THE CANCER LETTER

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NCI Is Considering New Core Grants For Prostate, Breast Research Centers

NCI is considering establishing a new core grant to support centers for prostate and breast cancer research, NCI Director Samuel Broder told a House subcommittee last week. The grants would enable scientists to take "a global new look" at these diseases. NCI would use a P50 mech-

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In Brief

ONS Lectures Announced; Brennan To Retire As Michigan Cancer Foundation President

ONCOLOGY NURSING SOCIETY annual meeting in San Antonio May 8-11 will feature the following lectures: Keynote speaker is **Sally Karioth,** a nurse, writer, and behavioral consultant; **Dorothy Smith,** M.D. Anderson Cancer Center, will deliver the Mara Mogensen Flaherty Lecture, titled "Two Faces Have I"; **Judith Paice,** Rush-Presbyterian-St. Luke's Medical Center, is the recipient of the ONS/Schering Clinical Lectureship Award and will deliver a lecture on "Unraveling the Mystery of Pain." . . . **VAINUTIS VAITKEVICIUS** has been appointed president of the Michigan Cancer Foundation, succeeding Michael Brennan on July 1. Vaitkevicius is professor of medicine in hematology-oncology at Wayne State Univ. Brennan has been the foundation's president since 1966, when the Detroit Institute of Cancer Research merged with the Michigan Cancer Registry and the Yates Memorial Clinic to form MCF. He was responsible for the creation of the Meyer Prentis Comprehensive Cancer Center of Metropolitan Detroit, founded by MCF and Wayne State Univ. Upon his retirement, Brennan will be named MCF president emeritus. . . . **DONALD SKINNER,** professor and chairman of urology at the Univ. of Southern California School of Medicine and its Kenneth Norris Cancer Hospital & Research Institute, received the 1990 Barringer Medal awarded biannually by the American Assn. of Genitourinary Surgeons. Skinner was recognized as "one of the outstanding urologists in the nation." . . . **ALBERT DEISSEROTH,** chairman of the hematology dept. at M.D. Anderson Cancer Center, delivered the 1991 Izak Memorial Lectureship at the Hadassah Medical Organization in Jerusalem last month. . . . **M.D. ANDERSON** Cancer Center celebrates the 50th year since its founding this month with an open house, 5K run, and public education activities. . . . **ABSTRACTS DEADLINE** for the International Assn. for Breast Cancer Research meeting has been extended to April 25. The meeting is scheduled for May 27-29 in St. Vincent, Italy. Contact Dr. Roberto Ceriani, John Muir Cancer & Aging Research Institute, 2055 N. Broadway, Walnut Creek, CA 94596.

NCI Considers New Core Grants For Prostate, Breast Centers

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anism to provide core and institutional support for these centers. Currently, NCI supported cancer centers are funded through the P30 core grant mechanism.

The proposal is in the planning stages, and NCI sources could not provide further details.

Broder's testimony last week before the House Labor, HHS, Education Appropriations Subcommittee to defend the President's FY 1992 budget for NCI of $1.8 billion covered a wide range of topics, from natural products research to suspected carcinogens in cooked red meat.

As has been his "good news, bad news" theme since taking the helm of NCI, Broder listed progress in treating many common cancers in persons under age 65: the death rate for colorectal cancer has fallen 15 percent in the last 20 years, death rate for ovarian cancer down 25 percent, about the same for stomach cancer, by 30 percent for bladder cancer, and 40 percent for cervical cancer.

But progress in treating cancers in those over 65 is slower, and some minority groups and the poor suffer disproportionate rates of cancer mortality, Broder said. The overall incidence of cancer has increased by 16 percent since the 1970s, and the mortality rate has increased 5.4 percent. "We need to do more and we need to be more effective," Broder said.

"To what extent do you think it's fair for the committee to judge our progress on the basis of death rates and incidence statistics?" asked Rep. William Natcher (D-KY), subcommittee chairman.

"Federal officials should be held to a very high standard. I think it's fair," Broder said. "However, death rate figures tell only half the story." Quality of life improvements, such as limb, bladder and rectal sparing treatments, may not be reflected in the statistics.

