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## NIH Slow To Implement Equality In Studies, GAO Says, But Waxman Assures Reauthorization

The decision by the National Cancer Advisory Board last year not to fund a multi-million dollar study of the link between cancer and fat content in the diets of women has come back to haunt NCI and NIH at Congressional reauthorization hearings. As NIH turns to Congress for

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*In Brief*

## Capp Heads Roentgen Ray Society; Annual Lecture, Chair Honors Charles Spurr

**PAUL CAPP**, chairman of radiology at the Univ. of Arizona, assumed presidency of the American Roentgen Ray Society at the organization's annual meeting in Washington DC. **John Kirkpatrick**, radiologist in chief at Children's Hospital Medical Center in Boston, was elected president elect. Other officers are **Everette James**, Vanderbilt Univ., first vice president; **Andrew Poznanski**, Children's Memorial Hospital, Chicago, second vice president; **Joseph Ferrucci**, Massachusetts General Hospital, secretary; and **Beverly Wood**, Childrens Hospital, Los Angeles, treasurer . . . . **CHARLES SPURR**, founding director of the Cancer Center of Wake Forest Univ./Bowman Gray School of Medicine, was honored June 1 at the First Charles L. Spurr Celebration. A symposium included delivery of the first Charles L. Spurr Lecture by Emil Frei, director and physician in chief of Dana-Farber Cancer Institute. An anonymous gift of more than $1 million was announced, which will fund the Charles L. Spurr Chair in Medicine. Robert Capizzi, present director of the Cancer Center, was named the Charles L. Spurr Professor. Spurr collaborated in one of the first clinical trials of nitrogen mustard in patients with lymphomas while at the Univ. of Chicago during World War II. These and similar studies opened the door to cancer chemotherapy. Spurr is professor emeritus at Bowman Gray and is chairman of the Southeast Cancer Control Consortium, an NCI funded CCOP. . . . **CARLOS CABAN**, program director for cancer control research in NCI's Div. of Cancer Prevention & Control, will move to the NIH Office of the Director July 1. He will be the extramural program policy officer in the Office of Extramural Research where he will develop policies for scientific review of grants, contracts, and cooperative agreements and will assist in carrying out those policies. Caban has been in the division for 15 years. . . . **WALTER HALL**, chief resident, Dept. of Neurosurgery, at Presbyterian-University Hospital in Pittsburgh, has been awarded the Van Wagenen Fellowship of the American Assn. of Neurological Surgeons. Hall will spend eight months in Norway and England studying effectiveness of immunotoxins in treating cancer.

## Women's Health Issues Haunt NIH Reauthorization Process

(Continued from page 1)

renewal of its authority which expires later this year, the institutes,including NCI, find themselves facing criticism that clinical trials they sponsor ignore women and that women's health issues are not given a sufficiently high priority by the institutes.

"Even preliminary animal studies are usually done with male rats," said Rep. Henry Waxman (D-CA), chairman of the Subcommittee on Health & the Environment of the Committee on Energy and Commerce.

As a result, Waxman said, "Drugs are developed with incomplete data on metabolic differences between men and women and diseases are studied without an understanding of the effects of hormones and reproduction."

In her testimony earlier this week before Waxman's subcommittee, Rep. Pat Schroeder (D-CO) characterized the institutes as an "ole boy network" and said that "American women are gravely concerned about the scant investment in research on women's health issues.

"Just ask the almost 150,000 women who will develop breast cancer this year. Yet we currently spend only $17 million a year on basic breast cancer research," Schroeder said. "Earlier this year, NCI refused to fund a major study on the effect of diet in reducing the risk of breast cancer and heart disease in women."

Schroeder was more than a mere witness at the hearing. She said that she took up the issue after a number of women investigators employed at NIH contacted her and Rep. Olympia Snowe (R-ME), after which the two House members contacted Waxman.

Waxman asked for a General Accounting Office investigation and called a hearing.

Asked by Waxman to explain the reasons for not going ahead with the Women's Health Trial, NCI Acting Deputy Director Richard Adamson said that the decision to cancel the trial was primarily a matter of funding.

