

THE

CANCER LETTER INTERACTIVE

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

Vol. 28 No. 33
Sept. 13, 2002

© Copyright 2002 The Cancer Letter Inc.
All rights reserved.
Price \$305 Per Year

As ImClone Investigation Continues, FDA Combines Drug, Biologics Review

FDA last week said applications for approval of therapeutic biologic agents would now be reviewed by the same center that reviews drugs.

The decision to transfer the application review function from the agency's Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research was announced by Deputy Commissioner Lester Crawford Sept. 6.

The change was announced at the time when a Congressional committee was questioning the review of the cancer agent C225 by CBER.

"By carefully combining part of our present biologics review operation
(Continued to page 2)

In Brief:

Zerhouni Appoints Two Institute Directors; Yale's Rakic Wins BMS Neuroscience Award

NIH DIRECTOR ELIAS ZERHOUNI has appointed two institute directors. **Ting-Kai Li** was appointed director of the National Institute on Alcohol Abuse and Alcoholism. Li is distinguished professor in the departments of medicine, biochemistry, and molecular biology at Indiana University School of Medicine, where he also serves as director of the Indiana Alcohol Research Center. He is expected to assume his new duties within the next few weeks. Li replaces **Raynard Kington**, who has served as acting director of NIAAA since January 2002 following the retirement of **Enoch Gordis**, director from 1986 to 2002. **Thomas Insel** was named director of the National Institute of Mental Health. Insel, a professor in the Department of Psychiatry and director of the Center for Behavioral Neuroscience at Emory University School of Medicine, is expected to begin his appointment in mid-November. He first joined NIMH in 1979 as a clinical associate in the Clinical Neuropharmacology Branch, and went on to hold several administrative and leadership posts in 15 years at NIMH before heading to Emory in 1994. . . . **SHELDON MILLER**, professor of molecular and cell biology at University of California, Berkeley, was named scientific director of the Division of Intramural Research at the National Eye Institute, said NEI Director **Paul Sieving**. . . . **PASKO RAKIC** will receive the annual Bristol-Myers Squibb Award for Distinguished Achievement in Neuroscience Research for discovering the principles and mechanistic basis of neuronal migration in the development of the brain. Rakic is the
(Continued to page 8)

FDA Consolidation:

"Lengthy Process"
Led To Decision
To Merge Reviews,
Crawford Says In Memo
... Page 3

Oncology Community
Praises FDA Move;
ASCO, NCCS Call
For Oncology Center
... Page 4

ASCO Statement:

Anastrozole Approval
Adds Treatment Option
For BC Recurrence,
But Tamoxifen Remains
Standard Treatment
... Page 5

NCI Intramural Research:

New Bioinformatics Tool
To Help Design
New Cancer Drugs
... Page 6

Funding Opportunities:

RFAs, PAs Available
... Page 6



Congressional Committee Takes Credit For FDA Move

(Continued from page 1)

responsibilities with our drug review operation, FDA will be optimally positioned to uphold that gold standard by continuing to review novel pharmaceutical products promptly and rigorously in an accountable and consistent manner," Crawford said in a statement.

"In addition, this consolidation will allow CBER to concentrate its scientific expertise and effort in the crucial areas of vaccines and blood safety," Crawford said. "These are top priority items critical to our national defense and public health. Moreover, CBER will be able to concentrate its expertise on such cutting edge biologic scientific areas as gene therapy and tissue transplantation."

The plan for consolidation of the review functions will be developed by January, Crawford said. The text of the FDA announcement of the merger appears on page 3. Professional societies, patient groups, and industry sources were generally supportive of the change. [Story on page 4.]

Though Crawford said the change was being made as a result of a lengthy process, leadership of a Congressional committee investigating the development and approval of C225 praised the change, and took credit for causing it to happen. C225, a monoclonal antibody also known as Erbitux, is sponsored by ImClone Systems Inc. and is partly

owned by Bristol-Myers Squibb.

