

## Cancer Groups Endorse Pazdur As Head Of FDA's Consolidated Oncology Office

*By Paul Goldberg*

Responding to controversies over drug safety and stifling of internal critics, FDA has vowed to make itself more transparent.

Now, the agency finds itself under pressure from the cancer groups and the staff of its own oncology drug division to name Richard Pazdur to the top job at the new Office of Oncology Drug Products.

So far, the selection process has had at least the appearance of transparency and involvement of oncology experts from outside the agency. As the field has narrowed to five candidates, FDA-watchers are looking  
(Continued to page 2)

### In Brief:

### Longtime Hutchinson Supporter Provides \$15 Million To Center Without Restrictions

**FRED HUTCHINSON Cancer Research Center** received the single largest private gift in the center's history, a \$15 million donation from Robert Arnold, retired banking executive, Seattle native and longtime supporter of the center, said **Lee Hartwell**, center president and director. The gift is unrestricted. "Whether it's recruiting the best scientists or supporting innovative directions in research, Bob's generosity will have a major impact on our work," Hartwell said. The Public Health Sciences Division facility will be named the Robert M. Arnold Building at a ceremony this spring. . . .

**M.D. ANDERSON Cancer Center** has renamed its pediatric program The Children's Cancer Hospital at the University of Texas M.D. Anderson Cancer Center. The new name reflects the range of clinical and support services offered through the outpatient clinic, inpatient hospital unit, and social and recreational facilities, the center said. The name brings together programs and care of the George E. Foreman Pediatric and Adolescent Inpatient Unit, the Robin Bush Child and Adolescent Clinic for outpatient visits and Kim's Place, an outpatient retreat for vocational training, education and recreation. . . .

**UNIVERSITY OF PENNSYLVANIA School of Medicine** was selected for membership of the NCI Mouse Models of Human Cancers Consortium. The research groups comprising the MMHCC at 24 sites connect more than 50 institutions in the U.S. and abroad and focus on mouse models for cancers of organ systems including prostate, breast, lung, ovary, skin, colon, brain, and the blood and lymph systems. **Lewis Chodosh**, vice chairman, Department of Cancer Biology, associate investigator, Abramson Family Cancer Research Institute, and program leader of the Breast Cancer Program at the Abramson  
(Continued to page 8)

FDA Oncology Office:  
Crawford Testimony  
In 2002 Promised Job  
To Richard Pazdur  
... Page 4

NCI Programs:  
CCR Director Barrett  
Leaves For Novartis,  
Karen Antman Named  
Provost, Dean At BU  
... Page 5

NCI, FDA Form Program  
To Train Fellows  
In Research, Review  
... Page 6

NCI Software Available  
For Sharing Data  
From Microarrays  
... Page 6

Funding Opportunities:  
Program Announcement,  
RFPs Available  
... Page 7

## Five Candidates In Running For FDA Oncology Position

(Continued from page 1)

attentively at the manner in which the final decision would be made, who would get to decide, and on what basis.

The pressure to promote Pazdur from his current job as director of the Division of Oncology Drug Products to the office-level position is unusual, if not unique, in the agency's history. The American Society of Clinical Oncology and the National Coalition for Cancer Survivorship submitted letters in support of his candidacy. Also, 43 employees of the oncology division—about 90 percent of Pazdur's staff—submitted a petition urging the agency to promote him.

"Since his decision to join FDA five years ago, Dr. Pazdur has been the clear intellectual leader for FDA's oncology program, not just with respect to review of new drugs but also in the development of oncology policy and outreach to the oncology community beyond the agency," ASCO President David Johnson wrote in a letter to FDA. "We are well acquainted with the qualities that Dr. Pazdur has brought to his current post as division director and believe he is by far the best situated to carry forward and expand the successes of his current tenure into the newly established Office of Oncology Drug Products."

More than a personnel decision is at stake, Pazdur's supporters say. For years, ASCO, NCCS, and

the Cancer Leadership Council, a patient-run group that includes many cancer organizations, have urged FDA to consolidate all its oncology units and place them in a single administrative structure managed by an oncologist.

The movement gained momentum—and a Congressional mandate—in the course of a Congressional investigation of FDA's handling of the application for approval of the ImClone Systems Inc. drug Erbitux.

