

Pediatric Oncology Groups Plan To Merge, Citing Greater Cost Efficiencies, Leverage

Last month, the leaders of four pediatric oncology groups gathered at a conference center at O'Hare Airport in Chicago. The objective of the meeting was to make it easier for the groups to work together.

They met the objective. Swiftly, spontaneously, unexpectedly, at the outset of the meeting, the heads of the four groups resolved to form a single pediatric clinical trials organization.

"The timing was absolutely right," said Sharon Murphy, chairman of the Pediatric Oncology Group. "We have endorsed this agreement to

(Continued to page 2)

In Brief:

Broder Resigns From IVX; Bishop To Receive Public Service Award; Johnston Rejoins NIAID

SAMUEL BRODER has resigned as senior vice president, research and development, for IVX Bioscience Inc., formerly known as IVAX Corp., the company announced. Broder, who joined IVAX in 1995 after serving six years as NCI director, was leaving the Miami-based pharmaceutical firm to "pursue other interests," the company said in a July 31 statement. "Sam Broder has made important contributions during his tenure with IVX Bioscience, and the whole IVX Bioscience family wishes him well," **Phillip Frost**, the company's chairman and CEO said. "We hope in the near future to announce a successor with broad-based pharmaceutical industry experience." . . . **J. MICHAEL BISHOP** was named the recipient of the Public Service Award of the American Society for Cell Biology. Bishop, chancellor of the University of California, San Francisco, and chairman of the National Cancer Advisory Board, will receive the award at the society's annual meeting in San Francisco in December. . . . **MARGARET (PEGGY) JOHNSTON** has been named assistant director for HIV/AIDS vaccines at the National Institute of Allergy and Infectious Diseases by NIAID Director Anthony Fauci. Johnston will also assume the position of associate director of the vaccine and prevention research program in the NIAID Division of AIDS. Johnston previously had been deputy director of the Division of AIDS, leaving in 1996 to become vice president for scientific affairs of the International AIDS Vaccine Initiative. . . . **ALLEN BOLTON** has rejoined the University of Alabama at Birmingham Comprehensive

(Continued to page 8)

Cooperative Groups: Decision To Form One Group Seemed "So Obvious"

. . . Page 4

Tobacco Control: Cigarette Price Hikes Reduce Smoking, Study Confirms

. . . Page 5

Cancer Policy: EMFs "Possible" Carcinogen, Panel Says; Plans Public Hearings

. . . Page 6

Funding Opportunities: RFAs For Mouse Models Consortium, Urology Research Centers

. . . Page 7

"Nuptial Agreement" Months Away For Pediatric Groups

(Continued from page 1)

do it once right, because that's where we would want to converge ultimately anyhow."

The decision to merge was made at the Pediatric Intergroup Summit July 17, and announced by Murphy at the NCI Clinical Trials Review Implementation Committee meeting July 31.

Now the groups will face the double challenge of designing a new governance system while keeping the existing four systems functional.

"We have just announced our engagement; it's months away from a nuptial agreement," Murphy said to the Implementation Committee. "We can't just put it all together, nor do we have a clear idea of how it's going to come together. This was a spontaneous decision without a lot of clear step-by-step implementation."

Advocates, clinical investigators, and NCI officials are showing no sign of shedding tears for the old, thoroughly Balkanized schema of pediatric cooperative groups competing with each other while studying cancer in children.

NCI "Pleased" With Announcement

NCI Director Richard Klausner said the Institute is "fully supportive" of the merger. "We are very *pleased with* the announcement, and NCI

will be fully supportive of both the transition and the successful functioning of the new organization," Klausner said to **The Cancer Letter**.

"This is a very exciting opportunity to create a national strategy for pediatric cancer patients," Susan Weiner, executive director of the Children's Brain Tumor Foundation, said to **The Cancer Letter**. "The country needs to have the capability of assessing the therapeutic value of new molecular agents quickly, and a single cooperative group structure will provide a more efficient way of doing that, so the time for getting pediatric cancer drugs to market would be much shorter."

