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OMB RESTRICTION ON REPROGRAMMING COULD RESULT IN INEFFICIENT LAST MINUTE SPENDING BY INSTITUTES

The last ditch maneuvering by the White House to squeeze all it can out of the NIH 1985 fiscal year budget is not likely to return any significant sums to the treasury; instead, it could lead to some
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In Brief

COOPER RESIGNS FROM DCPC BOARD, BETTINGHAUS NAMED CHAIRMAN; WILLIAM DEWYS LEAVES NCI

ROBERT COOPER, director of the Univ. of Rochester Cancer Center, has resigned as member of the Board of Scientific Counselors of the Div. of Cancer Prevention & Control for personal reasons. He was recently appointed chairman of the Board; he will be succeeded in that position by Erwin Bettinghaus, dean of communication arts and sciences at Michigan State Univ. Cooper also had been chairman of the Board's Policy Advisory Committee on the division's two low fat breast cancer trials. Paul Engstrom, Fox Chase Cancer Center, now will head that committee. . . . **WILLIAM DEWYS**, former DCPC associate director and head of the Cancer Prevention Program, resigned from the government effective Aug. 31. He is now practicing medical oncology with the Capital Area Permanente Medical Group in the Washington D.C. area. . . . **NORTON NELSON**, professor emeritus of environmental medicine at New York Univ. Medical School, will receive the 1985 Collegium Ramazzini award for his pioneering work in occupational health. He will share the award with Alberto Bisetti, Univ. of Modena, Italy. The award will be presented at the international conference "Living in a Chemical World" in Bologna, Italy, Oct. 6-10, sponsored by Collegium Ramazzini. . . . **NOMINATIONS** are now being accepted for the ninth annual Bristol Myers Award for Distinguished Achievement in Cancer Research. The award, a \$50,000 prize and sterling silver medallion, is presented to a candidate chosen by an independent selection committee. Nominations may be made by officers of medical schools, freestanding hospitals and cancer research centers. Two letters of reference from individuals from outside the nominating institution must be provided. Contact Kathryn Bloom, manager, public affairs, Bristol Myers Co., 345 Park Ave., New York 10154. . . . **WAYNE DORRIS**, chairman of social work at the Wilford Hall, U.S. Air Force Medical Center in San Antonio, has been appointed associate director of the department of social work at M.D. Anderson Hospital & Tumor Institute. . . . **PATRICIA REYMANN** has been appointed coordinator of the Gordon L. Ross Cancer Center at Baptist Medical Center Princeton in Birmingham, Ala. Her duties include coordinating the programs and services offered by the center.

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OMB ACTIONS LIMIT NIH FLEXIBILITY; NATCHER SUBCOMMITTEE MARKS UP BILL

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expenditures for lower priority items as institute directors scramble to spend their entire allocations by Sept. 30.

The order by the Office of Management & Budget restricting reprogramming of funds from the categories as spelled out in the President's budget (**The Cancer Letter**, Sept. 6) is an unprecedented limit on the flexibility of NIH managers to spend their dollars as they deem most effective. At NCI, at least, where budget allocations among the various categories and mechanisms is under constant review, program leaders and division directors compete right down to the end of the fiscal year for funds that remain uncommitted. It is impossible to project to the last dollar, when the budgets are made up a year in advance, spending in each category. Money saved by tight negotiations, terminations or other economies has been used to pay worthy grants otherwise unfunded, to bring some grants up closer to recommended levels, or for equipment procurements which don't involve future year commitments.

That probably will not be possible now, unless OMB can be pressured into backing down.

As the order now stands, reprogramming may be done only if it does not change the NIH wide totals for each category. That means that if NCI wants to move \$1.4 million from research projects to the cooperative groups and another \$1 million to cancer center core grants, as it had planned, it will have to negotiate with NIH and other institutes for someone to restore that \$2.4 million to research projects.

The OMB order said that any other changes among the categories could be made only with its permission. The goal of the entire exercise is obviously to cut back NIH spending closer to the amount asked in the President's budget, disregarding the actions by Congress in its appropriations legislation, which was signed by the President. It isn't likely that OMB will go along with any reprogramming requests if instead a few million can be returned to the treasury and claims can be made on reducing the deficit.

What this means for cancer centers and the cooperative groups is a further reduction in their already limited budgets. Even with the extra \$2.4 million, center core grants had been projected for funding at an average of 85% of the peer review recommended levels, and cooperative groups at 15-20% under the recommended levels.

