THE CANCER LETTER

DR S 5/25/82

Vol. 8 No. 21
May 21, 1982

Subscription $125 year North America/$150 yr elsewhere

P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

NCAB APPROVES SUBCOMMITTEE RECOMMENDATIONS ON ORGAN SITE PROGRAM—NIH REVIEW, ONE HEADQUARTERS

The National Cancer Advisory Board unanimously approved recommendations of its Subcommittee on Organ Site Programs to reorganize the four national organ site projects, return review of their grants to

(Continued to page 2)

In Brief

SENATE COMMITTEE FINISHES WORK ON RENEWAL BILL, BOTH HOUSES (SO FAR) LEAVE NCI AUTHORITIES INTACT

LEGISLATION RENEWING the National Cancer Act, included in House and Senate bills reauthorizing NIH, is moving along. The Senate Labor & Human Resources Committee has completed markup of its bill, leaving the Cancer Act intact for the most part. Changes pertaining to NCI would increase from $35,000 to $50,000 grants which may be approved by the NCI director without approval of the National Cancer Advisory Board (but after appropriate peer review by initial review groups); and require that the NCI director consult with the HHS secretary on construction support and appointment of advisory group members. The bill also includes some changes affecting all NIH, including deletion of payback requirements for National Research Service Awards; and creation of an appeals mechanism for the grants review process. IN THE HOUSE, markup by the Commerce & Energy Committee was continuing this week. Changes it would make so far include giving votes to the 11 ex-officio members of the NCAB; establishing offices of prevention and assistant directors for prevention in each NIH institute; providing that contracts over $500,000 would undergo peer review (which NCI does anyway) but not requiring council (or NCAB) approval, as had been proposed in an earlier version of the bill; establishing a line item dollar authorization for cancer center core grants. The House bill would continue the $35,000 limit on grants which could be awarded without NCAB concurrence. . . . PETER WIERNIK has resigned as director of the Univ. of Maryland Cancer Center "because the university has a different idea than I do on how a cancer center should be run." He has been replaced by Stephen Schimpff, who was chief of the Infection Research Section when the center was part of NCI as the Baltimore Cancer Research Program. Wiernik said he is looking for a job, either as a cancer center administrator or clinical director. . . . JAMES DONOVAN, first president of the Assn. of Community Cancer Centers, has resigned as associate administrator of the Health Care Finance Administration. Donovan said he wants to get back into the private sector, in industry or the administrative side of health care delivery. . . . MARY KNIPMEYER, formerly with the National Institute of Drug Abuse, is NCI's new legislative analyst.

SENATE NIH BILL AMENDMENT THREATENS TO OVERTURN NCAB ORGAN SITE DECISION

(Continued from page 1)

NIH and NCI, and consolidate the four headquarters into one.

NCI Director Vincent DeVita, who had argued for elimination of all the headquarters and transferring their communication and planning functions to NCI staff, said he was "prepared to accept the will of the board, on an issue as visible and controversial as this . . . . I don't feel that strongly about it."

Another development has surfaced, however, which has the potential of leaving the four projects in place, as they are now constituted. An amendment to the NIH reauthorization bill (S.2311) may be offered when the bill reaches the Senate floor which would mandate continuation of the four projects and establish a line item in the budget for them.

Sen. Daniel Moynihan (D.-N.Y.) has agreed to introduce the amendment.

William Powers, chairman of the NCAB subcommittee, said its recommendations were "in substantial agreement" with those developed by the ad hoc committee set up by the NCAB to review the four projects last November. The subcommittee reached its decision at a two day meeting last month (***The Cancer Letter,*** April 9). The subcommittee's statement submitted to the Board Monday recommended:

"1. That the Organ Site Program be retained with modification set forth below:

"a. That the organizing (coordinating) body (or headquarters) is to be operated outside NCI and be consolidated into a single unit charged with a mission to focus upon the four sites currently recognized; a further charge is continuing appraisal of the progress of the study of other sites with a view toward identifying such sites for future attention.

"There should be an open competition for the organizing body. The organizing unit is responsible for the organization, coordination, and overview of the clinical trials and with planning program review of the basic science component of the program. Communication between the clinical and laboratory segments will be maintained through workshops, conferences, etc.

"b. That the organizing body have at the outset two divisions: genitourinary and gastrointestinal.

"c. That basic (laboratory) research and epidemiology be reviewed and funded as R01s/P01s.

"d. That clinical trials research be reviewed and funded by mechanisms to be devised by the director and staff of NCI; that current applications be reviewed and funded by existing mechanisms.

"If these recommendations are approved the program henceforth will be called the Organ Systems Program (OSP).

"2. Procedural Request

"That funding be continued by the current mechanism with administrative extension of the headquarters as necessary until appropriate new applications can be processed. Staff will recommend to the OSP Subcommittee the procedural and operational changes to achieve this new Organ Systems Program."

