

**NATIONAL CANCER ADVISORY BOARD**  
**Subcommittee on Activities and Agenda**  
**Minutes of Meeting**  
**January 30, 1995**  
**Conference Call**  
**Bethesda, MD**

The teleconference meeting was formally called to order at 1:00 p.m. EST by the Chair, Dr. Barbara Rimer. Other NCAB members participating by telephone were: Dr. Fred Becker, Dr. Robert Day, Dr. Ellen Sigal, Dr. Philip Schein, and Dr. Charles Wilson with Dr. Marvin Kalt, NCI acting as Executive Secretary. NCI Staff included: Dr. Richard Klausner, Director, NCI; Dr. Paulette Gray, Deputy Director, DEA and Dr. Kirt Vener, DEA, NCI. No members of the public were present, although a public link was available in Executive Plaza North, Room 640.

The Chair opened the teleconference by welcoming the members and the staff who were in attendance. Dr. Rimer reviewed for the Subcommittee some of her liaison activities and recent meetings, including one in the Office of the Secretary, DHHS, to formulate plans for new initiatives on women and tobacco.

**SUBCOMMITTEE APPOINTMENTS**

It was announced that Dr. Robert Day will succeed retiring member Dr. Syd Salmon as Chair of the Special Actions Subcommittee. Dr. Day will also continue to Chair the Subcommittee on Centers. Dr. Michael Bishop will be asked to Chair the Subcommittee on Basic and Environmental Cancer Research, succeeding retiring Board member Dr. Fred Becker.

**STRUCTURE OF NCI PROGRAM REVIEWS**

The meeting began with the Chair and the Executive Secretary reviewing for the Subcommittee the planned list of program review activities being established under the new Boards of Scientific Advisors and Counsellors. They are as follows:

<u>WORKING GROUP</u>	<u>PARENT BODY</u>	<u>CHAIR</u>	<u>NCI EXEC.SEC.</u>
Centers	BSA	J. Simone	Paulette Gray
Cancer Control	NCAB	B. Rimer	Marvin Kalt
Clinical Trials	BSA	TBN	John Cole
Developmental Diag.	BSC	TBN	Sue Waldrop
Developmental Ther.	BSC	TBN	Vince Oliverio
Prevention Trials	BSA	E. Bresnick	Jack Gruber

Dr. Day reviewed for the Subcommittee the first meeting of the Centers Group, which was held in Bethesda on January 25, 1996. Major areas of consideration will include the definition of what a center should encompass, appropriate funding paradigms, possible revisions in guidelines and review criteria to increase flexibility, the impact of health care reform on operations and research, and the role of centers in clinical trials. It was noted that both the Working Group and NCAB Subcommittee on Centers will address the issue of designation as a comprehensive cancer center. The most appropriate focus of the Centers program should continue to be driven by science, not mechanism. Ways to make P30 awards function more like a grant and less like a cooperative agreement were suggested. A target date of September, 1996 is being planned for a first draft report.

The Subcommittee expressed an interest in assuring adequate and appropriate representation of the NCAB on all working groups, and asked that informational updates be provided on each to the Board as issues come up so that the Board might have appropriate input as reports are being formulated. The Board may also wish to refer specific issues to relevant NCAB subcommittees for parallel consideration where time is of the essence.

This line of discussion also led to further consideration of defining the overall role of the NCAB vis a vis its advisory function to the Director, NCI and Secretary DHHS. Members expressed a need to assure that issues concerning the broad overall directions and budget allocations be presented and discussed in a timeframe that allows Board input prior to the deadline for final decisions. The Bypass budget was cited as an exercise where communication and input has materially improved, but where additional opportunities exist to allow for input on recommendations of priorities.

## **ONGOING BUSINESS**

The desire was expressed for a periodic revisiting of progress being made toward meeting the goals established by the Bishop - Calabresi Report. It is expected that the Director will provide a progress report on the implementation of the recommendations made in the NCAB Report on the Organization of the NCI Intramural Programs (Bishop/Calabresi Report), specifically with respect to the redirection of intramural and AIDS funds. This should be addressed at either or both the February and May Boards.

A general tenet of involvement of the Board and development of reports should be that the NCAB be presented at the earliest possible moment with alternatives and potential choices on which to comment, and less with accomplished facts. If this requires a more general or strategic discussion in the absence of known budgets or outcomes, the Board still can enter into a dialogue about proportions and priorities of various areas and approaches.

It was noted that each change in membership of the Board or in NCI leadership necessarily requires redefinition of the relationship between the two, along with a plan for constructive

engagement on major issues facing the Institute. Given the recent appointment of the Director and the imminent change of one-third of the Board, it seems appropriate to plan for this kind of review to take place with the Director, perhaps in September.

### **PRIORITIES FOR SUBCOMMITTEES**

Dr. Wilson indicated that the Subcommittee on Special Priorities has just completed an extremely successful conference on improving the involvement of women and minorities in clinical trials, and will review a concept for regional conference grants on the same topic. It will explore further the focus on economic status, rather than race per se, being the major risk factor for many cancers. Obvious correlates of diet, access to health care, and environmental risk relate to this variable. An optimal framework for an economics research initiative may be considered.

