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NCI Expects Centers To Increase Cancer Control Efforts Despite Various Obstacles They Face

Although NCI apparently has no intention of reviving any semblance of the 1970s program which earmarked cancer control funds for cancer centers, increasing pressure will be brought on centers to step up their cancer control efforts. Jerome Yates, director of the Centers & Community Oncology Program in the Div. of Cancer Prevention & Control, made that clear when he told the National Cancer Advisory

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In Brief

Hatch Introduces Bill Banning Smoking On U.S. Public Conveyances; New OCC Staff Announced

BILL BANNING smoking on all regularly scheduled public conveyances traveling within the United States was introduced last week by Sen. Orrin Hatch (R.-UT). It would also prohibit smoking in waiting areas of terminals and restrooms, although operators of terminals could designate specific space as smoking areas provided they are physically separate from the nonsmoking sections. Citing the recently documented dangers of passive smoking, Hatch said "the 1,000 smokers who play Russian roulette with cigarettes and lose everyday take 12 to 15 innocent bystanders, nonsmokers, with them". . . . **NEW STAFF** in the Information Projects Branch of NCI's Office of Cancer Communications, as announced by Branch Chief Rose Mary Romano: Katherine Crosson, to head the patient education program--she has been director of the Community Health Education Div. of the Univ. of Massachusetts, and previously was with M.D. Anderson and Fox Chase in similar capacities; John Burklow, a one year appointment to work in prevention and patient education programs; and interns Joyce Williams and Debra Egan, graduate students at the Univ. of Michigan and Univ. of Washington, respectively . . . . **PAUL VAN NEVEL**, director of the Office of Cancer Communications, will announce soon the new chief of the Reports & Inquiries Branch. The former chief, Robert Hadsell, left last year to become director of public relations at Fox Chase Cancer Center. . . . **JOHN SECRIST**, associate director of organic chemistry at Southern Research Institute, has been appointed director of the Organic Chemistry Research Dept. there. . . . **JOHN ISAACS**, Johns Hopkins Univ., has been appointed managing editor of "The Prostate," eight year old journal published by Alan Liss and edited by Gerald Murphy and Avery Sanburg.

"Unique Position" Of Centers Should Increase Cancer Control Emphasis

(Continued from page 1)
Board last month that "centers are in a unique position to bridge laboratory and clinical research to application. . . the 1980s should be a period of increasing emphasis on cancer control by the centers."

In recounting the history of cancer center involvement with cancer control since the National Cancer Act of 1971 stimulated development of centers, Yates noted that "the first generation of cancer centers were after the Cancer Act were mostly appropriately concerned with the development of unified programs in areas of laboratory research and cancer training. These preceded similar efforts in clinical and cancer control research at most of the centers. In the mid 1970s explicit guidelines outlining the essential characteristics of a cancer center seeking core grant support were offered. With these guidelines, the core grant program has been extremely successful."

However, effective implementation of cancer control programs is essential to NCI's Year 2000 goals, and centers will have to play prominent roles in those programs if they are to succeed, Yates indicated.

"During the 1970s, the basis for receiving NCI support for cancer control came with demonstration projects, with the exception of rehabilitation research. Training and research interests in the laboratory and clinics grew in most centers. The centers succeeding in conducting cancer control built their programs as an extension of productive clinical investigation in cancer treatment. The first cancer control money for research was in the Cooperative Group Outreach Program, a program that continues to be successful to this day" (although it is no longer being supported by cancer control funds but has been moved to the Div. of Cancer Treatment and integrated with the Cooperative Group Program there).

When Peter Greenwald became director of DCPC in 1981, cancer control demonstration projects were dropped in favor of "rigorous research" which "improved cancer control," Yates said. "The introduction of a new strategic definition and a categorical structure for cancer control research is a milestone. The conceptualization of cancer control as a series of clearly defined steps in a sequential process has provided order to a very complicated system." Those steps are defined by DCPC as development from leads in basic research and epidemiology to hypothesis development (phase 1), methods development (phase 2), controlled intervention trials (phase 3), defined population studies (phase 4) and demonstration and implementation (phase 5). The final step is then implementation of nationwide prevention and health services programs.