The cutback possibly could result in one or two centers or groups going unfunded, although it is

more likely that the reduction would be spread around. That runs counter to congressional directives expressed in appropriations bill report language directing that grants be funded at their full recommended levels.

OMB's action represents President Reagan's decision, whether or not he actually knows what is going on. It apparently is not subject to any congressional action and can be reversed only if the President changes his mind.

Sounds like a job for Armand Hammer and the President's Cancer Panel.

It is obvious now that no 1986 appropriations bill will clear Congress before the fiscal year begins.

The House Labor HHS Appropriations Subcommittee, chaired by William Natcher (D.-Ky.), completed its mark up of the bill last week. A committee spokesman said the bill would not go to the full Appropriations Committee until "the end of the month."

As has been its usual practice, the subcommittee has kept a tight lid on the figures in the bill and does not intend to release them until after the full committee completes its work, a policy aimed at keeping the legion of lobbyists off members' backs.

The Senate subcommittee, chaired by Lowell Weicker (R.-Conn.), had not yet scheduled its mark up of the bill by press time.

The 1985 supplemental appropriations bill passed by Congress just before the August recess included an extra \$3 million for NCI that it had not expected, nor really wanted.

Sen. Orrin Hatch (R.-Utah) managed to get the money written into the legislation for one of his special projects. Two million dollars will go to complete radiotherapy and screening facilities, including a linear accelerator, in St. George, Utah. The other \$1 million will be used for screening research activities at the Univ. of Utah in Salt Lake City, in collaboration with the St. George group.

St. George is an isolated community with a large population of older persons. It had been previously assumed that the area had a higher than normal incidence of cancer because of fall out from nuclear testing activity in Nevada, but that has been determined now not to be the case.

NCI has never been comfortable with such line item appropriations, although other senators, notably Warren Magnuson (Washington) and Norris Cotton (New Hampshire) directed money in that manner to centers in their states. It bypasses peer review and is nearly impossible to award as grants. The Utah money probably will be awarded as a contract.

ACS DIVISIONS HELP FUND CIS WHILE OTHERS IMPLEMENT SOCIETY'S CRS

While some American Cancer Society divisions are debating whether to join ACS' Cancer Response System, one division has taken over funding of an existing Cancer Information System following the loss of its NCI contract in mid July.

The Minnesota/Mayo Clinic CIS received word this summer that it would not receive another NCI contract to continue operations. The Minnesota ACS has since agreed to pick up the bulk of the \$85,000 annual cost of operating the information system.

The system received about 9,000 calls last year from North and South Dakota and Minnesota, with the majority of calls coming from Minnesota. ACS divisions in both North and South Dakota will also provide financial support for the service, based on the percentage of calls received from the individual states.

The CIS expects to receive about 15,000 calls this year, according to Eva Anderson, coordinator of cancer communications at the Mayo Cancer Center. Anderson also serves as a liaison between the center and CIS.

Two full time workers are employed by the CIS, a supervisor and an assistant. A total of 15 trained volunteers answer the phone, with each working a minimum of four hours per week. The office is open from 8:30 a.m. until 4 p.m. on weekdays, with calls made on the weekend going to the national CIS back up service.

The Minnesota CIS has always worked closely with ACS since its original NCI contract in 1975, and has been housed in the ACS division office, she said. Anderson suggests that the Minnesota model represents a possible option for cancer information that hasn't been discussed much between ACS and NCI. Most discussion has centered on the possibility and effect of competing services, but little attention has been given to the possibility of working together in the manner Minnesota has, she said.

Anderson asserts that the continuation of an established system (CIS) by combining resources is a more cost efficient use of resources than the creation of a second very similar service.

Currently, there are 19 active CIS offices. Four offices are currently not funded by NCI, but continue to be part of the network. CIS offices operating without NCI funding are Minnesota, the Univ. of Alabama at Birmingham, the McDowell Cancer Network, and Ohio State Univ. OSU has reportedly received state funding in order to continue operations. Those four offices continue to have the same resource materials available to funded CIS offices, and are required to maintain the same

standards and guidelines.

NCI awarded a total of 16 contracts for the information system. New awards went to the Fred Hutchinson Cancer Center, which had previously operated a CIS without federal funding, and to the Mary Babb Randolph Cancer Center in West Virginia. That CIS is not yet operational, however.

