THE CANCER LETTER

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Sen. Bumpers Aims To Raise Health Research $$ With Cuts To Space Station, Supercollider, SDI

A series of amendments to be introduced by Sen. Dale Bumpers (D-AR) during Senate floor debates of the appropriations measures would aim to put more than $1 billion into the budgets of the NIH and Centers for Disease Control. The Bumpers amendments, which have not been outlined in a single bill, are expected to call for cutting the President's budget by $8 billion by eliminating the space station and the super-

(Continued to page 2)

In Brief

New York Legislature Votes $240 Mil. Bond Issue For Roswell Park Construction; Kripke Honored

NEW YORK LEGISLATURE has voted to include $241.5 million in bonding for new construction and renovation of the Roswell Park Cancer Institute campus. Most of the institute's buildings were constructed before 1955, and no new construction has occurred since 1975. Roswell Park is part of the New York State Dept. of Health. Projects to be funded by the bond issue will include a new diagnostic and treatment center, new and expanded outpatient clinics, a new hospital bed tower, a new research laboratory building, and renovations to upgrade remaining research space. Design work will begin immediately; construction will be in phases, with the last completed in 1997-98. "This is the most significant step toward bringing the institute into the 21st century," said **Thomas Tomasi**, institute director. "Clearly the legislature and Gov. Mario Cuomo have understood how important Roswell Park is to the citizens of New York State and the nation, and how critical the need is to rebuild it." Roswell Park is an NCI-designated comprehensive cancer center. . . . MARGARET KRIPKE, chairman of the Dept. of Immunology at M.D. Anderson Cancer Center, received an award from the Texas Federation of Business & Professional Women for "exemplary efforts in cancer research." Kripke's work demonstrated how UV radiation alters the immune system, leading to the creation of a new field of photo-immunology. . . . DIV. OF AIDS in the National Institute of Allergy & Infectious Diseases has named three new associate directors: **Lewellys Barker**, AD of the Clinical Research Program, was senior vice president and chief medical officer of the American Red Cross; **William Duncan**, AD of the Treatment Research Operations Program, returned to NIAID after a year at Canada's National Cancer Institute; **Margaret Johnston**, chief of the Developmental Therapeutics Branch, was named AD of the Basic Research & Development Program.

Bumpers Aims To Raise Health Funds By Cuts To NASA, SDI, Supercollider

(Continued from page 1)

conducting supercollider as well as by slashing the budgets for Strategic Defense Initiative and several aspects of the intelligence budget.

Two-thirds of the money would go toward deficit reduction, while the remaining $2.7 billion would go predominantly to health research. Health related agencies would receive all but about $810 million of the funds.

In preparation for his assault on the budget, Bumpers has obtained a letter of support from 59 research and health care groups.

"Funding for domestic programs is so constrained that if the Bumpers initiative isn't successful, we are looking at the President's budget," said Marguerite Donoghue, vice president for research and regulatory affairs at Capitol Associates, a group that represents the National Coalition for Cancer Research.

"One unfinished piece of business for the National Cancer Act is the funding of the bypass budget," said Robert Day, president of the Coalition. "The Bumpers initiative would provide an essential and important means to achieve this."

The President requested $9.4 billion for NIH in fiscal 1993, a 5 percent increase over the 1992 appropriation. Included in that amount is $2.01 billion for NCI, a $60 million (3 percent) increase over the Congressional appropriation of $1.98 billion. NCI's bypass budget--the professional needs budget submitted directly to the White House every year--requested $2.7 billion for FY93.

Bumpers has no plans to introduce any bills until the appropriations package reaches the Senate floor, said Melissa Skolfield, his press secretary. However, Bumpers offered an overview of his proposals in a recent letter to Sen. Jim Sasser (D-TN), chairman of the Committee on the Budget.

"Overall American spending on research and development has begun to decline for the first time since the 1970s," Bumpers wrote. "More troubling is where we have directed our limited federal research dollars. Basic and clinical research have been squeezed because excessive resources have been diverted to esoteric programs like SDI."

The measures Bumpers plans to introduce are more comprehensive than his last year's attempts at cutting the funds for the supercollider and the space station.