DeVita said the staff recommendation "is not substantially different, with the exception of the outside focus." His plan would transfer the headquarters planning and communication functions to the Organ Site Branch in the Div. of Resources, Centers & Community Activities (***The Cancer Letter,*** April 23).

"This has been a difficult process," DeVita told the Board. "I don't believe there is anything wrong with the state of the Organ Site Program."

His reason for dismantling the program, he said, was a matter of money. NCI supports each of the four headquarters (bladder, prostate, bowel and pancreas projects) with about a half million dollars a year each.

As perceived by NCAB members, the most serious deficiency turned up by the ad hoc review committee was that review of project grants was less than adequate. Review has been done by the working cadre of each group, most of whom are project grantees themselves. Some NCAB members felt that the project grants should be competed in the R01-P01 pool with review by NIH study sections, reducing the conflict of interest potential and charges of unfairness.

Board member Maureen Henderson made a motion to amend the subcommittee recommendation to eliminate the outside headquarters. Harold Amos seconded the motion when no one else would but immediately spoke against it. "My feeling about the question of having this totally inside is that it would probably fail to bring in more investigators. There is a good deal of work called organ site being done by people who don't know anything about organ sites. Much of the work in the Organ Site Program, particularly bladder and prostate, is looking for markers. Some things are needed besides those that the study sections are approving. I'm not convinced that the organ site approach ought to be subverted entirely to immunology, and those (marker studies) would go to the immunology study sections."

"What you are saying is little different than we perceive," DRCCA Director Peter Greenwald said. "The workshops and planning would not be done by in house staff, but would be pulled together by NCI staff, with outside consultants. There still can be a working cadre."

"If the planning and organization were done inside, we would have no choice but to call on outside people," DeVita said.

Henderson's motion was defeated when she cast the only vote for it. Janet Rowley abstained. Henderson and Rowley then joined the rest of the Board in ap-

proving the subcommittee's recommendation.

DeVita said the proposed amendment to the legislation "is worrisome. It would negate any decision made here." Powers agreed that if the amendment becomes law, "It would take precedence over anything we do."

The amendment, in addition to continuing the four existing projects, would permit establishing new ones and would lock in review by the project working cadre. Language of the proposed amendment:

"Sec. 403(a). The director if the (National Cancer) Institute shall continue existing Organ Site Task Forces and is authorized to establish new ones for targeting research on those cancers responsible for a high incidence of morbidity and mortality, toward the end of providing greater research administration flexibility, more rapid response to research leads, stimulation of new research on particular organ sites.

"(b) Organ Site Task Forces shall—

"(1) be headquartered at nongovernmental research institutions,

"(2) publish annually their specific research goals and publish annually data by which progress toward the goals can be measured,

"(3) invite and review applications for organ-related research,

"(4) disseminate through various means, including publications, conferences, and consultative services, research outcome of immediate use in patient care and research advancement.

"Sec. 410(d). There are authorized to be appropriated to carry out Section 409, $20 million for the fiscal year ending Sept. 30, 1983; $21.1 million for the fiscal year ending Sept. 30, 1984; and $22.1 million for the fiscal year ending Sept. 30, 1985."

In an action aimed at the organ site amendment and also at the provision in the House bill which would establish a line item in the budget for cancer center core grants, the Board approved a resolution calling on Congress to refrain from line items in the authorization legislation.

NCAB GIVES GO AHEAD TO CCOP; OKAYS COMPROMISE ON CONTROL; STAFF AGREES

The Community Clinical Oncology Program cleared the final hurdle before NCI asks for proposals to implement it when the National Cancer Advisory Board this week wrapped up more than a year of debate, discussion and haggling and approved the program's concept.

The Board voted 7-1 to proceed with the program, which NCI plans to initiate with a request for applications in June. The schedule NCI staff hopes to follow provides for submission of applications by Nov. 1, with completion of review and negotiations before the Board's meeting one year from now, in May, 1983. The awards will be in the form of cooperative agreements and will require NCAB approval.

CCOP (the verbal acronym has evolved into "Sea Cop") will be designed to support clinical research in community settings, with community oncologists providing the leadership. An effort will be made to distribute CCOPs geographically, so there probably will be no more than one in a community, although that depends on how the applications come in. Each CCOP will be expected to place a minimum number of patients onto research protocols each year, the majority of which will be carried out by the community physicians. Some will be referred to other institutions for all or part of their treatment.

A key aspect of the program is the requirement that each CCOP affiliate with one or more "research bases"—a cancer center or a national or regional cooperative group. Patient entry into clinical trials will be done through collaboration with the multimodality research bases.

The program has two basic goals—to make available the benefits of clinical trials to a greater number of patients in their communities, and to increase the total number of patients entering clinical trials, thus overcoming problems of patient accrual which have become increasingly severe for clinical investigators.