"Dr. Broder, I like the way you answer questions," Natcher said.

Rep. John Porter (R-IL), who in the past has publicly supported NCI's bypass budget, spent his allotted time asking about natural products research.

NCI has signed an agreement with Madagascar to harvest natural products in the search for new treatments. In exchange for the products, NCI will invite scientists from Madagascar to train in Bethesda. NCI is using the pact as a "model agreement" which it hopes to repeat with other countries.

"Natural products are going to be very important in the treatment of AIDS," Broder said. "NCI has made a great commitment to natural products research."

Rep. Louis Stokes (D-OH) asked about minority cancer incidence rates and NCI's minority initiatives. Broder noted that blacks overall have a 30 percent higher death rate from all cancers than whites. "This is a poverty-related issue, for the most part," Broder said. However, NCI "tries to do the things we know how to do best, such as epidemiology, prevention and control research, treatment research, career development and basic laboratory research to come up with new approaches."

Broder said NCI expects to spend $40 million in FY92 on minority programs. Prostate cancer and multiple myeloma disproportionately affect blacks and the reasons for that are not understood, he said. Also important is the training of minority physicians and scientists, Broder said.

"This is a new sensitivity at the Cancer Institute and I applaud your efforts," Stokes said.

Rep. Joseph Early (D-MA) quickly got to the heart of the matter in his questioning when he pointed out that NCI's budget has fallen 6 percent in real terms in the past decade. NCI is the only institute within NIH to suffer such a plunge.

"How much does NCI need in '92 to stabilize its programs?" Early asked.

NCI's professional needs budget, the bypass budget, calls for an additional $800 million, Broder said. This amount will allow NCI to "utilize the opportunities we have," he said.

Early also said he was concerned that the President's budget requires NIH to hold back some FY92 funds until Sept. 19, 1992, less than two weeks before the end of the fiscal year. NCI will be required not to obligate about $63 million until that time. NIH officials testified this was done so that budget outlays

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Editor: **Kirsten Boyd Goldberg**
Associate Editor: **Lisa M. O'Rourke**
Contributing Editor: Jerry D. Boyd

Editorial/Subscriptions Office
PO Box 15189, Washington, DC 20003
Tel: (202) 543-7665 Fax: (202) 543-6879

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will not exceed legal limits set by Congress. Early asked about the practical effect of this rule.

"It means my financial manager [John Hartinger] will be very busy those last two weeks" doling out the funds, Broder said.

"This is the worst thing you could do to science and the American people," Early complained to Dennis Williams, HHS deputy assistant secretary for budget.

Healy To Establish NIH Awards To Help Borderline Applications

Bernadine Healy, only one day into her new job as NIH director, announced the creation of a new class of awards to be funded mainly out of her directors' discretionary fund.

The awards, to be named after James Shannon, NIH director for 13 years, would go to applications for regular research project grants that just barely missed the payline.

NIH would provide about $40,000 to $50,000 to approximately 300 to 400 of these applicants to help them conduct pilot projects or work on parts of their proposed research, Healy told the House Labor, HHS, Education Appropriations Subcommittee on April 10.

"The James Shannon Director's Awards would address that group of scientists on the margin of funding, who are, for example, at the 27th percentile instead of the 25th percentile, with a small amount of money to enable these meritorious scientists to continue their work and address the concerns of peer review," Healy said. "We're not fully funding their science, but keeping them competitive."

In some cases, scientists might receive up to two years of funding, or $100,000. NIH would pay no more than 20 percent of indirect costs on these grants, since it would not represent full grant funding, Healy said.

Healy said she would use $20 million of the NIH director's discretionary fund appropriated by Congress in FY 1991 to fund the awards, and would take about $10 million from the institutes to complete the funding of the awards, using the director's new power to tap up to 1 percent from any of the institutes to move into any other NIH account.

The $10 million represents "much less" than her 1 percent authority, Healy said. "We think the institutes will be delighted with this." The grants would be awarded by this September, she said.

The Shannon awards "sound very exciting," Rep. Joseph Early (D-MA) said. He and other subcommittee members expressed their support for the NIH director's discretionary fund.