Currently, institutions that conduct pediatric clinical trials belong to one of two groups, POG or the Children's Cancer Group. Investigators at these institutions collaborate in studies conducted by two additional groups, the Intergroup Rhabdomyosarcoma Study Group and the National Wilms' Tumor Group.

The four groups will begin to form a single administrative structure. "We are going to need time to develop this single organization, we are going to maintain what we are doing now, our 8,000 to 9,000 protocol entries per year," Murphy said at the Implementation Committee meeting. "That can't stop. We have to maintain our parallel systems for the time being, as we gradually begin to create our own Clinical Trials Support Unit."

Incentive for Sponsors: Six Months of Exclusivity

The four groups had powerful incentives to merge.

To begin with, the merger could allow the groups to leverage their resources at a time when traditional sources for clinical research have been drying up.

In recent years, managed care organizations have been cutting into the funds institutions used to finance research. NCI support, too, has been insufficient to meet the needs of a system that has been able to place the majority of patients on clinical trials and produce cure rates that are significantly higher than those in adults.

Pediatric and adult cooperative groups are funded at about 60 percent of the level recommended by peer review.

In addition to leveraging dwindling resources, elimination of duplication in the pediatric trials system could allow the groups to make better use of a financial windfall that is expected to follow the

THE **CANCER**
LETTER

Member, Newsletter
Publishers Association

World Wide Web: [http://
www.cancerletter.com](http://www.cancerletter.com)

Editor & Publisher: Kirsten Boyd Goldberg

Editor: Paul Goldberg

Editorial: 202-362-1809 Fax: 202-362-1681

PO Box 9905, Washington DC 20016

E-mail: kirsten@cancerletter.com or paul@cancerletter.com

Customer Service: 800-513-7042

PO Box 40724, Nashville TN 37204-0724

Subscription \$275 per year US, \$295 elsewhere. ISSN 0096-3917.
Published 48 times a year by The Cancer Letter Inc. Other than "fair use" as specified by U.S. copyright law, 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 and \$100,000 damages.

Founded Dec. 21, 1973 by Jerry D. Boyd

new FDA policy of extending exclusivity for drugs that are used for pediatric indications.

Under the FDA Modernization Act signed into law last November, any drug that has been tested in pediatric populations would qualify for an additional six months of market exclusivity.

Thus, a drug that has a five-year chemical entity exclusivity would be protected for five and-a-half years from generic competition for drugs that had been studied in pediatric populations. Additional six-month extensions are possible for drugs that undergo *multiple pediatric studies*. Exclusivity would be extended for all indications.

Pediatric studies would be conducted in response to a "Written Request" issued by the agency. FDA guidance to industry on pediatric studies is available on the agency web site, <http://www.fda.gov/cder/guidance/index.htm>.

The regulation has increased the pharmaceutical industry's interest in pediatric research, said Archie Bleyer, chairman of the Children's Cancer Group. "We have seen a clear-cut effect of the regulation," Bleyer said to **The Cancer Letter**. "Pharmaceutical companies have been coming to us, instead of the reverse. I have never seen this before in the 27 years I have been treating children with cancer."

Formation of a single cooperative group would make it easier and more cost-effective for the industry to conduct trials, Bleyer said. "Suddenly, we are able to double the number of institutions conducting our trials, which means that we should be able to cut in half the time it takes to conduct a trial."

While in some instances a mega-group can function more efficiently than multiple groups, large organizations have been known to stifle new ideas, cautioned Stephen Carter, a pharmaceutical industry consultant.

"If I want to get trials done, I would sometimes find it easier to work with multiple groups than with one group," Carter said to **The Cancer Letter**. "What if there is only one group, and they have already agreed to do someone else's study? Where will I go? What if you have drug X, and you find that the group is committed to drug Y? I think there ought to be sensitivity to the fact that sometimes there should be more than one study going on in these populations," Carter said.

Bleyer agreed that mechanisms for testing competing ideas should be built into the structure of the new pediatric group. "I am not going to stand for

the new entity that cannot assure a healthy competition of ideas and treatments," Bleyer said. Since investigators and groups in pediatric oncology have been competing for years, the emerging structure will have to find a way to incorporate this competition into its peer review structure, Bleyer said.

A Demographic Necessity

The proposed merger is a demographic necessity, group leaders say.