"This is a trial that would cost $14 million a year and probably would last for 10 years before it is completed," Adamson said, adding that there were other programs, including the smoking cessation program, that were assigned a higher priority.

Waxman requested that Adamson prepare a list of considerations that led to the decision not to fund the study.

Last year a special study section gave the proposed trial a priority score of 152. Although evaluators called the plan "excellent," they noted a "high scientific risk."

"Problems which will arise during the study include compliance of subjects and a possible weak statistical outcome," the reviewers noted (**The Cancer Letter**, Sept. 29, 1989). The study section said the trial "addresses a pressing scientific problem in human biology and disease, and the findings, if convincingly positive or negative, will be very important."

Testifying before the committee, Maureen Henderson, the principal investigator of the study and head of the cancer prevention research program at the Fred Hutchinson Cancer Research Center in Seattle, said she believed assurances by NCI officials that the project was denied funding for financial reasons.

However, Henderson said, "The public finds it hard to pay serious attention to recommendations about major changes in diet when [NCI] does not actually back up its tentative recommendations with investment in research.

"Even more clearly, the institute has broken with precedent to not fund a peer reviewed scientifically meritorious dietary trial to prevent breast and other major cancers as well as heart disease in older women," Henderson said.

According to the GAO report requested by Waxman, NIH has just begun systematic implementation of its three-year-old policy to encourage the inclusion of women in study populations.

"The people we've talked with at the NIH were dismissive of this policy," said Mark Nadel, Associate Director for National and Public Health Issues at GAO. "They view it as political interference."

Asked by Waxman what level officials he is referring to, Nadel said, "Fairly senior."

The GAO report said the NIH institutes have not consistently applied this policy in grant review and,

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on top of that, it has no way to measure the policy's impact on the research it funds.

Furthermore, the policy applies to extramural research only, and not to projects conducted within NIH.

The report further stated that the Div. of Research Grants and some institutes instruct scientific review group members not to consider the inclusion of women and minorities in the study populations as a factor that would affect the priority score.

If the review group raises a problem with the composition of the study population, it is to be addressed in an administrative note in the summary statement, the report said.

Although the policy to broaden the research base was announced in 1987, a comprehensive memorandum applying the policy to all extramural research did not appear until July 1989, the GAO study said.

The application booklet, PHS Form 398, contains no reference to the policy on women, and a revised version of the form is not expected to appear until April 1991.

"Because of these delays, many scientific review groups are just beginning to send to institute councils summary statements that highlight concerns about the exclusion of women from studies," the report said.

"We reviewed about 50 recent grant applications," Nadel said. "Most of them proposed studies on conditions that affect both men and women.

"About 20 percent of the proposals provided no information on the sex of the study population. Over one-third indicated that both sexes would be included, but did not say in what proportions. Some proposals for all-male studies provided no rationale for that design," Nadel said.

NCI's Adamson as well as NIH Acting Director William Raub said the institutes are committed to including women in clinical trials.

"Clearly, the word didn't get to everybody," said Raub when told of the NIH senior employees who allegedly told congressional investigators that they viewed the inclusion of women as little more than political meddling.

NIH's authorities expire later this year, but no reauthorization bill has been submitted as of yet.

**Emphasizing that NIH reauthorization is in no danger, Waxman said, "We will, unquestionably, reauthorize the research programs of the NIH. But as we move toward the continuation of these programs that all Americans support, we must assure ourselves that all Americans will benefit."**

According to Congressional sources, NIH is expected to be reauthorized for three years.

It appears that there will be little controversy this time over NCI's special authorities, which the institute has had to defend vigorously in the past.

One of those authorities is the requirement to submit directly to the President a "professional judgment" budget request outlining cancer research needs and opportunities. This budget, called the Bypass Budget, is formulated with the NCAB and not modified on other levels of the Executive Branch.

NCI also has special authorities to support construction of laboratories and other cancer facilities, appoint advisory and peer review committees, support a broad array of training initiatives and promote international information exchanges. Other NCI authorities granted by the National Cancer Act include the President's Cancer Panel as well as the President's appointments of the NCI director and NCAB members.

Other concerns aired at the hearing included:

▸**Insufficient resources** allocated to cancer prevention.