A third goal is the "diffusion hypothesis" which NCI intends to test with CCOP: If a certain percentage of patients in a community are treated with the best and latest techniques, will those techniques be applied to treatment of the other patients in that setting? If so, will this affect morbidity and mortality in that community?

The program was drawn up, after NCI Director Vincent DeVita proposed it at a meeting of the Assn. of Community Cancer Centers in March, 1981, by a subcommittee of the Board of Scientific Counselors of the Div. of Resources, Centers and Community Activities. The subcommittee was chaired by Charles Moertel, director of the Mayo Comprehensive Cancer Center and included other members of the DRCCA Board, ACCC representatives, representatives of the cooperative groups and other nongovernment consultants. ACCC's Clinical Research Committee, meeting separately, also worked on developing the outline of the program and its recommendations were considered by the Moertel committee, and most were accepted.

The DRCCA Board gave its concept approval last October, but the NCAB, at its November meeting, indicated it wanted to see a full presentation of the program. That was done at the NCAB's February meeting, but some members were less than enthusiastic and asked for a delay (NCI staff had planned to release the RFA in March).

Board member Gale Katterhagen, chairman of the Board's Subcommittee on Cancer Control & the Community and director of a community cancer program in Tacoma, objected because NCI's CCOP proposals did not include support for any cancer control efforts. Katterhagen argued that cancer con-

trol programs such as those incorporated into the Community Hospital Oncology Program were necessary to involve primary care physicians in clinical trials. Without their cooperation, Katterhagen said, communities would be hard pressed to enter required numbers of patients in those trials.

Board member Rose Kushner also carried the ball for a cancer control component in CCOP. Her concern was that since it is being funded entirely with earmarked cancer control money, it should include some cancer control.

Katterhagen agreed with DeVita that clinical trials should be considered cancer control, but he continued to press for inclusion of some "CHOP-like" elements.

The subcommittee met last Sunday evening, and in a four hour plus session argued amongst itself, with other NCAB members, members of the President's Cancer Panel, and NCI staff over the cancer control issue and 19 other recommendations drawn up by Katterhagen. Board members Maureen Henderson and Janet Rowley argued that the program should be implemented, if at all, only as a small, feasibility study. Henderson suggested holding it to 20 CCOPs with no cancer control elements and 20 with. Rowley argued that existing mechanisms, such as the regional cooperative groups and the Cooperative Group Cancer Control Program with its community outreach aspect, be modified or expanded rather than start an entirely new program.

Katterhagen agreed to drop the strict requirement for CHOP-like elements and accepted instead language that would provide administrative support for each CCOP, support which could be used in part to help establish and direct cancer control efforts.

Since the subcommittee could not reach a consensus on all 20 of Katterhagen's recommendations (although agreeing on some), he proposed at the end of the marathon session that they be accepted "in principle." The subcommittee agreed.

Before Katterhagen made his presentation to the full Board Wednesday, he drew up a summary of the 20 recommendations as modified by the subcommittee discussion. That summary follows:

"In addition to the inclusion of the cancer management components (i.e., patient management guidelines, a local data system, a full time administrative director, and secretary to provide continuing support for physician and other health care professional committees) in each CCOP, which I discussed before, the subcommittee recommended:

"A. That the staff carefully draw the guidelines for participation to ensure that organizations with patients who have not been a part of the clinical research programs before are the recipients, and not organizations that have recently been reviewed and denied funding under an existing mechanism.

"B. We recommended that reviewers not be asked to re-review the research base. That if a research base was found unacceptable during peer review that an acceptable CCOP might be given the opportunity to re-affiliate. That NCI should consider providing centers with additional staff as they become research bases, since they will not all have the level of available resources in the major cooperative groups.

"C. We recommended that reviewers not be asked to re-review entire protocols, but be provided with the essentials of the initially selected protocols so they can determine whether the protocols are asking questions of some significance. More importantly, we recommended that the reviewers focus on the community's ability to deliver patients to protocols.

"D. We discussed how to ensure that communities get a voice in the affairs of the groups with which they affiliate. Dr. Bernard Fisher suggested that "market forces" will play a major role in advancing the community's cause. He also noted that community physicians do play a significant role in protocol review and formulation.

"E. We recommended that multiple research bases be allowed. Staff noted that they intended to give maximum flexibility to the formulation of applications, so that, for example, a specialty group could be considered a primary research base if it can document that it will be capable of putting sufficient patients on their smaller number of protocols.

"F. On the other hand, we recommended that staff carefully consider the difficulties of multiple research base affilations and the annual reviews of CCOP institutions by the research base. Multiple affiliations will mean multiple reviews of a CCOP, and everyone should be clear at the outset about who will review whom and with what consequences. Staff assured us that this will be addressed in the RFA.

"G. We recommended that research bases provide a separate budget, which can later be reviewed by NCI staff. We suggested that DRCCA might not be the appropriate budget from which to pay for clinical trials analysis; however, Dr. Peter Greenwald said he felt it was appropriate within his budget.