The Subcommittee on Cancer Centers will focus on the work now underway of the ad hoc Working Group on Cancer Centers being conducted under the auspices of the new Board of Scientific Advisors. The panel is being chaired by Dr. Joseph Simone. Drs. Day, Salmon and Bishop are liaisons. Dr. Simone will be invited to brief the Subcommittee on progress at the May NCAB meeting. The Subcommittee expressed some concern over the appropriate role for the Subcommittee as this external body develops its recommendations. The Subcommittee continues to be concerned about how issues of managed health care will also impact on the Centers; and about review and definition of comprehensiveness. It was re-emphasized that the Subcommittee still must approve final Center guidelines in this area. The Subcommittee should develop a list of questions and recommended interviewees to pass on to the Centers Working Group.

The Subcommittee on Basic and Environmental Research needs to consider its own possible reengineering to provide oversight and integration of the new intramural Division of Basic Science with the Extramural Division of Cancer Biology and the hybrid Division of Cancer Epidemiology and Genetics. It looks forward to hearing from the NCI about plans in cancer genetics and counseling. It is also interested in exploring the tradeoff between cost of regulatory programs designed to lessen environmental risk versus actual numbers and cost of potential cancers being prevented. The regulatory cost approach may be enormous, versus investment of incremental dollars in research in order to consider more effective application of such research.

The Subcommittee on Planning and Budget will continue to focus on involvement of the Board at earlier levels in the planning and budget formulation process, as well as the strategic planning process of the NCI. Interest was expressed in looking at the percentages of dollars devoted to large categorical set-asides of funds, how such decisions are generated, and how the Board might recommend early on in the decision making process its own priorities. A report on the planned movement of dollars from the intramural to the extramural setting, as recommended by the Bishop-Calabresi report, was also viewed as being essential.

The Subcommittee on Clinical Investigations will be involved with further discussions on the effects of managed care on institutions and clinical research, and on action plans emerging from both the DRG and NIH studies on clinical research. It is also interested in developing plans for integrated oversight of coordination and funding of clinical investigations in intramural and extramural programs, and with industry and the private sector. New developments in cancer therapeutics also will be monitored. This will necessarily include a discussion of effects of FDA policy on bringing new therapies to patients more quickly. Training and career development mechanisms and pathways need exploration in terms how to assure their continued existence, since such activities are not supported by the private sector.

## **NOMINATIONS AND ORIENTATION**

Dr. Klausner indicated that nominations to the NCAB have been forwarded through the Department to the White House, but there was not yet any indication as to when a response might be received. Assuming the 6 new appointees are available for the May, 1996 meeting, it was recommended that more experienced members of the Board, including the Chair of the Special Actions Subcommittee, participate in the orientation of new Board members, and that a more formalized type of mentorship role with senior Board members be put in place to speed the transition of the members.

Prior to Dr. Klausner joining the conference call, the Members had suggested that the Board and relevant organizations continue to directly submit nominations to the Secretary and White house, in addition to suggesting such names to the NCI. It was felt that this would assure consideration of a broader range of individuals, some of whom might hold slightly different viewpoints than those of the NCI. The Institute has benefitted in the past from the Board holding a variety of opinions and representations across the political and scientific spectrum as administrations have come and gone.

## **TOPICS FOR FUTURE MEETINGS**

**1. GENETIC RISK.** A universal theme needing discussion relates to genetic risk assessment counselling and molecular diagnosis, especially since commercial testing of individuals at risk for a number of cancers is imminent, even without concomitant effective strategies for using the knowledge gained from such tests. The ethical implications must be considered, as well as the legal and insurance issues raised by such screening technologies. An additional concern is recent redefinition and restrictions on the use of archival pathology specimens for genetic investigations. The role of Cancer centers in this issues might be addressed. Participants should include one or more individuals with divergent views from mainstream. A number of potential speakers were mentioned.

**2. GENE THERAPY.** A report on Gene Therapy would be appropriate and timely for September. Dr. Rimer will consult further with Drs. Bishop, Becker and Salmon. The recently released NIH report may have distorted the prospects for applications of this technology to cancer patients. While questions persist about the best targeting delivery vectors and level and persistence of expression, the use of gene therapy in cancer is significantly different than replacement of a single deletion in inherited gene deficient states. Thus, prospects may actually be better in cancer treatment. This needs to be emphasized given the many questions now being raised about the potential of this set of technologies.

## **DIRECTOR'S COMMENTS**

Dr. Klausner discussed the projected FY 96 RPG payline with the Subcommittee and announced the implementation of an accelerated executive review of exceptions for unamended R01 applications within 4 percentiles of the payline for basic research and 10 percentiles for patient oriented research. Separately, he discussed likely scenarios for the 97 Bypass and President's Budget, in view of the compression caused by the current impasse in funding bills for FY 96. He also informed the Subcommittee of a new partnership with the Department of Defense CHAMPUS health care program to allow covered dependents to receive reimbursement for participation in NCI and NIH approved clinical trials. This will cover 10 million enrollees and should materially enhance accruals while providing access to the best possible treatment for these patients. An office will be set up through the University of Michigan to inform patients and physicians of this new arrangement, and to track costs.

## **CLOSED SESSION**

The Subcommittee did not meet in closed session.

There being no further business, the Subcommittee adjourned the call at approximately 3:15 PM EST.

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Barbara K. Rimer, Chairperson