"The NCI's Prevention and Control Program has never received adequate funding to accomplish its mission," said Joseph Cullen, director of the AMC Cancer Research Center in Denver and former deputy director of Div. of Cancer Prevention and Control, who headed the Smoking, Tobacco & Cancer Program.

"National and world organizations in this past decade have concluded that 70 percent, or even as much as 90 percent, of cancer incidence is preventable. In other words, every case of cancer that comes to clinical attention is a failure of our society to achieve the ideal."

Cullen said he supports NCI's bypass budget request of $160 million for cancer prevention and control, an increase of $83 million over the President's budget.

However, Cullen said, he is not holding his breath for the bypass budget to be responded to positively. "It never has been!" Cullen said. "Indeed, the cancer prevention and control line is a lower percentage of the NCI total funding today than it was when the year 2000 plan [to reduce cancer mortality rates by half] began being drafted in 1984.

"Then it was 6.1 percent, now it is 5.1 percent, and has been since 1987."

The cancer control funds are provided as a line item in the NCI budget, and, in accordance with the National Cancer Act, Congress has the opportunity to increase the amount specifically earmarked for prevention and control.

▸**A proposed reorganization** of NCI's Smoking, Tobacco and Cancer Program within DCPC.

Although NCI officials, including the division Director Peter Greenwald, said the changes would make the operation more effective, Waxman said he was "alarmed."

Reorganization of the program would involve the following:

--The Smoking, Tobacco and Cancer Branch, located in Greenwald's office, is to be dismantled.

--Personnel and programs of the branch are to be moved into a reorganized Cancer Control Science Program, which would have four branches.

--Coordination responsibilities of the Smoking, Tobacco and Cancer Program will be handled in the office of the director of the Cancer Control Science Program, who is an associate director of the division.

--COMMIT, one of the major antismoking efforts being carried out by DCPC, would be located in the Prevention & Control Extramural Research Branch, along with other investigator initiated research.

--ASSIST, another major DCPC antismoking effort, would be located at the Public Health Applications Research Branch, along with other programs which relate to state health programs.

--The two other two branches of the Cancer Control Science Program would be the Special Populations Study Branch and the National Cancer Program Initiative Branch. The latter would include the National Black Leadership Initiative on Cancer and the National Hispanic Leadership Initiative, and other related activities.

In a statement following the hearing, DCPC officials said that change was needed because "current organization does not allow the branches to function as effectively as possible."

The statement continued:

"Smoking is an NCI wide crosscutting activity and has progressed to the point where its multiple activities should form the core of, and potential models for, other activities.

"Health promotion sciences is a mixture of applications and research, and as such each component would be enhanced by association with like activities. Applications, particularly public health applications, will be a major focus of the program over the next 10 to 20 years. The program is underway, but there are activities now separated from the public health applications that would be enhanced by close association--such as ASSIST. Also ASSIST may be the model for program expansion into other risk factors.

"Investigator-initiated research, particularly grant-based extramural research, is at the heart of the Cancer Prevention & Control Program, as well as the National Cancer Program. The management of this program component will be more effective and efficient by bringing the majority of these activities together. In particular, COMMIT--as a phase 4 cancer control activity--has much to offer as the core of these activities.

"Special populations research will be a major focus of the program for the foreseeable future and is sufficiently narrow a topic that a branch devoted to the topic is appropriate.

"Many new activities that lie in the area of resource development and coordination have been developed over the last several years including the National Black Leadership Initiative on Cancer and the National Hispanic Leadership Initiative and other related activities. The management of these activities needs to be coalesced into one area, hence the new branch."

Responding to Waxman's question, Cullen said he, too, felt uneasy about the proposed changes because, he said, it would be more effective to keep all smoking cessation employees working together, "in one critical mass," and that the reorganization could be construed as a "loss of territory" by the program.

▸**The low pay for government scientists.** Rep. Silvio Conte (R-MA), a ranking member of the Subcommittee on Labor-HHS-Education of the House Appropriations Committee, said an increasing number of NIH scientists are leaving the institute in pursuit of higher salaries in the private sector.