"The FDA has not said to us, 'We made this change because of your hearing, your inquiries, your letters, and your investigation,' but it's pretty clear to me that that's exactly what happened," said Rep. James Greenwood (R-Penn.), chairman of the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce.

The subcommittee has been critical of the FDA biologics center for not informing ImClone as early as possible in the approval process about weaknesses in its application. The agent was placed on the FDA Fast Track program, even though the case for its approval was based on a small, seriously flawed single-arm study.

"[C225] was a central case where there is a difference between the way the pharmaceutical side of FDA operates and the biologics side operates became such an issue," Greenwood said at a press conference Sept. 10. The committee focused on the differences between CDER and CBER following its June 13 hearing on the ImClone controversy (**The Cancer Letter**, June 21).

The committee also wrote a letter to the agency, and, in recent weeks, met with FDA officials to discuss differences between procedures employed by the two centers (**The Cancer Letter**, July 5).

Greenwood and Rep. Billy Tauzin (R-La.), chairman of the full committee, said additional hearings will be held in the ImClone matter. Investigators are focusing on FDA review procedures, the functioning of the Fast Track program, and the role the agency should play in matters that involve the price of stocks.

The investigation is also likely to involve issues of responsibility of board members of publicly traded companies.

"We have big issues to work out, including the question of how corporate boards are created, who serves on them, whether there are conflicts of interest on these boards, whether they are representing the stockholders, or whether they are representing the CEOs," Tauzin said.

In the ImClone probe, investigators have interviewed company board members Vincent DeVita, director of the Yale Cancer Center, and John Mendelsohn, director of M.D. Anderson Cancer Center (**The Cancer Letter**, July 5). In addition to serving on the board, Mendelsohn and DeVita had consulting contracts with ImClone.

FDA should be more open with sponsors, and



Member,
Newsletter and Electronic
Publishers Association

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

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

E-mail: news@cancerletter.com

Customer Service: 800-513-7042

PO Box 40724, Nashville TN 37204-0724

E-mail: info@cancerletter.com

Subscription \$305 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



should monitor the claims they make about their products, Greenwood and Tauzin said. "It is my personal view as someone who helped write the FDA reform act, that transparency is in the interest of the patients," said Greenwood.

By disclosing to sponsors that their applications are in trouble, the agency could help avoid calamitous declines in stock prices, as was the case with ImClone. The company's stock plummeted as a result of a "refusal to file" letter from FDA. The letter said ImClone's data were "uninterpretable" and that new studies would be needed to test the agent (**The Cancer Letter**, Jan. 4, Jan. 11).

"It would have been an entirely different situation had FDA said to ImClone, 'Why don't you go back to the drawing boards and do some more research,'" Greenwood said. "ImClone could have explained that to its investors and stockholders. It could have done some research, and none of this would have happened. So, we think transparency is the cure for this kind of problem."

The committee plans to close a loophole in FDA law that allows companies to hype their products, driving up stock prices at the time when the agency is reviewing the claim Greenwood said.

"When a drug is approved by FDA, there is a very prescriptive label that makes it very clear what you can say this drug can do, and what it can't do," Greenwood said. "And yet, prior to the drug being approved, a company trying to attract investors can say practically anything. And we think its an important area of inquiry and perhaps legislation, to say to FDA, 'You need to tell companies what they are allowed to say about potentiality of this product, particularly if it's on Fast Track.'"

The press conference was called primarily to announce the committee's referral of a case involving the home decorating entrepreneur Martha Stewart to the U.S. Department of Justice. The committee said Stewart's statements regarding her sale of ImClone stock were contradicted by other materials obtained by investigators.

Stewart, a friend of ImClone president and CEO Samuel Waksal, sold all her ImClone stock on Dec. 27, 2001, the day before the RTF letter. Waksal was recently indicted on charges that include insider trading, and Stewart is facing investigations by Justice and the Securities and Exchange Commission.