"This research involves many investigators," Yates continued, "occurs outside of the cancer center, takes a lengthy time for project completion, is difficult to control, has resulted in fewer definitive scientific publications per project, and as a discipline is under represented by experts--all factors which work to slow cancer center interest in cancer control. Centers, through cancer control investigation, are in a unique position to bridge laboratory and clinical research to application. In our view, the next generation of cancer center directors face broader problems. The merging of laboratory science through molecular and toxicologic epidemiology, the identification of high risk populations and the development of improved detection and diagnostic techniques are examples of the type of basic laboratory investigation at the centers which must be applied to cancer control research. Now, just as the 1970s was a period of growth in the number of cancer centers inside of universities, the 1980s should be a period of increasing emphasis on cancer control by the centers."

Cancer Control Obstructions

Yates cited recommendations of the Yarborough Panel, which led to the National Cancer Act of 1971, and pointed out the Panel emphasized the importance of geographic distribution of centers where scientific, professional and managerial personnel already existed.

"An integrated approach was considered important, and this was later incorporated in the comprehensive cancer center guidelines because it was felt to offer the best organizational structure for enhanced cancer center activity," Yates said.

"However, less apparent factors obstruct the implementation of cancer control at many centers and these should be quickly reviewed. Besides the NCI posture in the 1970s of not supporting most cancer control research, except in rehabilitation and clinical trials, there was and is a general suspicion from the

traditional cancer center research community that cancer control research could not be done or is a poor research investment. The organization of most medical schools in which the new centers were formed chose to remain aloof from the community while practicing introspection and saying that their only community obligation was to export qualified trainees who then would take responsibility for local cancer control efforts. Changes in the medical environment have been extensive in the past five years. Economic competition causing a decrease in referrals to research institutions, an increase in well trained practicing physicians in the community, and a renewed emphasis on research and training in cancer control by the leadership in the National Cancer Institute have provided new opportunities for cancer control research.

"Cancer centers are extremely diverse organizations with complex institutional affiliations, member participation, sources of support, reginal interactions, and research expertise and emphasis. Centers may be freestanding such as Memorial Sloan-Kettering or the Jackson Laboratories in Maine; they may be university based such as the comprehensive centers in Duke or the Univ. of Wisconsin; they can represent government institutions such as Roswell Park or M.D. Anderson; and lastly, other members of the centers network, namely the community clinical oncology programs, provide an ever increasing contribution to the national clinical research effort.

Sources of Support

"The sources of support for cancer centers are often complex and include funding from the federal grants and contracts, state budgets, universities, philanthropy, and patient care income generated by center staff.

"The existence of a cancer center in a community provides a target for philathropic donations such as the recent trust set up at the Univ. of Miami providing significant stability through resources that might not have been otherwise available.

"Cancer center diversity pertains also to cancer control with a range that extends from almost no activity to extensive regional interactions such as may be seen in Illinois at the Illinois Cancer Council or in Northern California.

"Both of these center consortiums provide a cancer control focus for a number of medical schools in their respective areas. Most centers have voluntarily chosen to limit their cancer control research and regional activities. The expectations that a uniform set of approaches as was outlined in the comprehensive cancer center guidelines appears unrealistic in retrospect. The diversity seen in cancer centers' interests in basic laboratory research based on available expertise and resources should have taught us to expect the same in such a diverse discipline as cancer control.

"There are four major components to a cancer center core grant, including administrative leadership, program leadership, shared resources, and developmental funding. The programs provide a matrix often cutting across conventional departmental lines and involving investigators through horizontal interactions across departmental lines or vertically from the laboratory to the clinic.

Information Diffusion

"Shared resources include examples such as special facilities for animals, pieces of equipment such as a flow cytometry, concentrations of expertise and equipment as in a pharmacology or pathology resource, and study design expertise and management tools as might be found in a computer center.

"This matrix effort superimposed on conventional departmental structures stimulates the diffusion of information and enlarges the available opportunity structure for research while improving the efficient application of research resources.

