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Government Remains Open Under Budget Agreement; New Deadlines Are Oct. 5 & 19

Since Congressional negotiators agreed on a budget for FY 1991 early this week, NCI did not have to close its doors at the start of the new fiscal year Monday morning--though it came down to wire. NCI Director

(Continued to page 2)

In Brief

First Peer-Reviewed Comprehensive Centers Named; Sawaya To Lead Anderson Neurosurgery

THE FIRST comprehensive cancer centers to be given that designation under NCI's new guidelines through the peer review process were announced this week. They are Roswell Park, Fox Chase and Yale, all of which were comprehensive centers previously. Their comprehensive designations were renewed by review of the Cancer Center Support Grant Review Committee. Previously announced comprehensive approvals were done through the administrative process, by John Durant, chairman of the NCAB Centers Committee, and Joseph Simone, chairman of CCSG. . . . **RAYMOND SAWAYA** has been appointed chairman of the new Dept. of Neurosurgery at Univ. of Texas M.D. Anderson Cancer Center. Sawaya has been director of the neuro-oncology division at Univ. of Cincinnati College of Medicine for the past five years. He will direct surgical services and related clinical research in the center's brain and spinal cord tumor program. . . . **ARTHUR JAMES** Cancer Hospital & Research Institute at Ohio State Univ. will hold its official opening ceremony on Oct. 20. The new facility was scheduled to open in January, but a winter freeze caused pipes on the hospital's top floor to burst, flooding the building. . . . **NCI STAFF CHANGES: Iris Obrams** has been appointed chief of NCI's Extramural Programs Branch in the Epidemiology & Biostatistics Program. She joined NCI in 1986 as program director for AIDS epidemiology and recently served as deputy chief of the branch. **Judy Karp** is on an interagency personnel agreement from Johns Hopkins serving as special assistant to NCI Director Samuel Broder. She has special expertise in leukemia. **Gisele Sarosy** was promoted to branch chief of the International Cancer Research Data Bank in the International Cancer Information Center. **Julianne Chappel** has been appointed chief of the Scientific Publications Branch of ICIS. **Iris Schneider**, assistant director for program operations and planning, will be on detail as acting deputy director of the new NIH Office of Research on Women's Health. **Katherine Marconi** has been reassigned as chief of the Cancer Control Applications Branch in the Cancer Control Science Program. **Charles Grieshaber,** formerly chief of the Toxicology Branch, has joined the FDA.

Doors Remain Open At NCI; Oct. 19 Is Next Deadline For Budget

(Continued from page 1)

Samuel Broder said he spent the weekend preparing to discuss that prospect with the National Cancer Advisory Board.

Where does NCI stand in relation to the recent budgetary events? At presstime, here was the situation in brief:

▸NCI is currently operating under a continuing resolution that expires Oct. 5. The resolution provides funding at the FY 1990 level of approximately $1.634 billion.

▸The Gramm-Rudman-Hollings deficit reduction targets will be revised under the new budget agreement, meaning the threatened 32 percent budget cut will not take place. However, there could still be some reduction, possibly in the neighborhood of the 1.4 percent reduction imposed last year. That cost NCI $23 million in FY 1990.

▸If Congress does not approve the framework for the budget by Oct. 5, "we're back in the soup," Broder told the NCAB on Monday. Congress could keep passing continuing resolutions until a budget is approved, but the resolutions would provide funding only at last year's level, which would in effect represent a major loss in funding. In the event a continuing resolution is not passed, Broder may get the chance to implement his contingency plans after all.

It appears that if the Oct. 5 deadline is missed, Congress will have another deadline, Oct. 19, to approve the budget.

Meanwhile, as of **The Cancer Letter's** presstime, the Senate Appropriations Committee had not approved its subcommittee's recommendations for the NIH budget. The Senate Labor-HHS-Education Appropriations Subcommittee has approved a $1.706 billion budget for NCI, a cut of nearly $43 million from the House figure, but the committee's report discussing that cut has not been made available.

The House Appropriations Committee approved a $1.75 billion budget for NCI in FY 1991, $91 million over the President's budget request, which was in itself a $60 million increase over the institute's FY 1990 budget. Neither the House nor the Senate figures include about $36 million for training, which is authorized in the reauthorization bills which have yet to be acted upon (see related story, this issue).