The committee asked Justice to launch an investigation of whether Stewart has violated the Federal False Statements Act, a law that makes it a

felony to make false statements to federal investigators.

Tauzin said the committee decided to refer the case to Justice, because it was tangential to the investigation.

Stewart has refused to meet with Congressional investigators, and her lawyers said that if subpoenaed, she would refuse to testify, claiming protection from self-incrimination under the Fifth Amendment.

Describing the Stewart matter as a "side show," Tauzin said the committee will now be able to focus on the other, more important issues of the ImClone investigation.

The matter merits investigation, Greenwood said. "She is a former stockbroker," he said. "She is a CEO of a very large corporation, and she sits on the board of directors of the New York Stock Exchange. That is quite different than your average little investor sitting at home in the kitchen."

The 8-page letter to Justice is posted at: http://energycommerce.house.gov/107/letters/09102002_714.htm.

Crawford: "Lengthy Process" Of Review Led To Decision

The following is the text of a Sept. 9 announcement of the CBER-CDER consolidation by FDA Deputy Commissioner Lester Crawford to the agency staff:

Last Friday, I announced a plan to transfer the therapeutic biologic review functions from our Center for Biologics Evaluation and Research (CBER) to our Center for Drug Evaluation and Research (CDER).

This decision was made after a lengthy process of fact finding and deliberation. As part of continuing efforts to improve Agency efficiency and consistency, the Office of the Commissioner hired consultants in the fall of 2001 to conduct an assessment of the drug review process to identify best practices and make recommendations for improving those processes. The consultants conducted extensive interviews with staff associated with the review processes in both CBER and CDER, and they reported their findings to me shortly after I arrived last February.

In addition, during the renegotiation of the Prescription Drug User Fee program, representatives of the regulated industry expressed their views to me as well as to Secretary Thompson and Deputy Secretary Allen concerning the importance of achieving consistency across all review divisions.

Members of my senior management team gathered data on specific issues that were of concern and developed a slate of options for improving the efficiency and



consistency of our organization. These options ranged from maintaining the organizational status quo to completely merging CDER and CBER into one organization.

After carefully reviewing the data and the options that were presented to me, I noted the wide variety of functions performed by CBER, many of which have a broad public health focus such as the regulation of vaccines and ensuring the safety of the nation's blood supply.

The therapeutic biologics review function was quite distinguishable from these activities. 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 CDER.

This finding was presented to the leadership of CBER who responded with written comments. After careful consideration of the points raised in these comments, I decided to proceed with the consolidation of therapeutic product review within CDER.

The consolidation implementation group that will manage this transition—a group that will be chaired by Dr. Murray Lumpkin—will begin its work with the following premises:

1) Review of biologic products other than vaccines, blood cells, tissues, gene therapy and related products will be transferred to CDER.

2) Scientific staff and support functions, including laboratories associated with review of these products, will be consolidated within CDER.

3) The transfer plan will be accomplished with the greatest attention given to minimizing disruption to staff and current product reviews.

4) There will be no reductions-in-force associated with these transfers.

I hold the professionalism of FDA staff in the highest regard and I know that you will work with me to assure a smooth transition for these important agency activities.

Oncologists, Advocates, Industry Praise FDA Move

Cancer patient advocates and professionals involved in drug development were largely positive in their reaction to the agency's plan to consolidate the review functions for the centers handling drugs and biologics.

"I applaud the decision," said Gregory Reaman, chairman of the Children's Oncology Group. "There is significant expertise in both divisions, and anything that is going to expedite the review process while maintaining safety is a real plus for all cancer patients, and particularly for children, for whom there is frequently inordinate delay in accessing new agents."

"Having a single review process for drugs as well as biologic agents—and most exciting new

agents are going to be biologics—is just great," Reaman said.

Michael Friedman, senior vice president for medical and public policy, Pharmacia Corp., a former FDA deputy commissioner for operations, and former NCI official, said the consolidation makes sense, as long as it does not delay any therapeutics applications currently underway.