"H. Although we realized that we could not restrict the research bases in their negotiations with CCOP applicants, we expressed the hope, as did Dr. Fisher, that major groups would not prohibit agreements that include the specialty groups.

"I. We noted that we expect CCOPs will be members of the group or center network and not affiliates of university affiliates, i.e., not satellites.

"J. We recommended that staff immediately consider how they intend to test the diffusion hypothesis. Several of us noted that if they intend to be able to gather data on how patients are treated and to do appropriate followup that the physicians will need to gather more than the log data which staff suggests. Data on the process of care that takes place in a physician's office (as opposed to a hospital) is rarely re-

corded. Since a major portion of the trials will be conducted in physicians' offices, as well as in hospitals, the evaluation will require data from hospital cancer data systems, and data which is not usually gathered or recorded on patient care in the physician's office.

"K. We recommended that the denominator of the trials be uniformly the hospital, with the addition of the physician's office practice. Both will be needed for the reasons I just mentioned.

"L. We recommended that staff drop the concept of a strict 10 percent tithe, since the denominator originally proposed had no meaning. Instead, we suggested that the applicants be asked how many patients beyond the initial 50 they intend to enter onto protocols, and how they arrived at their estimates.

"M. We recommended that larger consortia of hospitals be the preferred model for CCOPs, since they can provide more patients at lower cost, will provide a community wide base for future cancer control activities, and are more likely to be stable structures in the community setting. Also some direct hospital involvement will be required, since the CCOPs will need IRBs, pharmacy control of drugs, hospital records systems, hospital personnel for followup of patients, and each consortium will need a fiscal agent, etc.

"N. Staff noted that the current timetable will be a substantive letter of intent, due Aug. 1, with the final application due in November. This will still allow FY 1983 funding of the programs. Staff also noted that the reviewers will be primarily community physicians with research experience and with experience in cancer control. NCI will not provide potential applicants with a "fill-in-the-blank" grant application, but may hold a bidders' conference, and will provide some additional materials to applicants on fiscal policies.

"O. Finally, we also recommended that there be three separate budgets within the proposal: One for the clinical research portion of the program, one for the research base, and one for the administrative component, including the full time administrative director, the secretary, the local data system and other measures to support the involvement of primary care physicians in the local programs, thus getting their cooperation in involving patients in appropriate care."

The NCAB's vote was on accepting the subcommittee's recommendations.

Rowley cast the only vote in opposition (Henderson left the meeting shortly before the vote was taken). In favor were Harold Amos, Robert Hickey, Katterhagen, Kushner, LaSalle Leffall, Chairman Henry Pitot, and Morris Schrier.

NCI executives indicated after the meeting that they also would accept the recommendations "in principle."

"We will incorporate the basic philosophy of those recommendations," said Jerome Yates, who heads the Centers & Community Oncology Program in DRCCA. But he left no doubt that NCI will not go along with them in detail.

Katterhagen had pressed for limiting CCOP to consortia or large institutions, then compromised on this point. Yates said, "We will have no policy on consortia. In some communities, consortia will be appropriate, and in some they won't. We prefer leaving it to the reviewers to determine that."

The subcommittee recommendation that applications not be considered from institutions which have "recently been reviewed and denied funding under existing mechanisms" would exclude those who struck out in the regional cooperative group competition. Only two of 17 groups applying will be funded. This is one recommendation NCI will ignore.

"We feel it is reasonable that groups compete on merit," Yates said. "It would be unfair to exclude some unfunded programs. Let the reviewers decide."

Cooperative group members (other than the outreach satellites), cancer centers and university hospitals (except those that are primarily community hospitals) will be excluded as community participants. They are eligible, of course, as research bases.

On the equality issues, Yates said that those recommendations would dictate to groups how to deal with CCOPs. "There will be such a variety of responses that we think the fewer restraints we put on, the better off we'll be."

NCAB OKAYS $5 MILLION REDISTRIBUTION TO RAISE GRANTS PAYLINE FROM 180 TO 185

The National Cancer Advisory Board approved a redistribution of $5 million to the research grants pool in the current fiscal year, which will permit NCI to extend the priority score payline from 180 to 185.

Specifically, the payline extension will apply to tradition (R01), program project and cancer control grants. None of the new money will go into cancer center core grants--the payline there already had been established at 218.

The extra $5 million was accumulated through reductions in all grants under recommended levels (see below) and in penny-pinching negotiations on contracts.

Director Vincent DeVita had asked the Board for its advice on how the extra money should be used. He said NCI staff was split, some supporting the payline extension, others that it should be used to fund exceptions (grants over the payline but considered important and meritorious), still others to support young investigators whose grants did not score high enough to meet the payline.

DeVita said that to reach the 180 payline, it was necessary to fund grants in 1982 at less than their

recommended levels. Noncompeting grants had to take a four percent reduction; competing renewals were funded at last year's level plus eight percent; and new grants were funded at recommended levels, minus four percent.