In June 2002, during the first of the ImClone hearings by the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, Pazdur's responses to questions focused the attention of the panel on inconsistencies in FDA's handling of applications for the approval of drugs and biologics.

"[The] subcommittee learned from the testimony of Dr. Richard Pazdur... that there appears to be a different and better approach to the expedited review of cancer drugs at [Center for Drug Evaluation and Research]," Billy Tauzin (R-La.), then chairman of Energy and Commerce, and John Dingell (D-Mich.), ranking minority member, wrote in a June 27, 2002, letter to then FDA Acting Commissioner Crawford (**The Cancer Letter**, July 5, 2002).

At an October 2002, hearing of the subcommittee, Crawford at least partially agreed with that assessment and pledged that the FDA cancer programs would be consolidated into a unit directed by Pazdur (**The Cancer Letter**, Oct. 18, 2002). An excerpt from Crawford's testimony appears on page 4.

Last week, Crawford was nominated for the post of FDA Commissioner. The appointment is subject to Senate confirmation.

Three years ago, Crawford envisioned that the oncology divisions of CDER and Center for Biologics Evaluation and Research would merge their day-to-day operations. "I decided that the therapeutic biologic review could be handled with less duplication of effort and greater consistency if it was integrated into similar drug review functions that reside in [Center for Drug Evaluation and Research]," Crawford said in an announcement Sept. 8, 2002 (**The Cancer Letter**, Sept. 13, 2002).

Crawford's sworn testimony and announcement notwithstanding, his plan ran into stiff internal opposition, sources said. Though the biologics division that reviewed Erbitux was moved from CBER to CDER, the two units remain separate. On the FDA organizational schema, the divisions go through separate chains of command and ultimately report to John Jenkins, director



Member,  
Newsletter  
and Electronic  
Publishers  
Association

**Editor & Publisher:** Kirsten Boyd Goldberg

**Editor:** Paul Goldberg

**Editorial Assistant:** Shelley Whitmore Wolfe

**Editorial:** 202-362-1809 **Fax:** 202-318-4030

**PO Box 9905, Washington DC 20016**

Letters to the Editor may be sent to the above address.

**Customer Service:** 800-513-7042

**PO Box 40724, Nashville TN 37204-0724**

Customer service FAQ: [www.cancerletter.com](http://www.cancerletter.com)

Subscription \$335 per year worldwide. ISSN 0096-3917. Published 46 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, photocopying, or facsimile) without prior written permission of the publisher. Violators risk criminal penalties and damages.

Founded Dec. 21, 1973, by Jerry D. Boyd.

of the Office of New Drugs.

As the agency developed a gradual approach to consolidation, Friends of Cancer Research, a Washington group that works closely with the agency, advanced an alternative history, tracing the merger to a series of meetings of an "NCI-FDA task force" (**The Cancer Letter**, June 4, 2004).

The new office would be formed following FDA's move to a new campus in White Oak, Md. The office would consolidate cancer drugs and biologics, but not therapeutic vaccines. Its director would have signatory authority over cancer drugs, but would report to a higher-ranking administrator (**The Cancer Letter**, July 9, July 23, 2004).

To recruit the office director, FDA last fall advertised the position and received 16 applications, sources said. A search committee immediately disqualified three of the applications, because they didn't meet the basic qualifications, and seven candidates were called in to interviews.

Of the seven, one withdrew, and another was ruled out, sources said. This leaves the agency with five candidates.

Internal agency candidates are Pazdur, Patricia Keegan, director of the Division of Therapeutic Biological Oncology Products, and Karen Weiss, director of the Office of Drug Evaluation VI. Outside candidates are Charles Schiffer, of the Karmanos Cancer Institute, and John Marshall, of the Vince Lombardi Cancer Center.

These candidates would go through another round of interviews in mid-March, and the final decision would likely be made internally. Sources said they expected the decision would be made by Jenkins, Steven Galson, acting director of the CDER, and Janet Woodcock, acting deputy commissioner for operations. It is unclear whether the nomination of Crawford as FDA Commissioner would affect this process.