"In the past, you always had to make sure there was some consistency between oncology in CDER and oncology in CBER, and for other therapeutic areas," Friedman said. "While good people could make it work, inherently, it's just not as efficient as having it in one place."

"The idea of having a single, consistent, review process for reviewing all products that are therapeutically similar seems very appealing," Friedman said. "There is a lot to recommend the plan, depending on how it is executed. It shows flexibility and creativity on the part of FDA leadership to try to do this right now."

"We are pleased with the Bush administration's efforts to bring life-saving drugs to patients faster alongside greater consistency in the drug development and review process," said Carl Feldbaum, president of the Biotechnology Industry Organization, a group that lobbied for faster reviews of biologics by FDA.

"It is our understanding that therapeutic biologics will continue to be regulated under the Public Health Service Act, and that biologics license applications, and not new drug applications, will continue to be submitted for such products," Feldbaum said in a statement. "It is also essential that the FDA ensure the necessary resources and expertise are brought to bear on the biologics under the purview of CBER, including cell and gene therapy, vaccines, tissues and blood."

PhRMA, the pharmaceutical industry lobby, said it favored the consolidation. "There is the strong potential for greater consistency in therapeutics approval, because most drugs are already approved by CDER," said Jeff Trewhitt, spokesman for PhRMA. "Also, because CDER is the center that approves most therapeutic products, it gets a fair amount of the federal drug user fees. By having CBER concentrate on blood products and vaccines, that means CBER can really concentrate on expeditious vaccine review at a time when getting vaccines approved rapidly could be important because of bioterrorism."

However, the American Society of Clinical



Oncology said the consolidation, while welcome, falls short of a full-fledged “oncology center” in FDA.

“The goal for ASCO is to have a center for all cancer products, whether it be drugs, biologics, hormones, diagnostics, and potentially even devices,” said ASCO President Paul Bunn. “That hasn’t been accomplished, but most people would view this as step in right direction.”

Bunn, former chairman of the FDA Oncologic Drugs Advisory Committee, said ASCO is concerned that FDA not reduce the number of reviewers as a result of the merger. “Reviews would get longer if there is less staffing, or if people with the appropriate expertise in biologics are not reviewing biologics,” he said. “Most cancer therapies are important and it shouldn’t take more than six months to review them.”

“It has long been our goal to have a level playing field so that everybody knows what the rules are, and that the rules are the same for everybody,” Bunn said. “It makes it easier for companies to design trials and for reviewers to review therapies. The second thing everyone wants is timely review of new therapies.”

Ellen Stovall, president and CEO of the National Coalition for Cancer Survivorship, agreed with Bunn. “It’s an important first step in what we hope will be even more consolidation of FDA oncology reviewers and investigators to focus on the development of new biologics and drugs for cancer,” she said. “Taking it the next step in consolidation is something we look forward to talking to FDA officials, Congress, and the Administration about.”

“There are so many questions that can be best addressed by both biologics and drug investigators, and that is how to deal with quality of life issues and other endpoints that are less clear-cut than survival,” Stovall said. “We feel the coming together of these two centers is going to help expedite this process.”

Friedman said he wasn’t convinced that an oncology center is necessary. “I’m not sure what problems would be solved by further reorganization,” he said. “The issues for oncology are like those for any other therapeutic area—how to recruit and train the best people, keep them scientifically contemporary, and how to manage the workload.”

“When you talk about developing some new oncology organization, first tell me what problem we’re solving,” he said.

According to Bunn, “The cancer community thinks having an oncology center at FDA is a good thing. Hormones and supportive care agents get

reviewed by other committees. If you’re trying to design a pivotal study, you want it to be consistent with what FDA is looking for. If one part of FDA says you need one trial and another part says you need two trials, it makes it difficult for everybody.”