"There were many complaints," DeVita said. "People said we were distorting peer review. But if we had not done this, the payline would have been at 170 to 175."

DeVita pointed out that paying up to a priority score of only 180 is not as bad as it may seem compared with previous years. The scores used now are raw scores, after the switch from use at NIH of normalized scores. A score of 180 now is equivalent to a 210 normalized score. "We paid to a 210 normalized score in 1980, so the payline has not changed that much," DeVita said.

NCI staff considered funding on a sliding scale, from 100 to 180, with the top getting closer to recommended levels. "We found that those at 100 were being recommended at 99 percent of their requested budgets, while those at 180 were recommended for 75 percent," DeVita said. "So a sliding scale was built in."

Harold Amos suggested that construction grants might be increased, with only $1 million in the budget this year. "It may sound like an act of treason, but the construction program could use another million dollars. What kind of research can be done in locations where renovation is badly needed? Let's throw that in the pot."

DeVita said that NCI already has reached the maximum it can put into construction this year (based on language in the appropriations bill) without going to HHS and Congress for approval.

Board member Frederick Seitz moved that the $5 million be used to fund young investigators "where there is distress. The first priority is to pay young investigators."

DeVita commented that NCI has a special young investigators program, to encourage those applying for their first grants. The problem now with young investigators are those whose first grants are expiring and are coming in for renewals. Holding them to the low, first grant levels, even with an eight percent increase, is discouraging and stifling.

However, Board member Ann Landers argued that limiting the extra money to young investigators "would be seriously damaging to established investigators."

George Mandel, who made the appeal to the American Assn. for Cancer Research for support of an effort to channel more money into R01s (*The Cancer Letter*, May 7), told the Board that the problem was seriously affecting all investigators, not just young ones. "Many people are being cut out. Existing money should be redistributed, to get more participation, even if it means that people may get less money than they asked."

Board Chairman Henry Pitot said that universities tend to protect their tenured people and will pick up their salaries in many cases when those senior investigators lose their grant funding. "The established investigator knows more routes he can go to get support, so the young investigator is at a disadvantage," Pitot said.

"I agree with the general assessment of Dr. Mandel's remarks," Amos said. "Established investigators may not be protected. I am against Dr. Seitz' motion. Miss Landers is right, senior investigators have problems. It is an emergency, as Dr. Mandel says."

Seitz said he would withdraw the motion and allow NCI staff to make the decision. But DeVita said the staff was as split over the issue as the Board. Pitot called for a vote, and Seitz and Robert Hickey cast the only votes for it. Maureen Henderson's motion to use the money to extend the payline was approved, with Seitz, Hickey and William Powers opposed.

DeVita said that if additional money becomes available before the end of the fiscal year (Sept. 30), he would consider funding exceptions. This could include those whose grants were funded but at levels which unfairly restrict investigators.

DRCCA BOARD STILL COOL TOWARD CCN; BEHAVIOR PROGRAM SUGGESTIONS HEARD

Members of the Board of Scientific Counselors of NCI's Div. of Resources, Centers & Community Activities remained skeptical of the value of the Cancer Communications Network despite hearing details on the national evaluation of the program in progress.

The Board last year gave the program concept approval for three more years but demanded that an evaluation be undertaken before another extension was requested.

Thomas Kean, project officer for the program which includes toll free telephone service, dispensation of educational materials, and other special projects, presented an overview of the national evaluation plan. Phone call responses are checked for accuracy, convenience, appropriateness and staff sensitivity; user surveys are being undertaken; and studies of public responses to promotions of the service and to significant cancer related events and how they interact with the program are being carried out.

Board member Charles Moertel, who has been critical of the telephone service (which encourages patients, family members and those with various concerns about cancer to call for information and advice), noted that the estimated cost of that service last year was $30 per call. Kean said that the phone service accounted for about 50 percent of the program's budget and that dividing the number of calls into that figure (one half of $3.8 million a year) gave a cost of $11-12 per call.

"Primarily you are evaluating the instrument rather than the impact of the instrument," Moertel said. "The bottom line of evaluation is reduction in the morbidity, mortality and incidence of cancer."

"We are under no illusion that the service saves lives," Kean said. "To separate our impact from that of the system that is handling the patient is impossible."

"How will you evaluate the impact, then?" Moertel insisted.

"We can assess type of people using the service, and can look at whether people are taking action as the result of it," Kean answered.

"But not whether they would anyway, without the service," Moertel said.

"The end point can't be measurable, Board member Ernst Wynder said. "The end point has got to be reduction of risk factors, or morbidity and mortality. I would go for one center, to study and evaluate the end point, not 31 centers."

"What is the end point?" Kean responded. "We're not going after a single end point. It will vary. For some, it will be the practice of breast self examination, and it would take 20 years to see the impact on morbidity and mortality. The impact may be more immediate for some symptomatic end point."