"The university centers have developed this matrix overlay on their conventional departments organized around teaching responsibilities rather than research interests. Their program areas are more mission oriented and bring together investigators with common interests (programs) and technological needs (shared resources) achieving synergism and efficiency in research. The cancer center core grant provides the support for these core activities built on a foundation of excellence as measured by previously peer reviewed RO1 and PO1 support. The eminence of these institutions in cancer and their continued superior performance is a reflection of the importance of selecting only those institutions with the expertise and resources to conduct research.

"Lastly, there are community cancer centers which are springing up. Some of these are the direct result of cohesion brought about by the support of clinical research in the community through the community programs

supported by NCI. Others have resulted from local hospital investments in an effort to consolidate services and improve efficiency while making access easier for patients. Still others are calling themselves centers primarily for the purpose of marketing care in regionally competitive areas. The medical schools are being forced to recognize their need for making communities aware of differences between nominal and actual centers.

"There are three types of cancer centers which share some overlap in activity, but which are labeled differently because of the extent of their research effort. All share the common requirement for having a base of peer reviewed research support but differ in their participation in clinical research and cancer control. The laboratory centers are primarily devoted to wet bench science. However, some of these developed collaborations with clinical colleagues in areas such as biomarkers and genetic epidemiology. The second type of center is the clinical center which is expected to have both laboratory and clinical research, although core grant support for the clinical program is usually small or nonexistent.

Comprehensive Centers

The third type of center is the comprehensive cancer center which was expected to have laboratory and clinical research, but their primary distinction was some commitment to providing a regional leadership role in cancer efforts. Centers receiving the comprehensive designation were reviewed separately for comprehensive status and received no funding for this designation, with the only requirement for continued recognition being the necessity of holding a peer reviewed center core grant. Their interest in cancer control is mixed, but for many it only represents a label without substantive cancer control research or interest."

Yates noted that distribution of the types of core grants is about equal. Funding for core grants for the three types of centers--laboratory, clinical and comprehensive--is similar in terms of the allocation to shared resources and professional personnel. Of the 57 core grants presently in effect, 15 are to laboratory centers, 22 to clinical centers and 20 to comprehensive centers.

"The overall ratio of core grant support to cancer center support derived from other NCI sources is about 20 percent for each of the three types of centers and remains constant," Yates said. Comprehensive centers received in FY 1985 a total of $269.6 million from all NCI sources including core grants; clinical centers, $108.7 million; and laboratory centers, $60.1 million.

"The allocation of the total core grant budget to the three types of centers is evenly divided and has remained relatively constant over the previous years," Yates continued. "If one looks at the individual budgets, three examples, one from each type of center, the magnitude of support appears to be consistent with the size of the institution, the number of involved investigators, and the current support. The three centers chosen as examples include Memorial Sloan-Kettering as an example of a comprehensive center, Bowman Gray in North Carolina as an example of a clinical center, and the Armand Hammer Center for Cancer Biology (Salk Institute, San Diego) as a laboratory center."

MSK's core grant was listed by Yates as $4.3 million; NCI RO1s, $10.4 million; NCI PO1s, $8.5 million; and clinical research (cooperative groups), $19.1 million. For Bowman Gray, the core grant is $586,000; RO1s, $882,000; no PO1s; and clinical research, $317,000. For Hammer, the core grant is $753,000; RO1s $3.3 million; and no PO1s or clinical research funding. MSK placed 2,134 patients on protocol and Bowman Gray, 819. MSK has 418 professional staff members, Bowman Gray 96 and Hammer 16.

Consortium Center

"A fourth type of center is the center consortium for which guidelines were developed in 1984 to encourage center efforts in cancer control," Yates continued. "The successful cohesion of multiple institutions, including the health departments in the states of Illinois and California, served as a useful model for the promotion of these guidelines with the expectation that other similar consortium centers would evolve in other areas of the country. The medical/political neutrality of a consortium center appears to be more effective for some cancer control efforts because many universities are often isolated communities within communities, regional cancer control activities may be political, and health department involvement is desirable. This consortium may be particularly advantageous for addressing cancer control problems in targeted minority populations sharing similar cancer issues but

being geographically separated. Presently, NCI has funded a planning grant for three black institutions, attempting to put together their resources for a subsequent consortium application. This new mechanism should receive greater acceptability and serve as a training program for the development of much needed young investigators in cancer control."