In addition to Minnesota, CIS offices at Duke Univ. and Howard Univ. did not receive a new contract from NCI. Unlike Minnesota, however, both of those CIS offices have had to cease operations. Calls going to the Duke Univ. number are transferred to the national CIS number in Rockville, Md., whereas callers to Howard's CIS in Washington D.C., receive a recording to call another number.

Overall, CIS received 360,000 calls last year. Regional offices handle calls for about two thirds of the country, with the national office handling the remaining one third.

Critics of the ACS program have maintained that CRS may duplicate the existing CIS program, and that confusion may result as to where to call for cancer information. NCI's CIS program utilizes a national toll free number 1-800-4-CANCER. ACS' divisions participating in the CRS program use the toll free number 1-800-ACS-2345.

Others agree that because ACS offices often receive calls asking for cancer information, the society needs to upgrade the quality of its information. They express concern, however, that CRS may not be the answer.

"ACS does need to improve the information given out from their offices," Russ Schindra, director of Roswell Park's CIS, told **The Cancer Letter**. He added, however, "I'm afraid this is not going to do it," and that the system would "just add another layer."

Schindra's greatest concerns revolve around the expense of the program and the need for quality assurance. The CRS program plans to rely on volunteers at division offices to answer the phone, with only three full time CRS employees at ACS' national office.

Asserting that "it's very difficult to run an all volunteer service," Schindra contends that divisions will need to at least have a full time supervisor for the program. A cancer information program "is quite an expensive thing," he said, adding, "ACS divisions don't have a lot of money lying around."

Schindra is specifically concerned that budgetary constraints may result in poor service. For example, he said, CIS offices make test calls to the service to assess the quality of answers provided, and have to constantly update information and retrain volunteers.

Roswell Park's CIS has already received more than

18,000 calls this year, and expects to receive between 22,000 and 25,000 this year, he said. The office employs three full time people who answer phones, update information, train volunteers and supervise operations. A core staff of 15 volunteers is supplemented by students in the natural sciences, epidemiology, counseling and social work.

Marion Morra of the Yale Univ. CIS also expressed concern about the cost of operating the CRS program and the difficulty of running a program with volunteers alone.

A recent budget request for the ACS program asked for \$185,140 for first year funding of CRS. It is operational now at six divisions and ACS plans to add eight to 12 divisions in the first year.

The Connecticut CIS is sponsored jointly by Yale Univ. and ACS. While the program extensively utilizes volunteers, Morra shares Schindra's concerns that paid personnel may also be needed, and stressed the need for a dedicated full time staff person for duties such as supervision, updating resources, and conducting user surveys. Morra also questions whether divisions can handle the added costs associated with entering the system.

ELM AIMS FOR 10-15% OF U.S. CANCER PATIENTS ON CHOP-DS BY NEXT YEAR

ELM Services expects to have between 10 and 15% of U.S. cancer patients included in its National Cancer Data Base and Community Hospital Oncology Program Data System (CHOP-DS) within the next year, the firm's President Lee Mortenson recently told **The Cancer Letter**. The company's National Cancer Data Base currently includes more than 5% of all cancer patients in the U.S., a number Mortenson expects to double or triple within the coming year.

A recent analysis by the firm found that the total accumulation of all cancer patients seen by current CHOP-DS users accounts for more than 5% of the predicted new cancer patient load for the U.S. in 1985. While the company expects to more than double the number of new users in the next 18 months, it notes that 5% "is an excellent sample size for most studies and certainly is sufficient to give single hospital cancer programs data for comparative or matching purposes."

Started in response to a need for quality data registries by CHOPs, the data system became generally available at the end of 1983. More than 100 hospitals and 20 consortia are currently using the system, and five states are in the process of negotiating with ELM about using the system for their statewide tumor registries, Mortenson said. Between five and 10 new hospitals are joining the data base each month.

Advantages of the system are that it allows hospitals to compare their own data using advanced

statistical techniques, the company says. Hospitals can compare their data with that from their community as well as the national cancer data base, in addition to comparing technologies used. Users can also track their own selection of site specific items or compare such information with other institutions.

An example provided by the company of the analytic techniques available to users is an analysis of stage 2 breast cancer patients first seen in the user's institution, managed in 1981 and 1982, who were estrogen receptor positive. The system can answer additional questions about the group such as how frequently the group of patients had a CBC, a chest X ray, and what kinds of multidisciplinary consultations they had.