Bunn said the ASCO Public Issues Committee and the National Dialogue on Cancer supported the idea of an oncology center at FDA, but it has not been clear whether it would require legislation.

“Someday, there will be an FDA commissioner, won’t there?” Bunn asked. “We hope this consolidation is a sign that there is some movement.”

ASCO Statement: **Anastrozole Approval Adds New Option For BC Recurrence**

The FDA approval of anastrozole for adjuvant treatment of breast cancer “adds an important new option for postmenopausal women seeking to prevent the recurrence of primary breast cancer that is hormone-sensitive,” the American Society of Clinical Oncology said in a statement Sept. 6.

The role of anastrozole was reviewed by a panel convened by ASCO and presented at the society’s annual meeting last May. “The panel saw clear value for the use of anastrozole for several specific situations, but raised cautions concerning the lack of long-term follow-up for both efficacy and toxicity,” ASCO said. “While tamoxifen is still the preferred option at present for most patients who are candidates for hormonal treatment, the role of anastrozole may grow as further information becomes available.”

The panel’s findings were published in the Aug. 1 issue of the *Journal of Clinical Oncology*.

“For women already doing well on tamoxifen, there is no evidence to support a change in therapy,” said Eric Winer, director of the Breast Oncology Center at the Dana-Farber Cancer Institute and chair of the expert panel. “For most postmenopausal women with a new diagnosis of hormone receptor-positive, operable breast cancer, tamoxifen remains the best option as part of a total treatment plan. But anastrozole represents a reasonable and welcome alternative for some patients.”

Anastrozole might be preferred for patients who developed breast cancer while taking tamoxifen as a cancer preventative or raloxifene as a treatment for osteoporosis, those at high risk for blood clotting problems, and patients who cannot take tamoxifen because of side effects, the society said.



NCI Intramural Research: **New Bioinformatics Tool To Help Design Cancer Drugs**

A new method that allows researchers to link genomic and proteomic information from cancer cells to information about drug structure will be a powerful tool in the design and discovery of new drugs, researchers report in the August issue of *The Pharmacogenomics Journal*.

The bioinformatic approach, developed by NCI and LeadScope Inc., of Columbus, Ohio, relates gene expression patterns to more than 27,000 substructures and chemical features within compounds that have been tested for their effect on tumor cell growth.

This new approach improves upon previous methods that correlate molecular data with the anti-cancer activity of compounds, but not with the substructures within those compounds. The system was developed using gene expression data. It can easily be applied to protein profiles, as well, the researchers said.

“Someone who is trying to design or perfect cancer drugs would ideally like to relate a gene or protein profile directly to drug structure,” said John Weinstein, of NCI, one of the study's lead authors.

The new system does just that, said study co-author Paul Blower, of LeadScope, allowing researchers to understand which chemical features of drugs govern their behavior in various cell types. Researchers expect this new technology to help chemists select the most promising candidate drugs for further screening from large collections of compounds.

The method links three databases of information on cells and chemical compounds. The original “information-intensive” method of analysis developed by Weinstein and colleagues used data from more than 80,000 chemical compounds and 60 human cancer cell lines. Since 1990, NCI's Developmental Therapeutics Program has tested these compounds for their ability to inhibit growth in the cell lines, known collectively as the NCI-60. The NCI-60 are cells derived from nine different types of cancer (melanoma, leukemia, and cancers of the lung, colon, breast, prostate, kidney, ovary, and central nervous system).

The first of the new databases includes data on the inhibitory effect of the compounds against each of the cell lines. Gene expression patterns of each of the cell lines, determined by cDNA microarrays, make

up the second database. The LeadScope™/LeadMiner™ software relates this information to the final database, which identifies which of 27,000 structural features are present in each of the compounds. Scientists who use this tool in the future will be able to create and explore new datasets based on the compounds, cells, and expression profiles most relevant to their own research.

Databases linking biological activity and gene expression to the NCI cell lines are available at <http://discover.nci.nih.gov> and <http://www.leadscope.com>.