If the House figure were to survive in conference with the Senate, NCI would get about a $150 million increase over the 1990 budget. That House figure was determined before the crisis in Iraq, however, and in the current era it is highly unlikely such an increase would survive.

Even so, Broder discussed with the NCAB what could be accomplished with that increase:

--Under the House markup, research project grants would be funded at $835.8 million, a $51 million increase, or 6.5 percent, over the President's FY 1991 request.

--Cancer centers would receive $111 million, an $8 million (7.8 percent) increase over the President's request.

--Other research grants, including clinical cooperative groups and cancer education, would receive $92 million, a $9.5 million (11.5 percent) increase over the President's request.

--Intramural research would get $337 million, a $4 million (1.2 percent) increase over the President's request.

--Cancer prevention and control would receive $82.3 million, nearly a $7 million increase (9.1 percent) over the President's request.

--Construction would receive $8.4 million, a $7 million increase over the President's request. Language in the House budget report authorizes NCI to reprogram up to $7 million from other areas for construction.

NCI received the largest dollar amount increase of all the institutes covered in the House report, $91 million. Still, the percentage increase was about 5.5 percent over the President's budget, placing NCI squarely in the middle of the pack.

Summary of NCI budget increases in the past few years: From fiscal years 1989 to 1990, NCI's budget rose 4 percent; from 1990 to the 1991 President's budget, NCI received a 3.6 percent increase. Now, the House request is 5.5 percent above the President's request.

"I think this [increase] has been a symbol of

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Congressional sympathy to our cause," Broder said.

The House report contained strong language criticizing financial management at NIH (**The Cancer Letter**, July 20). The report said "critical" problems were low numbers of new grants, high levels of downward negotiations of grants, and a general lack of stability in government support for biomedical sciences. Problems the committee said contributed to this are the increasing average length of awards from 3.3 years to 4.3 years NIH-wide, and the increasing average cost of grants. The average cost of grants has gone up 94 percent from 1981 to 1990, almost double inflation.

The report made recommendations as part of what the committee saw as a four-year reform plan for NIH. The committee recommended limiting the time period for grants, increasing the number of new grants, and eliminating the practice of downward negotiation.

Broder stressed to the NCAB the seriousness of the report language, which unless it is specifically contradicted by the Senate, must be heeded. While the language does not have force of law, institute directors are wise to consider the committee's wishes.

Here is how the House committee's four year plan might affect NCI:

▸The average length of grants is not to exceed 4 years. Presently, the average time of grants is 4.1 years at NCI. "As lawyers would say, we are in substantive compliance," Broder said. However, any five year grant would have to be matched with a three year grant in order to maintain the four year average.

▸The average cost increase for research project grants should be no faster than the biomedical research deflator, a measurement of the "cost of living" for biomedical research.

▸Total cost of grants, including indirect costs, should be considered at each stage of review.

▸There should be no arbitrary downward negotiations. Broder said complying with this recommendation for the current fiscal year would be difficult.

▸The number of center grants for all of NIH should not exceed 640, which the committee said is 15 more than were funded in 1990. The committee said 10 to 15 center slots should be reallocated each year.

The cancer centers program is "vital" to NCI, Broder said. "I would be very concerned that if we wanted to approve an NCI cancer center, the [National Heart, Lung & Blood Institute] would have to drop one of its centers."

"A cry of desperation" from Congressional leaders and staff upset with a lack of leadership at NIH, is how Board Chairman David Korn described the House report. The House report said the committee would have preferred if NIH had come up with a financial reform plan itself.

"The whole system has been whipped around by unguided and misguided emotion," Korn said. "There has not been significant policy analysis. The system has responded to pressure to stabilize grants for investigators."

During the time of large budget increases, the policy of longer term awards worked, Korn said. "The scientific community thought it was great, but what wasn't happening was an analysis of what it meant in the out years, in a number of years down the road."

"We wouldn't be having these problems if budgets were adequate," Broder said. "I think we are doing better science than ever before." The high approval rate is the result of investigators doing better research and tinkering more with their proposals to make them acceptable, he said.