Yates discussed issues and problems facing cancer centers.

"Historically, the number of centers rose markedly in the early 1970s. They have dimished within the past decade," declining from 63 core grants to the present 57. "The budget has increased to $93.189 million for FY 1987. Over the past four years there have been a series of planning meetings to address a variety of issues facing cancer centers in the future." These include the number, type and location of centers; their research roles and participation in cancer control; the level of approved support; and guideline changes, including eligibility and increases in requested amounts.

"Some (of these) are resolved and others continue to be open to question and consideration," Yates said. "Because of the constrained funding, future funding plans must look at the number of centers, the cap on the amount centers may request, the percentage of core grant recommended by peer review, the percent of recommended support funded, and whether or not there should be changes in the guidelines to broaden the eligibility to encourage applications from new centers."

Optimal Support

NCI has stated, in its last three bypass budgets (those which go directly to the President without alteration by NIH or HHS), that among the resources needed to meet the Year 2000 goal of reducing cancer mortality 50 percent will be a cancer centers budget increasing to $166.6 million by FY 1992 which would support an additional 30 centers, and all center grants would be paid at close to their peer review recommended levels.

"Many scenarios could be developed depending on the assumptions about their number, size and growth," Yates said. "Besides funding issues, the question of total number of centers, the types of centers that should be added (should we add any more laboratory centers?), and the location of the new centers are all considerations.

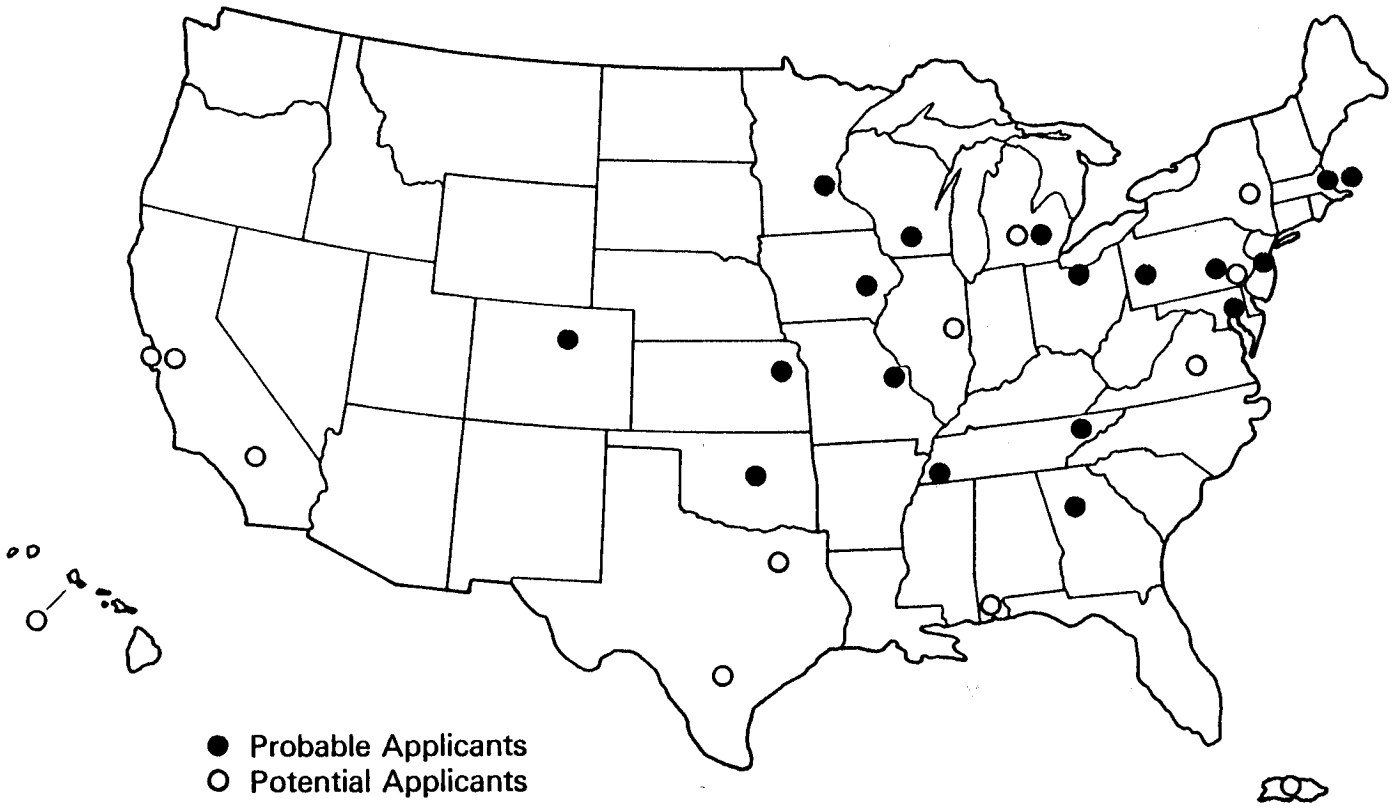
"During the 1970s, a number of studies addressing optimal geographic distribution were completed. A foundation of research excellence is not present in all areas of the country, but there are about 30 sites today that are possible future centers.' A review of the institutional RO1/PO1 support from NCI going to probable and possible core grant applicants again demonstrates a distribution comparable to the population density with some increased coverage in the Midwestern states possible. There is some sentiment that because of the high priority often given to laboratory centers when they are peer reviewed, they have an advantage in obtaining core grant funding. As one looks at the proportion of core grant funding going to laboratory centers in the past five years, this does not appear to be the case. However, with tighter funding there is more interest expressed by potential laboratory centers.