"When I started, when Sharon started, in the early 70s, the cure rates were low enough that it was much easier to work in smaller groups," William Crist, chairman of the Intergroup Rhabdomyosarcoma Study Group, said at the Implementation Committee meeting.

In recent years, cure rates in children's cancers have increased dramatically.

"When you start with an 80 percent cure rate and want to show it's 90, you need to do intergroup studies across the board in addition to the other economies of doing business in a streamlined, uniform fashion," Crist said at the Implementation Committee meeting.

"What's the point of having multiple groups, if we require all the patients in the U.S., or North America, or the developed world to do the studies?"

Currently, the pediatric groups put between 8,000 and 10,000 patients on clinical trials. This means that 50 percent to 60 percent of pediatric cancer patients under 15 receive care under clinical trials. To keep them on trials, the groups frequently have to convince insurance companies to reimburse patient care costs.

"This will enhance our ability to work with payers, because there will be a seamless, single organization for them to work with," Murphy said.

CCG Chairman Bleyer said the new group may be able to raise clinical trials participation to 85% among children under 15. "Together, we will be able to study less common cancers we were unable to study alone," Bleyer said. These would include germ cell tumors, retinoblastoma and histiocytosis. Together, these three tumors account for about 10 percent of cancers in children.

"There are also some stages of common diseases that we are unable to study alone," Bleyer said. "Together we will be able to study the more common diseases more completely.

"Our studies will be not only more efficient,

more rapid, but also more robust. They will be able to answer more important questions, such as whether high-dose chemotherapy with autologous rescue is of benefit in young children with brain tumors," Bleyer said.

Greater efficiency could allow the groups to close what is known as "the adolescent gap," by enrolling a greater number of 15- to 19-year-old patients. Currently, only 5 percent to 10 percent of patients in this age group are enrolled in trials.

"The new group will be in a better position to enforce rational patterns of care for children, adolescents, and young adults, and to obtain funding for patient follow-up," said Grace Powers Monaco, an advocate for pediatric cancer patients and director of Bethesda-based Medical Care Ombudsman Program.

"United, these groups may be in a better position to find sources of funding for studies of long-term effects of therapies that had ensured these spectacular cure rates in pediatric oncology," Monaco said.

Crist agrees that patient follow-up and quality of life research will have to expand.

"You can look at 80 percent survival and say, my God, you really did the job," he said. "But you have to remember that these kids are being treated with very toxic chemicals, they are getting second problems of all types that we as pediatricians worry about a great deal.

"So there is at least as much ahead to do as we have done in the past, and I think that if we don't go to this format, we are not going to do it nearly as well," he said. "This new mechanism to do our work and do it efficiently is just past its time, and it needs to be implemented quickly, and we need a lot of support to do it quickly."

In response to the funding pressures over the past few years, the clinical trials cooperative groups have begun to collaborate extensively in dealings with insurers and with NCI.

In 1996, POG and CCG, working with the Blue Cross and Blue Shield Association, formed a Pediatric Cancer Network to provide subscribers to the Blues' health plans better access to pediatric cancer treatment and clinical trials (**The Cancer Letter**, April 19, 1996).

At the same time, other cooperative groups began working together to negotiate with insurers, and last year, six of the groups formed the Coalition of National Cancer Cooperative Groups (**The Cancer**

Letter, Nov. 14, 1997).

Also last year, several cooperative group chairmen, including Bleyer, served on a panel that, in a report to NCI, urged greater uniformity of data collection and informatics among the cooperative groups and cancer centers (**The Cancer Letter**, Oct. 3, 1997).

While calling for increased funding for the cooperative group program, the report by the NCI Clinical Trials Program Review Group also suggested that the clinical trials system could be more cost-effective if NCI were to fund fewer cooperative groups. However, the panel did not make a recommendation about the structure of the group system. The Implementation Committee is studying ways to implement the recommendations of that report.

Old System Meets Unexpected, Peaceful End

Murphy's description of the meeting that relegated the old pediatric cooperative group system to the dustbin suggests that the system died because it was ready to.

