THE CANCER LETTER

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'We Want Our Voices To Be Heard' Coalition Tells NCAB; Seeks Seats On Advisory Boards

The National Breast Cancer Coalition earned its place on the agenda of last month's meeting of the National Cancer Advisory Board the hard way. The coalition last year organized, lobbied, held hearings, wrote letters, and sat on the steps of the Capitol to press for more money for breast cancer research.

The coalition's rallying cry for "$300 million more" made the professional cancer societies and NIH nervous, but when the dust settled,

(Continued to page 2)

In Brief

Peter Jones Is Interim Director Of USC's Norris; NIAMS Funds Skin Disease Cores At Yale, Texas

PETER JONES will serve as interim director of the Kenneth Norris Jr. Comprehensive Cancer Center at Univ. of Southern California while a search for a successor to **Brian Henderson** is conducted. Henderson announced recently that he will assume the presidency of the Salk Institute in La Jolla, CA, on Feb. 1. . . . **NATIONAL INSTITUTE** of Arthritis & Musculoskeletal & Skin Diseases has funded two new Skin Disease Research Core Centers, at Yale Univ. and Univ. of Texas Southwest Medical Center. The Institute plans to award about $2 million to each center over the next five years. Principal investigators are **Robert Tigelaar** at Yale and **Paul Bergstresser** of UTSMC. . . . **JOSE TRUJILLO**, head of the Div. of Laboratory Medicine at M.D. Anderson Cancer Center, died last month at the center. Trujillo published the first scientific report showing that lymph node tissue could be cultured for long periods in test tubes. His laboratory was the first to demonstrate the clinical relevance of chromosome abnormalities in leukemia, which led to routine tests to determine different types of leukemia and recommend optimal treatment. . . . **TWO HARVARD** Univ. scientists received the V.D. Mattia Award for outstanding contributions in immunology from the Roche Institute of Molecular Biology: **Jack Strominger** and **Don Wiley**. The scientists were honored for their work, over 10 years, of decoding the mechanism of immune recognition. . . . **NCI BRIEFING** on RFA CA-93-03, Therapeutic Studies of Primary Central Nervous System Malignancies in Adults," is scheduled for Jan. 19, in Conference Room H, Executive Plaza North, 6130 Executive Blvd, Rockville, MD to discuss this initiative. Two sessions, 9-11 a.m. and 2-4 p.m. To register contact Diane Bronzert, Cancer Therapy Evaluation Program, phone 301/496-8866.

Breast Cancer Coalition Meets NCAB, Seeks Voice In Research Spending

(Continued from page 1)

Congress had found money in the defense budget--$210 million--for breast cancer research. Congress also encouraged NCI to redistribute its funds to increase spending on the disease.

"We want our voices to be heard," said Coalition President Fran Visco, addressing NCI officials and advisors.

"We believe that there has been a fundamental change in breast cancer over this past year--We, the women with breast cancer, have taken matters into our own hands," Visco said to the NCAB.

"We can no longer sit back passively and be told that there is no money to find the answers we so desperately seek," Visco said. "We want to forge a partnership with the scientists, the physicians, the agencies that have such profound impact on our lives."

Communication And Accountability

To the coalition, that means having a seat on the NCAB, the body that advises the NCI director on policy and funding directions. It means breast cancer survivors on other NCI advisory groups, NIH study sections and cancer centers and cooperative groups around the country. It means communication and accountability.

NCAB members spoke in support of the coalition's lobbying effort for new cancer research money, but some members questioned whether the coalition is promoting directed research in breast cancer at the expense of research in other cancers and basic research.

Visco, a breast cancer survivor and partner in the Philadelphia law firm Ford, Shapiro, Pelcher and Cohen, and Susan Love, associate professor of clinical surgery at Univ. of California Los Angeles School of Medicine, said the coalition never supported cutting other cancer research.

'We Want Representation'

"What do we want? At this point we want accountability. We want representation and we want a shift in emphasis," Love, chairman of the coalition's Research Task Force, said to the board.

"We have been working very hard to increase the research budget for breast cancer. Yet we still don't have a full picture of how monies in the past have been spent, nor do we have a mechanism for monitoring the disbursement of current and future funds. We want to explore a variety of mechanisms of accountability that will ensure that taxpayers' money is well invested.