Board member Howard Temin expressed the concern that the U.S. biomedical establishment has become too large. "We have expanded the size of competent biomedical investigators and institutions, but we have far outstripped any reasonable rate of growth we can expect from the federal government. We have to get the message that the establishment is too big for the federal government. It's not a good idea to go on each year hoping to get some federal grant. If we get the money, then we'll just expand some more and have the same problems."

Board member Enrico Mihich argued that scientific peer review should not deal with the financial aspects of grant review.

In response, Broder stressed that whatever one's beliefs on the issue, the report does not reflect a lack of understanding of NIH procedures. "It was written by exceedingly competent people with expert knowledge of how we do business," he said.

"They are saying, 'Look us in the eye and tell us you really intended to fund a grant with a score of 490,'" Broder said. Grants with such scores should simply be disapproved, the committee report implied.

"They are saying NIH has done rather well [in appropriations] over the years, but each fiscal year there is enormous pressure to increase the total number of approved grants."

"I happen to feel the system is serving NCI well," Broder said. "I think the committee is prepared to see a counter-proposal [from NIH]. We should be prepared for reasoned debate."

Korn noted that in the mid-1970s, the approval rate for NIH grants was in the range of the mid-60s. Then,

NIH set a policy to use the full scoring range. That caused the approval rate to drop.

Broder said he thought the committee's discussion of the approval rate problem was a reflection of the fact that "most people want value for the dollar."

Korn disagreed. "I don't think that's what that means," he said. "It's a reaction because the percentage of awarded funded is always low. It's a fundamental misunderstanding."

He said NIH would have to develop "a new language" to address the issue of grant approvals. Korn provided an analogy for the problem: the difference between the college grading system and the graduate school grading system. While undergraduates are graded from A to F, with C being a passing grade, graduate students are graded A to C, with a B necessary to pass.

"I always thought that system was unfair when you have undergraduates and graduates mixed," Broder said. He countered with a baseball analogy: in 1900 it might have been easier to have a batting average of 400 because pitchers today are better and their techniques are perfected.

"I personally believe that the science is better now that what we were doing in the '60s and '70s," he said.

"That's what we have been testifying, but it's not getting across," Korn said. "The success rate is being used to keep racking up pressure on the budget. [In Congress] this is seen as a kind of gimmick."

On the touchy issue of indirect costs, Broder said he did not see these costs as "a pool of available funding." These grant costs go toward valuable services that allow universities and research institutions to exist, such as security or building maintenance. If indirect costs were cut, in effect there would be less money for research, Broder said. "If a study section is forced [to deal with indirect costs], it will be hard for some universities."

"If I were a dean of a university right now, especially a university in an area that depends on heating oil and other products from the Persian Gulf, I might be looking at some unexpected surcharges in the near future," Broder said.

"The review groups are not really prepared to deal with indirect costs, but we will have to have some way of addressing this."

Broder said his view is to limit peer review to the scientific issues and have the NCAB deal with cost questions.

If the committee insists on eliminating downward negotiations in this fiscal year, it could have a severe effect on the number of grants funded, Broder said. "They don't want downward negotiations and neither do we. There will have to be a unified NIH policy."

Broder estimated $60 to $70 million would be required to fully fund new and continuing grants. If there were no downward negotiations this year, "we would have to sacrifice 200 grants," he said.

"That's a 20 to 25 percent decrease in new and competing grants," Korn said.

"That's why we do downward negotiations," Broder said.

"What are you going to do about it?" Board member John Durant asked.

Broder said he would wait to see if the Senate report contains similar language, and then he would ask for more time to phase in a no-cuts policy gradually.

On the issue of centers, Durant asked NCI to provide a definition of centers across all of NIH. "I don't think some of those [non-NCI] centers are really centers," he said.

The report also requested NIH to do more to help improve minority health. "On this issue NCI is on very strong ground," Broder said. "I don't think we need to do anything different."

The report also called for more research on cancer prevention and control. "Many different components of Congress have told us we are not doing enough on cancer prevention," Broder said. "Either we have to show we are doing more or we have to do more, or both."

"That's high priced research to do it right," said Board member Bernard Fisher.

"We are going to have to make a commitment here," Broder said.

