growth have been retained for this group of applicants in that they are eligible to compete for supplemental awards. Dr. Klausner added that this experiment is expected to provide enough flexibility to manage individual cases and at the same time provide some level of budgetary predictability.

In discussion Dr. Royston, as one of two Board members who had been asked to assume responsibility for the primary review, expressed support of the proposal. Because Dr. Phillip Sharp, who was the second reviewer, could not participate in the teleconference, Dr. Kalt summarized comments he had made in a previous consultation. Dr. Sharp supported the need for this revision so long as it did not materially change the P01 dollars in the RPG pool compared with increases in funds for other types of award mechanisms, such as the R01. Dr. Klausner pointed out the difficulty of defining a fixed percentage to be applied regardless of changing approaches to, or ways of, doing science. In another discussion, Dr. Larry Norton raised the issue of conducting a study to determine the elements that are driving the increases in the cost of conducting research, and Dr. Li suggested the need for metrics to assess the productivity of P01s versus R01s as research mechanisms.

A motion was made to support the proposed policy revision regarding a budgetary cap for competing continuation (type 2) P01 grants. The motion was seconded and unanimously approved.

VIII. NCAB SUBCOMMITTEE ON MINORITY CODING REPORT— DR. FREDERICK LI AND DR. SUSAN SIEBER

Dr. Li, Subcommittee Chair, presented the Report of the Subcommittee on Coding for Research on Minorities for Board review and approval with a summary of the recommendations as follows: (1) “Racial” should be deleted when possible from the phrase “racial/ethnic minority group” because racial classifications are of limited value in health research; (2) research questions related to ethnic minorities should be distinguished from questions related to the medically underserved; (3) when used for considering and coding minority research, the term “special populations” should be defined as ethnic minorities, rural, low-income and low-literacy groups; (4) ethnic minority research should be coded as either 100 percent targeted (i.e., research that is culturally specific and focused on answering a question specific to an ethnic minority group or groups, or focusing on differences among groups) or <100 percent targeted (i.e., projects and activities targeted to issues, tumor types, or problems that differentially affect a U.S. ethnic minority group or groups, but are applicable to all); and (5) minority funding levels should be assessed for all projects, with target levels to be assigned to <100 percent targeted projects by knowledgeable NCI staff using formal guidelines. In addition, the report recommended a number of specific practices to be adopted when coding projects for their impact on minorities. Dr. Li called attention to the final recommendation that a standing subcommittee of the NCAB should be established to provide NCI with guidance and advise on coding-related issues, and he noted the willingness of members of the ad hoc subcommittee to continue to serve should the Board

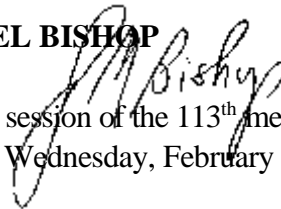
vote to that effect.

A motion was made to accept the Report of the NCAB Subcommittee on Coding for Research on Minorities. The motion was seconded and unanimously approved. A second motion was made to maintain the NCAB Subcommittee on Coding for Research on Minorities as a standing committee of the Board and continue its present composition. The motion was seconded and unanimously approved.

Dr. Susan Sieber, Acting Director, Office of Communications, NCI, and Executive Secretary of the Subcommittee, reported that the committee will work with the NCI Office of Special Populations Research to develop formal guidance for program directors and NCI staff that will be involved in coding for the future. A meeting with these individuals will be held to review the guidelines and provide examples, with a view to implementing the recommendations in the next fiscal year.

IX. ADJOURNMENT—DR. J. MICHAEL BISHOP

There being no further business, the open session of the 113th meeting of the National Cancer Advisory Board was adjourned at 11:34 a.m. on Wednesday, February 16, 2000.

A handwritten signature in black ink, appearing to read "J. Michael Bishop", is written over the text of the adjournment. The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.