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# THE CHARLESS LETTER

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## Five Awards Expected In Annual CCOP Review; 21 Applicants Compete For Limited Funding

NCI last week began informing applicants in the first annual recompetition of the Community Clinical Oncology Program of their priority scores, but Associate Director Leslie Ford warned that the (Continued to page 2)

#### In Brief

## Centers Awarded Gifts; Georgetown Launches \$40M Campaign; Herberman Named To PA Board

GIFTS & GRANTS--The federal research budget is tight, but consider these news items: Fox Chase Cancer Center was awarded a \$4 million, six year grant from the Lucille P. Markey Charitable Trust for research projects in its molecular oncology program. Alfred Knudson heads the program. UCLA's Jonsson Comprehensive Cancer Center received a \$2 million pledge from the Jeanie A. Wentz Cancer Foundation for conversion of clinic space to cancer research laboratories. Univ. of Southern California's Kenneth Norris Cancer Hospital & Research Institute received a \$3 million grant from the W.M. Keck Foundation, to create an ambulatory care center in a new addition to the hospital. Dana-Farber Cancer Institute, through a \$442,000 challenge grant from the Kresge Foundation, raised nearly \$3 million to purchase research equipment. Univ. of Texas Southwestern Medical Center received gifts totalling \$2.1 million; \$2 million from publishing heiress Wendy Reves and \$100,000 from George and Carol Poston of Dallas. And finally, Vincent Lombardi Cancer Research Center at Georgetown Univ. has launched a campaign to raise \$40 million for research, treatment, and facilities. The campaign has already raised \$19 million, according to a press release. . . . RONALD HERBERMAN, director of the Pittsburgh Cancer Institute, was appointed a member of the Pennsylvania Cancer Control, Prevention, and Research Advisory Board. The appointment required a proposal by the General Assembly and Senate confirmation. The board sets policy for the state's cancer appropriations. . . . LEE MORTENSON, long a "Mr." in a world of MDs and PhDs, has earned the right to add "Dr." to his name. Mortenson, executive director of the Assn. of Community Cancer Centers and head of ELM Services, this month received a doctorate in public administration from the Univ. of Southern California. . . . CLARIFICATION: GM-CSF will be marketed by Immunex Corp. under the trade name Leukine, if granted final FDA approval, while Hoechst-Roussel Pharmaceuticals Inc. will co-market GM-CSF as Prokine. A The Cancer Letter, Jan. 4, story provided only the Hoechst name. Immunex holds the license to manufacture and market the drug.

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## Five Awards Expected In First Annual CCOP Recompetition; Bases Renew

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number of spaces "is going to be very limited" since only \$450,000 is available in this round.

In the RFA issued for the program last June, NCI said it hoped to fund five CCOPs, for five, four or three year awards.

The National Cancer Advisory Board is scheduled to review those applicants in the probable funding range in a closed session during its meeting Feb. 4-5. After the meeting, Ford said, NCI staff will look at the budget and determine the payline.

Ford said there were 21 applicants for the five CCOP slots. Competing for this year's awards are any of those who did not get funded in the previous round as well as any new applicants. Ford said the length of the award would depend on whether a CCOP is current or a new applicant. Current CCOPs might get five year awards and new applicants would get three year awards.

Last year, the "CCOPs 3" recompetition had a payline of 211, and 47 awards were made, for five, four and three years depending on the score. From now on, the competition will take place every year, with roughly one-third of the CCOPs recompeting each time.

CCOP research bases are also up for renewal in this round. Their cooperative agreements expired along with those of the CCOPs in 1989, but were extended administratively to lessen NCI's review burden. In the RFA, NCI said approximately \$3.9 million is available to fund 17 research bases, and awards would be made for three, four or five years.

There were 15 applications from research bases, but

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Subscription rate \$205 per year North America, \$230 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter and AIDS Update. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, mechanical, photocopying, facsimile, or otherwise) without prior written permission of the publisher. Violators risk criminal penalties & \$100,000 damages. not all would necessarily be funded, Ford said.

One CCOP applicant told **The Cancer Letter** it had been "disapproved," a term that reflects the new NIH policy of not automatically "approving" applications with low scores. **The Cancer Letter** will publish the names of CCOPs in the probable funding range, as well as research bases, and invites applicants to call, at 202/543-7665.