Enrico Mihich asked Broder for an "inside the Beltway" view of the recent budgetary events in Washington and at what level NCI's FY 1991 budget might finally end up.

"I don't know. There are no experts anymore. Everything now is driven on an event basis. There was a wonderful period there when we talked about a 'peace dividend'--for about three days," Broder replied.

NCI's FY 1992 bypass budget has been submitted to the President. The budget, which is prepared by NCI and is a professional determination of what could reasonably be spent on cancer research, called for $2.6 billion in FY 1992.

For those who think the bypass budget is "an academic exercise," Broder said, the House and Senate reauthorization bills took their authorization figures

from the bypass budget. "It's good to note that the bypass budget is read and acted upon."

Fetal Tissue Obstacle Jeopardizes NIH Reauthorization, NCI Authorities

The House Energy & Commerce Committee last week passed a bill to reauthorize NIH that includes a provision requiring HHS to fund human fetal tissue transplantation research.

The provision overturning a Bush Administration ban on fetal tissue research threatens to throw the NIH reauthorization into a battle with the Administration, as well as the strong anti-abortion lobby, which believes fetal research would serve to encourage abortion.

The bill, introduced by Rep. Henry Waxman (D-CA), sailed through Waxman's Subcommittee on Health & the Environment, as well as the full committee, with no amendments.

The Senate version of the NIH reauthorization was passed by the Labor & Human Resources Committee in August and awaits a vote of the Senate (**The Cancer Letter,** Aug. 10). Introduced by Sen. Edward Kennedy (D-MA), the bill includes an extension of the moratorium on fetal tissue research.

Like the Senate bill, the Waxman bill includes provisions to improve the representation of women and minorities in NIH-sponsored trials.

Acknowledging the force of the "right to life" proponents, those backing the Senate version of the bill said it is highly unlikely the House bill could pass without the removal of the fetal tissue research provision, thus jeopardizing reauthorization. Even if the House version is enacted, a Presidential veto would be likely.

"Every women's organization around and the National Cancer Institute should be beating up on Waxman something terrible, because if he doesn't get [the fetal tissue research provision] out of the bill, there won't be a reauthorization," a Senate committee staff member told **The Cancer Letter.** "He should find another bill to put this into--maybe a farm bill."

A staff member of Waxman's committee pointed out that none of the Republican committee members threatened to amend the bill.

While reaching an agreement on the budget was perhaps of greater concern to many on Capitol Hill and on the NIH campus last week, the lack of reauthorization is yet another cause for anxiety.

NIH's current authorization ran out on Oct. 1, the start of the fiscal year. A continuing resolution passed last week enables NIH to continue to operate at the FY 1990 budget level.

If no reauthorization is enacted, NIH would not disappear. However, if NIH continues to exist merely on continuing resolutions, budgets would be held at current levels, resulting in a severe loss of funding.

In addition, NCI would fall back on general research authorities granted to the Public Health Service and would become "just another institute," in the words of one NCI staff member.

NCI would lose its special authorities, including its authority to support construction of cancer treatment and research facilities, its authority to submit a professional needs budget directly to the President, and other special authorities that set NCI apart from the other institutes.

In the past, NCI has had to fight to hold on to those special authorities (see related story).

The Waxman bill authorizes $1.8 billion for NCI in FY 1991 and "such sums as may be necessary" for FY 1992 and 1993. It also requires that beginning with FY 1992, 10 percent of the NCI's own recommended budget for cancer prevention and control activities be appropriated for those purposes. In the FY 1991 bypass budget, the recommended amount for cancer prevention and control was $156.6 million.

Following are other major provisions of the Waxman bill:

--Requires the NIH director and the Alcohol, Drug Abuse & Mental Health Administration administrator to ensure that women and minorities are appropriately included as subjects in all research supported by both NIH and ADAMHA.

--Requires that NIH and ADAMHA technical and peer review procedures include an evaluation of a proposal's compliance with the requirements concerning the inclusion of women and minorities as research subjects.

--Establishes an Office of Women's Health within the Office of the Director of NIH to identify women's health research needs at NIH and to assist the director in carrying out the requirements concerning the inclusion of women and minorities as research subjects.