While Pazdur's opponents at FDA have yet to make their case in public, on the larger political arena, Pazdur's detractors include the editorial board of *The Wall Street Journal*. On Dec. 20, 2004, a lead editorial in the *Journal* slammed him for enthusiastically agreeing with an ODAC member as she expressed frustration with the committee's willingness to recommend drug approval based on weak data.

#### **Letter From The Staff**

Five years ago, after Pazdur came to FDA from M.D. Anderson Cancer Institute, his division experienced considerable turnover, yet the letter signed by nearly all

his staff can be taken as evidence of satisfaction.

"Dr. Pazdur has been instrumental in fostering high morale within the division and high productivity," states the letter addressed to then HHS Secretary Tommy Thompson and dated Jan. 13. "The person chosen for Office Director of Oncology products should be someone with a proven track record of achieving results in both the regulatory environment and in oncology drug development, and that person should be Richard Pazdur."

According to his staff, Pazdur "developed an extensive outreach program to the oncology community." The letter lists the following initiatives:

--"Collaboration with internationally recognized oncology experts from ASCO and the American Association for Cancer Research on potential endpoints on drug approval;

--"Regular meetings with representatives from major U.S. oncology cooperative groups;

--"Promoting with the FDA Office of Special Health Initiatives further development of the patient advocacy program;

--"Partnering with outside oncology experts at crucial End of Phase II Meetings and Pre-NDA Meetings;

--"Promoting communication with the regulated industry and the American public to foster the sense of transparency at the FDA through regular publications in *ASCO News*, *Clinical Cancer Research* and *The Oncologist* journals;

--"Conceptualization of the enormously successful 'burst' e-mail project for Oncology Drug Approvals which transmits simultaneously to members of the ASCO, NCI and Oncology Nursing Society an e-mail announcing the approval of a new oncologic drug;

--"Partnering with international regulators to discuss common issues at the International Oncology Drug Regulator meetings held at the ASCO [annual meetings]."

#### **Endorsements from ASCO, NCCS**

The endorsement letter from ASCO was addressed to FDA Commissioner Crawford and signed by the Society President David Johnson.

The complete text of the ASCO letter follows:

"As the leading medical society for physicians involved in cancer treatment and research, the American Society of Clinical Oncology has an intense interest in the quality of review and regulation of new therapies to prevent, diagnose, or treat cancer. For this reason, ASCO was heavily involved in the discussions that led to

establishment of an Office of Oncology Drug Products. Now that FDA has announced the formation of the office and conducted a nationwide search for the office director, we would like to share our view as to the best candidate for that extremely important position.

“As FDA indicated in the public notice seeking applications for office director, the position requires a substantial depth and breadth of knowledge of oncology and of the clinical trials process so critical to new product development. In addition, experience with the regulatory environment of FDA is essential so as to avoid a situation in which the new director is effectively learning on the job. Although somewhat difficult to quantify, vision, integrity, and energy are all important qualifications, as well. Finally, proven management skills are required, particularly as FDA constantly faces new challenges in a resource-constrained budget climate.

“Consideration of these imposing criteria for selection leads ASCO to conclude that the best candidate for the position of director of the new Office of Oncology Products would be Richard Pazdur. Since his decision to join FDA five years ago, Dr. Pazdur has been the clear intellectual leader for FDA’s oncology program, not just with respect to review of new drugs but also in the development of oncology policy and outreach to the oncology community beyond the agency. His contributions in that regard have been notable and can be measured in the timely review and approval of a number of new cancer drugs. We note that his efforts have included significant improvements in the oncology review staff, and we understand that he enjoys the strong support of those who have reported to him during his tenure.

“There are no doubt many qualified candidates for this important position, both inside and outside the agency, but we have difficulty imagining that any other candidate would possess the unique blend of talent, experience, and leadership found in Dr. Pazdur. We are well acquainted with the qualities that Dr. Pazdur has brought to his current post as division director and believe he is by far the best situated to carry forward and expand the successes of his current tenure into the newly established Office of Oncology Drug Products.

“If you have any questions about this recommendation, the leadership of ASCO would be delighted to meet with you or your staff to explain further our thoughts on this important selection. Thank you in advance for your consideration of our views and for allowing ASCO the opportunity to collaborate with the agency in this effort.”

