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COMMERCIAL FIRMS GET FOOT IN THE DOOR WITH CREG, BUT WON'T BE PERMITTED TO MAKE MONEY ON GRANTS

The life sciences industry has won a limited but possibly significant victory in its effort to get HEW to lift the ban on grants to commercial research firms.

NCI has obtained approval from HEW for implementation of the Cancer Research Emphasis Grant (CREG) program, which will convert some research contracts held by academic and not-for-profit institutions to grants. In giving NCI the go-ahead, HEW agreed that commercial firms could compete for CREG awards.

If the grant review process determines that a commercial organization

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In Brief

STREAMLINING OF CONTRACT AWARD PROCESS STILL TOP PRIORITY AT NCI; TRAINING GRANTS NO CLOSER

WORK ON SLASHING the time required by NCI to award a contract–as long as nine months in some cases--was delayed by the change of command in the Research Contracts Branch. The President's Cancer Panel had asked former contracts Chief Carl Fretts to find ways to combine or move concurrently the 22 steps required from inception to contract award. Fretts was working on that when he left. NCI Director Frank Rauscher told new contracts Chief James Graalman that his first priority is to streamline the process. Panel Chairman Benno Schmidt observed that "the new man may not know all the things he is supposed to do (in the contract process) and can take some short cuts. But after he's been called down on it a few times, we'll be back to the same old thing. From time immemorial, when people try to speed up government, they eventually find they are outnumbered." . . . **NCI IS** officially the lead agency now in coordinating federal government research and regulatory activities relating to cancer, after HEW Secretary Weinberger signed the charter granting that authority to NCI . . . . **TRAINING GRANT** program implementation is still waiting on publication of guidelines in the *Federal Register.* NCI has little hope programs can be started this fiscal year, and in fact it is unlikely any will be developed in time for the start of the academic year next September. . . . **REQUESTS** for copies of contracts and grant awards by NCI are growing as awareness of freedom of information regulations increases. NCI (and the rest of NIH) still will not give out details from meetings not yet declared as open to the public, such as study section grant reviews. But NIH executives expect eventually to be required to furnish on request copies of "pink sheets", which contain summaries of review discussions. Some fear this will inhibit study section members, work against the peer review process; others think opening up study sections might strengthen the system, cut down on favoritism in grant ratings or at least quiet charges that favoritism and cronyism exist.

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TAX-PAYING ORGANIZATIONS CAN COMPETE FOR CREG, BUT THEY ARE UNIMPRESSED

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has submitted the best proposal, NCI may award it the grant. There is one catch, however: there will be no fee involved.

"I think this will still be unpopular with the commercial organizations," NCI Director Frank Rauscher said. "But it's the best we can do right now."

Commercial firms will not have to participate in cost sharing, as do other grantees. But the absence of a profit potential will dampen their enthusiasm for CREG or any other grant mechanism that does not provide for fees.

"I can't imagine any tax-paying organization being interested in this," said Donald Nielsen, president of Hazleton Laboratories and one of the organizers of the National Assn. of Life Science Industries. "I know our shareholders and board of directors would not be interested in that kind of government business."

Nielsen and his tax-paying colleagues have argued that NIH, like most other government agencies, should place its extramural work with the organization that can do the job best for the least amount of money. They contend that the use of grants as a financial prop for academic institutions is unhealthy and unfair.

Despite misgivings of the commercial firms, CREG could be a foot in the door for access to all grants.

NCI had proposed to HEW that, when a commercial organization came up with the best proposal, the job be awarded to them as a contract rather than a grant. This would have permitted a fee, or profit.

HEW executives pointed out that CREG was designed as a means to move some research out of contract programs and into grants because, for certain projects, the grant mechanism would be determined as the better way to handle them.

"They said that once a program has been defined as better suited for grants we should stick with that," said NCI Deputy Director Guy Newell.

The discussion with HEW touched on the possibility that all grants be thrown open to commercial firms for competition with academic and not-for-profit institutions.

HEW agreed that this was a possibility but insisted that tax paying organizations be limited to CREG for at least a year, to see how it works out, Newell said.

Nielsen said that some firms might compete for CREG awards to help recruit scientists they are after or to fill unused space at their facilities. "And it could be significant, if it opens up all grants to us," he said. "But grants of any kind without a fee will never be meaningful to us."

NCI had selected more than $20 million worth of existing contracts with academic and not-for-profit institutions as candidates for CREG. HEW insisted that the program be more limited to start, and will hold the number to $10-12 million in the first year.

CREG, as with other grants, will be administered by NCI's Div. of Research Resources & Centers.