Joseph Cullen, who will leave UCLA as deputy director for cancer control next month to become DRCCA deputy director, reminded the Board of the historical background for the program.

"A large commitment was included in the mandate of centers and the Cancer Control Program to provide information on cancer to the public," Cullen said. "Congress felt the American public was entitled to the best and latest information about cancer. This program is addressed to that problem. We have a responsibility to the public at large, and it ought to be an organized effort."

"I'm all for motherhood, apple pie and the American flag," Moertel said. "I'm all for communicating with the public. I'm not sure the best way is spending a half hour on the phone. It may be, but I would like to know if it is. This evaluation is evaluating the instrument, not whether its impact is better than some other instrument."

"There clearly is a dichotomy on the part of the Board on the value of this program," Board Chairman Stephen Carter said. "Obviously there will be some debate and differences of opinion when this comes up again for concept review."

A report was presented to the Board by its Subcommittee on Behavioral Medicine which was asked to evaluate the programs, activities and staff of DRCCA's Behavioral Medicine Branch.

Leonard Derogatis, chairman of the subcommittee, said the report was written following a two day meeting last month involving the 13 member subcommittee (five of them Board members), and BMB staff. Findings and recommendations of the subcommittee included:

—BMB staff, with Sandra Levy as chief, is "highly talented and capable, but stronger consultation in biostatistics, more sociologists, and a psychiatrist are needed. The branch is understaffed, but additional hiring should be done only as increased programs justify it.

—The branch should proceed with plans to undertake intramural behavioral research, but the NCI policy on separation of extramural and intramural activities should be observed.

—The current program in behavior modification related to tobacco use is not well defined, there is no overall plan with articulated and integrated goals and objectives, and there is no effort to set priorities. The subcommittee recommended:

1. The appointment of a small continuing working advisory group to BMB on tobacco use.

2. The appointment of a program director with totally dedicated responsibilities to the tobacco use program.

3. That particular care, attention and evaluation be given to the methods, instruments and data analytic approaches associated with survey research in the area.

—Behavioral scientists should be involved in chemoprevention studies from the inception of their designs. "Their knowledge of compliance phenomena should be highly relevant to chemoprevention... (those studies involve) certain social and cultural variables that will probably prove to be highly predictive as well."

—More should be done (than the efforts being generated through recent RFPs) by the branch in studying the problem of disproportionate prevalence of certain cancers among minority group members. "Differences associated with such psychological and social factors as differential life styles, health attitudes and health beliefs, health system access and demographic differences need to be accurately assessed along with any constitutional differences to help explain differential rates of disease prevalence among minorities."

—Strong interaction should be encouraged between BMB and the Occupational Medicine Branch on those concepts that possess significant behavioral components.

—Pain research is a highly relevant and important area of investigation that should be coordinated by BMB. Specific recommendations were:

1. Since a great deal of information already exists on effective pharmacologic and behavioral pain management, BMB should devote some significant effort toward developing a plan to effectively disseminate this information to treating doctors and nurses.

2. It is imperative that support be directed toward the development of a valid and reliable test instrument for the measurement of pain, since the validity of research in this area is totally dependent upon clinical judgments and unacceptable current instruments.

3. Efforts in pain research and dissemination of knowledge should not be nested solely within hospice contexts, or work with the terminally ill, but should cover the entire spectrum of clinical pain management.

–BMB should play a role in providing consultation and initiating projects on cancer control in aging populations, and these should be coordinated with the National Institute on Aging.

–Behavioral expertise should be available in design of studies and clinical trials in nutrition.

–Levy told the subcommittee she felt the Cancer Control Grant Review Committee, "although knowledgeable about cancer, lacked sufficient behavioral representation to adequately review grants in this area, while the Behavioral Medicine Study Section lacked sufficient representation and knowledge concerning cancer related phenomena," the report said.

Derogatis said four of the subcommittee members are members of those two study sections, "and they did not share that view. In each instance they felt that their study section did an adequate job in evaluating behavioral medicine grants."

The subcommittee agreed to send a letter to the respective executive secretaries informing them of the BMB staff's concerns.

HHS DEBARS STRAUS, WHO CONCEDES "SERIOUS DEFICIENCIES" IN TRIALS

The Dept. of Health & Human Services, as the result of the investigation by NIH and FDA of Marc Straus, has taken action to debar him from receiving any future HHS support and has declared him ineligible to receive investigational drugs.

The government struck a deal with Straus, agreeing not to seek criminal sanctions against him in return for his signed statement conceding "serious deficiencies" in clinical trials he conducted for the Eastern Cooperative Oncology Group at Boston Univ. in 1977-78. He also acknowledged that false reports were made, that some ineligible patients were put on trials, that some patients received drug dosages that deviated from the study plan, and that NIH regulations for protection of human research subjects were not followed, HHS said.

Straus has maintained that the false reports and other discrepancies were made by others, and his statement did not change that contention.

