

THE

CANCER LETTER INTERACTIVE

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

Vol. 28 No. 27
July 5, 2002

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

Investigators Plan To Interview DeVita, Mendelsohn On C225 Development

Broadening an inquiry into ImClone Systems Inc., Congressional investigators are preparing to interview members of the company's board of directors to establish the extent of their involvement in drug development and corporate governance.

"Clearly, the board of directors has a wealth of knowledge when it comes to medical issues," said Ken Johnson, a spokesman for the House Committee on Commerce. "We want to know why this wealth of knowledge was not used in a common sense sort of way."

The company's 10-member board includes three prominent cancer experts:

—John Mendelsohn, director of M.D. Anderson Cancer Center, who
(Continued to page 2)

In Brief:

Bennett, Turner & Coleman Law Firm Merges With Ropes & Gray To Expand FDA Practice

BENNETT, TURNER & COLEMAN, a Washington, DC, firm with a legal practice in food and drug law, health care policy, and regulation and legislative representation, has merged with Ropes & Gray, a national firm with 470 lawyers. With the addition of Bennett, Turner & Coleman's 11 lawyers, the merger brings Ropes & Gray's Washington presence to 44 lawyers. Bennett, Turner & Coleman has one of the largest practices in the country representing research-based pharmaceutical and biologics companies with respect to FDA and related issues, Ropes & Gray said in a statement. It also has established a distinctive niche in Washington in its representation of patient advocacy groups and other non-profit organizations on matters of health policy. "By merging into Ropes & Gray, we will be able to significantly expand the services available to our clients, and among other advantages, we will be one of the only firms with the capacity to provide the combination of sophisticated FDA and patent prosecution and opinion services," said **Alan Bennett**, of BTC. "In addition, we will now be able to provide our clients with an enhanced array of litigation and alternative dispute resolution services." **Douglass Ellis Jr.**, managing partner of Ropes & Gray, said, "The joining of our firms is part of our strategy to grow our health and life sciences practices in DC and across the firm, and to further enhance our representation to pharmaceutical and biotechnology companies nationwide." Ropes & Gray has offices in Boston, Washington, New York, and San Francisco. . . .

(Continued to page 8)

ImClone Investigation:
ImClone Paid DeVita,
Mendelsohn, Fees
For Consulting
... Page 2

House Members Urge
FDA To Review
Fast Track Policies
... Page 4

NCI Programs:
Advisors Approve
Concepts For Three
New Grant Programs
... Page 5

Funding Opportunities:
RFA, PA Available
... Page 7



Committee Seeks Interviews With ImClone Board Members

(Continued from page 1)

initiated preclinical work with C225 and joined the board in 1998.

—Vincent DeVita, director of Yale Cancer Center and former NCI director, who is regarded as an expert in clinical trials and who joined the board in 1992.

—Arnold Levine, a cancer biologist and former president of Rockefeller University, who joined the board in 2000.

Relying on an outside expert, the staff of the Subcommittee on Oversight and Investigations has analyzed records related to ImClone's development of the monoclonal antibody C225, finding that the development program was fundamentally flawed (**The Cancer Letter**, June 21).

Johnson said the investigators had a long list of questions for the board members.

"We want to know what the board members knew about the stock sales by the family," Johnson said, referring to sales of stock by ImClone's founders and top executives Samuel Waksal and his brother Harlan Waksal.

"We also want to talk with them about corporate governance and board responsibility," Johnson said. The committee plans to talk with Mendelsohn, DeVita, and three other board members. Sources said

the committee has no plans to interview Levine.

Samuel Waksal resigned as president and CEO of ImClone in May, and was subsequently charged with criminal conspiracy, securities fraud, and perjury. Waksal also faces civil charges brought by the Securities and Exchange Commission (**The Cancer Letter**, June 14).

The company, which is now run by Harlan Waksal, was notified by SEC that the commission staff plans to file charges against it. The "Wells Notice" stems from ImClone's statements following receipt of a "refusal to file" letter from FDA Dec. 28, 2001.

As the committee announced its next move, the company said to *The Wall Street Journal* that it has changed its corporate governance, cutting compensation for board members, and eliminating their business and consulting arrangements with the company.

This meant eliminating ImClone's \$100,000-a-year consulting arrangement with DeVita and a \$12,000-a-year arrangement with Mendelsohn.

DeVita and Mendelsohn are the only board members who have such consulting agreements. The agreements have been in place since 1999, company filings show. According to the filings, DeVita did not receive compensation as a board member while he provided "scientific consulting services" to the company.