In the 1989 CCOP recompetition, there were four carry overs who orignally were not funded, but then NCI was able to find more money for the program. Those CCOPs were funded for three years, not one year as has been previously reported in **The Cancer Letter.** Those were Bay Area Tumor Institute, Oakland, CA, Michael Cassidy, PI; Milwaukee CCOP, Ronald Hart, PI; San Diego/Kaiser Permanente CCOP, Scott Browning, PI; and Rapid City, SD, CCOP, Larry Ebbert, PI.

## First Cancer Patients Treated With Gene Modified TIL, TNF

NIH scientists this week treated the first cancer patients in a human gene therapy trial.

Two patients received transfusions of of tumor infiltrating lymphocytes, or TIL, that have been modified with a gene capable of producing the antitumor toxin, tumor necrosis factor.

NCI Surgery Branch Chief Steven Rosenberg leads a team of NIH scientists working on gene therapy, which includes Michael Blaese, an NCI expert on childhood immune diseases, and French Anderson, a National Heart, Lung & Blood Institute scientist and pioneer in gene therapy research.

The scientists have approval to use the therapy to treat up to 50 patients with advanced melanoma.

Since 1986, Rosenberg has been treating cancer with TIL that has not been altered by gene insertion. About half the patients with advanced melanoma show some improvement after unaltered TIL therapy.

"We need to improve TIL therapy, and one way may be with the addition of genes that can stimulate the production of antitumor toxins and thus enhance the ability of TIL to destroy tumor cells," Rosenberg said.

At the tumor site, TNF appears to work by cutting of the developing blood supply in that region. By using TIL to target the tumor and carry the TNF gene directly to the tumor site, the scientists hope to maximize the gene's benefit and also minimize the potential toxicity.

The trial follows two earlier trials with the new gene technology.

In a trial reported in the Aug. 30, 1990 "New England Journal of Medicine," the research team inserted gene altered cells into patients with advanced melanoma, but the gene had no therapeutic potential. The gene served only as a marker to identify TIL that could later be recovered from the patient's blood or biopsied tissue.

Last Sept. 14, the scientists transfused a severely immunodeficient four-year-old girl with her own white blood cells that had been altered in the laboratory by addition of the human ADA gene.

# **'Cooperation' ACS Theme For 1990s,** Dodd Tells Cancer Center Directors

Cooperation with cancer centers, hospitals, and other health care providers will be a "major theme" for the American Cancer Society in coming years, according to ACS President Gerald Dodd.

"We want to interact with all of you," Dodd told representatives from cancer centers who met with ACS executives in Houston Jan. 17.

Doad discussed the society's three year effort to develop a strategic plan and clarify its mission. The plan was approved by the society last November and will be implemented this fall, at which time, Dodd said, "The course of the society will be set for the decade."

#### Second of a Two-Part Series

In the 1990s, the society plans to:

--increase substantially its emphasis on primary cancer prevention, risk reduction, and early detection in all cancer control programs.

--strengthen its cancer research programs and expand support for research in areas of high importance and promise through its peer review granting mechanism.

--sustain the ACS cancer control program's multidisciplinary educational and training activities in cancer diagnosis, treatment, and rehabilitation, and expand its efforts in education of primary care health professionals in cancer prevention, risk reduction and early detection.

--expand the cancer control program's public education efforts to reach more people among population groups at high cancer risk.

--continue to offer service and rehabilitation programs to all cancer patients and their families and expand efforts to reach patients who are not served appropriately or completely by existing health care systems. --improve and expand efforts to recruit, develop, motivate, and retain volunteers at all levels of the organization with special emphasis on increasing the involvement of health professionals and individuals representing diverse cultural, ethnic, and economic backgrounds.

--expand efforts to recruit, develop, retain, and reward highly qualified staff professionals at all levels of the organization.

--expand corporate and foundation fundraising programs on both division and national levels.

--expand efforts to increase public awareness and understanding of the society as the only comprehensive, nationwide, voluntary health organization dedicated to eliminating cancer through programs of research, education, and service.

--expand the cancer control program's role in advocating public policy in preventing cancer, saving more lives from cancer, and diminishing suffering from cancer.

Dodd outlined the society's efforts in five areas, which will be emphasized as a result of strategic plan:

--Primary prevention: comprehensive school health education, the annual "Smokeout" tobacco control event, nutrition promotion, and technology transfer.

--Early detection and treatment: breast cancer detection, cervical cancer detection in high risk groups, shim cancer detection with emphasis on melanoma, promotion of mammography and pap smear.

--Research: enhance and promote research and cancer control.

--Patient services: provide resources, information and guidance, direct services to patients, education and support, and pain control.

--Advocacy: control of the use, sale, advertising and promotion of tobacco, cancer control for the socioeconomically disadvantaged, access to cancer prevention information and services, and protect the rights of cancer survivors.

#### Alliance In Programs, Personnel

ACS has 2.5 million volunteers working in 3,200 community based units in 57 divisions in the U.S., but many cancer centers are not taking full advantage of the society, even though virtually all former ACS presidents have been related to cancer centers, said Reginald Ho, chairman of the ACS Medical & Scientific Executive Committee.

"I hope we can form an alliance of programs as well as personnel," Ho said.

Most of the meeting was spent with ACS executives providing updates on their programs. Here

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are some highlights:

ACS has approved a \$10 million increase in the budget of its research program, bringing total funding for the program to \$90 million this year. John Laszlo, senior vice president for research, said of all ACS programs, the centers seem most aware of the research program, but there needs to be more recognition of the society's role.

"When something is hot or breaking in science, often the scientist doesn't stop to identify the funding source," he said. "It hurts us when someone announces a major discovery and doesn't say where his or her funding came from."

ACS funded 13 percent of new applications submitted last year. "ACS can't replace the deep deficits of federal funding, but we are available," Laszlo said. "When funding gets tight, there's more strain and stress. It's important for us to work together and define our common goals."

•ACS has produced a video for cancer patients explaining the clinical trials process, "starring" Walter Lawrence and Robert McKenna, two well known cancer researchers. The idea for the video grew out of a meeting ACS held on clinical trials in 1989, when ACS was concerned that less than three percent of adult cancer patients are entered at any time on an NCI sponsored clinical trial. Ho said ACS wants to work more with centers to overcome problems of access to and communication about trials.

•ACS is conducting community demonstration projects in cancer detection, prevention, and education geared to the socioeconomically disadvantaged. The projects have completed their first year and are being evaluated.

ACS has always depended on nursing specialists to reach cancer patients and the public, but now the society is targeting primary care nurses, who may not know about ACS as a resource, said Genevieve Foley, chairman of the ACS National Nursing Advisory Committee. The primary care nurses may be school health nurses, public health nurses, occupational health nurses, and nurse practitioners.

"We are in the midst of a renaissance in ACS looking at the role of nurses and what nurses can contribute to ACS," Foley said.

ACS offers scholarships in cancer nursing for two and four year periods, many of which have gone to nurses at comprehensive cancer centers. Foley said center directors should encourage their nurses to apply. "The rate of acceptance is relatively good and [nurses] should not get discouraged if they don't get one on the first try," she said. ACS also offers professorships in oncology nursing, which provide \$25,000 a year for five years.

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Among the society's new initiatives in nursing is a set of videos, titled "Cancer and the Older Person," on care of older patients. ACS also is sponsoring a conference on cancer nursing July 25-27 in Seattle.

ACS is targeting cancers of the lung, breast, uterus, and skin for increased public education efforts. "Since 80 percent of cancer may be related to lifestyle, the aim is to make the public aware they can do something," said Marion Morra, chairman of the ACS Adult Education Committee and associate director of Yale Comprehensive Cancer Center.

In Connecticut, Morra said, public education is most effective when the centers and ACS work together. "Believe me, it's not easy. Each organization has its own identity. When the issue of funding comes up, it threatens to divide us. We've tried to be honest and open, and we sit on each other's boards and committees," she said. "The cancer patient and the community gets more out of it than if we were to go it alone."

#### **Two ACS Programs**

Two ACS programs, the Cancer Response System and Look Good...Feel Better, were also described to the centers representatives in the hope that they would find ways to use the programs.

The Cancer Response System began about five years ago as a hotline for crisis counseling of cancer patients or their families. "The society needed to be closer at hand to the public and we saw how the Cancer Information Service helped NCI get closer to the public," said Michael Herron, ACS senior vice president for communications. "We wanted to do the same thing."

However, ACS found itself in direct competition with NCI. The role of patient counselor "was being filled by NCI, so we decided to reorient CRS to risk reduction and early detection," Herron said.

Now, by calling 1-800-ACS-2345, Herron said, callers can get answers to their "everyday questions" on such topics as radon, nutrition, caffeine, sun exposure, smoking, or other cancer related items that frequently are in the news.

"The target is the person who has read something in the paper or heard the news and needs more information," Herron said. CRS has over 5,000 files, and Herron passed out copies of the service's breast cancer file, which was 12 single-spaced pages long.

ACS refers callers seeking information on cancer treatment or clinical trials to NCI, while, Herron said, NCI refers callers to ACS for general information and public education. CRS gets 170,000 calls per year, 75 percent of which are made by women aged 25-45. About 62 percent of callers are the general public, 15 percent are friends of a cancer patient, and 10 percent of calls are made by patients.

Herron said ACS "will be seeking a higher profile" for the CRS phone number through advertisements. The service was recently publicized on NBC's "Nightline" program.

"I hope you in cancer centers will say, 'Gee, we should be referring calls to ACS," Herron said, rather than spending money to set up similar services.

However, Kenneth Olden, deputy director of the Howard Univ. Cancer Research Center, noted that the CRS is not a 24 hour service and therefore, may only reach the educated middle class. He said Howard has a 24 hour phone service that does help to reach the poor.

Another program ACS sponsors that centers can use--and at no cost besides some staff time--is Look Good...Feel Better, a service for women cancer patients undergoing chemotherapy or radiation therapy.

The program was developed in conjunction with the Cosmetic, Toiletry and Fragrance Assn. and the National Cosmetology Assn. to teach women techniques to enhance their appearance.

Cosmetic companies belonging to the CTFA donate all of the cosmetics used in the program, which are provided free to cancer patients. Local cosmetologists, trained by ACS about cancer and the effects of treatment, donate their time to teach patients the techniques in a group seminar.

The program provides a "psychological boost" to patients undergoing "devastating treatment," said Diane Erdos, clinical nurse specialist at Yale Comprehensive Cancer Center.

The program also can have some benefits for the center. "It gives a more human side to your cancer center," Erdos said. "It provides an enormous service to patients. We've even done it in a bone marrow transplant unit close to discharge."

ACS estimates that the program will serve 20,000 cancer patients this year. Information on setting up the program in a center may be obtained by calling ACS (at the toll-free number above) or the CTFA at 202/331-1770.

#### View From The Centers

ACS invited six of its division directors and five cancer center representatives to discuss ways ACS and centers could cooperate. The ACS division directors said their relationships with centers in general were good, but most said that, at the very least, communication could be improved. While some of the division directors described substantial involvement with centers, others said centers do not use ACS as well as they could. As James Poppell, director of the Virginia division, put it, medical centers in that state "don't seem to be interested in us except as a source of money."

In some cases, centers conduct programs that may be unnecessarily competitive with ACS. Bill Barram, director of the Michigan division, said that not long ago, ads in Michigan for the Cancer Response Service were plagiarized by a cancer center for its own tollfree phone number.

And most of the division directors said that smaller hospitals are not very well represented on their committees.

Here's what the centers representatives had to say about ACS:

•Michael Brennan, president of the Michigan Cancer Foundation--"ACS has a particular strength with the public. There's no question of self-serving when ACS instructs people to enter protocols. The public looks at us [in centers] and wonders whether we are in some way experimentalists. ACS can be our main strength in building up the clinical trials system.

"We have a terrible problem with care of the poor in this country. Here cooperation can be undertaken wholeheartedly." ACS and hospitals could improve their relationships, he said.

•Paul Carbone, director of the Univ. of Wisconsin Clinical Cancer Center--"Medicine is a competitive environment. One thing ACS can do is provide community and statewide events so there are no market share problems. We can be used to enhance ACS education programs. We can share expenses." Wisconsin groups got together and formed a coalition of over 50 cancer and health organizations.

ACS volunteers can help centers by lobbying for expansion of state tumor registries, by working with state health department nurses to enhance health care in the state, and to conduct needs assessments of the elderly, and in cancer pain. Carbone noted that an Eastern Cooperative Oncology Group analysis found that patients referred to cancer centers are on the whole 10 years younger than the cancer patients treated at local hospitals. "The elderly are offered less than optimal treatment," he said.

ACS and centers could share information better and increase publicity for clinical trials. Wisconsin's cancer coalition supported clean air legislation, low cost mammography, cancer pain initiatives, and upgrade of the tumor registry.

"Our missions, particularly at the regional level, are

very similar and need to be coordinated. We need to have more of these meetings."

•John Durant, vice president for health affairs and director of the Univ. of Alabama (Birmingham) Medical Center--"People don't understand the power of planning. Goals are not defined, objectives are not set. More formal planning could be done [Detween centers and ACS]."

Joint fundraising can be done, Durant said. Centers receive their largest donations from individual donorsthe people who "have things named after them," while ACS targets the smaller donors.

In a state like Alabama, Durant said, the center, which gets research funds from the ACS national office, "may produce a net positive cash flow for cancer" in the state. Centers need to be told how ACS is funded and ACS executives need to be told how centers are funded and run.

Centers "are not particularly good at dealing with the poor," and need help from ACS, while ACS hasn't used university schools of public health very well.

"If we plan together, we'll come out a whole lot better," Durant said.

•Lloyd Everson, Indiana Regional Cancer Center and member of the Assn. of Community Cancer Centers--Everson noted that 60 percent of the funds raised by ACS units are returned to the community, while 40 percent are sent to the national office.

"What I keep hearing is, 'Can't we have more money coming back to our state.' I would suggest ACS look at ways dollars raised can stay within the community." The money could be spent on small efforts, not necessarily research.

ACS should take a larger role in public issues, working with groups including ACCC, Assn. for American Cancer Institutes, and American Society of Clinical Oncology, he said. And ACS could help coordinate programs at community hospitals, where programming too often is "market-driven" and may be duplicative.

► Charles LeMaistre, president of M.D. Anderson Cancer Center--Total funding for cancer research in the U.S. in 1971 was only \$271 million, LeMaistre noted. "If you think how recent it all is, it's no surprise we don't communicate well. We're going to have to have totally integrated resources."

The ACS Texas division is leading an effort "to integrate all public and private resources for the care of the cancer patient," he said. The Texas legislature is more willing to listen to a coalition of groups than single cancer centers.

"Because of the network of research driven cancer centers, we are making progress" in cancer treatment.

## Estimate For Breast Cancer Risk Rises To One Woman In Nine: ACS

The American Cancer Society last week revised its estimate for the average American woman's lifetime risk for developing breast cancer from one in 10 women to one in nine.

ACS said the increased risk reflects both a rising incidence of breast cancer and an aging population.

The society's annual publication, "Cancer Facts and Figures," estimates that this year, 175,000 women will develop breast cancer and 44,500 will die of the disease. The recent increase in incidence rates and the aging of the "baby boom" generation, pushing a large group of women into higher risk age groups, were cited as probable causes of the increased risk.

"Even though the larger population of older women can account for some of the rise in numbers, that cannot fully explain why breast cancer incidence rates are increasing in American women," said Clark Heath, ACS vice president for epidemiology and statistics. "It may be possible that factors such as increased screening, which counts cancers that may be found with mammography but may not necessarily become clinical cases for many years, are contributing to the larger numbers. Other reasons for the increase in incidence rates may include diet and delayed childbearing, and other factors not yet understood."

Heath added that, "Every American woman should consider herself at risk and should follow ACS guidelines for early detection of breast cancer."

The guidelines are monthly breast self exam for women over 20, clinical breast exam every three years for women 20-40 and annually for women over 40, baseline mammogram for women 35-39, mammograms every 1-2 years for women 40-49 and annually for women over 50.

For women diagnosed with breast cancer between 1974 through 1986, the five year survival rate was 75 percent, ACS said. For cases diagnosed with local breast cancer, the rate was 91 percent; with regional disease, 69 percent; with distant disease, 18 percent. Also between 1974-86, 49 percent of breast cancers were diagnosed in a localized stage, 40 percent in a regional stage and 7 percent in the distant stage.

"It is imperative that all aspects of this devastating problem be examined, including funnelling more money into breast cancer resaerch, bringing substandard mammography facilities up to par, and focusing on socioeconomic groups that fall through the cracks of the medical system," said ACS President Gerald Dodd.

"Cancer Facts and Figures" also estimates that,

overall, 1.1 million new cases of cancer will be diagnosed this year and that 514,000 people will die of the disease, or about 1,400 people per day. The estimates are based on data from NCI's SEER program from 1985 to 1987, the latest year for which data are available.

Following are ACS data from selected cancer sites:

►Lung cancer: An estimated 161,000 new cases in the U.S. in 1991. The incidence rate, which had been increasing steadily in men and women for several decades, has begun to decline in men from a high of 86.6 per 100,000 in 1984 to 83.3 in 1987. The incidence rate in women continues to increase, to a high of 37.7 per 100,000 in 1987. There will be an estimated 143,000 deaths in 1991. In 1987, for the first time, more women died of lung cancer than breast cancer.

▶ Prostate cancer: An estimated 122,000 new cases in 1991. About one of every 11 men will develop prostate cancer. There will be an estimated 32,000 deaths in 1991, the second leading cause of cancer deaths in men.

•Pancreatic cancer: An estimated 28,200 new cases in 1991, and 25,200 deaths. Incidence and mortality rates have been fairly stable since the early 1970s, except among black women whose rates have increased slightly.

•Uterine cancer: An estimated 46,000 new invasive cases in 1991, including 13,000 cases of cervical cancer and 33,000 cases of cancer of the corpus of the uterus. « An estimated 4,500 deaths from cervical cancer and 5,500 from endometrial cancer or unspecified uterine cancer.

•Colon and rectum cancer: An estimated 157,500 new cases in 1991, including 112,000 of colon cancer and 45,500 of rectum cancer. An estimated 60,500 deaths; 53,000 colon, 7,500 rectum.

•Oral cancer: An estimated 30,800 new cases in 1991, and 8,150 deaths.

•Bladder cancer: An estimated 50,200 new cases in 1991; 37,000 in men, 13,200 in women. An estimated 9,500 deaths.

•Skin cancer: Over 600,000 cases a year, the vast majority of which are highly curable basal cell or squamous cell cancers. About 32,000 new cases of melanoma. An estimated 8,500 deaths, 6,500 from malignant melanoma and 2,000 other.

•Leukemia: An estimated 28,000 new cases in 1991, evenly divided into acute and chronic. An estimated 18,100 deaths.

•Ovarian cancer: An estimated 20,700 new cases in 1991, and 12,500 deaths.

## Urologists Support IL-2 Approval For Kidney Cancer, Poll Finds

The nation's urologic experts strongly support FDA approval of interleukin-2 as a treatment for kidney cancer, according to a poll conducted by the National Kidney Cancer Assn.

FDA approval of IL-2 is presently "in limbo," the association said. FDA's Biological Response Modifiers Advisory Committee heard evidence last July on the effectiveness of IL-2 as a treatment for metastatic renal cell carcinoma and requested more information on the drug. Cetus Corp. manufactures IL-2.

The association said it polled 118 physicians "to provide FDA a summary of the opinions of the nation's leading cancer experts," according to a statement released with the report. "The objective is to make sure that the FDA is well informed and to help the FDA make a decision which serves the best interest of patients."

Fifty physicians responded to the survey, over 80 percent of whom have treated patients with IL-2 and have "extensive knowledge of research on IL-2," the association said.

The majority of the physician/researchers prefer IL-2 as a treatment for kidney cancer and the majority said they would prefer IL-2 as a therapy for themselves if they ever have metastatic kidney cancer.

About 24,000 new cases of kidney cancer were diagnosed last year, and about 10,000 Americans died from the disease.

"IL-2 is no panacea for metastatic kidney cancer and it has significant side effects," said Eugene Schonfeld, president of the association. "But it has proven so effective for some patients that their metastatic disease has completely disappeared, saving their lives. Moreover, there is no other drug or therapy which has demonstrated such results."

The National Kidney Cancer Assn., based in Chicago, is a nonprofit organization supported by kidney cancer patients.

## **RFA** Available

#### RFA CA-91-06

Title: Analyses and physiology of anticarcinogens in soybeans Letter of Intent Receipt Date: March 1

Application Receipt Date: April 29

NCI's Div. of Cancer Prevention and Control invites applications for grants to quantify levels of total and individual anticarcinogens in soybeans and soy products and to study their absorption and metabolism in humans.

Epidemiologic and animal studies suggests soybean rich diets may reduce cancer risk. Populations consuming predominantly plant based diets, for whom legumes frequently represent an important protein source, tend to have lower rates of several cancers than populations who rely heavily on animal products. One legume, soybeans, via a variety of soy products (tofu, miso, tempeh, soymilk, natto), is commonly consumed throughout much of East Asia where breast and colon cancer rates are low incomparison to Western countries.

Soybeans contain several classes of compounds in particularly high concentrations with demonstrated anticancer activity, such as isoflavones, protease inhibitors, phytostarole, saponins, and inositol hexaphosphate. Others may also exist. Basic research on the absorption and metabolism of these compounds in humans and accurate analytical data on the levels of these compounds in commonly consumed soy products are needed. These data will help to determine the potential impact of soybeans on cancer prevention.

The purpose of this RFA is to solicit applications from qualified investigators to quantify levels of total and individual anticarcinogens in soybeans and soy products and to study their absorption and metabolism in humans. The analytical work should focus only on those compounds in soybeans and soy products that have demonstrated anticancer activity and are unique to soybeans and soy products or present at substantially high levels (relative to other foods). Total as well as individual anticarcinogens (e.g., total isoflavones and individual isoflavones, daidzein, genistein) should be quantified. All factors potentially effecting anticarcinogen levels/activity should be considered for investigation.

For the clinical work, studies on the absorption and metabolism of compounds in soybeans and soy products with demonstrated anticancer activity are to be conducted. When feasible, dose response relationships between soy product and anticarcinogen intake and anticarcinogen levels in blood and urine, and/or feces and bile should be conducted. When available, both commonly consumed soy products as well as soybean extracts or pure soybean anticarcinogens should be studied. Both long term feeding studies, in which anticarcinogen levels in subjects consuming soy products/extracts over an extended period of time, and short term studies, in which anticarcinogen levels for a minimal period after the consumption of a single administration of soy products, extracts, or pure compounds are studied, are appropriate under this RFA.

The support mechanism for this program will be the individual research grant (RO1). 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. Approximately \$900,000 in total costs per year for 3 years will be committed to specifically fund applications that are submitted in response to this RFA. It is anticipated that 3 to 4 awards will be made.

Potential applicants are asked to submit a letter of intent and that includes a descriptive title of the proposed research, the name and address of the principal investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application is being submitted. This letter should be received no later than March 1. For the full RFA document, contact Dr. Mark Messina, Program Director, DCI, DCPC, 9000 Rockville Pike, EPN 212C, Bethesda, MD 20892, Phone 301-496-8573.

### **Program Announcement Available**

#### PA-91-16

Title: Surgical oncology

Application Receipt Dates: June 1, October 1, February 1

The treatment of cancer has evolved as a multidisciplinary effort involving (but not limited to) the disciplines of surgical oncology, medical oncology, pediatric oncology, and radiation oncology. The disciplines of medical oncology, pediatric oncology, and radiation oncology have developed strong cadres of academic investigators while academic development in surgical oncology has not kept pace. It is believed that surgical oncology is not keeping pace because of an insufficient number of surgical oncology research programs and an insufficient number of surgeons undertaking research related to cancer.

Continued development of superior multidisciplinary treatment of cancer is the long range objective of the Div. of Cancer Treatment and the attainment of the goal requires sufficient academic strength in investigative surgical oncology.

DCT is seeking applications for research grants (RO1, R29, PO1) concerned with research in surgical oncology. Examples of relevant studies include mechanisms of metastases, effect of surgery on tumor cell kinetics, and tumor host responses to surgery. Preclinical and clinical research is encompassed in this program.

Categories of research include (but are not confined to) the following: (1) Pathophysiologic studies related to surgery and cancer in laboratory models or in humans; (2) Laboratory and clinical studies that examine the biochemical, cytokinetic, immunological, or nutritional effects of cancer surgery; (3) Therapeutic studies in which surgery or a surgical question is the primary treatment modality; (4) Novel immunotherapy procedures such as assessment of specific lymphokines, stimulated cells, and autologous vaccines which require surgical input; (5) New surgical techniques relevant to staging or care of patients; (6) Studies to identify prognostic factors relevant to the treatment of cancer patients; (7) Surgical supportive care; (8) Regional chemotherapy or hyperthermia or radiation in which a surgical approach to the treatment site is a major aspect of the procedure. This Program Announcement is not restricted to the areas of surgical oncology research listed above.

The total project period for applications submitted in response to the Program Announcement should not exceed five years. This is a continuous announcement until retracted. Generally future unsolicited competing renewal applications will compete as research project applications with all other investigator initiated applications. Applications will compete for available funds with all other approved applications.

Applications may be submitted by public or private nonprofit or for profit organizations such as universities, colleges, hospitals, laboratories, units of state or local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. 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. 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.

Applicants are encouraged to contact Dr. Roy Wu, Cancer Therapy Evaluation Program, Div. of Cancer Treatment, NCI, EPN Room 734, Bethesda, MD 20892, phone 301/496-8866.