Software for the NCI-60 databases will be available from LeadScope for interested researchers.

Funding Opportunities: **RFAs Available**

RFA CA-03-002: Network for Translational Research: Optical Imaging

Public Meeting of Applicants: Sept. 27, 2002

Letter of Intent Date: Dec. 17, 2002

Application Receipt Date: Jan. 21, 2003

NCI invites applications for cooperative agreement U54 awards to establish a Specialized Research Resource Center that will participate as a member of a network of inter-disciplinary, inter-institutional research teams for the purpose of supporting translational research in optical imaging and/or spectroscopy in vivo.

The full text of the RFA is available at <http://grants2.nih.gov/grants/guide/rfa-files/RFA-CA-03-002.html>.

Inquiries: Houston Baker, program director, Imaging Technology Development Branch, Biomedical Imaging Program, Division of Cancer Treatment and Diagnosis, NCI, EPN Room 6060, Bethesda MD 20892-7412, (or for courier service, Rockville MD 20852, phone 301-594-9117; fax 301-480-350; e-mail bakerhou@mail.nih.gov .

RFA CA-03-015: In Vivo Cellular and Molecular Imaging Centers

Letter of Intent Receipt Date: Oct. 21, 2002

Application Receipt Date: Nov. 25, 2002

NCI Biomedical Imaging Program, Division of Cancer Diagnosis and Treatment, invites applications for P50 Research Center Grants for studying cancer non-invasively, and in many cases, quantitatively, due to recent advances in molecular imaging modalities, as well as molecular and cellular biology.

The 5-year P50 grants will be appropriate for those institutions in which investigator-initiated multidisciplinary research involving imaging and molecular technologies are currently ongoing.

The RFA is available at <http://grants1.nih.gov/grants/guide/rfa-files/RFA-CA-03-015.html>.

Inquiries: Anne Menkens, Biomedical Imaging



Program, NCI, Executive Plaza North, Room 6068, Bethesda, MD 20892, phone 301-496-9531; fax 301-480-3507; e-mail am187k@nih.gov.

RFA CA-03-018: Cooperative Planning Grant for Cancer Disparities Research Partnership Program

Letter of Intent Receipt Date: Feb. 20, 2003

Application Receipt Date: March 20, 2003

NCI invites cooperative planning grant applications, using the U56 mechanism, to reduce negative consequences of cancer disparities seen in certain U.S. populations.

The grant will support the planning, development and conduct of radiation oncology clinical research trials in institutions that care for a disproportionate number of medically underserved, low income, ethnic and minority populations but have not been traditionally involved in NCI-sponsored research. The grant will also support the planning, development and implementation of nurturing partnerships between applicant institutions and committed and experienced institutions actively involved in NCI-sponsored cancer research. All approaches to planning are encouraged, as long as they address the following essential features: a focus on cancer disparities, radiation oncology clinical research, institutional commitment, organizational capabilities, facilities, and interdisciplinary coordination and collaboration.

The text of the RFA is available at <http://grants2.nih.gov/grants/guide/rfa-files/RFA-CA-03-018.html>.

Inquiries: Frank Govern, deputy chief, Radiation Oncology Sciences Program, NCI, Executive Plaza North, 6015A, 6130 Executive Blvd, MSC 7440, Bethesda, MD 20892-7440, phone 301 496-6111; fax: 301 480-5785; e-mail governfr@mail.nih.gov or Norman Coleman, chief, Radiation Oncology Sciences Program, NCI, DCTD, RRP, Executive Plaza North, 6015A, 6130 Executive Blvd, MSC 7440, Bethesda, MD 20892-7440, phone 301 496-6111; fax 301 480-5785; e-mail ccoleman@mail.nih.gov.