"I've been on that committee for 32 years, and things were never as bad as they are now," said Conte, whose bill proposes salary levels of $58,000 a year for young investigators and $190,000 for senior scientists.

Last week's reauthorization hearing was the subcommittee's fourth on the subject.

In previous hearings, the subcommittee discussed the use of animals in research, research involving fetal tissue transplantation as well as the issues of contraception and infertility.

## DCPC Plans For Future RFAs, But Most Depend On Bypass Budget

"I admire the Bypass Budget. It's intoxicating to think what could be done with it."

James Holland, chairman of neoplastic diseases at Mt. Sinai School of Medicine, cancer clinical trials pioneer and former chairman of Cancer & Leukemia Group B, and presently a member of the Board of Scientific Counselors of NCI's Div. of Cancer Prevention & Control, is not the only one who has harbored such thoughts.

Nearly every discussion by NCI staff members and

their advisors which involves research needs and priorities gets around to the Bypass Budget.

The Bypass Budget for the 1991 fiscal year--for which the appropriations bill Congress is presently working on--calls for $750 million more than requested by President Bush. The Bypass Budget was what Richard Nixon was referring to when he promised, after signing the National Cancer Act of 1971, to give NCI "all the money it needs" for an optimal cancer research effort. It was a promise neither Nixon nor his successors have kept.

Holland's remark was made at the spring meeting of the DCPC board, when a series of concepts for new cancer prevention and control research were approved, few of which will be funded unless NCI and the cancer control line item receive substantially more than requested by the President (**The Cancer Letter**, May 25). DCPC Director Peter Greenwald also mentioned additional concepts which will be presented later this year. Staff members revealed other plans for new or expanded efforts, and board Chairman Frank Meyskens reported on recommendations of a workshop which called for new chemoprevention trials by participants in the Community Clinical Oncology Program.

"In the 1990s," Greenwald said, "emphasis in prevention and control research will continue to be given to smoking prevention and cessation, diet and cancer prevention laboratory and intervention research, chemoprevention research, worksite cancer control and environment, early detection research, research on reaching minority and underserved populations, cancer control applications and communications research, community oncology and rehabilitation research, and health services research.

"Perhaps in this decade, greater emphasis also can be given to the potential for clinical and public health applications of endocrine/metabolic and viral/vaccine research for cancer prevention."

Greenwald added an appeal for more training programs "to ensure that investigators have the appropriate training" to carry out those efforts. "We need to substantially increase our efforts in training programs for cancer prevention and control. One area in which extramural and intramural programs are linked fairly tightly is in training for future scientists. One of our aims is to make cancer centers and NCI strong training grounds for cancer prevention scientists.

"Cancer prevention research needs to be built into the mainstream of leading American research institutions. By this I mean that the excellent basic and etiologic research in many institutions should be extended to intervention studies aimed at learning how to lower risk or having direct public benefit. At present, many institutions do the former, but only a few do the latter.

"The resources for prevention and control need to be greatly expanded to meet research, training, and programmatic opportunities. DCPC is considering a concept that we plan to bring to you in October, which will encourage cancer prevention training of clinical oncologists and cancer biology training for preventive medicine and public health specialists. This could be done by linking cancer centers and schools of public health. In addition, Dr. Douglas Weed of our staff is working at extending our cancer prevention fellowship effort at NCI.

"Future approaches to cancer prevention and control will result increasingly from multidisciplinary research. To encourage this research approach, DCPC and the Div. of Cancer Etiology are discussing the possibility of jointly sponsoring RFAs on studies of cancer control applications of etiologic research. We seek your advice about such an idea and will be considering concepts next year. As an example, should we consider developing an RFA on studies of cancer control applications of human papilloma virus research?

DCPC has been talking with the Div. of Cancer Treatment about adding some prevention training in the intramural clinical fellowship program. "These are the potential future department heads, and key people at centers. They can help us expand the scope of clinical oncology," Greenwald said.

"That's an excellent idea," Holland said. "Politically, if you could find your way to people who write board exams and convince them to add a few questions on preventive oncology, you would find quickly that all training programs include preventive oncology training."