The fund's $20 million, if divided among the 13 institutes, would be "pencil dust," but together the dollars can provide for innovative approaches, such as the Shannon awards, Healy testified. She also plans to use $1.5 million of the fund to establish the Office for Research on Women's Health, $1.5 million for minority health initiatives, and $2 million for medical rehabilitation training.

Healy Impresses House

The House appropriations subcommittee seemed genuinely impressed with Healy in her first appearance as NIH director.

"Dr. Healy, as the new NIH director and a lady, you'll do a good job, and maybe show these men a thing or too," Rep. William Natcher (D-KY), subcommittee chairman, said in his welcome to Healy.

"I'm looking forward to your leadership and your speaking out on issues," said Rep. Carl Pursell (R-MI).

Rep. Louis Stokes (D-OH) noted that Healy comes most recently from Ohio, where she was director of clinical research for the Cleveland Clinic Foundation. "We are proud of her," he said.

Rep. Joseph Early (D-MA) commended Healy for putting up with the FBI background search. "This is the most important job in the country right now. I don't know why it took so long to get you here--maybe it's because you're from Ohio," he quipped.

Rep. Steny Hoyer (D-MD) noted that Healy spent many years at Johns Hopkins Univ. Hospital, where she completed her residency and later became a professor of medicine, assistant dean of postdoctoral programs, and director of the coronary care unit. "We in Maryland are proud of what you've done," he said.

Budget 'Places Us At Risk'

Hoyer drew some of Healy's most outspoken comments on the President's FY 1992 budget for NIH, $8.77 million, a 6 percent increase over FY91. Hoyer noted that there is a belief that NIH, and the U.S. as a whole, is falling behind other countries in biomedical research.

"There is a perception that, if we're not falling behind now, we will in the future," Healy said. "We have a history in this country of falling behind in areas where we had the lead, such as electronics." Biomedical research opportunities "are extraordinary," Healy said. "I'm not sure you can say we are falling behind this year, or will next year, but I'm very, very worried."

"I hope you therefore can be an advocate within the administration, to look at this area with a critical eye toward advocacy," Hoyer said. "Does this budget place us at risk of losing ground?"

"It does place us at risk for the status quo, and

with such tremendous scientific opportunities, it might not be good enough," Healy said.

At the end of the hearing, which covered topics ranging from indirect costs to NIH trainee stipends, Natcher said, "it has been a tradition on this committee to add money to the President's budget. HHS Secretary Louis Sullivan is to be commended on the increase he succeeded in getting."

Natcher asked Healy to submit for the record an outline of how NIH would use an additional $250 million. "I don't know whether we can find this amount, but we'll try."

Freeman To Head Cancer Panel, Brinker, Jako To Fill Panel Seats

The White House last week announced its intention to appoint Harold Freeman as chairman of the President's Cancer Panel, and named Nancy Brinker and Geza Jako to fill the panel's two other seats.

Freeman, director of surgery at Harlem Hospital Center and professor of clinical surgery at Columbia Univ. in New York, served as president of the American Cancer Society in 1988-89.

The White House made the new appointments in a relatively short time, only four months after the death of Armand Hammer, who served as Panel chairman since 1981. The term of panel member John Montgomery had expired in 1989 and that of William Longmire ended in February.

In announcing the appointments, the White House officially named Freeman to succeed Longmire, but said that upon appointment, Freeman will be designated Panel chairman. Brinker was named to succeed Hammer, and Jako to succeed Montgomery.

Presumably this was done to give Freeman the longest term of the three appointments. His term expires in 1994, Brinker's in 1993, and Jako's in 1992. However, the law creating the panel allows members to serve until they are replaced.

Freeman could not be reached for comment by **The Cancer Letter's** presstime this week.

'New War Against Cancer'

During his tenure as ACS president, Freeman emphasized the issue of cancer as it affects socioeconomically disadvantaged Americans, an area that has interested him throughout his involvement with the society.

In an editorial in the April 17 "Journal of the National Cancer Institute," Freeman calls for greater funding of cancer research and treatment as it relates to the poor.