The system can also provide basic demographic information on the patients, a life table, a survival plot, and a comparison of how patients treated at the user's institution compared with hospitals of a similar size and the national data base. Statistical techniques available include binomial approximation, Chi squares, and T tests/Z tests.

The system is also designed to "take the drudgery out of tumor registry work" through automating patient follow up and labels, and updating the tumor registry software to assure it includes all the reports required for an American College of Surgeons approved cancer registry program, according to a company release. Only about 200 of the approximate 1,000 tumor registries in the U.S. are currently computerized, Mortenson said.

The system is also useful for hospital administrators in addition to tumor registrars and oncologists, Mortenson maintained.

The recent addition of the prospective payment's system of Diagnosis Related Groups (DRGs) to the data system will allow administrators to determine whether various sites and stages of cancer patients are presenting important cost problems or opportunities. While Mortenson acknowledges concerns that some hospital administrators will focus on the financial loss from a specific cancer site, he stresses that cancer is a "total product line."

For example, cancer departments can look at the data on the overall product line of cancer care in order to deal effectively with administrators. Using breast cancer patients as an example, Mortenson said the hospital may lose money on a mastectomy, but make it back on radiation therapy.

Mortenson expects the addition of DRGs to the data base to eventually allow an analysis of whether the financing system is affecting the quality of care for cancer patients. ELM recently conducted a

preliminary analysis of the impact of DRGs on cancer care for the Assn. of Community Cancer Centers (**The Cancer Letter** Sept. 6).

Another benefit of the system for hospital administrators is that it can determine where cancer referrals are coming from, and the particular type of cancer care that is problematic for the institution, he said. Hospitals can also sort by geographic area and determine market share.

The system is designed for use with IBM PCs or true compatibles.

ELM recently introduced a new service targeted at practicing oncologists. Also designed for use with IBM PCs, ELM's first offering in its Chemotherapy Treatment Planning Series is adjuvant breast cancer management.

The computer software package enables MDs to monitor patients' progress through tailored flow sheets; schedule and calculate chemotherapy dosages; plot lab WBC and platelet counts; scan a quick update on the literature of the disease; and review treatment regimens.

The discette, edited by John Yarbro, "provides a quick review of the key literature on the major adjuvant protocols and current research," the company says. The update includes information on each regimen including dosage recommendations, drug indications and pretreatment evaluation suggestions.

Upon entering a new patient, the discette checks on staging, recommends additional tests, suggests potential treatment regimens, records patient information and narrative and calculates drug dosages based on the regimen the physician chooses and the patient's body surface area.

The system also includes patient data collection and retrieval to provide information on patients' most recent visits, current schedule of treatments, and flow sheets, plots and recommendations for the current visit. The data base can be tailored to an individual MD's needs.

Flow sheets include patient information, cycle and day information, narrative information, body surface area calculation, symptoms summary, lab values, medications calculated and prescribed, next visit date and next follow up information.

Five "state of the art" regimens (PF, PFT, CMF, CMFVP and CAF) have been selected by the editorial board for inclusion in the adjuvant breast cancer management discette. While the computer will make recommendations on regimen selection, the selection is up to the MD. The program provides reference information, dosage calculations, test recommendations, preprogrammed scheduling and flow sheets on the five regimens. Each selection includes complete dosage information, dosage suggestions, recalculation of dosages on the basis of toxicity, drug information and other indications.

In addition, CTPS generates five standard patient schedules in calendar form based on the drug regimen selected by the physician. The schedule can detail which drugs are necessary, on what days, or can be taken home by the patient to remind him of office visits, testing and when to take medications at home. The discette also provides a physician schedule of patients for each week.

ELM's next CTPS will provide chemotherapy treatment planning information on advanced stage breast cancer. Other cancers scheduled for inclusion in the series include colon cancer and a "generic" cancer disc, Mortenson said.

DCPC BOARD COMMITTEE TO RECOMMEND APPROVAL OF THREE CONCEPTS TO BSC

The Committee for Centers & Community Oncology of the Board of Scientific Counselors for NCI's Div. of Cancer Prevention & Control will recommend approval of three concepts to be presented to the Board at its meeting next week.

The committee gave its approval to issuing an RFA for a five year program to develop, implement and evaluate interventions to improve the quality of survival for recovered childhood cancer patients. An estimated annual budget totaling \$400,000 would support two grants.