Last July, his attempt to eliminate the $500 million appropriation for the collider received 37 votes on the Senate floor. Later he received 35 votes on his proposal to eliminate the $2 billion space station budget and spend about a third of that money on science and health care for veterans.

This time the stakes are higher: Bumpers is suggesting deeper cuts, offering increased appropriations to well-defined constituencies and taking the time to organize those who are likely to benefit from his measures.

His supporters, in turn, hope that this year, with the domestic budget tight and the Soviet military prostrate, an increasing number of House and Senate members would look skeptically at the big bang projects of yesteryear.

Cancer and AIDS related groups that have signed a letter supporting the Bumpers initiatives include the Albert and Mary Lasker Foundation, American Assn. for Cancer Research, American Cancer Society, American Foundation for AIDS Research, American Society of Clinical Oncology, Breast Cancer Coalition, Joint Council for Allergy and Immunology and Susan G. Komen Breast Cancer Foundation.

"This shortsighted budgeting must end," the research societies wrote in the letter. "Much meritorious science is not pursued, many promising areas of research are neglected and millions of Americans are denied access to life saving and cost effective preventive medicine because of severe funding limitations.

"In 1991, NIH investment in basic and clinical research returned significant economic savings," the letter said. "But significant opportunities are missed due to limited funding.

"The benefits of preventive and screening programs are also very striking," the letter said. "Yet there are still children who are not immunized at the appropriate age and poor women in many states who are not benefiting from early breast and cervical cancer screening."

THE CANCER LETTER

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If all Bumpers amendments pass, NIH would receive $810 million, CDC preventive health programs, including breast and cervical cancer screening, would receive $243 million, and the Veterans Administration would receive $81 million for health research.

Other winners would be ADAMHA ($216 million) and VA health care ($540 million).

The remaining funds, about $810 million, would be split by the National Aeronautics and Space Administration, microelectronics research at the Dept. of Defense and basic research at the National Science Foundation.

"There are valid technological, economic and budgetary reasons to question the wisdom of moving ahead with the space station, the SSC and SDI, and they are particularly questionable projects given our spiraling budget deficits," Bumpers wrote in his letter to Sasser.

"At the time of crippling budget deficits it is no longer realistic for the federal government to invest in a large scale scientific project for which there is no strong scientific justification or economic payback, or in activities which are no longer necessary because of tremendous geopolitical changes," Bumpers wrote.

Silicone Implants Under Tight Control, But Still Available For Reconstruction

The Food & Drug Administration announced last week that silicone breast implants will be available only under controlled clinical studies. Women who need the implants for reconstruction will be assured access to those studies, the agency said.

The decision reflected the recommendations of the General & Plastic Surgery Devices Panel, which met in February to discuss safety issues surrounding the use of silicone gel breast implants.

The panel recognized that the implants serve an important need for breast cancer patients and recommended that they remain available for reconstruction under controlled trials. However, the panel expressed concern about special problems for augmentation patients because of their greater difficulty in obtaining good mammography and in determining whether an implant has ruptured (**The Cancer Letter,** March 6).

"I am acutely aware that the many women who already have these devices in place are eager for reliable clinical information," FDA Commissioner David Kessler said. "The decision announced today will require studies ensuring that information will be gathered so that we will learn, once and for all, how safe these devices are."

Two categories of reconstruction patients with an urgent need for the implants will be able to receive them without delay, the agency said. The first group consists of women in whom the reconstruction process had already been started prior to FDA's Jan. 6 moratorium on the implants. The second group consists of women who need their implants replaced for medical reasons such as rupture.

Other women desiring implants for reconstruction, including the correction of severe deformities, will be able to obtain them under "open availability" protocols, to be set up in a number of months, the agency said.

"I am highly conscious that some women need these implants for reconstruction after cancer surgery or traumatic injury, or for certain congenital disorders," Kessler said. "While this policy is meant to be compassionate toward these patients, it is not to be interpreted as 'business as usual.' Our primary goal is to put in place a process to obtain adequate information about the safety of these devices.

"All of the women in the open availability protocols will be enrolled in clinical studies, carefully monitored and followed for years to come. They will be informed of the potential risks involved and will have to give their consent. To be enrolled in these protocols, their physicians will have to certify that saline implants are not a satisfactory alternative, and both physician and patient must agree to abide by the conditions and followup required under the protocol," he said.