Greenwald reaffirmed DCPC's commitment to ASSIST, the massive effort in partnership with the American Cancer Society to reach 50 million persons in 20 states using proven intervention methods. ASSIST will be a coalition involving state health departments, ACS, universities, and many other channels to target women, minorities, heavy smokers, youth, smokeless tobacco users, and others.

ASSIST may be impaired by a lack of funds, however. "Our Smoking, Tobacco & Cancer Branch staff have estimated the potential impact of ASSIST on future smoking related mortality in this country," Greenwald said. "If ASSIST can be fully implemented for seven years at the Bypass Budget level of $150 million, more than 500,000 lung cancer and one million smoking related premature deaths can be

prevented. If the prevention and control budget is kept flat, less than half that number of lung cancer and premature deaths can be prevented."

Those estimates involve certain assumptions about sites that will apply and be eligible for funding and the resulting size of populations served by the intervention effort, Greenwald pointed out.

**New concepts** for RFAs or reissues of important existing RFAs in prevention research which will be taken first to the NCI Executive Committee and then to the DCPC board include, from the Chemoprevention Branch:

--Preclinical chemoprevention intermediate marker studies (six projects) that will define and validate intermediate markers of cancer risk and examine modulation of these markers in preclinical systems where potential agents have already been show to inhibit cancer endpoints in animals.

--Phase 2 studies of new chemopreventive agents (six projects) that will evaluate whether a specific substance has biological activity affecting some aspects of the carcinogenesis process. Results from these studies will provide an estimate of short term biological effective dose and schedule, further strengthening the rationale for phase 3 clinical trials.

--Chemopreventive trials endpoints modulation; a reissue of the RFA for intermediate endpoint studies.

The Diet & Cancer Branch's new projects proposed for FY 1991 or for FY 1992 include projects under development related to phytochemicals--designer foods, biomarkers, and a planning workshop related to dietary intervention that have been either approved by the board, reviewed by NCI, or are pending.

NCI and the National Heart, Lung & Blood Institute are convening a workshop July 9-10 on dietary intervention trials among women. Purpose of the workshop is to assist NCI and NHLBI in assessing options for a study of the impact of dietary change on cancer and cardiovascular disease incidence and mortality among women.

The workshop will address these questions:

1. What research strategies are available to study the health consequences on cancer and cardiovascular disease of a dietary change among women?

2. What are the strategies and weaknesses of the different intervention research strategies?

3. What are the recommendations regarding the intervention research strategies and the recommended next steps to be taken by the institutes?

In discussions between NCI and NHLBI, both institutes agreed that there is a need to determine the impact of a major change in diet, from the current high fat typical American diet to a low fat diet, in order to determine the impact of dietary change on disease incidence and mortality. Epidemiological and laboratory studies provide strong evidence for an effect, but do not provide the conclusive evidence that can be drawn only from a prospective trial. The institutes would consider joint funding of such a study aimed at a reduction of both cancer and cardiovascular disease.

The branch is also working on an RFA proposal related to oxidative stress and cancer risk. The aim will be to compare oxidative stress status among different risk groups to determine if oxidative stress status reflects risk. Activated oxygen species have been linked to a multitude of diseases including cancer. These studies may provide a short term means for evaluating the effectiveness of antioxidant diets.

Another project will be designed to determine the effect of quality and quantity of protein on parameters associated with cancer risk.

Greenwald pointed out that the Women's Health Trial was projected to cost $14 million a year. "We would need an increase [in DCPC's line item budget] greater than that [to fund the trial] if we decided that was the most important priority. The Executive Committee is not likely to allocate all the increase to that trial."

Meyskens said that a consensus had been reached "that a large trial should go forward" and asked for Greenwald to "come back with a plan."

"I would like to get to a dietary intervention trial," Greenwald said.

**DCPC's new intramural** Laboratory for Nutritional & Molecular Regulation is now equipped and functional in space allocated at the Frederick Cancer Research Facility. Chief of the lab is James Phang, formerly chief of the Endocrinology Section in the Metabolism Branch of the Div. of Cancer Biology, Diagnosis & Centers.

The lab has 10 FTEs (full time equivalent positions) at present. Greenwald said that it will need 45-50 "to get up to full speed." That number is probably not going to be available unless Congress orders the Administration to add positions to NIH and directs a significant number to NCI.