BUDGET CUT WOULD HOLD GRANT FUNDING TO 20%, DOWN FROM 61% LAST YEAR

Impact of the Administration's budget cuts on the cancer program, in the unlikely event Congress approves them, was pointed out to the President's Cancer Panel this week.

Only 20% of all approved competing grants will be funded if the President's request to slice $125 million from the current fiscal year budget is upheld by Congress. Only 13.1% of new approved grants and 37% of competing renewals would be funded.

In addition, budgets for most existing grants would have to be reduced substantially.

In fiscal 1974, NCI funded 61% of approved new and competing renewal grants.

Such a drastic reduction, which would stifle most new initiatives in cancer research for at least a year and perhaps much longer, indicates how out of touch with reality is the Office of Management & Budget.

"Every reading of the congressional attitude is that these recisions won't be approved," said Panel Chairman Benno Schmidt. "The money eventually will be spent, but less efficiently and less effectively over a shorter time span (than if funds were available now).

"If the cuts are made, they would come out of institutions that support the bulk of cancer research," Schmidt continued. It would come at a time when they are hard-pressed anyway to make ends meet, and would only intensify the depression, as far as they are concerned.

"But what is more foolish is that the savings won't take place. . . I've made these arguments (to OMB) and will continue to make them, but so far without much effect."

Director Frank Rauscher reported that OMB is remaining firm in its refusal to support more than 21 comprehensive cancer centers. The National Cancer Act specifically gives to Rauscher the authority to determine how many comprehensive centers will be needed, and he has estimated that about 30 will be required.

To date, 17 comprehensive centers have been identified by NCI, so Rauscher's show-down with OMB on that issue could be delayed until four more are selected, probably this year.

After that, Rauscher and the National Cancer Advisory Board could bring on a confrontation that could end up in the courts if OMB persists in holding to the limit of 21. If Rauscher recommends and NCAB approves additional centers, those centers could go to court to force OMB to release funds

for their support.

Another issue that appears headed for the courts is OMB's refusal to release funds for new construction. NCAB has awarded $8 million to Albert Einstein College of Medicine in New York for a cancer center, the Cancer Act specifically provides for NCI support of new construction, and the appropriations bill signed by the President includes those funds. Yet OMB is staying with the old Nixon Administration policy of refusing to fund construction of new health facilities.

NCI also is hampered by OMB's personnel ceiling. The institute had been authorized 1,855 positions for this fiscal year, but the order to all federal agencies to trim jobs by 2% reduced the ceiling to 1,818. NCI had 1,852 employees as of Dec. 31, so no new hiring will be permitted until attrition reduces the number to the new ceiling.

"That really makes it tough," Rauscher said. "That is nowhere near consistent with our responsibilities."

ACCC MAY HAVE LANDED A TOP SPEAKER FOR FEBRUARY MEETING IN WASHINGTON

Among the prominent individuals who have been invited to speak at the February meeting of the Assn. of Community Cancer Centers in Washington is one who may have more than a little personal interest in the cancer program--and who will have more influence than anyone else on the extent the federal government will support the program for the next two years, at least.

President Ford has indicated he will attend the Sunday morning, Feb. 2, session of the meeting, along with Mrs. Ford, who underwent surgery for breast cancer last year.

Other speakers who will attend the Sunday meeting include Mrs. Mary Lasker, noted health philanthropist, member of the National Cancer Advisory Board and a leader in the efforts which resulted in the National Cancer Act of 1971.

Congressman Daniel Flood (D-Pa.), chairman of the House Health Appropriations Subcommittee, also will speak at the meeting.

"We are trying to make this first national meeting both a working meeting and a forum for physicians and other health providers concerned with delivering quality cancer care at the community level," said James F. Donovan, ACCC president. "We've invited several key leaders who deal with cancer legislation and the national cancer effort to enter into a dialogue with us on getting that care to the people who need it."

The first day, Feb. 1, of the meeting will be devoted to a series of workshops on cancer care at the community level, money for cancer programs, help in establishing community cancer programs, hospital relations, tumor registries and relations with comprehensive cancer centers.

Registration forms for the meeting may be obtained by writing to ACCC, PO Box 30279, Bethesda, Md. 20014, or by calling ACCC executive secretary Lee Mortenson, 301-656-3987.

NEW DRUG SEMINAR HEARS UPDATE ON EFFECTIVENESS OF ADRIAMYCIN

A new drug seminar, the fifth such meeting sponsored by NCI's div. of Cancer Treatment, was devoted to reports on the use and effectiveness of adriamycin on a variety of tumors.

Findings previously reported by DCT Deputy Director Stephen Carter and Ronald Blum of Harvard in the *Annals of Internal Medicine* and at the International Symposium on Adriamycin in Brussels last May were discussed and updated.