When the discrepancies were called to ECOG's attention in 1978, Straus was immediately dropped from the group, and the data he had submitted were purged from the group's files. Straus later resigned under pressure, was hired as an investigator by New York Medical College and competed successfully for a program project grant from NCI. The fact that Vincent DeVita did not point out the charges against Straus when his grant came before the National Cancer Advisory Board got the NCI director into hot water with Sen. Orrin Hatch and his Labor & Human Resources Committee.

DeVita said he had not mentioned the charges to the Board because they had not been proven and in fact had not even been investigated. Some members of the study section which gave the Straus grant a very high priority were aware of the allegations but said they scored the grant on its merit.

An NIH investigation of Straus at NYMC allegedly found new problems there, including lack of satisfactory progress on the grant. The grant was terminated, and Straus subsequently resigned and went into private practice.

PROGRAM ANNOUNCEMENT

Preventive Oncology Academic Award (POAA)

The National Cancer Institute invites competition for Preventive Oncology Academic Awards. Each school of medicine, osteopathy, dentistry, public health, or NCI-designated cancer center in the United States and its possessions or territories is eligible to compete for one nonrenewable Preventive Oncology Academic Award for a project period not to exceed five years. The number of new awards made each year will depend on the availability of funds.

The Preventive Oncology Academic Award Program is intended to stimulate high quality research on which educational programs oriented toward cancer prevention could be based in schools which do not have such programs or to strengthen the research and education programs of schools in which high quality research in preventive oncology already exists. It is expected that each program in cancer prevention will build upon the institution's demonstrable expertise and experience in epidemiology, human genetics, biostatistics, clinical oncology, nutrition and other pertinent basic cancer research.

The Preventive Oncology Academic Awards, which are made on the basis of nationwide competition, are available to individual investigators with academic teaching and/or research appointments in their respective institutions. POAAs support these individuals for needed research and educational objectives and development, implementation, and/or improvement of a preventive oncology curriculum.

For purposes of POAAs, preventive oncology is mainly concerned with etiologic studies and the primary prevention of cancer. In certain instances it may be appropriate to evaluate the efficacy of preventive measures.

The POAA is available to:

1. Support an outstanding individual faculty member for participation in research experiences related to preventive oncology, enhancing relevant scientific skills if a need is demonstrated, and strengthening or implementing a preventive oncology curriculum and the research program on which it should be based.

2. Provide superior learning opportunities to students enrolled in the institution through their exposure to research and to courses relevant to preventive oncology.

3. Facilitate exchange of ideas and methods among institutions and centers with special interest and expertise in preventive oncology.

Competitive review for a POAA will assess the plans of both the sponsoring institution and the proposed candidate.

The institution must:

1. Select and sponsor a candidate with: (a) demonstrated competence in preventive oncology, as well as (b) a major career interest in research and educational programs. The candidate must be a citizen, a noncitizen national of the U.S., or have been lawfully admitted to the U.S. for permanent residence.

2. Provide the candidate with the opportunity to acquire the professional skills for which need is demonstrated, and adequate time to develop or improve the preventive oncology program.

3. Present institutional plans for the preventive oncology program which is to be developed under support of the POAA. These plans must state the program's objective in terms of measurable outcomes and provide benchmarks against which progress is to be measured. The plan should clearly distinguish between any ongoing activities and those to be accomplished as a result of the POAA, outlining the relationship between the proposed plan and related teaching and research programs of the institution.

4. Identify and demonstrate availability of resources (e.g., populations, patients, manpower, materials) necessary to implement the proposed program.

5. Provide access to physical facilities (e.g., computer, laboratory, clinical, classroom office facilities) for rigorous preventive oncology research.

6. Provide written evidence of commitment from the administration, and chairperson(s) of sponsoring department(s) and curriculum committee to the implementation and/or further development of the proposed program.

7. Propose mechanisms for continued institutional support of the preventive oncology program, following the award period.

The candidate must:

1. Hold a doctoral degree or its equivalent from an accredited institution (e.g. DDS, DO, Dr.PH, DVM, MD, PhD).

2. Possess an appropriate teaching and/or research appointment in the sponsoring institution at the time the award is activated.

3. Have sufficient training and experience so that no more than two years of intensive supplemental preparation is needed to meet minimal POAA requirements. These requirements include:

a. Demonstrated competence in biomedical research relevant to cancer prevention, including epidemiology and/or human genetics, clinical oncology and biostatistical research methods, plus

b. Substantive knowledge of cancer epidemiology and prevention, carcinogenesis research, health service delivery systems, public health regulation and practice, as well as medical education procedures and administration.

4. Specify a program for enhancing personal skills as needed, e.g., further education in epidemiology, biostatistics, genetics, nutrition, clinical oncology and/or other pertinent areas of research in cancer etiology and prevention.