"Representation by women with breast cancer in the decision making bodies, oversight committees, and monitoring panels regarding breast cancer issues can be a first step in achieving this accountability, as well as an influence in the future directions of breast cancer research.

"Initial opportunities for such representation and accountability should include:

--a seat on the NCAB,

--the creation of a permanent breast cancer subcommittee of the NCAB where we have some representation,

--the creation of permanent breast cancer study sections with consumer representation,

--the development of a reporting mechanism for the number of breast cancer grants submitted, the number approved for funding, and the number actually funded,

--a formal structure for the exchange of ideas with the Office of the Director of NCI, including collaboration in the establishment of the annual bypass budget,

--a formal structure for the exchange of ideas with each division of NCI, such as the newly formed subcommittee of the Board of Scientific Counselors of the Div. of Cancer Treatment.

--requirement by the NCI for consumer representation in all cooperative groups, SPOREs, comprehensive cancer centers and clinical trial subcommittees,

--discussions of other appropriate mechanisms for achieving these goals of accountability and representation."

Love said the coalition was pleased that Zora Brown, a breast cancer survivor, was reappointed to the NCAB for a full term. However, "we feel that it is unfair for one woman to be expected to represent the 2.6 million women living with breast cancer in this

THE CANCER LETTER

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country," Love said. At least one additional seat should be allocated to a woman with breast cancer, "preferably one who has access to a large national network of the women she represents."

Love said the coalition has had several substantive meetings with Broder, but a "more fruitful dialogue could be achieved if a formal mechanism existed for this communication."

'Two-Way Exchange Is Vital'

"We would like to be able to serve as a link between NCI and the taxpayers who pay its bills on these issues," Love said. "We feel that we could not only bring grassroots concerns to NCI, but also bring back to the women of this country a fair representation of what is actually going on in NCI.

"This two-way exchange is vital if we are to address the issues of most concern to women with breast cancer. We have found in our meetings that there is a lot more going on than certainly we had any indication of.

"By its example, NCI will demonstrate to all of its funding recipients the value of consumer input into decision making regarding breast cancer and will be an example for all cancers. It should require that any project or institution such as the SPOREs, comprehensive cancer centers, or cooperative groups receiving NCI funding have consumer input whether by an advisory board or a representative to an oversight and decision-making body."

The coalition and its member organizations have a large pool of breast cancer survivors and experts willing to serve, Love said. "We are in the process of surveying our membership to develop an even larger pool of ready volunteers for local, state, and national levels."

Accelerate Pace Of Research

"We also see an immediate need for a change in the direction and the pace of breast cancer research," Love said. "The 2.6 million women living with breast cancer are demanding a shift in emphasis with increasing funds going to breast cancer research and prevention, accelerating the discovery of breast cancer's cause and cure.

"Among the mechanisms to achieve this are, again, some broad based permanent breast cancer study sections, expedited review of breast cancer grant proposals, full funding of all meritorious grant proposals, identification and elimination of barriers to innovative investigator initiated research, methods by which new researchers at all levels can be attracted to the field, and encouragement of all institutes of the NIH to be involved in the research effort as outlined in the trans-NIH breast cancer initiative proposed by Dr. Broder in the 1994 bypass budget" (**The Cancer Letter,** Nov. 6).

The coalition met with Hillary Clinton several months ago, Love said. "To a woman, their request was simple. It was not for more research into treatments which might prolong or save their lives, it was for research into the cause and prevention of this disease. It was for their daughters.

"We must change the emphasis of breast cancer research into one of prevention and basic science. We can't afford to do one clinical prevention trial at a time. It is going to take too long to get the answers. We must do several at once if we are going to get an answer. We must develop intermediate markers so that we can do prevention research much more expeditiously and also so we can better identify the carcinogens which cause these fatal mutations. We must exploit the biology of the disease to develop more subtle treatments that will eliminate the problem before it ever gets to the point of surgery, radiation, or chemotherapy. We must make real progress in figuring out the cause of the disease that women fear most.

"This new emphasis must be enthusiastically embraced and proclaimed to the research community," Love said. "As researchers come to realize that there is an appropriate forum for review of the research proposals and adequate funding, they will be encouraged to develop new and creative ideas. This will help to attract new researchers. We need the brightest minds in America to work on this problem.

"The peer review system has to be re-evaluated to ensure that experienced investigators and a broad range of investigators are included, such as epidemiologists, clinicians, quality of life experts, psychosocial experts, and women with breast cancer, as well as basic scientists. This will ensure that all aspects of the proposals are being addressed.

"For example, the identification of a familial breast cancer gene needs to be funded in tandem with the appropriate psychosocial and quality of life research to ensure that women identified with the gene are appropriately treated....

"The input from a broad range of disciplines is crucial in setting priorities and rationing funding. We are very encouraged by the overarching position NCI is taking in the 1994 bypass budget. The trans-NIH breast cancer initiative is just the kind of integrative program that is necessary to take advantage of all the talent at our disposal...."

Suggests Federal Breast Cancer Office

"Finally, we are recommending the establishment of an office on Breast Cancer Coordination to oversee all

federal breast cancer activities, including agencies, projects, and initiatives," Love said. "This office would coordinate the breast cancer research agenda across all of the federal agencies, such as HCFA, CDC, DOD, as well as NIH and NCI, ensuring the elimination of redundancy and a fostering of an integrative approach to the elimination of breast cancer.

"Our goal is the eradication of breast cancer. We feel this is best achieved through a three-pronged approach: increased new dollars for breast cancer research, accountability to and representation by women with breast cancer regarding decisions about breast cancer research funding, and a change in the emphasis and pace of breast cancer research in this country. We believe that these goals are achievable and that we can work with you in their fulfillment. We ask for your help in our mission. Our lives and the lives of our daughters depend on it."

Board's Reaction

Board members had a variety of reactions to Visco's and Love's presentation:

▶ **Fear that the Army will waste the money.** "I am delighted that you got $200 million more in breast cancer research," NCAB Chairman Paul Calabresi said. "I am a little concerned and alarmed that this is being appropriated to the Army."

"We have the same concerns," Love said. "Their record has not been stellar in terms of how they pass out breast cancer research money."

Last year, the Army had $25 million for breast cancer research, which was spent on seven mammogram machines each for the Army, Navy, and Air Force, and the rest was opened for grants, she said.

"We continually remind them that they are being watched," Love said. "We plan to be right on them monitoring this process as much as possible."

▶ **Fear of decreased funding for other cancers.** "We would be concerned if the money and effort for one particular cancer took away from other cancer efforts," Harold Freeman, chairman of the President's Cancer Panel, said.

"We couldn't agree with you more, and we have tried scrupulously in our testimonies and with the press to accent that we don't want a bigger piece of the pie, we want a bigger pie," Love said. "That is how we got this money in the Dept. of Defense. It was trying to get new money into research."

▶ **Fear of activists demanding seats on committees.** "Suppose the prostate cancer people raise the same pattern of suggestions [regarding committee positions, study sections]?" Freeman asked. "Suppose the lung cancer people did the same thing? What would it do to the whole set-up?"

"What needs to be done is to figure out a way of having consumer representation at all levels of NIH and NCI," Love said. "Breast cancer can be a model.... When you get people with a disease involved in some of the decision making, it changes and shifts the approach to the problem.... We need to open up the process."

As the coalition began meeting with NCI and NIH officials, it became clear, Love said, that "a lot of things we thought weren't going on are going on, but the public is not aware of it.

"Having more representation is going to be useful in both directions."

▶ **More fear of activists.** "I could envision advocacy groups springing up for lung and prostate," said board member Fred Becker. "Soon the room will be filled with survivors and we will all be focuses on diseases."

"We hope that it will be filled with survivors," Love said.

▶ **Fear that directed research in breast cancer will take away from basic research.** "The two substantive advances that have been made from a basic standpoint that will benefit breast cancer were made by studying two of the rarest diseases we know, retinoblastoma in children and the Li-Fraumeni syndrome," Becker said. "If we don't watch out, not because of good intent, but in the way our political system works, where advocates are listened to but the 20 families with retinoblastoma might not have been listened to, that scientists will be forced to divert their efforts to those diseases which are popular and have advocacy groups.... Research has never worked well in medicine on a directed basis and we must keep a pool of funds available for those interventions which arise from the minds and creativity of scientists in undirected research."

"What we need is both--we need [basic science] and we need the additional funds directed to breast cancer," Love said. "The Army money is an example of new money, a whole new set of money we never had before."

The coalition's goal is to get new money into the field, Love said, adding that, "potentially, this is a good model for how the defense budget is going to be dismantled ultimately, I hope."

▶ **More fear of directed research.** "These new resources need to do more than not take away from existing basic research," board member Sydney Salmon said. "They have to give to basic [nontargeted] research."

NCI Director Samuel Broder said he hoped the coalition would work with NCI to develop a system

for tracking breast cancer research funding that would recognize work that is fundamental to the understanding of breast cancer but is done in other systems.

"If we are formula driven, we can end up with answers that bureaucratically make sense, but that really aren't influencing the health and progress of science," Broder said. "One of the fears I have is that we will be forcing ourselves into incremental knowledge and only incremental knowledge."

'There Is Never Enough Money'

Visco concluded the discussion with a plea for understanding. "A lot of what we talked to you about is innovative, it is change, and that is always difficult from your point of view and from ours. We expect basic science to continue in all areas. We understand the issues Dr. Becker raised.

"There never is enough money to fund everything that should be funded," Visco continued. "There never has been. But the decisions have been made of what to fund and what not to fund. We would like to be involved in the decision making and in shifting the focus."

DCT Board Forms Breast Cancer Committee

In response to the activists' requests for committees, Calabresi noted that the first subcommittee he formed when he was named NCAB chairman was the Subcommittee on Women's Health and Cancer, chaired by Brenda Johnson. He said breast cancer is a high priority for the subcommittee.

NCI's Div. of Cancer Treatment recently formed a subcommittee on breast cancer, which will have patient representation.

Werner Kirsten, Frederick Director, Dead At 67; Found Sarcoma Virus

Werner Kirsten, director of the Frederick Cancer Research and Development Center, died Dec. 24 of an apparent heart attack at his family's home in Chicago. He was 67.

Kirsten, a pathologist, investigated retroviruses as a possible cause of cancer. He discovered a virus that caused tumors in rats, which became known as the Kirsten sarcoma virus. His discovery stimulated the work of other scientists, who found that KSV yielded a viral gene responsible for transformation of the cell into a cancer cell. The viral gene, or oncogene of the ras family, was named K-ras, in his honor.

"He was a brilliant scientist and, of equal importance, an extremely kind person," NCI Director Samuel Broder said to **The Cancer Letter**. "He did an enormous amount in his career, including work on many of the fundamental issues we take for granted in retroviruses and oncogenes."

Kirsten was born in Leipzig, Germany, in 1925. His father was a engineer and his mother was a school teacher. He attended high school and college at St. Thomas School in Leipzig through World War II, and entered medical school at University Halle in 1947. He completed a medical degree at the Univ. of Frankfurt in 1953.

Kirsten moved to Chicago in 1955 to take an internship at Englewood Hospital.

In 1956, he became a resident in pathology at Univ. of Chicago, where he was to spend most of his career. He rose from an instructor to assistant professor, becoming a professor in pathology and pediatrics in 1968.

Kirsten was named chairman of the department of pathology in 1972, a post he held until he left for NCI in 1988. During that time, he was widely recognized as one of the leaders of American pathology, and was active in professional societies and in the NIH peer review system. He held volunteer positions in the American Cancer Society, the Leukemia Society of America, and the Damon Runyon-Walter Winchell Fund for Cancer Research.

"He was a master chairman of review committees," said Alan Rabson, director of NCI's Div. of Cancer Biology, Diagnosis & Centers. "He was always called upon to chair special review committees because he was really good at balancing everyone's interests. His wisdom, judgement, and overall understanding of science will be missed."

Key Force In Frederick Growth

Kirsten was a member and then the chairman of the advisory committee for the Frederick Cancer Research & Development Center in the mid-1980s. The center was established in 1971 when President Richard Nixon directed the Army to turn over its Ft. Detrick biological weapons center to NCI for cancer research.

"Werner was the key instrumental force in developing Frederick," said Peter Fischinger, former Frederick director and NCI deputy director, now at the Hollings Oncology Center in Charleston, SC. "He was enormously supportive in those early days. He made Frederick what it is today."

When Fischinger was tapped to coordinate AIDS activities of the Public Health Service in 1988, Kirsten chose to leave the Univ. of Chicago to direct Frederick.

"It was a sacrifice on his part," Fischinger said. "He left a fine position to come to Frederick." Kirsten's family remained in Chicago.

As Frederick director, Kirsten served on the NCI Executive Committee, the nine-member committee made up of the NCI Director and deputy director, and their division directors. He was an ardent supporter of basic research.

"Given all of his phenomenal accomplishments, he was profoundly modest," Broder said.

"He had a kindness and gentleness about him that made work with him so easy and pleasant," Fischinger said.

Friends said Kirsten did not appear ill before leaving Frederick to return to Chicago for the holidays.

"I shook his hand, wished him a happy holiday, and gave him a hug," said George Vande Woude, director of the basic research program at Frederick. "That's not a bad way to remember him."

Kirsten is survived by his wife, Inger, and three children, Christian, Olaf, and Thomas. A memorial service is planned at the Univ. of Chicago. NCI will sponsor a summer fellowship in Kirsten's memory.

ACS Announces 1994 Clinical Awards

The American Cancer Society announces its clinical awards for 1994 funding: the Clinical Oncology Fellowship (COF), the Clinical Oncology Career Development Award (CDA), and the Cancer Control Career Development Award for Primary Care Physicians (CCCDA).

The COF is a one-year institutional award intended to support a multidisciplinary training experience for physicians and dentists preparing for a leadership career in academic oncology. The fellowship is expected to provide unique training in addition to that which is normally provided in postgraduate training programs designed to fulfill requirements of specialty boards. The COF stipend is $10,000 per year.

The CDA is a three-year award given to promising junior faculty who will pursue academic careers in clinical oncology. A successful application must describe in detail a supervised program that will develop the candidate's clinical expertise and his/her capacity to perform independent clinical/laboratory research. The annual stipend for the CDA is $25,000 for the first year, and $30,000 and $35,000 for the second and third years, respectively.

In order to encourage and support activities in cancer control, the Society offers a limited number of CCCDAs to physicians specializing in primary care. It is anticipated that physicians trained under these two-year grants will improve cancer control through involvement in primary care practice, education, and research activities related to cancer control. These awards are intended to develop academic leaders in primary care specialties emphasizing cancer control.

Candidates for awards must be citizens or permanent residents of the US. The application deadlines are July 1 for the COF; Aug. 1 for the CDA; and Aug. 15 for the CCCDA.

Applications are available from Virginia Krawiec, Professional Education Department, American Cancer Society, 1599 Clifton Rd. NE, Atlanta, GA 30329-4251; phone 404/329-5734.

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 NCI-CB-33014-32

Title: Maintenance of an animal holding and breeding facility and provision of attendent research services

Deadline: Approximately Feb. 22

NCI seeks a small business contractor to provide an animal facility capable of 1) maintaining a colony of mice, rabbits, rats and hamsters to support ongoing research in the areas of immunobiology, cancer biology and diagnosis, and transplantation, 2) breeding special strains of mice, 3) providing a technical staff capable of limited types of animal manipulations, and 4) maintaining a freezer bank of biological products. This solicitation is a recompetition of an existing contract. This solicitation contains a mandatory evaluation criterion which the offeror must have at the time of best and final offers. The mandatory criterion specifies that the contractor have an approved animal assurance. The present contractor is Bioqual Inc. It is anticipated that a four-year, cost reimbursement type contract will be awarded.

Contract specialist: Richard Hartmann
RCB Executive Plaza South Rm 620
301/496-8611

RFP NIAID-DIADS-93-14

Title: Storage, repackaging, and distribution of investigational agents for AIDS

Deadline: Approximately Jan. 14

The Pharmaceutical and Regulatory Affairs Branch of the Treatment Research Operations Program, Div. of AIDS, National Institute of Allergy and Infectious Diseases, is seeking a contractor to operate and maintain a Clinical Research Products Management Center for investigational agents used in clinical trials sponsored by the DAIDS. This center receives shipments from a variety of sources, stores the study products under specified conditions, provides inventory and distribution record maintenance, and ships to clinical study sites. In some cases, packaging and/or labeling, including patient specific packaging, is required. A computerized data processing system will be used for record keeping and other functions. The contractor must possess distributor's, manufacturing and Drug Enforcement Agency licenses as well as an Environmental Protection Agency toxic waste generator permit.

To receive a copy of the RFP, supply three self-addressed mailing labels to: Brenda Velez, Contracting Officer, 6003

Executive Blvd. Solar Bldg. Rm 3C07, NIAID, Bethesda, MD 20892, phone 301/496-7117.

RFAs Available

RFA CA-93-01

Title: **Radiologic Diagnostic Oncology Group V: Stereotactic breast biopsy for non-palpable lesion characterization**

Letter of Intent Receipt Date: Jan. 12

Application Receipt Date: March 12

The Radiation Research Program of NCI's Div. of Cancer Treatment invites applications for cooperative agreements to establish a multi-institutional scientific group in order to optimize a clinical algorithm for non-palpable breast lesion characterization.

Non-profit and for-profit organizations and institutions, governments and their agencies, and foreign and domestic institutions are eligible to apply. Applications from minority individuals and women are encouraged. Applications may be submitted from institutions that desire to be a participating clinical institution in a consortium and/or as a headquarters institution. The same institution may serve in both capacities within this cooperative agreement.

Awards will be made as cooperative agreements (U01). Approximately $1,500,000 in total costs per year for four years will be committed. It is anticipated that a consortium of about ten clinical institutions and the headquarters component will be funded. It is anticipated that approximately one-fourth of the total funds expended each year will be devoted to the headquarters function, and approximately three-quarters will be awarded to the participating Clinical Institutions.

The objective of this RFA is to invite applications to perform centrally coordinated multi-institutional cooperative clinical trials to develop an optimal clinical algorithm for characterization of small non-palpable breast cancers. The successful applicants will form RDOG V. The results of the RDOG V studies should have a direct and immediate impact on management of minimal breast cancer. Sufficient numbers of patients must be available in each institution for successful completion of the proposed clinical trials. The RDOG was formed by NCI in September 1987. The RDOG objective is timely evaluation of current and emerging imaging modalities in the management of patients with cancer.

Inquiries may be directed to: Dr. Faina Shtern, Chief, Diagnostic Imaging Research Branch, Radiation Research Program, NCI, Executive Plaza North, Suite 800, Bethesda, MD 20892, phone 301/496-9531.

RFA OD-93-01

Title: **Extramural research facilities construction projects**

Letter of Intent Receipt Date: Feb. 17

Application Receipt Date: March 30

NIH announces the availability of an RFA for the construction of facilities of urgent national importance for biomedical/behavioral research and/or services to support such research. Applications for construction grants that were previously submitted to the NIH must recompete under this RFA.

The main objective of this construction program is to facilitate the conduct of biomedical/behavioral research by providing funds for construction of new facilities and for the purchase of associated fixed research equipment essential for the operation of these facilities. Support may be requested for the construction of new facilities and additions or renovations to existing facilities to meet the biomedical/behavioral research and/or services to support such research needs of an institution, or of a research group at that institution or elsewhere that utilizes the resources of that institution. The purpose of the proposed facility must be within the scope of one of the statutes authorizing the awards. Those statutes authorize construction grants that would benefit the fields of cancer, vision, heart, lung and blood, AIDS research, and drug abuse, pharmacotherapeutic research.

Domestic, non-Federal, public and private non-profit institutions, organizations, and associations that conduct or support biomedical/behavioral research are eligible to apply. An institution may submit only one application in response to this announcement. The award mechanism will be the construction grant award (C06). Up to 50 percent of the allowable costs of a project may be awarded, not to exceed $2 million. Prior to grant award, the applicant must provide an assurance of required matching funds and that additional funds will be secured to meet any projected costs in excess of the award amount. Requests of less than $500,000 will not be accepted. No indirect costs or continuation costs will be awarded.

This one-time solicitation based on the FY 1993 appropriation provides $4,960,000 for this initiative. It is anticipated that three to four awards will be made.

Inquires may be directed to: Kenneth Brow, Chief, Research Facilities Branch, Div. of Cancer Biology, Diagnosis, and Centers, NCI, Executive Plaza North Room 300, Bethesda, MD 20892, phone 301/496-8534.

RFA CA-93-07

Title: **Phase 1 trials of new anti-cancer agents**

Letter of Intent Receipt Date: Jan. 22

Application Receipt Date: March 23

NCI's Div. of Cancer Treatment (DCT) invites cooperative agreement (U01) applications from single institutions wishing to perform phase 1 trials of promising anti-cancer agents in patients with cancer refractory to currently available therapy and to conduct laboratory studies in support of the clinical trials such that their conduct leads to a greater understanding of the relationship between drug administration and biological changes in patients. It is expected that the application from any one institution will focus on studies of one or more classes of agents, reflecting the interest, expertise, and experience of the applicant investigators. Patients should be treated only at the applicant institution, although support for laboratory studies may be conducted by collaborators at other institutions.

Domestic for-profit and non-profit organizations are eligible to apply. Applications from minority individuals and women are encouraged. Approximately $2 million in total costs per year for four years will be committed. It is anticipated that six to eight awards will be made. The total project period may not exceed four years. The earliest feasible start date will be Dec. 1, 1994.

Phase 1 clinical trials have as their objectives the characterization of drug toxicity, maximally tolerated dose, pharmacokinetics, and biological effects (pharmacodynamics) of drugs. These anti-cancer agents have traditionally been obtained either from the NCI drug development program or through collaborative drug development agreements with the pharmaceutical industry. Recent advances in understanding of the pathobiology of malignancy are leading to the development of a wide range of novel anti-cancer therapeutic agents that require phase 1 testing. Furthermore, mechanisms of action of these new anti-cancer agents available for clinical study include not only the mediation of anti-cancer effects through cytotoxic mechanisms, but also through growth inhibition by interruption of specific oncogene-associated biochemical functions, inhibition of protein synthesis through targeted toxins, induction of differentiation and/or programmed cell death (apoptosis), and through anti-tumor angiogenesis. In addition, new strategies to overcome resistance to conventional cancer therapeutic approaches are also of interest.

In addition to the funding assistance offered to the investigator(s) by this RFA, NCI may sponsor (in the FDA sense) or co-sponsor the agents under development. This will increase the likelihood that agents will be further developed so that they will ultimately be broadly available for use in cancer treatment and will accelerate the time frame in which this process would occur.

The aims of this initiative are: 1) to provide support for phase 1 trials of promising new anti-cancer agents in cancer patients; and 2) to provide support for complete pharmacokinetic, pharmacodynamic, and other important laboratory correlative studies in cancer patients receiving these anti-cancer agents. The laboratory studies should be in support of the clinical trial, such that their conduct leads to a greater understanding of the relationship between drug administration and biological changes in patients.

Specific objectives and scientific approaches will be investigator-originated and should reflect the creativity and capability of the investigators. This RFA provides an opportunity for clinical and laboratory investigators within an institution to develop a program in drug development that utilizes the strengths of pre-existing basic scientific expertise and available clinical resources. Each phase 1 awardee institution will be expected to complete an average of two to three phase 1 trials per year, with each trial encompassing 20-40 patients. Each applicant institution is responsible for coordination of protocol development and submission, study conduct, quality control, data management and analysis, adherence to NCI requirements for investigational agents, adherence to FDA/DHHS regulations, and performance reporting of data from the phase 1 trials. For phase 1 trials with NCI-sponsored investigational agents, the NCI has contracted for a Clinical Trials Monitoring Service (CTMS) to document regulatory compliance, to maintain a computerized data base of the biweekly phase 1 investigator data submissions, and to produce periodic routine reports of the results and special reports as necessary. The awardee institution's source documentation will be reviewed on-site three times per year by the CTMS.

Inquires and letter of intent may be directed to: Dr. David Parkinson, Chief, Investigational Drug Branch, Cancer Therapy Evaluation Program, NCI, Executive Plaza North, Room 734, Bethesda, MD 20892, phone 301/496-5223, fax 301/480-4663.

NCI Contract Awards

Title: Pathology and veterinary support for preclinical toxicology studies
Contractor: Pathology Associates Inc., Frederick, MD; $803,515.

Title: Preclinical toxicology of drugs for cancer and AIDS, and AIDS related illnesses
Contractor: Midwest Research Institute, $3,186,037.

Title: Preclinical toxicology of drugs for cancer and AIDS, and AIDS related illnesses
Contractor: Univ. of Illinois, $2,124,649.

NCI Advisory Group, Other Cancer Meetings For Jan., Feb., Future

NCI Div. of Cancer Prevention & Control Board of Scientific Counselors--Jan. 7-8, NIH Bldg. 31 Conf. Rm. 10, open 8:30 a.m.

President's Cancer Panel Special Commission on Breast Cancer--Jan. 11-12, Atlanta, GA. Hyatt Atlanta Airport. Topic: Treatment, rehabilitation and quality of life for women with breast cancer.

Developmental Therapeutics Contracts Review Committee--Jan. 15, Bethesda Holiday Inn, Bethesda, MD, open 9-10 a.m.

Radiation Therapy Oncology Group Semi-Annual Meeting--Jan. 15-17, New Orleans, LA. Contact Nancy Smith, RTOG, phone 215/574-3205.

Specific Immunotherapy of Cancer with Vaccines--Jan 21-14, 1993, Washington, DC. Contact Conference Dept., New York Academy of Sciences, phone 212/838-0230.

Positive Partnerships HIV Therapeutic Alliance Meeting--Jan. 23, Kansas City, MO. Contact Ken Fornataro, phone 212/268-4196.

Frontiers of Immunology & Cancer Immunology--Jan. 25-26, New York City, Memorial Sloan-Kettering Cancer Center. Contact Tricia Schafer, phone 212/639-3136.

Queen's Cancer Institute Symposium on Women and Cancer--Jan. 27-29, Honolulu, HI. Contact Grace Iwahashi, Queen's Medical Center Cancer Institute, 1301 Punchbowl St., Honolulu, HI 96813, phone 808/547-4660, fax 808/537-7819.

National Biotherapy Study Group Nursing Biotherapy Symposium--Jan. 27-28, San Diego, CA. Contact NBSG Central Office, phone 615/791-6393.

Breast Cancer in Premenopausal Women--Jan. 28-29, Bethesda, MD, NIH Masur Auditorium. Contact Dr. Edward Trimble, 301/496-2522.

International Congress on Biological Response Modifiers--Jan. 29-31, San Diego, CA. Contact Dr. James Rusthoven, phone 416/387-9495.

Oncogenes and Antioncogenes in Differentiation, Development and Human Cancer--Feb. 1-6, Big Sky, MT. Contact AACR, phone 215/440-9300.

Basal & Squamous Cell Head and Neck Skin Cancer--Feb. 6, Houston, TX. Contact Carol Harreld, phone 713/792-2222.

American Cancer Society/American College of Clinical Pharmacology Conference on New Oncologic Agents: Practical Applications--Feb. 4-6, San Diego, CA. Contact Andy Cannon, phone 404/329-7604, fax 404/636-5567.

Clinical Implications of Prostate Cancer Biology--Feb. 12-13, Houston, TX. Contact Cindia Stauss, phone 713/792-2222.

Gastrointestinal Malignancies: A Challenge in Cancer Care--Feb. 16, Pittsburgh, PA. Contact Pittsburgh Cancer Institute, 412/624-7899.

Future Meetings

National Meeting for State Cancer Pain Initiatives--March 4-7, Charleston, SC. Contact Sarah Aslakson, phone 608/263-2856.

Stem Cell Factor & Related Cytokines in Bone Marrow Congenital Dysplasias--March 8-9, Cattolica, Italy. Contact Marina minzoni, Studio ER Congressi, Via Riva Reno 47, 40122 Bologna, Italy, phone 39-51-235-293.

Mechanisms of Action of Retinoids, Vitamin D, and Steroid Hormones--March 15-20, Banff, Alberta, Canada. Contact American Assn. for Cancer Research, phone 215/440-9300.

Diagnosis & Treatment of Neoplastic Disorders, Medical, Surgical & Radiotherapeutic Aspects--April 1-2, Baltimore, MD. Contact Johns Hopkins Office of Continuing Education, phone 410/955-2959.

International Conference Series on Nutrition & Health Promotion: Breast Cancer Research--April 25-28, Atlanta, GA. Contact Andy Cannon, ACS, 1599 Clifton Rd NE, Atlanta, GA 30329, phone 404/329-7606.

Autografting for Chronic Myeloid Leukemia--Aug. 20, Portofino, Italy. Contact Dr. Ann Murphy, AlphaMed Press, 4100 South Kettering Blvd., Dayton, OH 45439.

American Cancer Society National Conference on Breast Cancer--Aug. 26-28, Boston, MA. Contact Andy Cannon, ACS, 1599 Clifton Rd NE, Atlanta, GA 30329, phone 404/329-7606.