Augmentation Limited

Further tightly controlled research studies will be set up to obtain more information on safety and effectiveness, FDA said. These studies will allow limited availability for women desiring the implants for augmentation, as well as for certain reconstruction patients. Manufacturers will be required to conduct a separate study for each model of implant they wish to market. The studies will focus on specific safety questions about the implants--for example, the frequency of rupture or capsular contracture. Only enough women to answer these questions will be enrolled in the studies and receive the implants.

Both the research studies and the open protocols will be sponsored by the implant manufacturers and must receive FDA approval.

The agency said the studies will help answer questions about side effects, such as capsular contracture, calcium deposits, interference with mammography readings, implant leakage or rupture and changes in the sensation of the breasts.

Questions about possible long-term effects such as immune-related disorders and cancer will be answered

by epidemiological studies of women who already have implants. Such studies are already underway at New York Univ. and Univ. of Michigan. NCI is planning to begin a third study on cancer risk this year.

Manufacturers will also be required to follow each patient and keep records on her health experiences.

If the studies establish safety and effectiveness, the manufacturers will be able to reapply for marketing approval.

In addition, FDA is working with the current and former manufacturers to set up a centralized registry so that women with implants can be notified quickly of significant new findings about the devices.

FDA will also require laboratory studies to be conducted by the manufacturers, under a strict time table, to look at the chemical composition and toxicity of the silicone material that "bleeds" out of the implant shell, the strength of the implant shell, its resistance to rupture and the physical and chemical changes that the implants may undergo in the body.

FDA has established a toll-free telephone line to provide information materials to consumers on breast implants. The number is 1-800-532-4440.

About one million women in this country have received breast implants for augmentation or reconstruction. Silicone gel breast implants were on the market prior to 1976, when FDA was given authority to regulate medical devices. The implants were permitted to remain on the market until FDA required the submission of data supporting the implants' safety and effectiveness.

The manufacturers who are seeking marketing approval are Mentor Corp. and McGhan Inc. The largest manufacturer previously was Dow Corning Wright, which recently announced it would stop making the devices.

Adamson, Henney Chair Silicone Task Force

In a related development, the Public Health Service recently formed a task force on development of a research strategy for the study of issues related to silicone gel-filled breast implants.

NCI Div. of Cancer Etiology Director Richard Adamson and FDA Deputy Commissioner for Operations Jane Henney were named co-chairmen of the task force by HHS Assistant Secretary for Health James Mason.

The task force had its first meeting recently.

"We will be discussing epidemiological research, clinical research, including but not limited to adverse reactions, rupture, leakage of implants, materials research, an ideal implant, benefits of implants and research needs," Adamson said.

He said the goal of the task force is to "establish a coordinated research effort." The group will meet for a limited duration and "is not to become involved in the regulatory processes of the FDA," said Adamson.

FDA Publishes Parallel Track Rules, Accelerated New Drug Approval

FDA has begun to implement four initiatives for speeding access to new drugs and improving the drug review process.

The initiatives follow through on recommendations of the President's Council on Competitiveness last November to provide earlier access to new drugs (**The Cancer Letter,** Nov. 22, 1991). The recommendations also were the culmination of several years of discussion with NIH officials, particularly NCI and the National Institute of Allergy & Infectious Diseases, with cancer and AIDS patient activists, and groups such as the Lasagna Committee.

The four initiatives are:

▶Accelerated Approval--Proposed rules are being published to accelerate the approval of new "breakthrough" drugs. The rules will allow these therapies to be approved at the earliest time in their development at which safety and effectiveness can be reasonably established, FDA said. Under these new procedures, in making an approval decision, FDA will use surrogate endpoints that indicate that a drug is effective and then further confirm its effectiveness through additional human studies that will be carried out after marketing approval. "We used surrogate endpoints in approving the AIDS drug DDI. DDI was approved in just months--not years, as would normally have been the case," FDA Commissioner David Kessler said.

Under the new procedures time to approval could be reduced by as much as one to three years for "breakthrough" drugs, FDA said.