As she began the Chicago meeting, Murphy wrote the names of the four cooperative groups in the center of a blackboard. Then, following the perimeter of the board, she wrote in the relationships that each of these groups manages separately.

The groups had separate dealings with federal government agencies, advocacy groups, the pharmaceutical and insurance industries.

"Then I [drew] a box around [the names of the groups], and said, 'What do you all think?'"

That question was all that was required to bring about a proposal to form a single group. "So we did it, and we spent a day-and-a-half thinking about the implications," Murphy said.

Bleyer said he, too, was pleasantly surprised by the resolution. "No one had any preconceptions about it," Bleyer said. "Although we had been wondering about it for years, it seemed so obvious when the construct was put on the board."

It's not clear how much time would be required for the groups to form a single administrative structure, Murphy said.

"The biggest issue we are going to have to address is that we will have to create a new governance and a new organization with a constitution and bylaws," Murphy said. "We are going to involve all members of our organizations to get a buy-in from everybody.

"And then, after there is a nominating committee and a constitutional systems in place, the executive committee chairs will step down, and we will get a new leadership group and a new chair in place," Murphy said.

Two Pilot Studies For Adult Groups?

The pediatric groups' announcement was made at the time when NCI and cooperative groups are rethinking the clinical trials system.

The committee charged with making the final proposal to the NCI Board of Scientific Advisors will meet one more time, on Sept. 9, to complete the recommendations that will be submitted to the BSA Sept. 22.

At this writing, the Implementation Committee is considering proposals for two demonstration projects that could be carried out concurrently. One of the projects was developed by the NCI Cancer Therapy Evaluation Program, and the other was proposed by chairmen of the cooperative groups (*The Cancer Letter*, June 12, 1998).

Both proposals have an important common feature: NCI's planned Cancer Trials Support Unit, an administrative structure that will be used to accrue patients and offer regulatory, educational and informational support to investigators working in lung, GU and breast cancer trials. Accrual of patients for breast cancer trials will continue to be carried out through existing intergroup mechanisms, but other support functions will be handled by the CTSU.

A contract or cooperative agreement for the CTSU is expected to be awarded before Oct. 1, 1999, and the unit would become functional before the year 2000.

The demonstration project proposed by CTEP will evaluate all phase III GU and lung trials. The group chairmen's plan presented at the Implementation Committee meeting July 31 proposed to evaluate intergroup trials in GI cancers, acute leukemia and breast cancer. However, discussion indicated that breast cancer trials may be excluded from the proposed demonstration project.

The major difference between the plans lies in their peer review structures. Under the CTEP plan, all phase III trials would go through a newly designed peer review by a proposed "disease-specific concept review committee."

Under the group chairmen's plan, cooperative groups whose treatment committees had received "excellent" to "outstanding" review marks would

be exempted from submitting their phase II and phase III intragroup trials to CTEP review in cases where the group holds the IND for the treatment.

The chairmen's plan is yet to define the peer review mechanism for intergroup studies.

The pilot projects would need to be carried out with additional funds, said John Glick, co-chairman of the Implementation Committee.

Tobacco Control: Cigarette Price Increases Reduce Smoking, Study Finds

A study by the Centers for Disease Control and Prevention shows that lower-income, minority, and younger populations are more likely than other groups to quit or cut down on their smoking in response to cigarette price increases, resulting in considerable health benefits.

According to the CDC analysis of 14 years of health data, smokers with family incomes equal to or below the study sample median (\$33,106 in 1997 dollars) were more likely to respond to price increases by quitting than smokers with family incomes above the median.

"All experts agree that one of the most important steps we can take to reduce smoking is to raise the price of a pack of cigarettes significantly," said HHS Secretary Donna Shalala, in a July 30 statement. "To make a lasting reduction in tobacco use, Congress must enact bipartisan, comprehensive tobacco legislation that is based on the President's five key principles. These include a significant price increase, as well as full FDA authority to regulate tobacco products, getting tobacco companies out of the business of marketing to children, furthering public health research and goals, and protecting tobacco farmers and their communities."

Controlling for factors including income and education, blacks are twice as responsive as whites to price increases and Hispanics are even more price responsive. These differences by race are not fully understood, but provide reassurance that cigarette price increases would lower smoking rates and enhance public health outcomes especially for minorities and ethnic groups, CDC said.