The Community Oncology & Rehabilitation Branch, which initiated the concept, said that some interventions might focus on preventing side effects of treatment while others may address how to minimize existing sequelae or reduce their effects. Interventions may be directed towards cancer survivors themselves, their families, the community, or health care professionals.

Examples listed of possible interventions included teaching children who receive cranial irradiation how to compensate for possible learning problems; improving survivor experiences in obtaining employment and insurance; promoting emotional adjustment; enhancing awareness or availability of social service or health care resources that address the financial impact on families; increasing knowledge of survivor needs among teachers, school nurses, employers, or insurance companies; teaching community physicians and nurses how to assess and monitor former childhood cancer patients; and assessing the long term consequences of new cancer treatments.

The committee also approved the concept of providing a supplement totaling \$190,000 a year for two years to the Radiation Therapy Oncology Group to support a randomized trial of crico-pharyngeal myotomy in patients undergoing surgical resection for supraglottic and laryngeal carcinomas.

RTOG has access to a large number of patients with head and neck cancers. The Community Oncology

& Rehabilitation Branch, which also initiated this concept, suggested that a randomized trial following patients with and without crico-pharyngeal myotomy would provide useful information about the relative benefits of this surgery. Standardized measures of speech and swallowing would add the assessment of treatment morbidity.

"The biases of the surgeon appear to determine whether or not this operation is carried out," CORB said in its justification for the concept. "The efficacy of this surgery in improving swallowing remains to be demonstrated."

The committee recommended approval of another \$190,000 to complete the hospital cost and clinical research study being carried out in collaboration with the National Center for Health Services Research.

This study was initiated when centers and hospitals involved in clinical cancer research realized that the prospective payment reimbursement system initiated by the Health Care Financing Administration would not cover costs for protocol patients which previously had been paid by Medicare. The study has been financed, totaling \$516,000 so far, out of the evaluation set aside funds from the assistant secretary for health.

Jerome Yates, who heads DCPC's Centers & Community Oncology Program, said that NCI will ask for the \$190,000 from the set aside funds; the Board's approval for NCI expenditure of that money is required in case the request is denied.

The study is based on a sample of approximately 55 of the 310 hospitals which participated in NCI sponsored clinical trials from 1980 to 1985. The hospitals are stratified by location and type of NCI affiliation (cancer center, cooperative group, or Community Clinical Oncology Program hospital). The contractor, Systemetrics, is obtaining the hospital discharge abstracts for 1980-85 and patient level billing data for 1982 and 1985 for all patients with the diagnosis of cancer in the participating hospitals. These abstracts and bills are being matched to lists of patients enrolled on protocols during the same years in order to enable the researchers to distinguish protocol from nonprotocol patients.

The study is attempting to answer these questions:

*How does the hospital length of stay compare between protocol and nonprotocol patients?

*Are the hospital care costs of protocol patients more than the costs of nonprotocol patients?

*Do the DRG based payments for protocol and nonprotocol patients cover the costs of providing hospital care?

*Has the case mix of protocol and nonprotocol patients changed as a result of Medicare's PPS?

*Has hospital participation in clinical research changed as a result of PPS?

NCI BSCs TO CONSIDER FOUR CONCEPTS DEVELOPED BY OSCC WORKING GROUPS

Four concepts for new research initiatives recommended by the Organ Systems Coordinating Center will be presented to NCI's boards of scientific counselors at their fall meetings.

Andrew Chiarodo, who heads the Organ Systems Program in NCI's Div. of Cancer Prevention & Control, told the DCPC BSC Committee on Centers & Community Oncology last week that:

—A concept for grants to support research on markers of premalignancy of colon cancer in populations at high risk will go to the Div. of Cancer Etiology BSC. This will be an RFA, which will include a specific sum set aside to fund the grants. This RFA was recommended by OSCC's Large Bowel Working Group.

—The same group will recommend to the Div. of Cancer Treatment BSC a program announcement asking for grant applications to study the mechanisms of drug resistance in the treatment of colon cancer. Chiarodo said that DCT has had similar program announcements but they did not generate any grants in colon cancer.

—The Prostate Cancer Working Group will recommend to the Div. of Cancer Biology & Diagnosis BSC a program announcement for grants to study the mechanism of metastasis in prostate cancer.