"As NCI moves to increase the emphasis on early detection and prevention with new thrusts in cancer control, the role of the centers program in these efforts is somewhat clear. Cancer control initiataives over the past four years has stimulated activity in the cancer centers with 38 percent of all cancer control research funding going to centers.

"Developing collaborative research networks in the use of the FACS for the early detection of bladder cancer in five centers was received with enthusiasm," Yates said. "Funding restraints abridged the MRI network which we hope will be in a position to compete for support in the future. Their interactions with their communities, clinical trials research efforts, and cancer control research appear to be in a state of transition. Many centers make major time commitments to local hospitals, providing consultative expertise at tumor boards.

"This interaction needs to be extended. With the emphasis on cancer control research and the development of new expertise in this discipline, the availability of the consortium grant as a potential instrument for multi-institutional cancer control efforts, the stimulation from the Community Clinical Oncology Program with some centers acting as the research bases for this protocol driven cancer control research, and a focus on the general guidelines established by the objectives for the Year 2000; a milieu is present that should enhance center involvement in cancer control. These factors were not present 10 years ago. These networks of clinical trials and cancer control should

Potential Applicants for Core Grants



provide new meaning to the words 'cancer center' as well as a renewed interest in the original congressional intent of the comprehensive designation.

"There now is in place a network of clinical trials, cooperative groups, centers, community programs, and research support available from NCI to expand our knowledge and effort to impact cancer mortality over the next few decades. We know the cancer centers led the way in laboratory and clinical research, but their challenge for the next decade will be to demonstrate that they can do the same in the area of cancer control."

Probable, Potential Applicants For Center Core Grants Identified

Jerome Yates displayed a slide of the map above during his presentation to the National Cancer Advisory Board when it met last month at Memorial Sloan-Kettering Cancer Center. He did not, however, identify the "probable" and "potential" applicants for cancer center core grants, leaving it up to speculation on whom they might be.

At **The Cancer Letter's** request, Yates provided the following ID (note that these are based for the most part on the amount of NCI RO1 and PO1 research presently funded at each of the prospective applicant institutions; there are other potential applicants, Yates acknowledged):

From the far left, in the Pacific, the Univ. of Hawaii; Stanford Univ. and Univ. of California (San Francisco) in Northern California, and Loma Linda Univ. in Southern California.