"Poor Americans constitute a high risk group for developing and dying of cancer," Freeman wrote. "Accordingly, substantial resources should be directed toward prevention, detection, diagnosis, and treatment of cancer in the economically disadvantaged."

To accomplish NCI's "Year 2000" goal of a 50 percent reduction in the cancer mortality rate, Freeman wrote, "we must declare and conduct a new kind of war against cancer--a guerrilla war to tear down the economic and cultural barriers to prevention, early detection, and treatment of cancer. This hand to hand combat must be carried out in the neighborhoods of America where people live and die. Therefore, the designated battlegrounds for waging such a guerrilla war should include geographically and culturally delineated areas of high cancer incidence and mortality. Such areas should be targeted with an intense approach to providing culturally relevant education, control of tobacco use, appropriate access to early diagnosis and treatment, and an improved social support network."

A native of Washington, D.C., Freeman received his MD from Howard Univ. and completed his residency in surgery at Howard Univ. Hospital and Memorial Sloan-Kettering. He has been affiliated with Columbia Univ. since 1967, and became a full professor in 1989.

He has held many other appointments, and is currently a senior member of the American College of Surgeons Commission on Cancer, a member of the Executive Council of the Society of Surgical Oncology, and on the board of directors of the New York City division of ACS.

Brinker: Cancer Work A 'Mission'

Brinker started the Dallas-based Susan G. Komen Foundation for the Advancement of Breast Cancer Research in memory of her sister, who died of the disease in 1980. Since its founding in 1982, the Komen Foundation has grown to a major national organization that funds breast cancer education programs and supports breast cancer research projects.

Brinker is not the first woman to be appointed to the Panel. That distinction belongs to the late Elizabeth Miller, an eminent scientist from the McArdle Laboratory at Univ. of Wisconsin, who was on the panel in the late 1970s.

"I am terribly interested in cancer as it concerns women and minorities, and vitally interested in the work of the National Cancer Institute, seeing that the institute is well funded and appreciated," Brinker told **The Cancer Letter.** "I am very interested in seeing advances move from bench science to the bedside."

Brinker was appointed to the National Cancer Advisory Board in 1986 and still has more than a year of her term to serve. She said she did not know

whether she would have to vacate her NCAB seat, but it is not likely that would be the case. The White House named her to succeed Armand Hammer, who as Panel chairman also served on the NCAB.

Brinker emphasized the Panel's role in drawing attention to the National Cancer Program.

"I hope the panel will continue to take the important work of the Cancer Institute to the public and that way generate more support from the public," Brinker said.

"Whatever issues we mutually agree upon to bring to the public, I can tell you I will not be sitting on my hands, and I'm not one to be quiet. I take this responsibility very seriously. My work in the cancer field has always been a mission to me."

Brinker has been successful in capturing the attention of politicians to her cause. Barbara Bush was an honorary speaker at the foundation's Women's Leadership Summit in 1989, and in 1990, Vice President Dan Quayle and Marilyn Quayle chaired the foundation's "Race for the Cure" in Washington, in which many members of Congress participated. The foundation holds an annual awards luncheon during which former first lady Betty Ford presents the Betty Ford Award. Recipients have included Nancy Reagan, Happy Rockefeller, Selwa Roosevelt, Barbara Bel Geddes, and the late Jill Ireland.

The foundation also has funded $9 million in cancer research grants to 15 institutions, including many based in Texas, such as M.D. Anderson Cancer Center, the Dallas Public Library, Univ. of Texas Health Science Center, Southwestern Medical School, Parkland Memorial Hospital, as well as other institutions in the U.S., including Johns Hopkins Medical School, The Betty Ford Center, Lombardi Cancer Center at Georgetown Univ., Univ. of Illinois, the National Alliance of Breast Cancer Organizations, and NCI.

Brinker, a native of Peoria, IL, received a BA in liberal arts from the Univ. of Illinois. After graduating, she moved to Dallas and entered the executive training program at Neiman Marcus. She was a radio reporter and talk show host at WRR-AM Radio in Dallas from 1973-75, and then worked in public relations. She was active in fundraising for the American Cancer Society during her sister's illness, serving as volunteer public relations director for the Cattle Barron's Ball.