Program Announcements

PAR-02-142: Tools for Genetic Studies in Zebrafish

Letter of Intent Receipt Dates: Oct. 21, 2002, '03, '04

Application Receipt Dates: Nov. 19, 2002, '03, '04

The PA encourages investigator-initiated applications for research designed to exploit the power of mutagenesis screening in zebrafish in order to detect and characterize genes, pathways, and phenotypes of interest in development and aging, organ formation, behavior, and disease processes. Applications that propose to advance the technologies associated with such phenotyping also are welcome. A secondary goal is to ensure that these tools are widely available to the research community.

Of particular interest to NCI: Generation and study of zebrafish models to identify and place genes in functional pathways that affect growth and development;

in particular, genes/pathways that, when altered, result in uncontrolled or cancerous growth.

The PA is available at <http://grants1.nih.gov/grants/guide/pa-files/PAR-02-142.html>.

Inquiries: Judith Mietz, program director, Division of Cancer Biology, NCI, 6130 Executive Blvd., Suite 5032, MSC 7385, Bethesda, MD 20892-7385, phone 301-496-7028; fax 301-496-1037; e-mail mietzj@mail.nih.gov.

PAR-02-143: Development of Cell-Selective Tools for Studies of the Bladder, Prostate, and Genitourinary Tract

Application Receipt Dates: Feb. 1, 2003, '04, and '05.

The PA supports strategies that include 1) discovery of genes selective to individual cell types, 2) characterization of cell-selective promoters, 3) generation of transgenic mice carrying gene-disruptions under cell-selective or temporal control, 4) generation of antibodies to cell-selective proteins, 5) development of novel imaging techniques to study individual cell-types, 6) discovery of biomarkers that indicate health or mass of individual cell-types, 7) development of cell-selective drugable targets and assays for such targets in animal models and/or humans, and 8) identification of cell specific markers to aid studies of epithelial-stromal interaction in normal and malignant tissues.

The text of the PA is available at <http://grants1.nih.gov/grants/guide/pa-files/PAR-02-143.html>.

Inquiries: Judith Mietz, program director, Division of Cancer Biology, NCI, 6130 Executive Blvd., Suite 5032, MSC 7385, Bethesda, MD 20892-7385, phone 301-496-7028; fax 301-496-1037; e-mail mietzj@mail.nih.gov.

Program Announcements Recently Reissued By NCI

Development of Novel Technologies for in vivo Imaging-SBIR-STTR: http://deainfo.nci.nih.gov/concepts/vivoImagingSmBus_rePA.htm.

Development of Novel Technologies for in vivo Imaging-R21/33: http://deainfo.nci.nih.gov/concepts/vivoImaging_rePA.htm.

Molecular Targets for Cancer Drug Discovery: SBIR/STTR Grants: <http://deainfo.nci.nih.gov/concepts/TPA-02-177.htm>.

Molecular Targets for Cancer Drug Discovery: Exploratory Grants: <http://deainfo.nci.nih.gov/concepts/TPA-02-176.htm>.

The Molecular Epidemiology of HIV-Associated Cancers: <http://deainfo.nci.nih.gov/concepts/TPA-02-179.htm>.

Quick-Trials for Novel Cancer Therapies: <http://deainfo.nci.nih.gov/concepts/TPA-02-173.htm>.

Exploratory Studies in Cancer Detection, Prognosis and Prediction: <http://deainfo.nci.nih.gov/concepts/TPA-02-174.htm>.



In Brief:

Genome Grants Awarded To Berkeley Institute, Stanford

(Continued from page 1)

Dorys McConnell Duberg Professor of Neurobiology at Yale University School of Medicine. "His research on the basic events of neurogenesis, neuronal migration and the formation of synaptic circuitry is the most commonly cited work for understanding numerous genetic and acquired human brain disorders," said **Frank Yocca**, executive director, neuroscience drug discovery, Bristol-Myers Squibb Pharmaceutical Research Institute. Rakic will receive a \$50,000 cash prize and a commemorative silver medallion. . . . **NATIONAL HUMAN GENOME RESEARCH INSTITUTE** Centers of Excellence in Genomic Science Program has awarded grants to Stanford University School of Medicine and to the Molecular Sciences Institute of Berkeley, Calif. The program assembles interdisciplinary teams of scientists to explore genomic function, said NHGRI Director **Francis Collins**. Each awardee will receive \$3 million a year for the next five years. The first CEGS, led by **William Talbot**, of Stanford University in Palo Alto, will examine the genomic basis of vertebrate diversity through experimentation with two model organisms, the three-spine stickleback and the zebrafish. The second CEGS grant, awarded to **Roger Brent**, scientific director and president of the Molecular Sciences Institute, will study how cells interpret and relay information. His group of physicists, mathematicians, chemists, engineers, computer scientists, and biologists includes colleagues from MSI as well as the California Institute of Technology, University of California, Berkeley, Pacific Northwest National Laboratory, and the Massachusetts Institute of Technology. NHGRI will make ten CEGS awards. The next application receipt date is Oct. 1, 2002, for CEGS planning P20 grants and June 2, 2003 for center P50 grants. For further information, see <http://www.genome.gov/Grants/>. . . . **JAMES P. WILMOT CANCER CENTER** appointed two hematologists to its lymphoma program. **Steven Bernstein**, of Roswell Park Cancer Institute, was named associate professor of hematology/oncology. **Jonathan Friedberg**, of the Dana-Farber Cancer Institute, was named to the staff of the center. **Gordon Phillips II** was named director of the Blood and Marrow Transplant and Leukemia Program at the Wilmot Cancer Center. He

was director of the Blood and Marrow Transplant Program at the University of Maryland Greenebaum Cancer Center. His research interests include stem cell transplantation, including nonmyeloablative transplants and alternative donors for allogeneic transplants. **Richard Fisher**, director of the Wilmot center, has announced a plan to boost research and clinical programs and build national prominence for the center. He plans to recruit 15-20 oncologists who will help handle the growing volume of patients and expand translational research. . . . **KIDNEY & UROLOGY FOUNDATION OF AMERICA** has awarded a total of \$1.4 million for seven research and fourteen clinical fellowships for 2002-2003. The 21 renewable grants, for \$30,000 each, cover a range of research from functional genomics of diabetic nephropathy to the correlation between depression and urinary incontinence. . . . **ROSWELL PARK CANCER INSTITUTE** appointed **James Kepner** chairman of clinical biostatistics. Kepner was associate professor and principal investigator at the Children's Oncology Group, Research Data Center. **Joyce Yasko** was appointed director of clinical research services at RPCI. Yasko was associate director of the Clinical and Network Programs at the University of Pittsburgh Cancer Institute. RPCI also appointed two physicians to its staff. **Petr Starostik** was named chief of molecular diagnostics in the Department of Pathology and Laboratory Medicine. He was director of the Molecular Diagnostic laboratory at Wuerzburg University. **Gary Yang** was appointed attending physician in the Department of Radiation Medicine. He was a fellow at the Johns Hopkins Oncology Center. . . . **JOSEPH GOLDSTEIN** has been elected a trustee of the Howard Hughes Medical Institute. Goldstein, chairman of the Department of Molecular Genetics at the University of Texas Southwestern Medical Center at Dallas, served on the HHMI medical advisory board from 1985 until his appointment as chairman in 1995. **Craig Thompson** has been named to succeed Goldstein as chairman of the medical advisory board. Thompson, a cancer biologist and former Hughes investigator, is scientific director of the Abramson Family Cancer Research Institute at the University of Pennsylvania. . . . **CORRECTION:** In the Sept. 6 issue, **Karen Graham's** service with the Oncology Nursing Society was incorrectly reported. Graham will serve as a member of the ONS consumer advisory panel. She is not president of ONS. **Judy Lundgren** is the current ONS president.



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, email: kirsten@cancerletter.com

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