Adriamycin has proven useful in treating advanced breast cancer, soft tissue and bone sarcomas, solid tumors in children, bladder cancer and cancer of the lymphatic system, Carter said.

Blum, reporting on clinical studies around the U.S., said that 27% of all patients with various sarcomas responded to adriamycin.

Carter previously had felt that adriamycin might be effective in treating lung cancer. But he reported at the seminar that studies indicate now it is no better than other drugs.

Adriamycin is now available commercially in the U.S. for anticancer use. Developed by Farmitalia, Italian pharmaceutical firm, it is the most expensive anticancer drug on the market.

Livio Zeller-Cleso of Farmitalia, who was at the seminar, said the cost should decrease as demand and production increase.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute, unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP. Some listings will show the phone number of the Contract Specialist, who will respond to questions about the RFP. Contract Sections for the Cause & Prevention and Biology and Diagnosis Divisions are located at: NCI, Landow Bldg. NIH, Bethesda, Md. 20014; for the Treatment and Control Divisions at NCI, Blair Bldg., 8300 Colesville Rd., Silver Spring, Md. 20910. All requests for copies of RFPs should cite the RFP number. The deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NCI-CM-57000

Title: *Study of the pharmacology of potential antileukemia drugs*

Deadline: *Mid-February*

The Div. of Cancer Treatment is seeking proposals

from qualified sources for research studies to develop therapeutic and qualitative and quantitative toxicological data for:

1) The evaluation of two-drug combinations selected either on the basis of prior demonstration of therapeutic advantage or through the establishment of optimal therapeutic schedules and sequences in mouse tumor systems.

2) The translation of established combination regimens from mouse tumor models to man with intervening toxicological evaluation in sub-human primates and/or dogs. These studies are directed towards maximizing the therapeutic usefulness and minimizing the potential for toxicological hazard of two-drug combinations in human malignancies.

More specifically, the contractor will conduct studies of two-drug combinations in selected mouse tumors to establish optimal therapeutic schedules and sequences for the candidate drugs and to collect data on hematologic depression and rate of recovery in normal and tumor-bearing hosts as they relate to the optimal therapeutic regimens.

Where additive toxicity and lack of schedule dependency is observed in mice, then studies should be performed in monkeys and/or Beagle dogs to establish quantitative aspects of simultaneous use of two-drug combinations.

When the optimal therapeutic regimen in mice is dependent on schedule and/or sequence of drug administration, then studies should be performed to elucidate the influence of schedule and sequence of drug administration on toxicity in the large animals.

The specific cancer chemotherapeutic agents will be supplied and selected by the project officer. A minimum of one two-drug combination will be studied per year.

Contract Specialist: Joseph Kerner
Cancer Treatment
301-427-7463

RFP WA-75-R146

Title: *Conduct a wide variety of toxicity testing for toxic substances, some of which could be carcinogeneic*

Deadline: *Probably mid-February*

(This RFP is being issued by The Environmental Protection Agency. Write to EPA, Contract Management Div., Attn. W.M. Rugemer Jr., Washington Contract Operations, R&D Procurement Section, Washington D.C. 20460)

The types of toxicity testing will fluctuate with the specific chemical under investigation and the time constraints for obtaining the information. The contractor will have to demonstrate ability to conduct a wide variety of chronic and acute toxicity testing services.

With few exceptions, the contractor will provide two categories of services, routine and high priority. In both cases, the contractor will provide immediate manpower and facilities to conduct the assigned tasks.

CONTRACT AWARDS

Title: Technical services in support of the National Cancer Program Bulletin
Contractor: Aries Corp., Arlington, Va., $49,380.

Title: Continue studies of the incidence of salmonella carriers in mice
Contractor: Battelle Memorial Institute, $14,900.

Title: Chemotherapy, drug distribution & genetic center for rodents
Contractor: Microbiological Associates, $149,610.

Title: Brain tumor chemotherapy studies
Contractor: Indiana Univ. Foundation, $22,524.

Title: Continue studies of the incidence of salmonella carriers in mice
Contractor: Battelle MEmorial Institute, $14,900.

Title: Preparation and testing of Vitamin B12 analogs
Contractor: Scripps Clinic and Research Foundation, $12,000.

Title: Development of a National Cancer Program project analysis model
Contractor: TRW Systems Group, $93,033.

Title: Technical services in support of the National Cancer Program's Management Information System
Contractor: The Mitre Corp., $711,780.

SOLE SOURCE

Proposals listed here are for information purposes only. RFPs are not available.

Title: Therapy of patients with testicular carcinoma
Contractor: New York State Dept. of Health

Title: Comprehensive cancer centers communications network
Contractor: Fox Chase Cancer Center.

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