Simon & Schuster published her book, "The Race Is Run One Step At A Time," last fall.

Jako: Active In Republican Politics

Jako is professor of otolaryngology and of head and neck surgery at the Boston Univ. School of Medicine. He is also chief of ear, nose, and throat and head and neck surgery at Wakefield Hospital in Melrose. His special interest has been the development of laser surgery and of microsurgery with and without lasers.

His appointment in 1982 to the National Cancer Advisory Board, along with that of former Congressman Tim Lee Carter, prompted fellow board member Janet Rowley to write a letter to "Science" blasting political appointments to scientific review bodies.

Jako frankly admitted that his appointment to the Panel was a political one and sees nothing wrong with that. "It's a political position, after all," he commented to **The Cancer Letter.**

Jako said he has "always been involved in Republican Party politics," and is currently vice chairman of the Republican City Committee of Melrose, MA, where he lives. In the early 1970s, he served as chairman of the Hungarian-American Republican National Federation, giving him the opportunity to become acquainted with George Bush, who was at that time chairman of the Republican National Committee.

However, "I think I have progressed scientifically with my own work. I don't think I'm a political person who got into this only by political involvement." He said his accomplishments in medicine include being the first to use microsurgery in treatment of soft tissue sarcoma and cancer of the larynx; and the first to use lasers for practical surgical applications.

Jako's service on the NCAB was marked with controversy not so much because of the alleged lack of qualifications but because of his propensity for opposing NCI's leadership and the board majority on various issues.

He infuriated then director Vincent DeVita by contending that chemotherapy of cancer was overrated and attempting to support that position with outdated survival figures. He also opposed DeVita's eventually successful effort to bring the Organ Systems Program entirely back into NCI; and he frequently sided with outside critics of NCI such as John Bailar.

When Jako's term on the NCAB expired in 1988, he left with a blast (in a letter to Sen. Orrin Hatch) at NCI, his fellow board members, the bypass budget, the Year 2000 goals, and the National Cancer Program in general (**The Cancer Letter**, April 18, 1988). His letter was denounced by NCAB Chairman David Korn, and fellow board member Helene Brown threatened legal action if Jako refused to apologize.

There was no apology (at least publicly), and no legal action. Jako says now that he has no intention of pursuing the points he made in the letter, and that

he wants to leave all the previous controversy behind.

"I want to try this time to be more cooperative, with the new director, the new Panel members and the NCAB. Those old issues are passe. I want to take more of a positive attitude. I will be working with a new group of people and I hope we can push ahead and accomplish something."

Jako said that he intends to use his position on the Panel to improve detection and treatment of lung cancer, primarily with the use of better endoscopy, microsurgery, and intraoperative ultrasound. "With better detection and better and more precise surgery, I think we can get five percent improvement in lung cancer mortality by the Year 2000," he said.

Jako is working in Massachusetts for an additional five cent per pack cigarette tax which would be used to provide free screening chest x-rays for persons at high risk of lung cancer, as determined by age and smoking history.

"I think we can turn this around, like we did with screening mammography," he said. "But we need to take a look at how to screen, who to screen, and how to pay for it. We owe that to the public, especially now that lung cancer is the number one cancer killer of women. The growing interest in women's health care adds an extra dimension to the lung cancer problem."

As for the Panel's charge, to ascertain problems and impediments to progress in the National Cancer Program and make them known to the President, Jako said, "I hope we will have the chance to do that. I also hope we will act as a stimulant for improvements."

Panel As Entre To White House

The President's Cancer Panel was created by the National Cancer Act of 1971 as part of the compromise that toned down the Senate bill, which would have taken NCI entirely out of NIH. Proponents of the Senate bill argued that cancer research interests frequently became submerged or ignored at NIH and department levels because the rest of the biomedical research establishment outweighed and outvoted them. The Panel was intended to give cancer (as represented by NCI) entre to the White House, along with increased public visibility.