In the past, board members were paid \$10,000 a year plus stock options. Now, the pay is \$30,000, with no stock options.

Also, the company said to the *Journal* that it has terminated its money management contract with Concord International Holdings, a limited partnership where ImClone board chairman Robert Goldhammer is a partner. Last year, ImClone paid Concord over \$370,000 in fees.

Board members of publicly traded companies have the fiduciary responsibility to protect the interests of shareholders, and side business dealings with the company are usually considered inappropriate.

Being a board member at ImClone was an unusually lucrative deal, especially when the company completed its \$2 billion transaction with Bristol. The structure of the deal was unprecedented in biotechnology, committee investigators say.

Instead of using a standard tender offer procedure that would have given Bristol's money to ImClone, the companies hammered out a deal where Bristol bought stock from existing shareholders.

THE CANCER LETTER
Member, Newsletter and Electronic Publishers Association
World Wide Web: <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 written permission of the publisher. Violators risk criminal penalties and damages. Founded Dec. 21, 1973, by Jerry D. Boyd



According to a calculation by Congressional investigators, board members ended up with about 15 percent of Bristol's \$1 billion investment.

"A number of experts in the financial and biotech areas told committee staff that there is no precedent in pharmaceutical-biotech alliances for the BMS and ImClone deal, which resulted in the immediate personal enrichment of top executives through a tender offer to existing shareholders," the committee investigation report states. "The more typical alliance formed between a major pharmaceutical company and a small biotech firm is centered on milestone payments that provide much-needed cash to the biotech firm."

According to disclosures of trades by board members, at the time the Bristol transaction was completed, Samuel Waksal's take was highest: \$57 million. Harlan took home \$54.4 million, Goldhammer \$25.5 million, and Mendelsohn \$6.3 million. Levine's stock proceeds were \$93,000, and DeVita's \$9,000.

The insiders' take was enhanced through loan arrangements that allowed the Waksals, Goldhammer, and Levine to borrow money from the company to purchase stock options at the time when the deal with Bristol was being negotiated.

The company lent \$18.2 million to Samuel Waksal, \$15.7 million to Harlan Waksal, \$1.2 million to Goldhammer, and \$87,000 to Levine. The loans were made after a deal with Bristol was assured, the committee report said.

At a subcommittee hearing June 13, Waksal said ImClone would no longer lend money to board members.

In public appearances, Mendelson routinely discloses that he holds ImClone stock, sits on the company's board, is not involved in clinical development of C225, and hasn't treated patients with the agent.

In public statements, Mendelsohn does not address the ImClone controversy. He has been supportive of Samuel Waksal, and during his Karnofsky lecture at the annual meeting of the American Society of Clinical Oncology, he acknowledged the contributions of Harlan Waksal, the ImClone official responsible for disastrous clinical development of the agent.

Mendelsohn serves on Bristol's physician advisory board. Until recently, he also served on the audit committee of the Enron Corp. board of directors.

DeVita has not been as consistent as Mendelsohn in disclosing his involvement with

ImClone.

Last summer, as Bristol and ImClone were negotiating the deal, DeVita discussed in television and radio appearances his views on therapies that target EGF receptors and FDA policies for approval of such therapies. He did not disclose his connections with a publicly-traded company that was seeking approval of such a therapy.

FDA is "encrusted" in its approach to evaluation of new therapies, DeVita said on the Charlie Rose television show May 30, 2001. However, the agency has demonstrated its ability to adapt to new approaches to drug evaluation, approving the Novartis drug Gleevec in record time, DeVita said.

"They have to change their procedures as they go along," DeVita said. "I think they originally didn't intend to approve Gleevec that soon, but it became so apparent to everybody around the country that they should, that they responded appropriately and did approve it... So they learned, and it gave them an opportunity to see what they can do with Gleevec, and I think it will spill over to other drugs."

A day later, on Ira Flatow's Talk of the Nation/Science Friday show on National Public Radio, DeVita discussed the potential merits of agents that target the EGF receptors.

"There's a receptor called the EGF receptor, which is being targeted now as a therapy with some antibodies that are expressed very, very vigorously by the liver," DeVita said. "And yet, when you give the antibody to the people, they have no side effects. So it looks like the normal cells are able to compensate much better than a cancer cell. A cancer cell is vulnerable by having so much activity that it's killed more readily. So even when they are not as specific as Gleevec, they tend to work much better in cancer cells than they do—harm normal cells."