--Establishes a National Women's Health Data Bank to collect, analyze and distribute data regarding women's health conditions.

--Requires the HHS secretary to contract with the Institute of Medicine to conduct a comprehensive study on women's health research.

--Establishes an Office of Scientific Investigations within the Office of the Director of NIH to monitor investigations of scientific fraud.

--Requires the secretary to issue guidelines to

provide protection against "whistleblowers" who have made allegations of scientific misconduct or have cooperated with an investigation of scientific misconduct.

--Requires the secretary to issue guidelines to ensure that entities which receive funds from NIH do not engage in any activity that constitutes a conflict of interest.

--Establishes an advisory committee on health sciences within the NIH director's office to review and make recommendations on the organizational structure of NIH.

--Authorizes $1.2 billion for FY 1991 and "such sums as may be necessary" for FY 1992 and 1993 for the National Heart, Lung & Blood Institute.

--Authorizes $500 million for FY 1991 and "such sums as may be necessary" for FY 1992 and 1993 for the National Institute on aging.

--Allows the director of the National Institute of Allergy & Infectious Diseases to provide support for the development and operation of chronic fatigue syndrome research centers.

--Provides increased emphasis on NIH supported research on opportunistic infections that kill AIDS patients.

--Allows the NIH director to withhold for FY 1991 and 1992, up to $8 million for improvement of regional primate centers. Applicants for the funds must agree to provide a 100 percent match.

--Establishes a Senior Biomedical Research Service within PHS.

In another development, a new amendment to the Senate bill has added authorization of $150 million for NIH construction grants in the current fiscal year. That money would be split by the institutes which have construction grant authority, which are NCI, the National Heart, Lung & Blood Institute and the National Eye Institute.

Previous Cancer Act Renewals Marked By Disputes Over NCI

It is ironic that NIH reauthorization, including renewal of the National Cancer Act, has been seriously threatened at a time when NCI's special authorities under the act are not being contested. Most previous renewals since the National Cancer Act was passed in 1971 have been marked by disputes ranging from mere grumbling about specific authorities to outright, overt opposition to the entire act.

When the first renewal came up, then Assistant Secretary for Health Charles Edwards said he was against the whole thing and would recommend against renewal. He said that the cancer program should be part of his overall "national health strategy" and that NCI should be stripped of the special authorities. He was supported by HHS Secretary Caspar Weinberger, but President Richard Nixon ignored their recommendations, and the White House went along with renewal with few substantive changes.

The Nixon and Gerald Ford Administrations later sought to limit the number of comprehensive centers which could be designated by NCI, and Weinberger sought to eliminate the dollar authorizations, all without success.

The Jimmy Carter White House, while not actively opposing renewal, did considerable damage by ignoring the act in some ways: delays in appointments to the National Cancer Advisory Board and President's Cancer Panel, permitting the Panel to become nearly inactive, and totally ignoring the bypass budget.

President Reagan's Administration also was late in making appointments and ignored the bypass budget. During the first renewal/reauthorization of the Reagan years, Sen. Orrin Hatch announced that he wanted to drop the bypass budget. He later recanted, and has been a strong backer of renewal since then.

Ronald Reagan is the only President to have vetoed the NIH reauthorization bill, and suffered his most lopsided defeat in Congress when the veto was overridden by huge margins in both houses. Reagan was not opposed to NCI special authorities but to other provisions in the bill.

Three years later, NIH Director James Wyngaarden, stung by NCI Director Vincent DeVita's successful use of the President's Cancer Panel and the bypass budget process to reach Congress, the White House, and the public in going over Wyngaarden's head with their disputes, announced he favored eliminating NCI's special authorities. He said, in fact, that if those authorities were not removed, he would rather see NCI taken completely out of NIH.

Wyngaarden's views at first appeared to have some support at HHS, but when renewal bills came up in Congress, there was no Administration opposition, and Reagan signed the bill that time without a murmur.

Throughout the history of the National Cancer Act, Sen. Edward Kennedy has been strongest and most consistent source of support for the act originally and in each renewal. He introduced the original legislation as recommended by the Yarborough Panel, after having taken over as chairman of the Senate Health Subcommittee after the defeat of Sen. Ralph Yarborough of Texas. To secure President Nixon's support, Kennedy allowed his bill to be substituted for the Administration's bill, retaining everything but the

name, permitting Nixon to claim credit for it without changing the substance. He negotiated a compromise with the House which then became the National Cancer Act of 1971, and he has defended it at every renewal.

Jackson Lab Wins $9.5 Million For Mouse Facility Reconstruction

The Jackson Laboratory, Bar Harbor, ME, has received a $9.5 million grant from NCI for the reconstruction of its mouse production facility that was destroyed in a fire last year.

The funding came out of a special $14.8 million appropriation granted by Congress earlier this year in response to requests from the laboratory and from the scientific community. Congress recommended up to $10 million in funding for construction of an animal production facility but did not earmark the funds for the laboratory. The Jackson Laboratory had to compete for the grant.

The grant money will be used to build three new mouse buildings and to make renovations to facilities damaged in the May 1989 fire, the laboratory said. Some of the grant will also be applied to support services for these buildings. The new buildings will provide 40 percent of the laboratory's mouse breeding capacity and approximately 30 of the laboratory's current employees will work there.

Last fall NIH conducted hearings to assess the impact of the fire at the Jackson Laboratory, and hundreds of scientists from around the U.S. documented their need for mice produced by the laboratory. Before the fire, the laboratory provided 490 strains of mice, of which only 4 percent are available from commercial sources.

At present, the laboratory has reached 80 percent of its pre-fire mouse production facility, according to laboratory Director Kenneth Paigen.

"There still remains much to be done but this is a major first step forward," Paigen said. "I'm sure the news will come as welcome relief to labs around the country."

"The [Jackson Laboratory] facility has been a unique national resource of many years. This award is the federal response to help restore the facility to full operation within two years," said HHS Secretary Louis Sullivan last week.

The Congressional appropriation also made funds available for other peer-reviewed construction projects considered to be of high priority. Two awards were announced earlier: nearly $1.2 million to the Kenneth Norris Jr. Comprehensive Cancer Center at Univ. of Southern California for completing a facility for the center's Div. of Cancer Cause and Prevention, and nearly $400,000 to the Univ. of Wisconsin Clinical Cancer Center for construction of a cancer biostatistics center.

Two more awards were announced last week:

--Univ. of Michigan will receive a little more than $1 million from NCI for completing construction to house a cancer genetics research facility and two core laboratories.

--Purdue Univ. will receive $1.5 million from NCI for construction to consolidate most of the major programs of the Purdue Cancer Center in the Hansen Life Science Research Building.

NCI Director Samuel Broder, speaking at the National Cancer Advisory Board meeting this week, noted that NCI had received the bulk of the $14.8 million allocated
for construction grants by Congress, or about $13.5 million including the $9.5 million for the Jackson Laboratory.

"This is a step in the right direction," Broder said.

He noted that language in the House Appropriations Committee's budget report for NCI would permit the Cancer Institute to "reprogram," or move from other areas, up to $7 million for construction grants. This would help alleviate the logjam that has taken place over the last several years when Congress has been unwilling to provide funds for construction.

Other institutions that received funding out of the $14.8 million were:

--Doheney Eye Institute at the Univ. of Southern California, $480,938 from the National Eye Institute for converting existing space into a research laboratory and central support facility for its Center for Molecular Biology of Vision.

--Univ. of Iowa, $655,358 from the National Heart, Lung & Blood Institute for remodeling existing space to support cerebral vascular research within the Div. of Neuropathology of the Dept. of Pathology.

FDA Oks Treatment IND For GM-CSF In Bone Marrow Transplantation

FDA last week authorized the expanded use of GM-CSF to help save bone marrow recipients from life threatening infections.

Immunex Corp., which had filed a treatment investigational new drug application for GM-CSF, said it is making the drug available to bone marrow transplant patients suffering graft failure and delay of engraftment.

The new drug is a genetically engineered version of a human granulocyte macrophage colony stimulating factor. It is the first drug that promotes development of the white blood cells.

More than 3,000 bone marrow transplants are performed each year to treat some forms of anemia, leukemia and other malignancies. Patients receiving donor marrow or their own marrow must undergo a conditioning regimen of intensive chemotherapy, sometimes combined with total body irradiation.