Former Panel Chairman Benno Schmidt used that entre and visibility with great effectiveness. After department Secretary Caspar Weinberger tried to kill biomedical research training, Schmidt induced the White House to establish the National Research Service Awards. Schmidt went to the mat on other issues, and when he couldn't get through the White House door, he either went public or went to Congress.

Joshua Lederberg's short time as Panel chairman was uneventful, but Armand Hammer aggressively used the congressional mandate. Hammer was greatly disappointed when Presidents Reagan and Bush did not accord him the access that Presidents Nixon and Ford did for Schmidt. Hammer tried to overcome that with his own flair for publicity, by going to Congress, and by using some of his own immense wealth. He did get 15 minutes of President Bush's time last August, in the midst of the Persian Gulf crisis, to submit in person his annual report on the Panel's activities and a copy of NCI's FY 1992 bypass budget.

Hammer's most effective use of the Panel's mandate was perhaps the forum he gave to Director Vincent DeVita. DeVita took that mandate literally and never hesitated to go public at Panel meetings with his problems with the White House, Dept. of Health & Human Services, and NIH. So effective was DeVita in using the Panel to go over NIH Director James Wyngaarden's head that Wyngaarden publicly called for elimination of the Panel.

Director Samuel Broder so far has not made similar use of the Panel. Wyngaarden left shortly after Broder's appointment; possibly it was either unnecessary or inappropriate for the new NCI director to take on NIH Acting Director William Raub.

Pittsburgh, Kenneth Norris Awarded Bristol-Myers Unrestricted Grants

Bristol-Myers Squibb Co. will award unrestricted cancer research grants totalling $1 million to the Pittsburgh Cancer Institute at Pittsburgh Univ. and to the Kenneth Norris Jr. Comprehensive Cancer Center at Univ. of Southern California.

Each institution will receive $100,000 a year for five years.

Ronald Herberman, director of the Pittsburgh Cancer Institute, and Franco Muggia, director of medical oncology and clinical investigations at the Norris Cancer Center, will oversee the grants.

PCI will apply its grant to the study of biological therapies in treating cancer, the institute's specialty. Herberman said PCI will probably be the first center outside of NIH to conduct gene therapy experiments. The institute has recruited some key people, including Michael Lotze of NCI and Olivera Finn, of Duke Univ.

Muggia's group at Norris will use the grant to find more effective ways to use chemotherapy in patients with breast, gastrointestinal, and cervical cancers.

The awards bring Bristol-Myers' commitment to cancer research grants to $14.34 million through 29 grants to 26 institutions in the U.S. and abroad. The program was begun in 1977.

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 NCI-CN-15342-04

Title: Prostate, lung, colorectal and ovarian cancer screening trial--screening centers

Deadline: Approximately June 10

NCI's Div. of Cancer Prevention & Control, Early Detection Branch, is interested in soliciting proposals from organizations for screening centers for the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial.

Up to 15 screening centers will be established, each recruiting no less than 5,000 subjects and 5,000 controls to the trial. A total of 148,000 men and women will be recruited to the trial in approximately equal numbers. Female subjects will be screened for colorectal, lung, and ovarian cancers. Male subjects will be screened for colorectal, lung and prostate cancer. Screening will be annually for four years for prostate, lung, and ovarian cancers, and only in years one and three for colorectal cancer. Subjects and controls will be followed for at least 10 years.

A coordinating and data management center will develop and maintain systems and procedures for biomedical data management, study coordination, statistical analysis and report writing.

NCI has selected the cancer sites and screening modalities. Screening centers, in cooperation with NCI, will develop screening logistics and diagnostic protocols.

A pre-proposal conference will be held and the date will be specified in the complete RFP, available from the contract specialist named below.

Contract Specialist: Christopher Myers
RCB Executive Plaza South Rm 635
301/496-8603

RFA Available

RFA CA-91-14

Title: Public health approaches to breast and cervix screening

Letter of Intent Receipt Date: June 7

Application Receipt Date: Aug. 2

NCI's Div. of Cancer Prevention & Control invites grant applications from a consortium of public health agencies or institutions to develop, implement, and evaluate programs designed to increase breast and cervical cancer screening of older, low income, low education, and minority women.