—The Breast Cancer Working Group will ask the Div. of Cancer Prevention & Control BSC to approve a program announcement for grants to study interactions among micronutrients in experimental mammary cancer.

Chiarodo said OSCC has a number of other concepts "in various stages of development."

Chiarodo noted two recent changes in OSCC leadership: Gerald Murphy, who headed OSCC as principal investigator for the grant to Roswell Park Memorial Institute supporting the program, had to give up that position when he moved to State Univ. of New York at Buffalo; OSCC interim director is James Karr, who had been deputy director.

Also, James Jamieson, professor of biology at Yale, has replaced Vay Liang Go as chairman of the Pancreas Cancer Working Group. Go has left his position at Mayo to join the National Institute of Arthritis, Diabetes & Digestive & Kidney Diseases at NIH.

Chiarodo reported that the workshop recommendations for new working groups for central nervous system and upper aerodigestive system tumors will be presented to the National Cancer Advisory Board.

"We're all concerned that when you convene a

group with particular interests (to consider whether new working groups should be established), the concept will be approved automatically," Committee Chairman Virgil Loeb commented.

Chiarodo said that a range of criteria are used to consider the justification for a new group—high incidence, increasing morbidity and mortality, the expectation that coordination of research (a chief purpose of the Organ Systems Program) would result in synergistic efforts, and the level of activity in that area. "In cancer of the upper aerodigestive system, there is virtually nothing in RO1 or PO1 grants," he said.

Two concepts previously approved by the DCPC Board will result in grant awards to be made this month, Chiarodo said. They include five awards for flow cytometry in bladder cancer, totaling \$400,000 in the first year, and another to establish a magnetic resonance imaging coordinating office, at a cost of \$210,000 the first year.

DCPC Associate Director Jerome Yates said that the MRI office would help "tie researchers at the various institutions together, to generate common protocols."

"It's a shame this has taken so long," Loeb said. "We've been talking about coordinating MRI for well over a year, and in the meantime, that work has been going on uncoordinated."

CITY OF HOPE'S ANIMAL PROBLEMS MAY COST IT \$269,000 CONSTRUCTION GRANT

The City of Hope's Beckman Research Institute apparently will not get the \$269,000 previously approved for payment in the 1985 fiscal year for its construction grant from NCI, thanks to the institution's problems with laboratory animal procedures.

The National Cancer Advisory Board had approved \$825,671 for the grant, with \$269,000 (all that was left in the NCI construction grants budget) to be paid in FY 1985. However, when the Dept. of Health & Human Services ordered that no further grants could be made to City of Hope until the animal problems had been corrected, all of the Duarte, Calif., institution's NIH support was in jeopardy, including the construction grant.

"We're looking for a way to reallocate that \$269,000," Centers & Community Oncology Program Director Jerome Yates said last week.

Charles Mittman, principal investigator for the construction grant, was not available this week. Tom Galinski, City of Hope administrative officer, told **The Cancer Letter** that the suspension would apply only to grants which directly involve animal research. "Our cancer center grant at first was under suspension, but that has been lifted because it did not directly involve animals." He insisted

that the construction grant did not involve animals.

NCI has determined otherwise, however, contending that at least one City of Hope investigator using lab animals was involved in the construction project. A.E. New, director of laboratory animal science in the office of NCI Director Vincent DeVita, has directed that payment of the City of Hope grant be suspended.

NCI will have to commit the \$269,000 before the end of the fiscal year, Sept. 30, so it cannot wait until the City of Hope problems have been corrected, which Galinski would be accomplished by November. Albert Einstein School of Medicine is next in line for construction funds; it appears that is where the \$269,000 is headed.

RFPs AVAILABLE

Requests for proposal 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. 20205. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring, Md., but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-57721-48

Title: Cancer Therapy Evaluation Program Information System

Deadline: Approximately Sept. 30

The announcement for this RFP appeared in the July 19 Cancer Letter. It is being amended to restrict the solicitation to small business.

For the purpose of this procurement, a small business is defined as a firm, including its affiliates, that is independently owned and operated, is not dominant in the field of operations in which it is proposing on government contracts, and its average annual receipts for its preceding three fiscal years do not exceed \$3.5 million. The Standard Industrial Classification Code applicable to this procurement is 7392.