▶Parallel Track--Experimental therapies will be made available to AIDS patients as early as possible in the drug development process, a departure from the current practice of making investigational drugs available initially only through controlled clinical studies, the agency said. The parallel track policy was published in the "Federal Register" earlier this month. It will permit access to drugs by those patients with AIDS who are unable to participate in the controlled clinical trials. The new policy, initially aimed at AIDS, may be evaluated for other serious diseases, the agency said.

▶Safety Testing Harmonization--Through guidance based on consensus among the European Community, Japan and the United States, safety data based on

animal testing in one of the participating countries will now be accepted by the others. This will eliminate the need to duplicate valid animal testing, and will reduce the time currently required for long-term testing by six months or more, FDA said.

"As a result, safety data developed in accordance with one country's standards will be accepted by another, and drug sponsors will no longer face the burden of performing multiple studies on new drugs to meet varying national requirements. This will cut the time and resources currently required for such testing," Kessler said.

▶Outside Expert Reviews--To reduce the backlog of new drug applications, FDA is undertaking an external review program to use qualified experts from outside the government to review certain routine types of applications. FDA has solicited a proposal for a pilot external review. A contract to manage and conduct this review is being negotiated with the MITRE Corp. A notice appeared April 3 in "Commerce Business Daily" soliciting additional qualified organizations to participate in this program. Although FDA will retain final approval authority, the expert reviewers will assume much of the burden of analyzing the data in these applications.

"These actions will save both lives and money and reduce human suffering. They will substantially improve FDA's ability to respond vigorously to the nation's health needs by allowing important new drugs to be approved months or even years earlier than was previously possible," HHS Secretary Louis Sullivan said.

Kessler said that the changes will streamline the drug development process without sacrificing rigorous oversight. "While drug reviews will be accomplished faster, patients can be assured that only drugs that are both safe and effective will be approved," he said.

Administration Okays Selections For Cancer Panel Special Committee

Bush Administration officials have given final approval of the 16 members selected for the President's Cancer Panel Special Commission on Breast Cancer.

Members of the Special Commission on Breast Cancer are:

Karen Antman, associate professor of medicine, Dana-Farber Cancer Institute (Boston, MA); **Zora Brown**, founder and chairman, Cancer Awareness Program Services (Washington, DC) and member of the National Cancer Advisory Board; **Pelayo Correa**, professor of pathology, Louisiana State Univ. Medical Center (New Orleans, LA); **Karen Hassey Dow**, nurse researcher, Beth Israel Hospital (Cambridge, MA); **Harmon Eyre**, chief of the Medical Service, Dept. of Veterans Affairs (Salt Lake City, UT); **William Hall**, assistant to the chairman of Hallmark Cards Inc. (Kansas City, MO); **Jay Harris**, clinical director and professor of radiation oncology, Shields Warren Radiation Laboratory, Joint Center for Radiation Therapy, Harvard Medical School (Boston, MA); **Kathryn Horowitz**, professor of medicine and pathology, Univ. of Colorado Health Sciences Center (Denver, CO); **Barbara Hulka**, chairman of the Dept. of Epidemiology, Univ. of North Carolina (Chapel Hill, NC); **Mary-Claire King**, professor of epidemiology, School of Public Health, Univ. of California (Berkeley, CA); **Sherry Lansing**, producer for Lansing Productions (Beverly Hills, CA); **Sam Shapiro**, professor emeritus, School of Hygiene & Public Health, Johns Hopkins Univ. (Baltimore, MD); **Eva Singletary**, chief, Breast Surgical Section, Dept. of General Surgery, M.D. Anderson Cancer Center (Houston, TX); **Marie Swanson**, cancer center director, Michigan State Univ. (East Lansing, MI); **Reed Tuckson**, president, Charles R. Drew Univ. of Medicine & Science (Los Angeles, CA); and **Walter Willett**, professor of epidemiology and nutrition, Channing Laboratory, School of Public Health, Harvard Univ. (Boston, MA).

Chairman of the commission is **Nancy Brinker**, founder and chairman of the Dallas-based Susan G. Komen Foundation.

Vice President Dan Quayle, in a letter last year to Panel Chairman Harold Freeman, suggested that the Panel establish a breast cancer commission to advise him on the state of breast cancer research, detection and treatment, and make recommendations for improvements (**The Cancer Letter**, Oct. 11, 1991). The commission was chartered for two years, beginning last month.

The commission has tentative plans to meet during the last week in May, in Bethesda or Washington.

NCI Begins Initiatives To Promote Mammography To Hispanics, Blacks

In partnership with private groups, NCI has launched two initiatives to promote mammography among Hispanic and black American women.

The projects are:

▶Project Awareness, a national program that provides underserved women with breast cancer education, mammography, clinical breast exams and follow-up medical care.

The project will be launched in eight U.S. cities this year by NCI, the Cancer Research Foundation of America, the YWCA, the Congressional Families Action

for Breast Cancer Awareness, the Auxiliary to the National Medical Association, the National Medical Association, The Links, Chi Eta Phi Sorority, and the NCI National Black Leadership Initiative on Cancer and Cancer Information Service.

The project is funded by the Cancer Research Foundation of America and the Revlon Foundation through the Revlon/UCLA Women's Cancer Research Program.

▶A Spanish-language version of the television drama "Once a Year... For a Lifetime," an outgrowth of a partnership between the NCI and the Revlon/UCLA Women's Cancer Research Program. The same partnership had produced the English language version of the film.

The film was broadcast on Univision, the Spanish language television network, as public service programming. Both the English and Spanish language versions of the film were funded by the Revlon Foundation and NCI.

"We know that there are special needs in the black and Hispanic communities," said HHS Secretary Louis Sullivan as he announced the new programs during National Minority Cancer Awareness Week that began April 12. "We need to reach these women about the life-saving value of mammography," Sullivan said.

NCI Advisory Group, Other Cancer Meetings For May, June, Future

Advances in Internal Medicine--April 27-May 1, Ann Arbor, MI. Contact Angela Stewart, Univ. of Michigan, 313/763-1400.

European Assn. for Cancer Education Annual Scientific Meeting--April 28-May 2, Prague, Czechoslovakia. Contact Dr. W. Bender, Centre for Med. Education, Research & Development, Bloemsingel 1, 9713 BZ, Groningen, Netherlands.

Innovations in Oncology Social Work--April 29-May 2, Detroit, MI. Contact Andrea Andrlik, Social Work Service, VA Hospital, 708/216-2100, fax 708/832-6945.

Cytometry 2000 Annual Cancer Symposium--April 30-May 2, Detroit, MI. Contact Dr. Alexander Nakeff, Wayne State Univ. Div. of Hematology/Oncology, phone 313/577-7923.

Stem Cell Factor & Cytokines in Congenital Bone Marrow Dysplasias--May 1-2, Bologna, Italy. Contact Dr. Ann Murphy, Hipple Cancer Research Center, 513/293-8508, fax 513/293-7652.

World Conference on Tobacco & Health--May 3-7, Buenos Aires, Argentina. Contact Conference Secretariat, Union Antitabaquica Argentina, Riobamba 1124 4 piso, 1116 Buenos Aires, Argentina, phone 814-0342, fax (54-1)814-0342.

National Cancer Advisory Board--May 5-6, NIH Bldg. 31 Rm 10. May 5, open 8 a.m.-3 p.m., closed 3 p.m.-adjournment. May 6, open 8:30 a.m.-4 p.m.

NCAB Committee on Information & Cancer Control for the Year 2000--May 5, Bldg. 31 Rm 8, 7-8 a.m.

NCAB Committee on Activities & Agenda--May 5, Bldg 31 Rm 10A03, noon-1 p.m.

NCAB Committee on Minority Health, Research & Training--May 5, Bldg 31 Rm 8, 1-2 p.m.

NCAB Committee on Planning & Budget--May 5, Bldg 31 Rm 9, 1-2 p.m.

NCAB Committee on Aging & Cancer--May 5, Bldg 31 Rm 9, 2-3 p.m.

NCAB Committee on Women's Health & Cancer--May 5, Bldg 31 Rm 8, 2-3 p.m.

NCAB Committee on AIDS--May 5, Bldg 31 Rm 8, immediately following NCAB meeting adjournment.

NCAB Committee on Cancer Centers--May 5, Bldg 31 Rm 9, immediately following NCAB meeting adjournment.

NCAB Committee on Environmental Carcinogenesis--May 5, Bldg 31 Rm 9, 6 p.m.

NCI Div. of Cancer Prevention & Control Board of Scientific Counselors--May 7-8, NIH Bldg. 31 Rm 10. Open 1-5 p.m. on May 7 and 8:30 a.m.-adjournment on May 8.

American Urological Assn. Annual Meeting--May 10-14, Washington, D.C. Contact AUA, 1120 N. Charles St., Baltimore, MD 21201, phone 301/727-1100.

American Roentgen Ray Society--May 10-15, Orlando, FL. Contact the Society, 1891 Preston White Dr., Reston, VA 22091, phone 703/648-8992.

Oncology Nursing Society Annual Meeting--May 13-16, San Diego, CA. Contact ONS, phone 412/921-7373

NCI Div. of Cancer Etiology Board of Scientific Counselors--May 14-15, Hyatt Regency Bethesda (location change). Open 11 a.m.-recess on May 14, and 9 a.m.-adjournment on May 15.

Assn. of Biotechnology Companies International Meeting--May 17-20, San Diego, CA. Contact ABC, 202/234-3565.

American Society of Clinical Oncology Annual Meeting--May 17-19, San Diego, CA. Contact ASCO, phone 312/644-0828.

American Assn. for Cancer Research Annual Meeting--May 20-23, San Diego, CA. Contact AACR, phone 215/440-9300.

Advances in Pain Management--May 28-31, Cleveland, OH. Contact Cleveland Clinic Educational Foundation, 800/762-8173, fax 216/445-9406.

Medical Application of Cyclotrons--May 31-June 4, Turku, Finland. Contact Uno Wegelium, Turku Univ. Central Hospital, 20520 Turku, Finland, phone 358-21-612770.

New Directions in Cancer Treatment--June 2, Washington, D.C. National Academy of Sciences. Contact Weizmann Institute of Science, 212/779-3209.

Prevention of Human Cancer: Nutrition & Chemoprevention Controversies--June 3-6, Tucson, AZ. Contact Arizona Cancer Center, 1515 Campbell Ave., Tucson, AZ 85724, phone 602/626-2276.

NCI Div. of Cancer Biology, Diagnosis & Centers Board of Scientific Counselors--June 9, NIH Bldg 31 Rm 6, open 3 p.m.-adjournment.

Critical Issues in Tumor Microcirculation, Angiogenesis & Metastasis: Biological Significance and Clinical Relevance--June 8-12, Boston, MA. Contact Norman Shostak, Dept. of Continuing Education, Harvard Medical School, phone 617/432-0196.

Long Term Survivors of Childhood Cancer--June 12-14, Buffalo, NY. Contact Dr. D.M. Green, Dept. of Pediatrics, Roswell Park Cancer Institute, Elm & Carlton Sts., Buffalo, NY 14263.

NCI Div. of Cancer Treatment Board of Scientific Counselors--June 15-16, NIH Bldg 31 Rm 10. Open 8:30 a.m.-adjournment.

Recent Advances in Urological Cancer Diagnosis & Treatment--June 17-19, Paris, France. Contact Dr. Saad Khoury, Clinique Urologique, Hopital de la pitie, 83 bd de l'Hopital, 75634, Paris Cedex 13, France, phone 45.70.38.62, fax 45.70.30.78.

Molecular Basis of Human Cancer--June 18-21, Frederick, MD. Contact Margaret Fanning, 301/898-9266.

Assn. of American Cancer Institutes Annual Meeting--June 23-24, Buffalo, NY. Contact Dr. Edwin Mirand, Roswell Park Cancer

Institute, 716/845-3028.

Annual Meeting on Oncogenes--June 23-27, Frederick, MD. Contact Margaret Fanning, 301/898-9266.

Future Meetings

Mechanisms in Nutrition and Cancer--Oct. 12-14, Venice Italy. Contact Dr. J.H. Weisburger, American Health Foundation, 914/789-7141, fax 914/592-6317; or Dr. C. Ferrari, European School of Oncology, 39-2-7063-5923 or 236-0410, fax 39-2-266-4662.

Molecular Biology & Natural History of Prostate Cancer--Oct. 15-18, Prouts Neck, ME (Black Point Inn). Contact Dr. James Karr, Roswell Park Cancer Institute, 716/845-2389.

Cancer Symposium for Nurses--Oct. 26-28, San Diego, CA. Contact Meeting Management, Cancer Symposium, 619/535-3880.

Leukemia Society of America Medical Symposium--Nov. 1-2, Phoenix, AZ. Contact Hillary Brotman, 212/573-8484 ext. 138.

Pittsburgh Cancer Conference--Nov. 19-20, Pittsburgh, PA. Contact Diane Applegate, Univ. of Pittsburgh, 412/647-8263.

International Conference on the Adjuvant Therapy of Cancer--March 10-13, 1993, Tucson, AZ. Abstract deadline Dec. 1. Contact Nancy Rzewuski, Arizona Cancer Center, Univ. of Arizona College of Medicine, 1515 N. Campbell Ave. Rm 2933, Tucson, AZ 85724, phone 602/626-2276, fax 602/626-2284.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. 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 NIH-WH-92-19

Title: Vanguard clinical centers for the clinical trial and observational study of the Women's Health Initiative

Deadline: Approximately June 15

The National Institutes of Health seeks approximately 15 Vanguard Clinical Centers for the Clinical Trial (CT) and Observational Study (OS) components of the Women's Health Initiative. CT objectives are to test the benefits and risks of hormone replacement therapy, dietary modification, and supplementation with calcium plus Vitamin D on the overall health of U.S. post-menopausal women ages 50-79. Approximately 57,000 women will participate in the various components of the Clinical Trial.

OS goals are to: (1) improve risk prediction of coronary heart disease, breast cancer, fractures, and total mortality in postmenopausal women; (2) examine the impact of "spontaneous" changes in characteristics on disease and total mortality; and (3) create a resource of data and biologic samples that can be used to unearth new risk factors and/or biomarkers for disease. The OS cohort will comprise approximately 100,000 U.S. women.

The Vanguard Clinical Centers shall cooperate with a Clinical Coordinating Center in developing, testing, and refining the overall program and in writing the final protocol, Manual of Operations, and training materials before recruitment commences in the approximately 15 Vanguard Centers and in approximately 30 additional Clinical Centers. A separate solicitation will be issued at a later date for these additional Clinical Centers. Each Vanguard Clinical Center shall be responsible for screening, recruitment, randomization, and follow-up of approximately 1,270 CT participants and 2,222 OS participants (with a minimum of 1,000 CT and 2,000 OS).

A copy of RFP NIH-WH-92-19 may be obtained by written request, including two self-addressed mailing labels, to: National Institutes of Health, WHI, Research Contracts Branch, DCG Federal Building, Room 1C11, Bethesda, MD 20892.

RFP NCI-CM-37814-30

Title: Master agreements for large-scale isolation of antitumor and anti-AIDS agents from natural sources

Deadline: Approximately June 8

NCI's Div. of Cancer Treatment, Development Therapeutics Program, is interested in receiving proposals from, and establishing Master Agreements with, offerors with the capability to: (1) extract bulk plant, animal, and microbial materials to provide primary extracts; and/or (2) isolate and purify natural products from primary extracts of plant, animal, and microbial materials on a pilot plant scale. Two separate work areas are available for offerors. Separate proposals will be required from offerors responding to both work areas. The government will supply the plant, animal, or microbial material to be processed and details of the known isolation processes. The successful offerors will supply all equipment, solvents, reagents, and other materials needed for the project.

Work area No. 1: Offerors must provide equipment to grind and extract a variety of natural products in quantities ranging from 50 kg to 10,000 kg of bulk crude materials. This includes frozen storage capabilities for up to 1,000 kg of marine materials and equipment for the safe, non-destructive removal of extraction solvents. The government will supply the plant, animal, or microbial material to be processed. The experience and ingenuity of the offerors' process development for pilot plant extractions and isolations using standard or novel techniques will be important factors in the evaluation of the proposals.

Work area No. 2: Offerors must provide equipment for large-scale isolation and purification of natural products, and have refrigerated storage capacity for up to 750 gallons of primary extract. The agents isolated must be high purity, suitable for subsequent manufacture of clinical dose forms, and all work must be carried out in compliance with the FDA Current Good Manufacturing Practices. A requirement is that the contractor's facilities must be in compliance with FDA-CGMP regulations at the time a Master Agreement Order is awarded under the Master Agreement. The experience and ingenuity of the offerors in process development for pilot plant extractions and isolations using standard or novel techniques will be important factors in the evaluation of the proposals.

It is anticipated that multiple Master Agreement Awards will be made. Each Master Agreement Award is anticipated for a five-year period, beginning approximately April 30, 1993.

Contract specialist: Elsa Carlton
RCB Executive Plaza South Rm 604
301/496-8620

Program Announcements

PA-92-69

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 humans. Clinical research, by definition, involves a clinician/patient-subject interaction with a therapeutic intent. This Program Announcement encompasses a full range of therapeutic studies and clinical trials employing drugs, biologics, radiation, and 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.

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private. Foreign

institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award (R29). Applications from minority individuals and women are encouraged. An application may include one or more institutions with established clinical, laboratory, and statistical resources. Awards will be made as investigator-initiated research grants (R29, R01 and interactive R01s).

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 (CTEP), 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 a Request for Applications (RFA) represents a single solicitation, a PA provides the opportunity for the receipt of new applications on a continuing 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.

Clinical studies must involve human subjects and be designed to ultimately improve cancer treatment. The applications may include single or multi-institutional 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, mechanism of action and metabolic studies of antitumor agents; (2) studies of mechanisms of hormone-, drug-, or radiation-resistance and reversal; (3) 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; (4) mechanism of action of new growth factor targeted therapies; (5) new radiation therapies or radiation modifiers to enhance cell kill or protect normal tissue; (6) 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 a therapeutic intent.

The aims of this initiative are two-fold: (1) to support innovative correlative laboratory studies relevant to therapeutic clinical trials and (2) to stimulate development of innovative therapeutic clinical studies with laboratory correlations to foster the development of interactions between basic science laboratories and clinicians performing these clinical trials.

Written and telephone inquiries are encouraged and may be directed to Dr. Roy Wu or Ms. Diane Bronzert, NCI Program Directors, Cancer Therapy Evaluation Program, Div. of Cancer Treatment, National Cancer Institute, Executive Plaza North, Room 734, Bethesda, MD 20892, phone 301/496-8866, fax 301/480-4663.

NCI Contract Awards

Title: "Chemotherapy and You"
Contractor: Broudy Printing Inc., Pittsburgh, PA; $318,411.

Title: Tracing individuals through motor vehicle bureaus
Contractor: Equifax Government & Special Systems Inc., McLean, VA; $12,584.

Title: Leukemia among Chernobyl clean-up workers
Contractor: Finnish Cancer Registry, Helsinki; $195,215.

New Publications

--Five new "Oncology Overview" titles are available from NCI. These are specialized bibliographies with abstracts referencing hundreds of recent publications on a clinical cancer topic of high interest.

The new titles include: "The Cell Cycle in Cancer Prognosis," "Antiangiogenesis," "Current Management of Childhood Leukemia," "Therapeutic Use of Interleukin-2" and "Childhood Brain Tumors."

For ordering information, write to NCI, Bldg 82, Rm CL, Bethesda, MD 20892. Also available for free by writing to Bldg 82 Rm RRR is the booklet, "Scientific Information Services of the National Cancer Institute."

--"Living With Lung Cancer: A guide for patients and their families," by Barbara Cox, David Carr and Robert Lee, was recently released in a new edition, $8.95; Triad Publishing, 1110 NW 8th Ave., Gainesville, FL 32601, phone 904/373-5800.

--"Women and Tobacco," C. Chollat-Traquet et al, $23.40, World Health Organization, 1211 Geneva 27, Switzerland.

--"Blood Cell Growth Factors," proceedings of symposium in Beijing last summer, $89, AlphaMed Press, 4100 South Kettering Blvd., Dayton, OH 45439, phone 513/293-8508.

--"Cancer in Los Angeles County, a portrait of incidence and mortality, 1972-1987," by Leslie Bernstein and Ronald Ross. Copies available for $15 from Leslie Bernstein, Kenneth Norris Jr. Comprehensive Cancer Center, Univ. of Southern California, 1420 San Pablo St., PMB A-202, Los Angeles, CA 90033. Make check payable to "USC/Cancer LA."