The endorsement from NCCS was signed by Ellen

Stovall, president and CEO.

The text of the document follows:

“The National Coalition for Cancer Survivorship was among the very first organizations to advocate the establishment of a new Office of Oncology Drug Products at the FDA, and we are delighted that the office is not only under development but a national search for its director has been completed as well. With the conclusion of the search process, NCCS would like to recommend without reservation the appointment of Dr. Richard Pazdur to the position of Director of the Office of Oncology Drug Products. While we are sure that the search identified notable candidates, both from FDA and from elsewhere, we doubt that any of them would possess the remarkable set of qualities that makes Dr. Pazdur the clear choice for the dons of cancer survivors for whom we advocate.

“Since he made a significant personal sacrifice five years ago to leave a secure and prestigious academic appointment in favor of a job at FDA, Dr. Pazdur has made the concerns of cancer patients a constant priority. His efforts at outreach and straightforward communication with patient advocates is, in our experience, unprecedented, and his leadership in that regard has also prompted a new openness among his colleagues at FDA. At the same time that he has so effectively reached out to patient groups, he has also maintained the highest credibility with his peers in academic oncology circles. Indeed, in our view, his dual achievements in patient advocacy and professional alliances have greatly facilitated and supported FDA’s mission in developing new interventions for the prevention, diagnosis and treatment of cancer.

“As FDA finalizes details for the new Office of Oncology Products, there is no doubt that the Office will require extraordinary leadership. With his widely acknowledged expertise in clinical trials and drug development, as well as his recent five-year history of successfully managing FDA’s oncology drug review process, Dr. Pazdur would seem to be the ideal candidate, and we hope that you will fulfill the hopes of so many cancer patient advocates and health care providers by appointing him to the position of director of the new office.”

## **Crawford Testimony In 2002 Promised Job To Pazdur**

In testimony before the Subcommittee on Oversight and Investigation of the House Committee on Energy and Commerce three years ago, then FDA

Acting Commissioner Lester Crawford said the agency's oncology divisions would be consolidated under the leadership of Richard Pazdur.

A transcript of an exchange from the Oct. 10, 2002, hearing follows:

**Rep. James Greenwood** (R-Pa.), then chairman of the subcommittee: "Well, who has signatory authority on oncology products at CDER now?"

**Lester Crawford** (then acting FDA Commissioner): "The director of the division of oncology."

[The division director has signatory authority over supplemental NDAs, but not new drugs. After the oncology office is formed, its director would have signatory authority over NDAs.]

**GREENWOOD:** "Is that Richard Pazdur?"

**CRAWFORD:** "It is."

**GREENWOOD:** "And who is going to have signatory authority on oncology products after the transfer?"

**CRAWFORD:** "It would be him."

**GREENWOOD:** "So, what issues does FDA have to resolve first before implementing this reorganization? What do you have to do?"

**CRAWFORD:** "What we did was to put together a task force of personnel from both centers to hear about what categories of compounds should be transferred and what special considerations so that we don't delay the process, would come to the fore. Basically, it's to be sure that we don't lose efficiency by trying to get more efficiency."

**GREENWOOD:** "So why don't you just briefly outline what you think the advantages will be of this reorganization."

**CRAWFORD:** "The advantage will be that in the Center for Drug Evaluation and Research, there is expertise and also a unit that reviews drugs that are very similar to these therapeutic biologics. And so since they already have the unit set up and since it's functioning, if you put these in there, you would—you should get more efficiency because you have a critical mass. When you have review units you have to have statisticians. You have to have pathologists, biochemists and so forth. And so what we're trying to do in FDA and have been for some time is not have to recreate this critical mass of expertise in order to get the job of review done. And when that has been done correctly, we have experienced efficiencies."

The transcript is posted at: <http://energycommerce.house.gov/107/hearings/10102002Hearing746/hearing.htm#Hearing%20Transcript>.

## NCI Programs: **Two Top NCI Officials Depart For Industry, Academia**

*By Kirsten Boyd Goldberg*

Two top NCI officials announced their departures from the Institute earlier this week, setting off a round of promotions.