The laboratory conducts research in basic science relevant to nutrition and cancer, emphasizing the basic mechanisms by which nutrients, directly or indirectly, augment or inhibit tumorigenesis.

Plans for the future of the lab include the capability for doing clinical/metabolic studies and expanding the current basic research effort with space and staff. Some additional laboratory space at FCRF is expected

when certain renovations are completed for other NCI activities. For FY 1992, a revised facilities plan has been requested that includes construction of a new laboratory at FCRF that would accommodate all of the intramural nutrition research effort including a capability for clinical nutrition studies.

**Meyskens reported** on the conclusions reached by the workshop on CCOPs and chemoprevention trials:

1. Chemopreventive agents.

Availability of chemopreventive agents to CCOPs and research bases is a critical issue. Mechanisms need to be developed to assure the availability, purchase, and distribution of drugs/compounds in a timely manner.

The process by which a chemoprevention agent is approved for use by FDA as a drug is not well defined. Chemoprevention agents are currently located in many different areas of FDA. DCPC staff needs to work with the Oncologic Drugs Advisory Committee of FDA to establish a process.

New personnel resources need to be released immediately to facilitate these goals.

2. Types of prevention trials.

CCOPs and research bases are best equipped and structured to perform trials of the prevention of second malignancies and preneoplasias. Both types of studies will require the identification of new types of medical expertise (e.g. dermatologists, gastroenterologists) not now prevalent in the CCOPs or research bases.

CCOPs may be able to participate in large prevention trials such as those involving prepaid health plans, but proposals will probably need to be developed by lead institutions and brought to the CCOPs.

Resources for support of research specialists in the large research bases to allow the timely development of chemoprevention trials should be a high priority.

3. Intermediate endpoints (biomarkers).

The study of endpoints provide a unique opportunity to understand the biology of early human cancer development and prevention. The measurement of intermediate endpoints should be integral to all chemoprevention trials, whenever possible.

The opportunity to expand programs to include DCPC interactions with DCE and other divisions is considerable, and mechanisms should be developed and resources provided to support this process. The development of a number of joint RFAs in this area seems highly appropriate.

4. Dietary/nutrition.

A clear set of instructions should be developed for chemoprevention trials so that appropriate tracking and assessment (e.g. calcium, carotene) of relevant nutrients can be performed. Centralized, well formulated protocols need to be developed to which CCOPs can respond.

It may be possible to develop a focused infrastructure within the research bases that can allow the development of large, cost effective trials using CCOPs.

If new funds become available, an investment to support research specialists in research bases is highly recommended.

Board member James Gaylor noted that "90 to 95 percent of drugs are developed or discovered by industry, but they are not organized to discover or develop prevention drugs. I suggest that you include the drug industry on committees and groups addressing these issues."

Greenwald agreed and pointed out that "some compounds are naturally occurring food substances, so there is no incentive for industry, no prospect of patents. I've allocated another position to the Chemoprevention Branch to work on developing the CCOP chemoprevention effort."

"Has there been any effort to broker a marriage between centers and CCOPs on chemoprevention?" board member Edward Bresnick asked.

Meyskens said the suggestion has been made for NCI to make cancer center chemoprevention research awards which would require participation of CCOPs. He added that M.D. Anderson and Univ. of Arizona centers have been "very active" in involving CCOPs in prevention projects.

Board member Lloyd Everson asked about the mechanism of disseminating research ideas to CCOPs. Leslie Ford, chief of the Community Oncology & Rehabilitation Branch, said that "they have to be brokered by a CCOP or center." She said that eight centers currently are approved as research bases for CCOPs (in addition to the cooperative groups).

Board member Ross Prentice asked about the leadership role of cooperative groups in prevention clinical research.

"The large number of clinicians and nurses available through the cooperative groups is a vast resource," Meyskens said. "Whether they can or will develop ideas and assume the leadership, I don't know."

Greenwald said he felt that certain aspects of prevention clinical trials would appeal to the groups.

Meyskens said that "there has been a lot of interaction with the Oncology Nursing Society" on the matter of training nurses in prevention. "They are very interested in prevention and control."