Priority will be given to applications specifically designed to include evaluation of breast and cervical screening utilization of women over age 65 and those targeting populations residing in rural areas.

Among hispanic women, priority will be given to applications targeting Puerto Rican and Cuban populations to provide more comprehensive information on hispanic populations. NCI currently funds projects targeting hispanic women of Mexican descent.

The goal of this project is to develop, implement, and evaluate programs designed to increase breast and cervical cancer screening of older, low income, low education, and minority women.

The primary objectives of this research are to demonstrate how a consortium of community agencies can:

1. Characterize utilization patterns for breast and cervical screening in the target population through baseline surveys. These data will establish frequency of screening, as well as assess barriers to utilization.

2. Design and pilot test interventions to recruit women in need of breast and cervical cancer screening regimens that can be integrated with other health services used by these women and affect the behavior of non health agency clients.

3. Evaluate the effectiveness of specific interventions to reach the target population for breast and cervical cancer screening.

4. Ensure compliance with follow up recommendations for women with anything but completely normal mammograms (i.e. indeterminate or suspicious findings) and smears (i.e. further action recommended).

5. Establish a mechanism to describe prospectively the screening behavior of the targeted women in view of current NCI recommendations, i.e., establish whether or not women are coming back at recommended intervals for screening.

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in study populations, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

Grants in aid may be awarded to profit and nonprofit organizations and institutions, and governments and their agencies within the U.S. However, it should be noted that this RFA is primarily targeted at demonstrating a consortium approach, involving public agencies or institutions, such as health departments, community and migrant health centers, or public hospitals with established linkages to the target population (e.g., the health department or community health center may have experience with providing or contracting for the health services, a regional agency on aging may have established networks with elderly women, and a voluntary organization may have experience with providing public education campaigns).

This approach seeks to address the problem in a coordinated fashion while taking advantage of the public agency's role as noncompetitive collaborator, stimulator, convener, and facilitator of existing resources to increase mammography and pap smear utilization in women least likely to be screened.

The lead agency must demonstrate experience with disease control but does not necessarily need to be the direct provider of the screening services. In many communities, the lead agency is likely to be a health department, however, other public agencies could fill this role. Among the team of applicants or consortium, one institution must be proposed as the lead institution to serve as the applicant and assume responsibility for the conduct of the award.

Support of this program will be through an NIH R01. Applicants will be responsible for the planning, direction, and execution of the proposed project. Allowable direct costs for the intervention will not include funds to pay for mammograms and pap smears. However, expenses incurred in developing and promoting the utilization of these services, such as baseline and follow up surveys, design of materials, and public and professional education are considered allowable costs.

This RFA is a one time solicitation. Future unsolicited competing renewal applications will compete with all investigator initiated applications and be reviewed by the Div. of Research Grants.

However, if NCI determines that there is a sufficient continuing program need, a request for renewal applications will be announced. Only recipients of awards under this RFA will be eligible to apply.

Approximately $5.4 million in total costs for four years ($1.2 million for year one and for year four, $1.5 million for years two and three) will be committed to fund applications submitted in response to this RFA. It is anticipated that three to four awards will be made, depending on the receipt of a sufficient number of applications of high scientific merit. The total project period for applications submitted in response to this RFA must not exceed four years.

Copies of the complete RFA and additional information may be obtained from Helen Meissner, program director, Public Health Applications Research Branch, NCI, EPN Rm 239G, 9000 Rockville Pike, Bethesda, MD 20892, phone 301/496-0273.

Program Announcement

PA-91-42

Title: Clinical cancer therapy research

Application Receipt Dates: June 1, Oct. 1, Feb. 1

NCI seeks grant applications to conduct clinical therapeutic studies of neoplastic diseases in human subjects. Clinical research, by definition, involves a clinician/patient subject interaction with therapeutic intent. This program announcement encompasses a full range of therapeutic studies and clinical trials employing drugs, biologics, radiation, or surgery.

The intent of the announcement is to encourage clinical researchers to translate insights in cancer biology and the development of new agents into innovative cancer therapeutic studies.