Carl Barrett, director of the Center for Cancer Research, which includes the NCI intramural basic and clinical research, is leaving to become global head of oncology biomarkers at the Novartis Institutes for Biomedical Research, in Cambridge, Mass. Prior to joining NCI in 2000, Barrett worked for 23 years at the National Institute for Environmental Health Sciences.

Karen Antman, NCI deputy director for translational and clinical science, was named provost of the Boston University Medical Campus and dean of medicine of the BU School of Medicine. Antman joined NCI in 2003 and led the revision of guidelines for the cancer center and Specialized Program of Research Excellence grants.

"We are going to lose two very key, very critical, members of our senior leadership team of this organization, but we are celebrating that loss, painful as it is," NCI Director Andrew von Eschenbach said to the National Cancer Advisory Board at its Feb. 16 meeting. "The reason we are celebrating that loss is that these two individuals are going on to positions of enormous importance and responsibility that will also change the world and contribute to our ultimate goal."

Von Eschenbach appointed CCR Principal Deputy Director Robert Wilttrout to succeed Barrett. Wilttrout, who also serves as associate director of NCI-Frederick, joined NCI's Laboratory of Experimental Immunology in 1986 and is known for his work in cytokine-mediated immunology.

Craig Reynolds, director of the Office of Scientific Operations, the project office for the contracts that run NCI-Frederick, was promoted to replace Wilttrout as associate director for NCI-Frederick.

It's unclear whether Antman will have a direct successor. The Clinical Trials Working Group, in a report to the NCAB, recommended that NCI reorganize to better coordinate its clinical trials, but the deliberately vague wording left the specific changes up to the Institute (*details in next week's issue*).

Von Eschenbach named Lee Helman, CCR deputy director and chief of the Pediatric Oncology Branch, as acting scientific director for clinical research in CCR. Helman began his career at NCI in 1983 as a research fellow.



“In this new role in CCR, Dr. Helman will lead a renewed focus on clinical research as the process of re-engineering the intramural research program moves forward,” NCI said in a statement.

Antman said the opportunity to return to her home in Boston after being away for the past 12 years was the most important factor in her decision to leave NCI. “I’m delighted to be back in Boston,” Antman said to **The Cancer Letter**.

The new ethics regulations for NIH officials, announced earlier this month, were not a consideration, she said. “No one should perceive this as having to do with the ethics rules,” she said. “This was cooking long before the new rules came out. It was the right opportunity, in the right place, though perhaps at the wrong time, because I might have wanted to stay at NCI for a few more years.”

Before joining NCI, Antman served for 10 years on the faculty of Columbia University College of Physicians and Surgeons, where she was Wu Professor of Medicine and Pharmacology and director of the Herbert Irving Comprehensive Cancer Center.

“Dr. Antman is an outstanding choice for these two posts,” Aram Chobanian, president ad interim of Boston University, said in a statement issued by the university. “She is a proven administrator and educator, she is an excellent clinician and clinical scientist, and she is an established leader on health policy issues. We are indeed fortunate to find an individual who combines all of these strengths, and I am sure she will be an exemplary leader for both our School of Medicine and the entire Medical Campus.”

Antman will step into the two positions vacated by Chobanian when he was appointed president ad interim of the University in November 2003.

The Boston University Medical Center, located in the city’s South End, includes the School of Medicine, the Goldman School of Dental Medicine, and the School of Public Health, along with 17 major research centers and institutes, which together comprise the BU Medical Campus. Boston Medical Center, a teaching hospital affiliated with the University, is located there. The university also is developing BioSquare, a 16-acre biomedical research park, with Boston Medical Center and corporate partners.

\* \* \*

At a Feb. 15 “NCI All-Hands” meeting, von Eschenbach presented the NCI Director’s Gold Star Award to five staff members in recognition of special accomplishments. Recipients were Michelle Christian, Cancer Therapy Evaluation Program; Gregory Downing,

Office of Technology and Industrial Relations; Daniel Gallahan, Division of Cancer Biology; Jon Kerner, Division of Cancer Control and Population Sciences; and Sanya Springfield, Comprehensive Minority Biomedical Branch.

## **Training Program In Research, Review, Formed By NCI, FDA**

NCI and FDA announced that they have formed the NCI-FDA Research and Regulatory Review Fellowship program.