The study also found that, even after controlling for income and other variables, Hispanic and black smokers were much more likely than white smokers to quit in response to price increases. For example, among younger smokers (age 18-24 years), the study

estimates that a 10 percent price increase would result in about one-quarter of Hispanics who smoke quitting altogether, an approximately 10 percent decline among blacks, and a nearly 1 percent decline among whites.

For Hispanics and blacks, the effect of price increases on quitting declines considerably with age.

“Bad nutritional habits, the use of tobacco, the lack of physical activity and other risky behaviors are increasingly threatening the health of America’s minority communities,” said Surgeon General David Satcher. “This report underscores the need for all of us to focus on the issue of tobacco use, in particular. Churches and local community groups are in a unique position to be the agents of preventive medicine, not only within their congregations and membership but also throughout the neighborhoods in which they reside.”

The study analyzed data from 14 years of the National Health Interview Survey, which is administered to people age 18 and over. Thus, the study could not estimate the effect of price increases on smoking among underage youth. However, previous studies have shown that teenagers are more price-sensitive than adults.

“This study shows that in addition to prevention programs aimed at keeping teens from beginning to smoke, we also need cessation programs for adults over age 40 who are addicted and are most likely to continue *smoking* and paying the higher cigarette prices,” said Michael Eriksen, director of CDC’s Office on Smoking and Health.

Other measures recommended by CDC for reducing smoking among youth and adults include enforcing minors’ access laws, restricting smoking in public places, restricting tobacco advertising and promotion, school based education, and conducting counter-advertising campaigns.

Cancer Policy:

EMFs “Possible” Carcinogen, Panel Finds; Vote Is Divided

The National Institute of Environmental Health Sciences released the full text of a report from scientists concluding, by a divided vote, that electrical and magnetic fields around power lines, home wiring, home appliances and some industrial uses should be regarded as a “possible” human carcinogen that needs further research.

However, in a July 30 statement, the Institute

asked for additional public and scientific comment before it prepares its own report to Congress.

The panel of experts split, with 19 voting that it was a “possible” human carcinogen while 10 other experts abstained or found the data unconvincing or negative as to EMF’s possible carcinogenicity. None of the panel voted for the stronger categories of “known” or “probable” human carcinogen.

Panel chairman Michael Gallo, of the University of Medicine and Dentistry of New Jersey-Robert Wood Medical School commented that the report does not suggest that the risk that may be associated with EMF is high, compared to many other public health risks.

The majority view was based on population studies, and was made in the face of the panel’s finding that data from recently concluded animal and other laboratory studies failed to support such a link.

The conclusions of the scientists’ review were announced June 24, but the 508-page report of the review became available July 30, along with a request for comment. The report and *public comments* will be submitted to Congress later this year.

Public comment on the report will be accepted until Oct. 9. In addition, four public hearings have been scheduled as follows:

—Tucson, AZ, Sept. 14 and 15, at the Inn Suites, 475 Granada Ave.

—Washington, DC, Sept. 28, at the Ronald Reagan Trade Center, 1300 Pennsylvania Ave. NW.

—San Francisco, CA, Oct. 1, at the regional EPA office at 75 Hawthorne St.

—Chicago, IL, Oct. 5, at the University of Chicago’s Gleacher Center, 450 N. Cityfront Plaza Drive.

All the sessions except the ones in Tucson will begin at 3 p.m., with late registration beginning an hour before the meeting. The sessions are planned to end at 8 p.m. The public comment sessions in Tucson will begin at 1:30 p.m. and end at 5 p.m.

To register to *speak*, *members of the public* should provide name, affiliation, mailing address, phone, fax, email and sponsoring organization (if any) to EMF/RAPID, Post Office Box 12233, NIEHS Mail Drop EC-16, Research Triangle Park, NC 27709 or by fax to (919) 541-0144.

Written comments may also be sent to the same address (by Oct. 9) and the full scientific report or a non-technical summary may be requested by writing to the same address.

“Public and scientific comment is important to

us as we prepare our own report on the research, as mandated by Congress when it began a six-year program of accelerated studies to try to resolve this issue," NIEHS Director Kenneth Olden said.