Greenwald and his colleagues with special interest

in cancer prevention and control have been frustrated and angry over the "flat" cancer control line item in appropriations bills for most of the last decade. The increases have not kept up with inflation, nor the small increases for NCI as a whole.

The line item does not tell the entire story on cancer control funding, however. Carlos Caban, program director for cancer control research who is leaving DCPC July 1 to take a position in the office of the NIH director (see In Brief, page 1) commented in his letter of resignation to Greenwald on the long range research programs variously named CCRU, CPRU, and CCSP, and the cancer control small grant program which Caban administered:

"These programs have met the highest scientific standards of NIH, as evidenced by their ability to compete against and receive funding from the NCI research project pool, rather than the cancer control budget. Your support in obtaining this funding, when needed, has been appreciated by me and the grantees. The effect has been to supplement the chronically flat NCI cancer control budget of $63-69 million by approximately $25 million in FY 1990, or 36 percent."

## Foreign Awards Less Than 1% Of NCI's Budget; Canada Has Most

National Cancer Advisory Board member Howard Temin had expressed concern, at a previous meeting, about the advisability of awarding NCI grants to foreign institutions at a time when the institute could fund only 20-25 percent of approved U.S. grantees, at reduced levels. He asked for a report on the extent and nature of NCI foreign grants and contracts.

After NCI Administrative Officer Philip Amoruso presented that report at the board's recent meeting, Temin responded to a needle from Chairman David Korn: "Once I learned that all foreign grants fell under the payline, and that they amount to less than one percent of the NCI budget, my concerns evaporated."

Amoruso pointed out that a provision in the National Cancer Act authorizes the NCI director, in consultation with the NCAB, to "support (A) research in the cancer field outside the United States by highly qualified foreign nationals which can be expected to benefit the American people, (B) collaborative research involving American and foreign participants, and (C) the training of American scientists abroad and foreign scientists in the United States."

NIH guidelines for foreign grants include the following criteria:

▸ The project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries which are not readily available in the U.S. or which provide augmentation of existing U.S. resources.

▸ The project has specific relevance to the mission and objectives of the awarding NIH component and has the potential for significantly advancing the health sciences in the U.S.

▸ The application must be at or above the median (50th) percentile of priority scores for approved applications at that review cycle. Copies of the guidelines may be obtained from Fogarty International Center, NIH, Bethesda, MD 20892.

Amoruso presented a breakdown of NCI foreign grants and contracts for the 1989 fiscal year. NCI awarded a total (U.S. and foreign) of 4,444 grants and contracts that year, at a total cost of $1.156 million. The foreign total was 91 awards, $13.15 million, less than one percent. There were 69 foreign grants, at $6.2 million, and 22 foreign contracts, at $6.9 million. Canada received nearly half of the grants, with 30, funded at $2.4 million, plus four contracts worth $630,000.

Finland had only two contracts but they totaled more than $3.6 million, or 28 percent of the entire foreign award budget. Those were for large epidemiology\dietary studies awarded by the Div. of Cancer Prevention & Control. Awards by country:

Australia--Five grants, $392,000, no contracts.

Belgium--Two grants (to the European Organization for Research on Treatment of Cancer, which is headquartered in Brussels), $274,000, no contracts.

Canada--30 grants, $2.4 million, four contracts, $630,000.

China--One grant, $6,000, five contracts, $1.3 million.

Denmark--No grants, three contracts, $164,000.

Finland--No grants, two contracts, $3.6 million.

France--Seven grants (including the World Health Organization and International Agency for Research on Cancer, headquartered there), $1.2 million, no contracts.

Israel--Seven grants, $524,000, one contract, $62,000.

Italy--Two grants, $324,000, no contracts.

Jamaica--No grants, one contract, $590,000.

Japan--One grant, $38,000, one contract, $170,000.

Sweden--Six grants, $552,000, four contracts, $208,000.

Switzerland--Two grants (to the International Union Against Cancer, headquartered there), $133,000.

Trinidad--No grants, one contract, $207,000.

United Kingdom--Six grants, $349,000, no contracts.