The program is designed to train a cadre of researchers to bridge the processes from scientific discovery through clinical development and regulatory review of new oncology products. Fellows will work and train primarily at FDA’s offices and laboratories in the Washington, D.C., area, and will be exposed to the regulatory requirements that must be built into the early stages of medical product development.

The program is an initiative of NCI’s and FDA’s Interagency Oncology Task Force, a collaboration between the two agencies.

The fellowships will consist of four different programs, each with its own curriculum:

Program One—Clinical Oncology Product Research/Review for Oncology Fellows. Designed for M.D.s or M.D./Ph.D.s.

Program Two—Clinical Oncology Product Research/Review for Board-Certified Oncologists.

Program Three—Oncology Product Research/Review Fellows. Designed for M.D.s, Ph.D.s or M.D./Ph.D.s.

Program Four—Cancer Prevention Fellows. Designed for M.D.s, Ph.D.s or scientists with equivalent doctoral degrees.

Further information about the program is available at <http://iotftraining.nci.nih.gov>.

## **NCI Releases Software For Sharing Microarray Data**

NCI has released new software intended to facilitate sharing and analysis of microarray data by researchers.

The open-source, open-access software tool, caArray version 1.0, developed by the NCI Center for Bioinformatics, can be used to create public repositories of microarray data. The tool provides the means for storing, accessing, and exchanging information created through standard platforms. Mechanisms to ensure the controlled and secure sharing of sensitive data are

included. The beta version of caArray has been tested at several NCI Cancer Centers.

Researchers can now download and install the software at <http://ncicb.nci.nih.gov/download>, provided they adhere to the open source license. Researchers can submit data at <http://caarraydb.nci.nih.gov>.

### Funding Opportunities:

## **Program Announcement**

### **PA-05-048: Protein Biomarker of Infection-Associated Cancers**

Letters of Intent Receipt Dates: Not applicable

Application Receipt Dates: Standard dates, see <http://grants.nih.gov/grants/funding/submissionschedule.htm>.

The announcement promotes research to identify protein biomarkers for cancers where etiology of the disease is attributed to infectious agents. Therefore, the PA seeks to identify those who are at increased risk of developing cancer among infected individuals and to detect early stage cancers in this population. The initiative encourages research to identify proteomic markers for risk assessment and early detection in individuals exposed to infectious agents that have been linked to cancer. Proposals may involve a number of infectious agents showing associations with cancer. Noteworthy viral agents of interest to this program are HPV, Hepatitis B and C viruses, EBV, and Simian Virus 40.

Furthermore, an escalating association of early cervical, lung, and colon cancers has emerged, among HIV patients. Proposals are also invited to investigate bacterial etiology in cancer, such as the role of *Helicobacter pylori* with gastric cancers. The NIDCR has particular interest in EBV and HPV-associated head and neck cancers. Proposals covering basic science (infectious life cycle, viral replication, etc.) or treatment studies of these infectious agents are not encouraged by this PA. The funding opportunity will use the R01 and R21 award mechanisms. The PA is available at <http://grants1.nih.gov/grants/guide/pa-files/PA-05-048.html>.

Inquiries: Scientific/Research Contacts: Karl Krueger, Division of Cancer Prevention, NCI, 301-435-1594; fax 301-402-8990; e-mail [kruegerk@mail.nih.gov](mailto:kruegerk@mail.nih.gov).

## **RFPs Available**

### **N02-CP-51011-66: Laboratory Support for Processing and Storage of Biological Specimens from Persons at High Risk of Cancer**