Olden said concern over the possible effects of electrical and magnetic fields was set off by a 1979 Denver study which appeared to show that children with leukemia were more likely to have resided within 131 feet of a power line than other children.

More than 13 other similar epidemiological studies have subsequently been carried out to test *this hypothesis, with mixed results*. But the scientific panel found there is also some data suggesting adults in electricity-intensive industries such as aluminum manufacture may have a slightly elevated risk of chronic adult leukemia.

Funding Opportunities:

RFAs Available

RFA CA-98-013

Title: **Mouse models of human cancers consortium**

Letter of Intent Receipt Date: Dec. 17

Application Receipt Date: Jan. 21

NCI invites cooperative agreement and NIH intramural applications from groups of investigators who are capable of, and interested in, becoming components of the NCI Mouse Models of Human Cancers Consortium. The purpose of this consortium is to accelerate the pace at which mice with heritable malignancies that are accurate, reproducible models of human cancers are made available to the research community for further investigation or application.

NCI will select as components of the Consortium groups of investigators whose scientific and technical expertise will enable them to derive the models, characterize them thoroughly, and validate them for various aspects of basic, developmental, or applied cancer research. The approaches used for generating, characterizing, and validating the mice for cancer research purposes will reflect the blend of experience and creativity of the consortium component groups, and will be originated by these investigators. They will contribute to the consortium their collective knowledge of mouse genetics, experimental genetic manipulation of mice and phenotypic and genotypic analysis of the resulting strains, mouse genomics, animal husbandry, mouse and human cancer pathology, basic studies of human malignancies, small animal imaging technologies, and the clinical properties of human cancer that inform the design of therapy, prevention, and early detection strategies.

Through formation of the consortium, the component groups will have access to resources, information, technologies, ideas, and expertise which are

beyond the scope of any single research team. The ultimate goals of the consortium are to choose which existing mouse cancer models to characterize fully for their relevance to human cancer, or which new models to derive de novo and to characterize fully when no model exists for a given malignancy, and to define the standards by which to validate the models for their relevance to human cancer biology and for testing therapy, prevention, early detection, or diagnostic imaging strategies. As the models are developed and validated, NCI will provide the mechanism to disseminate the models and information related to them to the research community.

The funding instrument to be used for non-NIH applicants will be a cooperative agreement (U01). Funding for NIH intramural applicants will be derived from existing intramural resources. NCI anticipates funding up to six U01 awards for project periods of five years. U01 application budgets may not exceed \$500,000 direct costs in the first budget period. In addition, NCI anticipates incorporating up to two NIH intramural projects as components of the consortium.

Inquiries: Cheryl Marks, Div. of Cancer Biology, NCI, Executive Plaza North, Room 501, Bethesda, MD 20892-7381, phone 301-435-5226, fax 301-496-8656, email cm74v@nih.gov.

RFA DK-98-018

Title: **Urology Research Centers**

Letter of Intent Receipt Date: Oct. 20

Application Receipt Date: Nov. 20

This RFA invites investigators to submit research grant applications for the George M. O'Brien Research Centers Program. The emphases for this program are to (1) attract new scientific expertise into the study of the basic mechanisms of urological diseases *and disorders*; (2) encourage multidisciplinary research focused on the causes of these diseases and disorders; and (3) extend the development of innovative clinical and epidemiologic studies of the causes, therapy and possible prevention of urological diseases and disorders.

It is anticipated that extensive collaboration will be required between individuals in the clinical and basic sciences, including for example investigators with training and expertise in cell biology, molecular biology, immunology, genetics, epidemiology, biochemistry, physiology, and pathology. An intent of this RFA is to attract new investigators not active in this field and to explore new basic areas that may have clinical research applications. Individual institutions with both basic and clinical research capabilities are eligible to apply. Interinstitutional collaborative research arrangements are appropriate and encouraged. Coordination for such arrangements must be evident and clearly meaningful and appropriate for the research proposed.

NCI plans to provide support for this initiative in the area of prostate cancer. Studies to be supported may

include the full range from laboratory to clinical investigations encompassing biology, etiology, detection, diagnosis, treatment, prevention and control. Of particular interest is multidisciplinary research that links basic research to applied settings involving patients and populations.