5. Present a program: (a) for developing or improving preventive oncology research and education in the grantee institution, and (b) for evaluating the outcome of the effort. This program should include detailed plans including the proposed curriculum, course description and syllabi, where appropriate.

6. Commit a substantial portion of time and effort to preventive oncology research and to the proposed programs.

7. Submit an annual program performance report along with the continuation support application (Type 5).

8. Agree to meet annually with other recipients of POAAs to exchange ideas, methods and program evaluations, as specified in the POAA objectives. The meeting is to be sponsored by the National Cancer Institute, with travel costs borne by POAA grant.

POAA funds may be used for:

1. Personnel: salary support for candidate and all other personnel, in direct proportion to the effort expended on the program, to include, e.g., PO assistants and associates, curriculum specialists and other faculty, as justified and specified by level of professional development, and in accordance with institutional policy.

2. Consultants costs for a limited number of experts in the areas of PO research and education.

3. Equipment necessary to develop PO curriculum.

4. Supplies by category necessary to achieve PO program objectives.

5. Domestic travel to other institutions and meetings to enable the candidate to develop essential skills, and also to meet with other candidates to exchange ideas, methods, and program evaluations.

6. Other expenses may include: (a) stipend, tuition and fee costs related to the implementation by the

candidate of a proposed program for enhancement of personal skills; (b) computer costs, teaching aids, materials and books relevant to the development of the PO program, and (c) postage, copying costs, telephone costs.

POAA funds may not be used for patient care costs, alterations and renovations, and contractual or third party payment costs.

Limited funds, if requested, may be used at the discretion of the candidate to support short term research or teaching experiences in preventive oncology. Such experiences may be designed to educate faculty or students in principles and techniques of preventive oncology research or feasibility studies integral to research planning.

Annual receipt date for POAA applications will be Sept. 1. The requested begin date for funding should be July 1 of the following year.

Application forms (PHS 398, Revised 5/80) may be obtained from the institution's application control office. If not otherwise available, they can be requested from: Office of Grants Inquiries, Div. of Research Grants, NIH, Room 448 Westwood Bldg., Bethesda, Md. 20205.

Type the phrase "Preventive Oncology Academic Award" as the title for the proposal on the front page of the application. Use the Special Guidelines for preparation of a Preventive Oncology Academic Award. These and limited staff consultation relating to eligibility and appropriate areas of emphasis may be obtained from: Special Programs Branch, NCI, Room 8C16 Landow Bldg., NIH, Bethesda, Md. 20205; telephone 301-496-9600.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs to the individual named, the Blair Building room number shown, National Cancer Institute, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies reported here will include the complete mailing address at the end of each.

RFP NCI-CP-FS-21030-63

Title: *Computerized abstracts of medical records representing each new patient visit at university veterinary medical teaching facilities in North America*

Deadline for Capability Statements: *June 14*

The Environmental Epidemiology Branch at NCI has been conducting epidemiologic investigations of animals which have been seen at various university veterinary teaching facilities in North American over the last 15 years. The proposed contract is to provide error free computerized abstracts of the medical records representing each new patient visit to these facilities and others in five one-year data blocks beginning July 1, 1980 through June 30, 1985.

The awardee will provide abstraction of the following data items: university designation; patient number; date of discharge; length of stay; attending clinician; patient sex, species, breed, age, weight, and discharge status; ≤ 5 diagnoses, and recheck designation applicable to each diagnosis; ≤ 3 operative procedures; zip code designating the home of the owner of the animal; and deletion code, if applicable.

All abstraction will be performed directly from the original hospital documents, and by or under the direct supervision of a qualified Medical Records Administrator.

All records and documents pertaining to each hospital visit by a patient must be abstracted.

Abstracted data must be coded and edited according to a coding scheme and error routine approved by NCI. Diagnoses and operative procedures will be coded according to the Standard Nomenclature of Veterinary Diseases and Operations, 2nd (abridged ed., 1975, DHEW Pub. No. (NIH) 76-1028, U.S. GPO, Washington, D.C.). Error records must be corrected before submission to NCI.

Five unit periods of data will be abstracted and provided to NCI; each period spans July 1—June 30 of the following year. All data from each period must be completed, edited, corrected, and ready for submission to NCI within six months after the end of the recording period.

Data must be provided on computer tape in acceptable format meeting current processing procedures utilized by NCI.

Data must at least be provided from veterinary teaching facilities at the following universities: Michigan State, Missouri, Minnesota, Iowa State, Guelph (Ontario, Canada), Purdue, Georgia, Ohio State, California (Davis), Kansas State, Illinois, Saskatchewan (Canada), Colorado State, Auburn, Tennessee, and Texas A&M.

Statements of capabilities should contain information of relevant experience and documentation of access to records of veterinary teaching facilities needed to perform the project as outlined.

Contract Specialist: Donna Rothberg
RCB, Blair Bldg. Rm. 114
301-427-8888

The Cancer Letter _Editor Jerry D. Boyd

Published forty-eight times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter.