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Senate Voices Discontent With NIH, NCI Budget; Gorton Presses Raub On Cancer's 'Low Priority'

The Bush Administration's $8.7 billion FY 1992 budget for NIH "barely keeps pace with biomedical inflation," Sen. Tom Harkin, chairman of the Senate Labor, HHS, Education Appropriations Subcommittee, complained

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In Brief

Everson, Clarke New ACCC Leaders; Katterhagen To Move To Burbank; Vote On Healy Expected

LLOYD EVERSON, director of the Indiana Regional Cancer Center in Indianapolis, is the new president of the Assn. of Community Cancer Centers, taking over from **Jennifer Guy** the annual meeting in Washington DC. **Robert Clarke**, CEO of Memorial Medical Center in Springfield, IL, is the new president elect. Other new officers are **Carl Kardinal**, Ochsner Clinic, New Orleans, treasurer; **Albert Einstein**, Virginia Mason Medical Center, Seattle, secretary; and **John Feldman**, Mobile, AL, **Michael Ryan**, Willmar, MN, **Ronald Deisher**, Kansas City, KS, and **Connie Henke Yarbro**, Columbia, MO, trustees. . . . **GALE KATTERHAGEN**, executive director of the Regional Cancer Center at Memorial Medical Center in Springfield, IL, has accepted the position of medical director of the cancer center at St. Joseph's Hospital in Burbank, CA. **Anne Katterhagen**, vice president of Alternative Care Services at Memorial, will accompany her husband and is considering a position in the Southern California area. . . . **BERNADINE HEALY** was expected to be confirmed as NIH director this week in a vote by the Senate Labor & Human Resources Committee. The committee held a hearing last week on the Cleveland Clinic Foundation cardiologist's nomination. . . . **ISAIAH FIDLER**, chairman of cell biology at M.D. Anderson Cancer Center, delivered the sixth Paul Sherlock Distinguished Lecture at Memorial Sloan-Kettering. . . . **SUSAN HARLAP**, a physician epidemiologist who is renowned in the field of reproduction, has been appointed chief of the Epidemiology Service at Memorial Sloan-Kettering Cancer Center. . . . **DAVID SWITT**, Washington DC newsletter publisher who collected a "six figure settlement" last year from a Fortune 500 company he accused of copyright violations, has sued a Washington law firm for "regularly and repeatedly" making "multiple illegal photocopies" of his newsletter, "Product Safety Letter." Maximum statutory damages could amount to $14 million. Switt also has sued Connaught Laboratories, of Swiftwater, PA, for "regularly, repeatedly, and illegally" making multiple photocopies of "The GMP Letter," a monthly newsletter.

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NIH Placed 'Low Priority' On Cancer Over Past Decade, Sen. Gorton Says

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last week. However, at the subcommittee's hearing on the NIH and NCI budget, Harkin did not indicate whether the subcommittee would be able to improve the NIH funding level, which is 6 percent above the FY 1991 budget.

The President's FY92 budget request for NCI is $1.81 billion, a 5.6 percent increase over FY91.

In his opening statement, Harkin said the budget "does reflect some progress" in higher funding of research project grants. In addition, he commended NIH for development of the cost containment plan mandated by the appropriations committees last fall.

Harkin also said he was concerned about high indirect cost rates, which, he said, referring to recent news reports, "pay for everything from flowers to china to yachts."

But it was the newest member of the subcommittee who grilled Acting NIH Director William Raub about the deterioration in NCI's budget compared to the overall NIH budget over the last 10 years.

Sen. Slade Gorton (R-WA), recently appointed to the Appropriations Committee, said the Administration's budget for NCI is "not likely to meet inflation, especially inflation in this field." He cited figures showing that NCI's budget actually fell in real dollars by 6 percent in the past decade, while funding for all types of NIH research programs have increased by 27 percent in real dollars.

GORTON: "Am I accurate in my observation, and if I am, what is the rationale for this relatively low priority on cancer, a disease that kills more Americans than perhaps any other?"

THE CANCER LETTER

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RAUB: "Your characterization is accurate. One of the elements in this budget is to begin attempting to correct that. The trend came about by many factors, but I believe it was the combination of a heavy emphasis on one type of funding mechanism, namely research project grants, through the decade of the 1980s, against the backdrop where much of the spending of the National Cancer Institute up until that time also was heavily placed in other types of mechanisms of support--research contracts, research centers, in particular. Those latter two over the course of the '80s did not fare anywhere near as well either in the internal priority setting or the overall budget context. When that is compounded year after year, it creates the trend that you described. At the same time, through the '80s, some of the most exiting basic science anywhere in biology and medicine has been going on in relationship to cancer, in particular the role of the so-called oncogenes and tumor suppressor genes. And in recognition of that, [NCI Director] Dr. [Samuel] Broder has made a very strong case...that these issues ought to be redressed, and that we ought to be sure that as best we can our budget allocation provides favorably for those new opportunities."

GORTON: "Where do I see that in the figures in this budget?"

RAUB: "The overall figure relative to cancer appropriation does not stand out, I agree, from the overall NIH, but there is a particular allocation within the research project grant line and within the cooperative clinical research line where we tried to give a special boost for the cancer research program. We agree though that one year won't do that. It will need to be a sustained effort."

GORTON: "You're representing that there is a return of attention on, or increasing attention, to cancer and cancer research, that that is a fundamental goal of NIH?"

RAUB: "Yes."

Raub was referring to the 7.2 percent increase in funding of NCI's research project grants in the Administration's FY92 budget and the 6 percent increase in funding for clinical cooperative groups, which would provide the groups with a total of $66 million, $3.75 million more than FY91.

Broder Lists Achievements

In his testimony to the subcommittee, NCI Director Samuel Broder listed the following achievements of NCI in the past year and priorities for the future:

▶"NCI has pioneered methods of rapid communication about advances in clinical research and continues to disseminate state of the art information in the U.S. and throughout the world.

▶"New cancer drugs have been developed, and new prevention strategies using vitamin derivatives have proven effective.

▶Scientists from NCI and the National Heart, Lung & Blood Institute have pioneered gene treatment studies, including the study of gene therapy for the adenosine deaminase deficiency. "Preliminary results in the first patient, a four-year-old girl, suggest that her immune function has improved. Most recently, two patients with melanoma were treated with tumor infiltrating lymphocytes armed with tumor necrosis factor." In response to a question from Harkin on how long the four-year-old will be treated, Broder said, "This is the first patient on earth to have this treatment. We're learning as we go along. We will continue the treatment as long as we think she is benefitting."

▶"Major progress has been made in reducing deaths from childhood cancers, and in preventing or treating many common cancers in adults as well. However, there has been less progress in reducing the death rate from the common solid tumors in patients aged 65 and over.

▶"Many Americans--the poor, the underserved, and members of some minority groups--do not have access to state of the art prevention, early diagnosis and treatment, and have disproportionately high cancer incidence and mortality rates. We must increase our efforts in cancer prevention and control.

▶"Research on cancers that affect women is a high priority for NCI as cancer is the second leading cause of death among women in the U.S., with more than 150,000 women expected to die in 1991 of cancers of the lung, breast, colon and reproductive tract.

▶"NCI supported scientists are unraveling the genetic mysteries of the cancer cell. Important new theories of how cancer evolves from the normal cell are emerging with increasing information about oncogenes and suppressor genes. In addition, there has been an astonishing level of application in recombinant DNA technology, boosting the productivity of the biotechnology industry, due in great measure to the basic cancer research funded by NCI.

▶"The NCI cancer centers provide interdisciplinary cancer research and state of the art diagnosis, treatment, rehabilitation, prevention and cancer control, as well as community outreach and research on AIDS related cancers throughout the nation. Additionally, NCI's ability to transfer technology effectively rests on community programs such as the Clinical Cooperative Groups and the Community Clinical Oncology Program.

▶"Among other new cancer drugs, there is great interest in taxol as it can kill various cancer cells. It is derived from the bark of yew trees and is in very short supply, but NCI is undertaking taxol development from alternative renewable sources.

▶"Prevention is the most effective way to eliminate a disease. NCI is studying smoking cessation, diet, chemoprevention, cancer vaccines, and the use of hormones to prevent tumors. NCI has assisted in evaluating potential environmental issues such as those related to nuclear power plant facilities.

▶"NCI has an important mission in AIDS research and works closely with other federal agencies. NCI scientists have made vital contributions in areas such as basic biomedical research on the pathogenesis and natural history of HIV infection, drug development, and vaccine development. The NCI intramural program is a leader in developing new therapies for children with AIDS. As people with AIDS are surviving longer, the incidence of AIDS related cancers is increasing. NCI is working to meet this challenge.

▶"One measure of the success of the National Cancer Act is that there are over six million cancer survivors in the U.S. today. We have accrued understanding of the basic biology of cancer, which in turn is pointing to effective prevention, diagnosis and treatment."

Women's Health Trial

Harkin asked Broder about the controversy over the Women's Health Trial, the proposed multimillion dollar randomized trial to see whether a reduction in fat would have a significant impact on the incidence of breast cancer, other cancers, and heart disease. "I don't fully understand the controversy--should we proceed with this study?" Harkin asked.

Broder said the controversy centers on the fact that, "a number of scientists of great intellect and goodwill are looking at the same data and coming to opposing conclusions." He listed "two or three camps" of those who are against the trial:

--Those people who say that it is known that a decrease in fat consumption will result in lower rates of cancer, so there is no need to study the question and low fat diets should be adopted now.

--Another group feels that the answer is not known, but that the particular protocol as it is designed would not provide the answer. This includes the controversy over animal vs. dairy fats.

--A third group says total calories, not fat, are the culprit and that the trial as designed would not take calories into consideration.

"The most significant concern I personally feel is that we don't have an adequate preliminary database

on poor and minority women," Broder said. At issue, he said, is "whether we have enough cultural sensitivity and appropriateness in addressing how to implement a low fat diet for that group. Poor and minority women have the worst cancer statistics, and in my personal point of view, it would be unthinkable [to conduct the trial only in middle class, white women] "without ensuring that we understand how to do fat reduction [in poor and minority women]."

NCI will conduct a three year, $7.5 million feasibility study to "ask whether we can do a culturally appropriate dietary intervention in those groups."

Broder did not list, and Harkin did not ask for, the arguments in favor of conducting the trial.

Harkin also said he thought NCI should be open to unconventional treatments, and mentioned the recent Office of Technology Assessment report on unconventional therapies.

Broder said NCI had responded to the report and had "made suggestions for increasing lines of communication" to practitioners of unconventional therapy. He noted that NCI has followed up on unconventional ideas in the past, including a study of laetrile, hydrozine, and an ongoing randomized study of vitamin C.

Praise For Raub

Sen. Mark Hatfield (R-OR) noted that the Senate confirmation hearing for the new NIH Director Bernadine Healy was taking place last week at the same time as the NIH budget hearing. He called Acting NIH Director William Raub "a man of extraordinary talent who managed to hold together this federation of institutes for two years under the title of acting director." Hatfield thanked Raub for his service, but said the gap between permanent directors was an "unconscionable delay."

Tamoxifen Trial May Be Funded In Part From CCOP $$; Maybe Not

Some participants in the Community Clinical Oncology Program were apprehensive when they heard that the CCOP budget would be tapped to help support the tamoxifen breast cancer prevention trial.

They heard Peter Greenwald, director of NCI's Div. of Cancer Prevention & Control, tell them that the tamoxifen trial would be carried out through CCOPs and that as much as half of the first year estimated cost of $4 million would be from the CCOP FY 1991 budget.

CCOP people have never felt the program has been adequately funded. Costs they incur in carrying out protocols with their research bases almost always exceed amounts they receive from NCI. What's more, there are at least 20 and probably more community hospital cancer programs which could be funded CCOPs if more money were available.

Greenwald's message, delivered at the annual meeting of the Assn. of Community Cancer Centers, therefore was not happily received. It could turn out not to be all that bad, however.

The estimate of $4 million for the first year was not a hard figure. That estimate was made before the two proposals were in, the successful one from the National Surgical Adjuvant Breast & Bowel Project, the other from the Eastern Cooperative Oncology Group. Both were "excellent" proposals, Greenwald said, and both had been approved by the National Cancer Advisory Board before NCI's Executive Committee selected that of NSABP.

"Both were sound in terms of science," Greenwald said. "The major issues were cost and anticipated rate of accrual."

NCI and NSABP are negotiating the fine points, including details of the protocol. The final contract could come in less than the $4 million for the first year.

DCPC received an increase of $8 million in its budget for the current year, over the amount in the President's budget request. Greenwald said that $2 million of the increase was allocated to the tamoxifen trial, and that was added to CCOP's $14.5 million budget.

Whatever amount exceeding $2 million that the tamoxifen trial will cost in the first year will have to come from the remaining CCOP funds. When Lee Mortenson, ACCC executive director, asked Greenwald if that would reduce funds for CCOP treatment clinical trials, Greenwald said it might but "I hope not."

The fact is that CCOPs already are obligated to use some of their NCI funds for cancer prevention and control, in protocols generated by themselves and their research bases and approved by NCI. Greenwald told **The Cancer Letter** that participation in the tamoxifen trial definitely would qualify toward fulfilling that obligation.

Greenwald also said that the $2 million added to the CCOP budget for the tamoxifen trial might not be the last word on distribution of NCI's FY 1991 money. Some funds remain uncommitted until midsummer, and dollars made available through unexpected savings of various kinds may be reprogrammed right up to the end of the fiscal year, Sept. 30.

There is also the possibility that the trial will not get off the ground during the 1991 fiscal year. In that

case, with the trial's first year costs to come out of the FY 1992 budget, there might be no infringement at all on CCOP funds. Greenwald said that if the President's request for the 1992 budget is the minimum approved by Congress, the additional $4.5 million earmarked for DCPC would permit him to add another $2 million to the tamoxifen trial. He anticipates that additional tamoxifen funds thereafter would permit completion of the seven year study without a negative impact on the CCOP budget.

Greenwald had originally hoped that all the national multidisciplinary cooperative groups--NSABP, ECOG, Southwest Oncology Group, North Central Cancer Treatment Group, Cancer and Leukemia Group B--would work together in the tamoxifen trial, joining together in a single protocol. Only NSABP and ECOG were interested, and each wanted to develop its own proposal.

Greenwald still had hopes that the two groups might work together, with other cooperative groups including ECOG joining in the NSABP protocol. NSABP Chairman Bernard Fisher said this week that he would welcome participation of "anyone with the interest and resources, whoever can help us meet the goal."

That goal probably will include accrual of 16,000 women, most at high risk for breast cancer, within four years or sooner. Followup initially will be three years, but both NCI and National Heart, Lung & Blood Institute sponsored investigators probably will follow the cohort longer. NHLBI has committed $9.5 million total to assess tamoxifen's ability to reduce risk of heart disease.

Stop Cancer Still Working To Raise $12.5 million; Film Event April 16

The late Armand Hammer's Stop Cancer Foundation still intends to fulfill its $12.5 million obligation to NCI, hoping to raise the rest of that amount at the organization's "culminating event" April 16 in Los Angeles.

A party at the Armand Hammer Museum & Cultural Center will follow the world premiere of the film, "Chernobyl: The Final Warning." The movie depicts the story of Hammer's efforts to speed medical assistance to the stricken area of the Soviet Union. Jason Robards plays the role of Hammer, and John Voight portrays Robert Gale, the UCLA clinician and scientist who led the medical team gathered by Hammer.

Myra Silverman, who has headed the West Coast office of the foundation since its inception three years ago (Executive Director Denver Frederick works out of New York), told **The Cancer Letter** that "we hope that with what we make that evening and the pledges still to come, we will reach the $12.5 million."

Hammer had announced in 1989 that he had raised $12.5 million for the Stop Cancer campaign, and he so notified Congress, whose leadership had promised to match dollar for dollar any sums up to $500 million generated by the campaign. Congress kept its word and added $12.5 million to NCI's FY 1990 appropriations bill.

It turned out, however, that Hammer had only about $2.5 million in hand, with the rest in pledges. When he died last December, he had turned over to NCI only a little more than $5 million.

Frederick and Silverman feel that most of the pledges will eventually come in, and that the "Chernobyl" party will cover any deficit.

"Twelve and a half million is a long way from $500 million," Silverman said, referring to Hammer's original, ambitious goal. "But the extra $25 million this will get for cancer research certainly is worth the effort."

Silverman said no decision had been made on whether Stop Cancer would be continued past the April 16 event.

NCI Issues Clinical Announcement On Stage 2,3 Rectal Cancer Therapy

Final analysis of the North Central Cancer Treatment Group's 1980-86 rectal cancer clinical trial led NCI last week to issue a clinical alert (or "clinical announcement" as NCI now is calling it). Unlike previous clinical alerts sent to the country's physicians by NCI, this one is relatively noncontroversial and it follows the new guidelines for such announcements which the institute adopted last year.

The announcement recommends that for patients with stage 2 or 3 rectal carcinoma who cannot or will not participate in a clinical trial, physicians should consider combined modality treatment of radiotherapy plus 5-FU.

Significantly, that recommendation does not include methyl CCNU, which was part of the NCCTG regimen in the 1980-86 study. The final report on that trial was published last week in the "New England Journal of Medicine."

The trial tested radiotherapy alone against radiotherapy plus 5-FU and MeCCNU. For the 100 patients in the radiotherapy alone arm, five year disease free survival was 42 percent, and five year survival was 47 percent. For the 104 patients in the combined modality arm, five year disease free survival was 63 percent, and five year survival was 58 percent.

NCI's announcement referred to a later NCCTG led intergroup study, which from 1987 to 1990 randomized 453 patients to combined modality therapy with or without MeCCNU. An interim analysis, which will be presented at the annual meeting of the American Society of Clinical Oncology in May, reveals a rate of recurrence 1.2 times higher for patients receiving MeCCNU. NCI said that statistically rules out the likelihood that MeCCNU provides any benefit. Because of toxicity associated with MeCCNU, including increased risk of leukemia, it was not included in the recommended regimen.

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 Executive Plaza South room number shown, National Cancer Institute, Bethesda MD 20892. Proposals may be hand delivered to the Executive Plaza South Building, 6130 Executive Blvd., Rockville MD. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NIH-NIDR-2-91-5R

Title: Role of herpes simplex virus in the pathogenesis of oral mucositis associated with cancer chemotherapy

Deadline: Approximately April 30

The National Institute of Dental Research has a requirement to study the role of herpes simplex virus (HSV) in the pathogenesis of oral mucositis associated with intensive chemotherapy, and to determine whether the antiviral agent acyclovir can reduce the incidence and severity of mucositis in severely immunocompromised patients. The study will consist of a double-blind, placebo-controlled trial of daily oral acyclovir for the prevention of HSV infection and mucositis in HSV-seropositive patients undergoing intensive chemotherapy for the treatment of leukemias or lymphomas.

At the completion of this two-year study, an analysis will be made of the severity and frequency of oral ulcerations and the association of HSV culture/antigen-positive lesions in patients on acyclovir and those on placebo.

If the study demonstrates that herpes simplex virus is involved in the pathogenesis of oral mucositis and that acyclovir can reduce the frequency and/or severity of mucositis, then an informed recommendation can be made that all HSV seropositive patients undergoing intensive chemotherapy for acute leukemia or lymphoma receive routine prophylactic acyclovir therapy for each course of chemotherapy.

NIDR expects to make one award from this solicitation.

The RFP package will be available upon written request to: Marilyn Zuckerman, Contracting Officer, Contract Management Section, NIDR, Westwood Bldg, Rm 521, 5333 Westbard Ave., Bethesda, MD 20892.

RFP NCI-CM-27707-09

Title: Support services for the regulatory affairs branch

Deadline: Approximately May 13

The Cancer Therapy Evaluation Program, Div. of Cancer Treatment, NCI, is responsible for administration and coordination of most of the extramural clinical trials supported by DCT. The contractor for this project shall furnish services, qualified personnel, material, equipment and facilities not otherwise provided by the government to the Regulatory Affairs Branch, CTEP in meeting FDA regulatory requirements for investigational agents.

Specifically, the contractor shall: 1) staff on-site Protocol and Information Office responsible for; a) receiving all proposed protocols, b) abstracting scientific and administrative information for the CTEP information system, c) scheduling and following the protocols through CTEP review, d) tracing the progress of approved protocols including status information, e) scanning the literature for protocol related publications; and 2) provide off-site staff and capabilities to a) coordinate recordkeeping for reported adverse drug reactions, b) prepare IND filings, c) update clinical brochures for DCT-sponsored agents, and d) coordinate mailing of copies of adverse reaction reports, annual reports and other IND related information to pharmaceutical companies.

This acquisition is being offered for competition limited to eligible 8(a) concerns. The Standard Industrial Classification (SIC) code is 7375.

Contract Specialist: Mary O'Leary
RCB Executive Plaza South Rm 603
301/496-8620

RFP NCI-CM-27714-74

Title: In vivo evaluation of combination therapy for anticancer activity

Deadline: Approximately May 3

NCI's Div. of Cancer Treatment is seeking a contractor to evaluate the preclinical antitumor activity of drug combinations in order to determine whether any combination of cytotoxic antitumor agents, biological response modifiers or a biochemical modulator is more efficacious than the individual agents alone.

The majority of the studies will be conducted in vivo and, as appropriate, will utilize either murine tumors or human tumor xenografts growing in either pathogen-free immune-competent or immune-deficient (e.g., athymic of SCID) mice. On occasion, in vitro evaluations of drug combinations may be conducted in order to gain insight into the potential synergy of a combination and/or the importance of drug sequencing.

Results from the project will be used to help guide clinical trials involving drug combinations. Compounds to be studied will be selected and assigned by the government. As compounds of a proprietary nature to competing companies may be evaluated, pharmaceutical, chemical and biotechnology companies will be excluded from the competition. Also, since structural formulae of commercially confidential materials may be provided by the government on occasion, the organization must be willing to sign a confidentiality of information statement.

The organization shall provide facilities for handling pathogen-free immune-competent and immune-deficient mice and utilize methods to protect the facilities from pathogenic organisms. The contractor also shall provide facilities/equipment for frozen storage of tumors, tumor transplantation, drug preparation, and treatment; facilities/equipment for the handling of potentially carcinogenic or hazardous materials; facilities/equipment for propagation and testing human and murine tumor lines in vitro.

The principal investigator should have a MD, DVM or PhD in one of the relevant biological sciences (or equivalent experience), should have experience in managing an in vivo screening program utilizing small animals or in evaluating the efficacy or toxicity of antitumor agents, should understand the principles of cancer chemotherapy and should devote approximately 25% of

his/her time to the project. It is anticipated that one incrementally funded contract will be awarded for three years. Each increment will be for one year. The contract will be written on a "level of effort" basis specifying that the contractor is to furnish approximately 19,182 hours over three years.

Contract Specialist: Odessa Henderson
RCB Executive Plaza South Rm 603
301/496-8620

RFP NCI-CM-27708-09

Title: Preclinical pharmacology studies of antitumor and anti-HIV agents

Deadline: Approximately May 15

The Developmental Therapeutics Program, Div. of Cancer Treatment, is soliciting organizations having the necessary experience, scientific and technical personnel and facilities to conduct a series of preclinical pharmacokinetic and other pharmacology studies in non-disease bearing animals on compounds having demonstrated antitumor or anti-HIV activity and considered by DCT to merit further development.

The studies to be performed will include: the development of methodology for the quantitative measurement of the compound and/or metabolites in animal body fluids and tissues; stability studies of the compound in biological fluids; plasma protein binding determinations; characterization of the plasma concentration-time profile and calculation of relevant pharmacokinetic parameters; determination of the most effective mode of compound administration to achieve and maintain effective concentrations in body fluids and tissues; bioavailability studies following administration of an agent by various routes; tissue distribution and urinary excretion studies; structural determination of metabolites and transformation products of the parent compound, and where appropriate, relating this information to mechanisms of action.

The government will supply all animals (mice, rats, dogs), test agents, and radiolabeled test agents. Contractors will be expected to provide all equipment, solvents, reagents and animal facilities needed to conduct this type of work. It is anticipated that six awards will be made as a result of this RFP, each for a three year, incrementally-funded level of effort contract. Only one award will be made to an institution.

The following Mandatory Qualification Criteria will apply:

(1) The contractor may not be a pharmaceutical or chemical firm since compounds of a commercially confidential nature (discreet) may be evaluated;

(2) since structural formulas and other information on discreet compounds may be included in a Task Assignment Request, contractors must be willing to sign a confidentiality of information statement;

(3) the contractor must possess a valid NSC license permitting the purchase, storage, and use of typical quantities of radioisotopes (e.g., 3H, 14C, 35S) likely to be used in the proposed pharmacological research.

This project was originally announced under NCI-CM-27701. All those who responded to that announcement need not respond to this one. Original requests will be transferred to this project.

Contract Specialist: Mary O'Leary
RCB Executive Plaza South Rm 603
301/496-8620

RFP NCI-CN-15431-50

Title: Prostate, lung, colorectal and ovarian cancer screening trial: Study coordinating and data management center

Deadline: Approximately May 14

NCI's Div. of Cancer Prevention & Control, Early Detection Branch, is interested in soliciting proposals from organizations for maintaining a Study Coordinating and Data Management Center for the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial.

The purpose of the Coordinating and Data Management Center is to develop and maintain systems and procedures for biomedical data management, study coordination, statistical analysis and report writing. The Coordinating Center must receive and process data from up to 15 screening centers in all phases of the proposed 16 year study, plus possess the ability to provide logistical support for meetings and other activities required by the project. It is anticipated that the Coordinating Center staff shall be required to interact with NCI project officers on a daily basis.

Contract Specialist: Karen McFarlane
RCB Executive Plaza South Rm 635
301/496-8603

RFA Available

RFA CA-91-11

Title: Minority oncology leadership academic award

Letter of Intent Receipt Date: April 5

Application Receipt Date: May 17

The Comprehensive Minority Biomedical Program, Div. of Extramural Activities, NCI, invites academic health centers or schools and other health professional schools that employ, educate, or serve a preponderance of minority faculty, staff, trainees and communities to submit applications for the support of an individual to pursue leadership activities in the development of research and training programs in clinically oriented cancer research (defined as including population research; surgical, medical or radiation oncology; cancer prevention and control; epidemiology and biostatistics; nutrition; clinical pharmacology and clinical trials; behavioral medicine and related areas of cancer research).

This award is aimed at encouraging and assisting a designated leader in any of the minority health professional schools to increase his/her institution's efforts in clinical cancer research in the areas such as medical oncology, prevention, etiology, diagnosis, treatment, and control; and to aid in establishing a cadre of faculty and staff capable of developing new research protocols and to participate in intervention studies and clinical trials in these areas.

These awards offer opportunities for supporting start up expansion of such activities, and are intended to meet needs that have not been addressed by other types of awards available from NCI or other federal agencies. Priority is given to those minority institutions with an interest in and commitment to expansion of clinical cancer research related activities in local populations.

Support of this program will be through the NIH grant in aid (K07). Applicants will be responsible for the planning, direction, and execution of the proposed project. Up to $350,000 in total costs per year will be committed specifically to fund applications submitted in response to this RFA. It is anticipated that between two and four awards will be made. The earliest feasible start date for the initial award is Sept. 30. Awards may be made for three to five years.

Applicants are asked to submit by April 5 a letter of intent that includes descriptive title of proposed research, name and address of principal investigator, names of other key personnel, the participating institutions, and the number and title of the RFA. The letter should be sent to Dr. Lemuel Evans, Comprehensive Minority Biomedical Program, Div. of Extramural Activities, NCI, NIH Bldg. 31, Rm 10A04, Bethesda, MD 20892, phone 301/496-7344, fax 301/402-0062.

For information regarding budgetary/administrative issues related to this RFA, contact Leo Buscher, Chief, Grants

Administration Branch, NCI, Executive Plaza South Rm 216, Bethesda, MD 20892, phone 301/496-7753.

Errata: Upper GI Carcinoma

RFA CA-91-03

Title: Clinical treatment and correlates of upper GI carcinoma
Letter of Intent Date: Feb. 25
Application Receipt Date: April 8

NCI's Div. of Cancer Treatment would like to clarify RFA CA-91-03 with regard to appropriate upper gastrointestinal (GI) tumor sites (**The Cancer Letter,** Jan. 11). Carcinoma of the upper GI tract is now defined to include "pancreatic carcinoma" in addition to esophagus and stomach carcinomas. The RFA invites research grant applications (RO1) from interested investigators to assess new clinical correlates and develop new treatment modalities in upper gastrointestinal carcinoma.

Inquires concerning the objectives of this RFA or whether or not specific research would be responsive should be directed to Diane Bronzert, Program Director, Cancer Therapy Evaluation Program, NCI, Executive Plaza North Rm 734, Bethesda, MD 20892, phone 301/496-8866, fax 301/496-9384. For fiscal and administrative matters contact Mary Niemiec, DCT Grants, Grants Administration Branch, NCI, Executive Plaza South Rm 242, Bethesda, MD 20892, phone 301/496-7800.

Program Announcement: OIG Grants

PA-01-28

Title: NCI Outstanding Investigator Grant
Application Receipt Date: June 1

NCI will continue to accept new applications for the Outstanding Investigator Grant, as well as competing continuation applications from currently funded OIG recipients in the fifth year of the initial award period. The purpose of the OIG is to encourage investigators to continue or embark on projects of unusual potential in cancer research. Emphasis will be placed on evidence of recent substantive contributions (i.e., seminal ideas and innovative approaches to resistent problems) and the potential for continued work of high caliber.

This announcement significantly modifies applicable guidelines for the OIG. Special attention should be given to the requirements for "Eligibility" and to the "General Requirements" for preparation of new competing continuation applications as noted below.

Eligibility: Applications may be submitted only by domestic institutions on behalf of investigators who have recently demonstrated outstanding research productivity for at least five years. There are no age restrictions. Only U.S. citizens, nationals or permanent residents may be presented as candidates for this grant.

Applications will be accepted by NCI only when they are cancer-related as defined by the Div. of Research Grants grant referral guidelines. Investigators whose current research support is derived predominantly from sources other than NCI may not be eligible as OIG awardees. As a general rule, investigators will be allowed to consolidate only NCI supported active cancer-related peer review grants into the OIG research effort.

The OIG Principal Investigator is required to commit 75 percent of his or her time and effort to cancer research supported by the OIG, and the institution sponsoring the OIG application is required to commit itself to providing 25 percent of the investigator's salary support. However, NCI will entertain requests, on a case-by-case basis, for time and effort commitments of less than 75 percent (with a proposed minimum of 50 percent) to the OIG project based upon allowable retention of other ongoing peer review grants.

General Requirements:

New (Type 1) and competing continuation (Type 2) OIG applicants will be required to provide a detailed proposal emphasizing his/her accomplishments prior to (Type 1) and during (Type 2) the first grant period and a detailed description of the activities to be supported under the next competing award period. The budget request must be in specific terms and a zero-based budget should be developed to assist reviewers in making explicit budget recommendations.

How to Apply: The date of receipt of all OIG applications, including competing continuation applications, has been changed to June 1 of each year. They will be processed for review at the earliest possible meeting of the NCAB.

Applications for this award should be made on Form PHS 398, available at most academic or research institutional business offices and from the Office of Grants Inquiries, Div. of Research Grants, NIH, Rm 449, Westwood Bldg, 5333 Westbard Ave., Bethesda, MD 20892. The title "NCI Outstanding Investigator Grant, PA-901-28" must be typed in section 2 on the first page of the application. A letter indicating clear and continual institutional commitment by the Institution to the applicant must accompany the application in order for the NCI to begin the review process.

--Applications must be accompanied by a curriculum vitae and a complete bibliography. Abbreviated curricula vitae of all professional persons (doctoral level or equivalent) listed on the personnel page should be included. Reprints of no more than five publications may be submitted.

For a new application that proposes primarily the consolidation of existing NCI supported research grants, the prose portion may not exceed 10 typewritten pages. For these applications, detailed descriptions of methods are not required because the evaluation of the new OIG application will be based mostly on the applicant's track record in the context of current peer reviewed support. However, these new applications must outline the main objectives to be pursued and discuss the significance of the research.

When objectives are proposed that are outside the context of current peer-review activities, portions of the application addressing those aims should be written in more detail. Therefore, for applications proposing new research areas, and for competing renewal applications, up to 18 pages of prose are allowable.

--The applicant investigator and his/her institution must present a workable plan for consolidation of the applicant's current research support and conversion of staff and facilities to be supported by the OIG. This must be submitted as a separate section of the grant application immediately following the budget section.

--The original and six legible copies of the application should be submitted to DRG, NIH, as directed in the instructions of the grant application.

Inquiries: All potential applicants of this award are advised that the full text of this Program Announcement, containing currently applicable guidelines, is now available and should be requested prior to submitting an application for the June 1, 1991 receipt date.

For further information on application development, contact Barbara Bynum, Director, Div. of Extramural Activities, NCI, Bldg. 31, Rm 10A03, Bethesda, MD 20892, phone 301/496-5147.

For fiscal and administrative matters, contact Crystal Elliott, Grants Management Specialist, NCI, Executive Plaza South, Rm 243, Bethesda, MD 20892, phone 301/496-7800 x19.

NCI Contract Award

Title: Laboratory rodent and rabbit facility
Contractor: Biocon Inc., Rockville, MD; $1,897,368.