Support will be through the NIH specialized center (P50) award. NIDDK and NCI expect to award one center grant for research into urologic disorders in fiscal year 1999. The anticipated award is for five years. Total amount of available funds is anticipated to be no more than \$725,000 per year. No applicant may request more than \$750,000 in total costs including both direct and indirect costs in the initial budget period. A standard escalation factor may be used for subsequent budget periods.

Letters of intent and requests for copies of the complete RFA may be sent to Ann Hagan, Div. of Extramural Activities, National Institute of Diabetes and Digestive and Kidney Diseases, 45 Center Drive, Room 6AS-37F-MS-C 6600, Bethesda, MD 20892-6600, phone (301) 594-8885, fax (301) 480-3505.

Inquiries regarding cancer related programmatic issues may be directed to Jorge Gomez, Office of Centers, Training and Resources, ODDES, National Cancer Institute, Executive Plaza North, Suite 512, Bethesda, MD 20892, phone (301) 496-8528, email jg1w@nih.gov.

Program Announcement

PA 98-092

Title: **Shared Resources for Scientists Outside NCI Cancer Centers**

Letter of Intent Receipt Date: Oct. 9

Application Receipt Date: Nov. 13

The objective of this program announcement is to provide groups of six or more NCI funded investigators in institutions that do not have NCI funded cancer centers with additional shared resource support. The resource related support grants mechanism (R24) will be used. Approximately \$3 million total cost will be available for the first year, which should fund 10-15 resource related grants. The funds requested should be based on the requirements of the project and the requested costs should be fully justified. NCI direct cost support will be limited to \$200,000 for each application. For projects whose costs exceed \$200,000, the availability of the necessary additional institutional or other support must be documented in a letter of commitment from the applicant institution or from another funding source.

An institution can submit more than one application, but the sum of resource support requested cannot exceed 10% of its NCI sponsored direct cost research base (all grant and contract mechanisms), as derived from NCI's financial data base. If more than one resource grant is submitted, each must have a different PI and provide substantially different products or services. While the

same six NCI funded users can be listed for more than one resource, their need for access to each resource must be clearly justified. This cap applies only to annual regular operational costs. One time purchase of equipment as an integral part of a resource will not count against the cap.

Funds must be requested in modules of \$25,000 (direct cost) and no more than eight modules (\$200,000 direct costs) per year may be requested. No escalation is provided for future years, and all anticipated expenses for all years of the project must be included within the number of modules being requested. Only limited budgetary information will be required and any budget adjustments made by the initial review group will be in modules of \$25,000. Instructions for completing the biographical sketch have also been modified as part of the initial application.

The letter of intent may be sent to and copies of the program announcement obtained from Roger Aamodt, Div. of Cancer Treatment and Diagnosis, NCI, Executive Plaza North, 6130 Executive Boulevard, Room 700, Bethesda, MD 20892-7399; or Rockville, MD 20852 (for express/courier service), phone (301) 496-7147, FAX (301) 402-7819.

In Brief

Hartinger Promoted At NCI; New Appointments At CINJ

(Continued from page 1)

Cancer Center as executive administrator, succeeding **Larry Williams**, who resigned after 10 years to join the Hollings Cancer Center in Charleston, SC. Bolton was director of community affairs and development at UAB from 1992-94, when he left to head the Greater Dallas Injury Prevention Center in Texas. . . **JOHN HARTINGER** was appointed assistant director for financial management at NCI. Hartinger was chief of the Financial Management Branch. In the new position, Hartinger will oversee the FMB as well as the Extramural Financial Data Branch. The two branches form a new Office of Financial Management, which reports to NCI Director Richard Klausner. . . **CANCER INSTITUTE** of New Jersey has made the following new appointments: **Parvesh Kumar**, chairman of radiation oncology at St. Peter's Medical Center and at CINJ, as well as for UMDNJ-Robert Wood Johnson Medical School; **Edmund Lattime**, associate director for education and training, and director of surgical oncology research at the medical school; and **David August**, acting director of surgical oncology.