Contract Specialist: Thompkins Weaver
R CB Blair Bldg Rm 228
301-427-8737

RFP NCI-CM-57751-22

Title: Storage and distribution of clinical drugs

Deadline: Approximately Nov. 7

The Pharmaceutical Resources Branch of NCI's Developmental Therapeutics Program in the Div. of Cancer Treatment is seeking a contractor to store and distribute formulated clinical drug products and keep adequate records of such distribution in support of the clinical programs of DCT. The project

will involve the receiving of drugs from various sources, storage of the products under specified conditions, repackaging and subsequent shipment to NCI authorized investigators in the U.S. and many countries throughout the world. Manual and computerized processing systems will be used for various record keeping and repository functions.

The contractor selected must meet at least the following minimum requirements:

1. Provide at least 5,000 square feet total available floor space which shall include the following:

A. 3,750 sf of controlled room temperature (15-30 degrees C) storage space.

B. 4,800 cubic feet of refrigeration (2-8 degrees C) storage space.

C. 1,300 cubic feet of -20 to -10 degrees C freezer storage space.

D. 19 cubic feet of -80 to -70 degrees C freezer storage space.

E. Meet all application FDA current good manufacturing practices regulations.

2. Possess an Environmental Protection Agency toxic waste generator permit and the necessary state and local permits for generation and transportation of toxic waste drugs before the award of the contract.

3. All personnel must be bonded prior to performing on this contract.

The contract period will be for five years, beginning approximately Aug. 15, 1986. The incumbent contractor is Flow Laboratories Inc.

Contract Specialist: Elizabeth Moore

RCB Blair Bldg Rm 216A
301-427-8737

RFP NCI-CM-57772-09

Title: Services in support of the Developmental Therapeutics Program

Deadline: Approximately Nov. 8

The Developmental Therapeutics Program has primary operational responsibility for all aspects of the preclinical development of antitumor drugs for the Div. of Cancer Treatment. The extramural component of DTP consists of (1) contract programs for the acquisition, antitumor evaluation, pharmaceutical formulations, large scale drug preparation and toxicology and pharmacology studies on new candidate anticancer agents; (2) a program of cancer related chemistry, biochemistry and pharmacology grants; and (3) a broad national program of cooperative drug discovery groups designed to identify new, active antineoplastic compounds for development to clinical trial.

DTP desires to obtain the services of a contractor to provide assistance throughout the program in a variety of activities. The major tasks consist of (1) assistance in the logistical management of data arising from the screening effort,

including service tasks supporting the functions of selected committees and working groups involved in the extramural drug evaluation and development processes; (2) management and associated general logistical activities for DTP sponsored conferences, seminars and workshops; (3) maintenance, and storage on a limited basis, of files for the grants, contracts and drug discovery programs; (4) preparation of reports and other program related documents including typing, editing and, as required, production in final form; (5) provision of graphics, slides and prints on a rapid turnaround basis when use of other resources is not feasible; (6) arranging and coordinating the itineraries of visiting delegations from the national and international scientific community; and (7) creation of customized computerized files requiring programming expertise.

The nature of the activities, particularly those involving the maintenance of commercially discreet data requires some members of the contractor's staff to perform on site at the extramural offices of DTP in Bethesda, Md. Office space for other staff and files must be provided by the contractor and must be in proximity to the DTP offices in Bethesda in order to be readily accessible on demand within a working day.

Since this contract involves the use of information on compounds which is commercially confidential, pharmaceutical and chemical companies are excluded from participating.

Proposals are solicited for the level of effort of 6,840 staff hours per annum. It is anticipated that an incrementally funded contract will be awarded for a period of three years.

The principal investigator should possess at least a BS degree in biology or related discipline and preferably have recent experience in the evaluation of in vivo and in vitro testing in a drug screening program. He/she should possess overall management capabilities which would permit effective implementation of all phases of the project, with particular emphasis on screening data management and review, and conference, seminar and workshop planning, development and staging.

Composition of the project team should be of a nature which provides (1) knowledge in and experience with the determination of biological activity, evaluation of test results of both in vivo and in vitro test systems and data entry through remote terminals; (2) capabilities to support all of the major phases of the workscope as summarized above. At least one member of the team should have qualifications and experience which equips them to serve as backup to the PI.

Contract Specialist: William Roberts

RCB Blair Bldg Rm 224
301-427-8737

The Cancer Letter _ Editor Jerry D. Boyd

Associate Editor Patricia Williams

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