This type of grant solicitation is utilized when it is desired to encourage investigator initiated research projects in areas of special importance to NCI. Applicants who will be funded under this PA will be supported through the customary NIH grant in aid (R01, R29).

In the past several years, the research effort into understanding the basic biology of the cancer cell has been highly productive. Recent discoveries concerning the role of growth factors, genes that promote and suppress neoplasia, mechanisms of treatment sensitivity and resistance, and the biology of the immune systems have provided the basis for the development of novel and improved cancer treatments. The rate of progress in the treatment of cancer will depend upon the translation of these basic and preclinical discoveries into clinical cancer therapies.

NCI supports an extensive network of clinical and laboratory research studies related to cancer therapy through contracts, grants, and cooperative agreements. At present, the traditional research grant mechanism (R01, R29) is underutilized by clinical investigators for the support of clinical research. The Cancer Therapy Evaluation Program, Div. of Cancer Treatment, the program primarily responsible for the promotion and translation of new basic and preclinical research into therapeutic advances, receives relatively few research grant applications. Whereas an RFA represents a single solicitation, a PA provides the opportunity for the receipt of new applications on an indefinite basis. NCI encourages clinical investigators to submit clinical therapeutic studies and is committed to moving advances in basic biology and drug development into the clinical setting.

The Div. of Cancer Treatment is requesting qualified investigators to develop research grant applications involving clinical therapeutic studies of neoplastic diseases. Clinical studies must involve human subjects and be designed to ultimately improve cancer treatment. The applications may include single or multi-institutional (e.g., consortia, cooperative groups) research studies with appropriate biological correlates linked to these studies. New clinical therapeutic studies may employ drugs, biologics, radiation, or surgery used as single agents/modalities or in combination. Biological correlative studies that have clinical relevance to cancer therapies and are aimed at improving cancer treatment are also appropriate.

Some examples of clinical therapeutic studies include: 1) therapies based on novel mechanisms of action, 2) mechanism of action and metabolic studies of antitumor agents, 3) studies of mechanism of hormone, drug, or radiation resistance and reversal, 4) mechanism of action of biological response modifiers in the treatment of cancer, e.g., cancer immunotherapy (monoclonal antibodies, cytokines, antisense, and vaccines) alone or in combination with chemotherapeutic agents, 5) mechanism of action of new growth factor targeted therapies, 6) new radiation therapies or radiation modifiers to enhance cell kill or protect normal tissue, 7) surgical therapies in combination with therapeutic agents.

Some examples of biological correlative studies include: 1) phenotypic or genotypic alterations that appear to correlate with the development of drug, hormone, or radiation resistance, 2) oncogenes, growth factors, and specific antigen expression on tumor cells, 3) pharmacokinetic and pharmacodynamic measurements, 4) biochemical pharmacologic parameters, 5) imaging studies to assess efficacy of treatment.

Investigators are not limited to the above areas of potential studies. Clinical research, by definition, must involve a clinician/patient subject interaction with therapeutic intent.

Applicants from institutions that have a General Clinical Research Center funded by the NIH National Center for Research Resources are requested to identify the GCRC as a resource for conducting the proposed research.

Applicants will be responsible for the planning, direction, and execution of the proposed project. Domestic applicants may request no more than five years of support, and foreign applicants may request no more than three years. Applications submitted in response to this PA will compete for funds with all other investigator initiated applications.

Nonprofit organizations and institutions, governments and their agencies, and individuals are eligible to apply. For profit organizations are also eligible unless specifically excluded by legislation. Both domestic and foreign applicants may apply. Applications may be submitted from a single institution or may include arrangements with multiple institutions. Applications from minority individuals and women are encouraged.

NIH policy requires applicants for clinical research grants to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study.

The usual NIH policies concerning research on human subjects also apply.

Written or telephone inquiries concerning the objectives and scope of this PA are encouraged and should be directed to the program directors, Diane Bronzert and Roy Wu, Cancer Therapy Evaluation Program, Div. of Cancer Treatment, NCI EPN Rm 734, Bethesda, MD 20892, phone 301/496-8866, fax 301/480-4663.