Response Due Date: April 6

NCI Division of Cancer Epidemiology and Genetics is seeking a contractor to maintain the inventory of biologic specimens and to receive, process and store new samples as they are collected. The contractor will provide services in accordance with contractor developed, Government approved protocols for: a) Separation and viable cryopreservation of blood mononuclear lymphocytes; b) Separation, aliquoting and storage of serum, plasma and/or urine as

needed; c) Cryopreservation of bone marrow samples; d) Cryopreservation of whole tumor tissue; e) Viable cryopreservation of previously established lymphoblastoid cell lines; f) Storage of DNA and other biological materials as specified by the Project Officer (e.g., pathology slides and tissue block); g) Extraction of DNA from biologic materials; h) Specimen processing as required by NCI to preserve special biologic materials; i) Logging in, labeling and tracking of each vial of each sample employing an NCI developed computerized specimen tracking system, including all laboratory safeguards to insure the fidelity and purity of each sample; j) Maintenance of the previously-established repository currently containing more than 2.9 million biological specimens and allowance for an estimated increase of up to 50% of freezer storage space; k) Under the direction of the Project Officer conduct laboratory methods studies that establish optimal conditions for collection, processing, shipping and storage of biologic materials.

The RFP is available at <http://www.fbodaily.com/archive/2005/02-February/17-Feb-2005/FBO-00751137.htm>.

### **NOT-CA-05-014: Early Therapeutics Development with Phase II Emphasis**

NCI Cancer Therapy Evaluation Program is seeking, on a contract basis, organizations or consortiums with the capabilities and facilities to provide a resource for the conduct of phase II and early clinical trials of NCI-sponsored agents, to evaluate biologic effects of the agents on their molecular targets, to evaluate other relevant biologic effects, and to determine clinically relevant outcomes/correlates. Major emphasis shall be on phase II studies, pilot protocols that explore promising combination therapies, and high priority studies that are pivotal for drug development and require rapid initiation, completion, and data reporting. NCI staff will notify the Contractor of high priority studies as they are identified. NCI will also consider investigator-initiated trials for credit under this contract, based on available resources and priorities.

CTEP requires a total resource that will provide 1600 to 2000 patients accrued to 32 to 64 trials per year. CTEP intends to make multiple contract awards. These contracts will require multi-institutional consortia of clinicians, statisticians, data managers, research nurses, and others with early phase clinical trial expertise with investigational agents in cancer. Contractors must be organized to attract adequate patient cohorts for prompt completion of trials. Contractors will have flexibility to reform consortial arrangements or to subcontract with additional sites to meet accrual goals, enhance accrual of unusual patient populations, increase accrual rates for high priority trials, and/or provide biologic/cellular pharmacology expertise for correlative studies.

Offerors for the contracts must demonstrate that they have expertise in cancer drug development, and knowledge in the clinical management of specific tumor types, phase II clinical trials, pharmacology, and pharmacodynamics. They

need to provide evidence of their own expertise, or access to such expertise, in diagnostic and functional imaging, interventional radiology, pathology, and other potentially relevant laboratory methodologies. The notice is available at <http://grants1.nih.gov/grants/guide/notice-files/NOT-CA-05-014.html>.

Up to eight awards will be made and that the resulting contracts will be awarded on an incrementally funded basis for a period of 3 years plus 2 additional option years.

Inquiries: Annmarie Keane, contract specialist; NCI, Treatment, Biology, and Science Section, RCB, Voice 301-435-3814; Fax 301-402-6699; e-mail [keanea@mail.nih.gov](mailto:keanea@mail.nih.gov).

### *In Brief:*

## **Univ. of Pennsylvania Joins Mouse Models Consortium**

(Continued from page 1)

Cancer Center, heads one of four MMHCC sites at which breast-cancer models are being developed and studied. Chodosh will oversee a \$2.5 million, five-year program based at Penn that encompasses multidisciplinary research from six institutions in three countries. The co-principal investigators are: **Mitchell Schnall**, associate chairman of Radiology at Penn; **Robert Cardiff**, of the University of California, Davis; and **William Muller**, of McGill University. Additional investigators in the Penn MMHCC group include **Britton Chance**, **David Tuveson**,; **Jerry Glickson**, **Paul Acton**; **Joel Karp**, **Abass Alavi**, **Chandra Sehgal**, and **Hank Kung**, as well as **Ruth Muschel**, of Children's Hospital of Philadelphia and **John Condeelis**, of Albert Einstein College of Medicine. . . . **ONCOLOGY NURSING SOCIETY** announced its 2005 awards. **Marilyn Frank-Stromborg** received the ONS Distinguished Researcher Award for research that has enhanced the science and practice of oncology nursing. She is a distinguished research professor at the Northern Illinois University School of Nursing, and assistant state's attorney, DeKalb County State's Attorney's Office in Sycamore, Ill.. Frank-Stromborg serves on the National Advisory Council for Nursing Research at NIH. **Claudia Conroy** received the ONS Pearl Moore Making a Difference Award for her contributions to the profession at the local and regional levels. Conroy, known for her work in pain and symptom management, venous access device management, and chemotherapy administration, is an oncology clinical nurse specialist at St. Alexius Medical Center in Hoffman Estates, Ill. . . . **ALBERT LOBUGIO**, director of the University of Alabama at Birmingham Comprehensive Cancer Center

until last October, has assumed new responsibilities. He is co-director of the Tumor Immunology Program and advisor to the center director. He also was named Distinguished Professor and Director Emeritus by the Board of Trustees in February. **Peter Emanuel**, senior scientist at CCC, has been named acting director until a search is completed. . . . **JOSEPH ROSENBLATT**, of the University of Miami Sylvester Comprehensive Cancer Center, received the Emanuel G. Rosenblatt Award for Scientific Achievement from Israel Cancer Association, USA. Rosenblatt is associate director of clinical and translational research, chief of the Division of Hematology/Oncology at UM/Sylvester. He was selected for both his cancer research and for organizing the first Joint American-Israeli Conference on Cancer, March 16-18, at the Inbal Hotel in Jerusalem, said **Ronni Epstein**, executive director of the Israel Cancer Association, USA. Along with Rosenblatt, organizers of the conference are **Hyam Levitsky**, of the Sidney Kimmel Comprehensive Cancer Center, and **Robert Korngold**, from the Cancer Center at Hackensack University Medical Center. . . . **ANNA GIULIANO**, program leader for risk assessment, detection and intervention at H. Lee Moffitt Cancer Center and Research Institute, received a \$10 million grant from NIH for human papillomavirus research with an emphasis on Latin American populations. The study would determine the rates of new infections by looking at the role of men in spreading HPV and whether or not a vaccine would be effective in preventing cervical cancer. . . . **PAUL DOETSCH** was named associate director for basic research at Winship Cancer Institute. Doetsch, professor of biochemistry, radiation oncology and hematology & oncology at Emory University School of Medicine, will remain an active laboratory investigator as well as assume Emory University leadership responsibilities for more than 70 laboratory based faculty. Doetsch is known for his studies in DNA damage, repair and genetic instability in eukaryotic systems. . . . **DAVID HUSSEY** was elected president of the Radiological Society of North America for 2005. Hussey is a clinical professor in the Department of Radiation Oncology at the University of Texas Health Science Center in San Antonio. . . . **NATIONAL LIBRARY of Medicine** has added the papers of **Francis Crick** to its Profiles in Science Web site. The collection is a collaboration between NLM and the Wellcome Library for the History and Understanding of Medicine in London, which holds the Crick papers, said **Donald Lindberg**, director of the National Library of Medicine The Web site is available at [www.profiles.nlm.nih.gov](http://www.profiles.nlm.nih.gov).



## Copying Policy for The Cancer Letter Interactive

The software that comes with your issue allows you to make a printout, intended for your own personal use. Because we cannot control what you do with the printout, we would like to remind you that routine cover-to-cover photocopying of The Cancer Letter Interactive is theft of intellectual property and is a crime under U.S. and international law.

Here are guidelines we advise our subscribers to follow regarding photocopying or distribution of the copyrighted material in The Cancer Letter Inc. publications in compliance with the U.S. Copyright Act:

What you can do:

- Route the printout of the newsletter to anyone in your office.
- Copy, on an occasional basis, a single story or article and send it to colleagues.
- Consider purchasing multiple subscriptions. Contact us for information on multiple subscription discounts.

What you can't do without prior permission:

- Make copies of an entire issue of the newsletter. The law forbids cover-to-cover photocopying.
- Routinely copy and distribute portions of the newsletter.
- Republish or repackage the contents of the newsletter.

We can provide reprints for nominal fees. If you have any questions or comments regarding photocopying, please contact Publisher Kirsten Boyd Goldberg, phone: 202-362-1809.

We welcome the opportunity to speak to you regarding your information needs.