Univ. of Colorado, in Denver; Univ. of Oklahoma, in Oklahoma City; Univ. of Texas, in Dallas; Baylor College of Medicine, in Houston; Louisiana State Univ. (with other institutions) in New Orleans; Univ. of Kansas, Kansas City; Univ. of Minnesota, Minneapolis; Univ. of Iowa, Iowa City.

In Wisconsin, a statewide consortium; Univ. of Illinois, Champaign; Washington Univ., St. Louis; Univ. of Tennessee, Memphis; Vanderbilt Univ., Nashville; Emory

Univ., Atlanta; Univ. of Michigan, Ann Arbor, and Michigan State Univ., East Lansing.

Cleveland Clinic, Ohio; Pittsburgh Cancer Institute; Pennsylvania State Univ. (Hershey); Jefferson Univ., Philadelphia; Univ. of Virginia, Charlottesville; Univ. of Maryland, Baltimore; New Jersey School of Medicine & Dentistry; Albany Medical College, New York; Univ. of Massachusetts and Boston Univ., Boston; and Univ. of Puerto Rico, San Juan.

Payline For 1988 Would Be Around 160 Under President's Budget Request

More ramifications of the Administration's FY 1988 budget request for NCI:

--The priority score payline for RO1 and PO1 grants in 1988 is estimated, with the amount of money requested by the President, at about 160. That would fund approximately 35 percent of approved competing grants.

--The payline for RO1s and PO1s in FY 1987, if $64 million is transferred out of the 1987 budget and moved to 1988 as requested by the White House, would be around 160, about two points less than it would be if that money is kept in the 1987 budget. An estimated 114 fewer grants would be funded, and the rest of the money would be squeezed out of the remaining grants by renegotiating their budgets downward.

--The 1988 budget for the clinical cooperative groups would be the same, $57.6 million, as in 1987. Other than the $100 million reduction for research project grants, most other funding mechanisms were unchanged, except for construction, which was eliminated entirely, and AIDS research, which got an increase of $23 million.

--The spectre of Gramm-Rudman-Hollings, which threatened to devastate the NCI and NIH budgets last year at this time, does not at the moment seem so frightening. Both the 1987 and 1988 budgets appear to be meeting the GRH deficit reduction targets without invoking the across the board cuts.

The President's budget request includes the request to Congress to transfer $64 million from NCI's FY 1987 grants budget to 1988 (**The Cancer Letter**, Jan. 9). For all of NIH, that transfer request totals $334 million, and would cut the number of new and competing grants from 6,354 funded by Congress in the 1987 appropriations bill to 5,654.

The President's budget request for all of NIH is nearly $8.3 billion, but that includes the $334 million transferred from 1987, and it also includes the "forward funding" of 1988 grants for the entire three year life of those grants, requiring another $2.7 billion. When those add ons, which Congress is unlikely to approve, are deducted, the true NIH budget request is $5.5 billion.

It is obvious that OMB did not think through the ramifications of this new forward funding request. In the first place, given the hostility shown by Congress when a similar ploy was made two years ago, it should be obvious that it has no better chance of succeeding now than it did then. In the second place, not all grants are for three years, and in fact an increasing number are being made for five years. What happens to the final two outlying years under the new scheme? NIH could be locked into a system which delays adjustments almost until it would be too late to bother with.

The transfer of 1987 funds, which really amounts to a cut rather than transfer, is just as disruptive. NCI and the other institutes have had to withhold full amount of grant awards, and delay making others, in order to meet the requirements of the reductions. OMB will have to submit that proposal in the form of a rescision, when the formal budget is submitted Jan. 26. The budget that went to Congress last week was an unusual, early submission, some say intended to divert attention from the other problems facing the White House (Iran, Contras, etc.).

Nexon Heads Kennedy Health Staff; Resolution Asks May As "NCI Month"

David Nexon, who was the minority health staff director of the Senate Labor & Human Resources Committee while the Republicans were in control, has been elevated to the same position on the majority side, now that Democrat Sen. Edward Kennedy has replaced Sen. Orrin Hatch as chairman of the committee.