The conditioning dangerously lowers neutrophils and other white blood cells, causing the patient to be highly susceptible to bacterial and fungal infections.

In clinical trials performed at more than 25 centers in the U.S., GM-CSF was given to more than 100 patients suffering graft delay or failure.

Most of the patients responded to treatment, as measured by a rise in neutrophils within the first two weeks of drug administration.

Survival rates appear to be higher in the patients treated with the drug.

GM-CSF was clinically evaluated by comparing drug-treated patients with those who, prior to the drug's development, received only supportive therapy. Survival rates for GM-CSF treated patients appear to be higher than for historical controls in most of the studies.

Administered by intravenous infusion, the drug causes side effects which are relatively mild, including fever, nausea, swelling and skin rash.

GM-CSF had earlier been given FDA orphan drug designation, which provides incentives for the development and production of drugs and other medical products to treat rare diseases and conditions.

Under the treatment IND designation, Immunex will be allowed to distribute the drug to desperately ill patients before the completion of review for final approval.

Immunex, based in Seattle, WA, has said it will provide GM-CSF on request at no cost to physicians performing bone marrow transplants.

RFAs Available

RFA CA-90-21

Title: Digital imaging of chest x-ray

Application Receipt Date: Dec. 11

NCI's Radiation Research Program within the Div. of Cancer Treatment announces the availability of an RFA on the above program. The objective of this RFA is to support meritorious research in the application of digital chest radiography in the detection and characterization of the solitary lesions often associated with lung cancer.

Radiographic examination of the chest is the most commonly performed study in diagnostic radiology. Despite the advent of new imaging techniques and the highly sophisticated technology, such as computer tomography, ultrasonography and magnetic resonance imaging, chest x-ray remains the mainstay of thoracic imaging. Chest radiography has not appreciably benefited from the diagnostic imaging evolution of the last decade. Digitization of the chest radiograph is technically difficult.

It requires high spatial resolution to capture the fine details of the vessels, bronchi, and to detect small lesions. No universally acceptable digital chest system has been developed; but as systems improve, more sophisticated processing options will arise. More advanced algorithms will open digital chest radiography to quantitative analysis, particularly concerning application of dual energy techniques.

The complexity of chest radiography and lack of standardized chest technique make the digitization of chest x-ray a formidable task. This RFA is designed to advance all aspects of x-ray digitization and to stimulate research leading to the improvement of chest radiography that may potentially result in earlier cancer diagnosis and treatment.

The objective of this RFA is to support meritorious research in the application of digital chest radiography in the detection and characterization of the solitary lesions often associated with lung cancer. The ultimate goal of digital radiography is to enhance diagnostic imaging, improve image communication, archiving, reduce cost of patient care and improve cancer detection.

Approximately $600,000 in total costs per year for three years will be committed specifically to fund applications which are submitted in response to this RFA. It is anticipated that approximately three or possibly four scientifically meritorious applications will be funded.

Requests for copies of the complete RFA should be addressed to Dr. Matti Al-Aish, Program Director, Diagnostic Imaging Research Branch, Radiation Research Program, NCI, NIH, Executive Plaza North Suite 800, Bethesda, MD 20892, phone 301/496-9531.

New Publications

"Drug Resistance: Mechanisms and Reversal" consists of the complete proceedings of the first annual Pezcoller Symposium held in Trento, Italy, in June 1989. The volume is edited by Enrico Mihich, associate director for sponsored programs at Roswell Park Memorial Institute, and a member of the National Cancer Advisory Board.

The symposium included the participation of internationally recognized leaders in the biochemical and clinical pharmacology of anticancer drug resistance. The major focus was on the molecular and pharmacological basis of individual and multidrug resistance and on means to overcome it.

The volume is available for $75 from John Libbey-CIC, Via L. Spallanzani, 11 00161 Rome, Italy.

The second Pezcoller Symposium was held last June and focused on "The Therapeutic Implications of the Molecular Biology of Breast Cancer." The proceedings of this symposium are scheduled for publication in early 1991.

The Pezcoller Foundation is supported by the personal estate of Alessio Pezcoller, an Italian surgeon who cultivated the desire to support and stimulate medical research.