Meanwhile, the 100th Congress is starting to get, or soon will, legislation affecting NCI and the National Cancer Program.

One of the first items is House Joint Resolution 54 designating May, 1987, as "National Cancer Institute Month." It was introduced by Rep. Claude Pepper (D.-FL), who as a first term senator cosponsored the bill which created NCI in 1937. Pepper served in

the Senate until 1948, later was elected to the House where he has served for more than 25 years and has continued his strong support of biomedical research. He is chairman of the powerful Rules Committee.

NCI's year long observance of its 50th anniversary, which coincides with the recognition of NIH's 100th anniversary, will include an alumni reunion day May 16 at the Bethesda campus. All past NCI employees, along with current staff members, are invited to participate. Alumni are invited to write for further details to Bayard Morrison MD, Bldg 31 Rm 10A52, NCI, Bethesda, MD 20892.

Still not introduced by **The Cancer Letter** press time this week but certain to be soon was the bill providing "technical amendments" to the Biomedical Research Authorization Act which NCI desperately wants adopted. Among other corrections, this would restore the 1971 language to the National Cancer Act which would require the Office of Management & Budget to apportion NCI's appropriated funds directly to NCI, rather than going through NIH. OMB took advantage of inadvertent omission of that language in the authorization renewal to make the apportionments directly to NIH, along with the provision that any reprogramming of funds would have to be approved by NIH. That has in effect made it very difficult for NCI to switch funds from one program area to another and greatly limited flexibility.

There are other nettlesome matters which could be addressed in the technical amendments. Hatch had included those changes in the bill he introduced near the end of the last session, but that bill did not reach the Senate floor, and was never introduced in the House.

Rep. Henry Waxman (D.-CA), chairman of the House Health Subcommittee, has agreed to introduce a similar bill this session.

Another measure left from last session is Sen. Daniel Moynihan's (D.-NY) effort to require the Health Care Financing Administration to exempt cancer centers from the Medicare prospective payment (DRG) reimbursement regulations. That had obviously been the intent of Congress in the legislation establishing prospective payment.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair building room number shown, National Cancer Institute, NIH, Bethesda MD 20892. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring MD.

RFP NCI-CO-74108-10

Title: Technical writing, publications and distribution, and telephone answering services in response to cancer related inquiries
Deadline: Approximately Feb. 15

This project is to assist the Office of Cancer Communications in providing technical writing, publication distribution and telephone answering services in response to cancer related inquiries. The number of inquiries annually is expected to be (1) written, 410,000; (2) telephone, 100,000; and (3) publication ordering service (telephone), 130,000.

The offeror's office must be located within the Washington DC metropolitan dialing area. The offeror also must be available for consultation at NCI in Bethesda within one hour's notice.
Contracting Officer: Patricia Rainey
RCB Blair Bldg Rm 314
301-427-8745

RFP NCI-CM-87209-30

Title: Maintenance of rodent production centers
Deadline: Approximately April 1

NCI is seeking an organization with the capabilities and facilities for producing pathogen free rodents. To be considered for award of a contract, respondents should meet the following criteria:

1. Have existing facilities which have the capability and performance records which document the successful exclusion of plathogenic organisms.
2. The principal investigator and other key personnel should have experience and expertise with rodent inbreeding procedures, and with the production of highest quality rodents.
3. Organizational experience with the production of highest quality laboratory animals.

It is anticipated that one contract will be awarded for this effort, as a result of this RFP, for a period of 60 months. This award will be for 2,000 cages (mouse equivalent. This RFP is a recompetition of the project being performed by Charles River Laboratories, Harlan-Sprague Dawley, and Simonsen Laboratories.

This proposed procurement is designated as a 100 percent small business set aside, the size standard for which is 500 employees or less.
Contract Specialist: Elsa Carlton
RCB Blair Bldg Rm 224
301-427-8737

NCI CONTRACT AWARDS

Title: Biological specimen repository for patients at high risk of cancer
Contractor: Biological Research Faculty, $1,063,440

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