Asked by Flatow whether scientists doing research for private companies are contributing to hyping drugs, DeVita said hype stems from other sources: misunderstandings on the part of the press.

"I don't think most people I see saying these things in the press [are] doing that for purposes of driving up the stock," DeVita said.

"However, I do think there is hype, and we all worry about it... There is a difference between proof of principle in a human being... and proof of principle in an animal model. And sometimes the press doesn't draw a distinction. So somebody does something that's glorious in mouse and say this is going to be glorious for humans—there is not a one-to-one



relationship between a mouse and a human. And so I sometimes think the hype comes from not sorting the two out.”

Two weeks later, a Newsday reporter asked DeVita why he didn’t mention his role with ImClone. “I thought about saying something, and I should have said something,” DeVita said to Reg Gale, the reporter. “There just didn’t seem to be an appropriate moment to make that kind of comment.”

Jerome Groopman, chief of experimental medicine at Beth Israel Medical Center, and a professor at Harvard whose article in The New Yorker issue of June 4, 2001, was the subject of the two shows, said medical experts should err on the side of disclosure.

People who hear pronouncements by top experts “make... medical and financial judgments based on those statements,” Groopman said to Newsday at the time. “They’re opinion leaders, that’s the phrase, right?”

At the time of his appearances on Chalie Rose and Science Friday, DeVita was completing his work as co-chairman of the National Cancer Legislation Advisory Committee, a controversial group funded by the American Cancer Society to prepare legislation to overhaul cancer policymaking in the U.S. The group’s goals included significant changes in the process of approval of cancer drugs.

Just before the advisory group completed its work, DeVita and co-chairman John Seffrin, who also serves as the ACS chief executive, made an unsuccessful effort to recommend creation of a White House commission to “set government-wide goals” and “review and comment on cancer budgets of cancer programs.” The commission was to have been headed by a Cancer Czar, a post similar to the Drug Czar (**The Cancer Letter**, June 1, 2001).

Ultimately, the DeVita-Seffrin group’s recommendations for FDA reform were based on the erroneous premise that FDA requires new oncology drugs to demonstrate improvement in survival (**The Cancer Letter**, Sept. 28, 2001). In reality, the agency requires that new therapies demonstrate *a benefit to the patient*, which is interpreted to include pain relief, tumor shrinkage, delays in time to progression, and an improvement in the quality of life.

The DeVita-Seffrin committee recommendations on FDA reform were not reflected in the legislation introduced by Sen. Dianne Feinstein (D-CA), who convened the committee. The bill, S. 1976, which was intended to replace the National Cancer Act of 1971,

was introduced last February and remains in the Senate Committee on Health, Education, Labor, and Pensions.

Materials related to the Congressional investigation of ImClone are available at: <http://energycommerce.house.gov/107/hearings/06132002Hearing587/hearing.htm>

House Members Urge FDA To Review Fast Track Policies

In a letter to acting FDA deputy commissioner Lester Crawford, members of the House Committee on Energy and Commerce urged the agency to develop a uniform policy for its Fast Track drug approval process.

The letter, dated June 27, was signed by committee chairman Billy Tauzin (R-LA), ranking member John Dingell (D-MI) and other committee members. The letter states that the hearing June 13 revealed significant differences in the evaluation procedures for cancer drugs and biologics.

The text of the letter follows:

On June 13, the Subcommittee on Oversight and Investigations held a hearing concerning the events surrounding the accelerated-approval submission to, and the refusal-to-file decision by, the FDA in response to the Biologics Licensing Application of Erbitux [C225], a monoclonal antibody biologic developed by ImClone Systems for third-line treatment of colorectal cancer.

In so doing, this Committee examined the drug approval process at FDA’s Center for Biologics Evaluation and Research.

While the evidence presented in the hearing record supports the justification for FDA’s action in refusing to file the BLA for Erbitux, the hearing also showed that the fast-track process in CBER needed improvement. Further, the subcommittee learned from the testimony of Dr. Richard Pazdur, the Director of the Division of Oncology Drug Products at the Center for Drug Evaluation and Research, that there appears to be a different and better approach to the expedited review of cancer drugs at CDER.

There are differences between small molecule drugs and biologics that require different expertise in the review process. FDA, however, uses the same advisory committee to advise the agency about clinical efficacy data for both cancer drugs and biologics, including the data submitted in abbreviated reviews designed to get promising compounds to market



quickly when there is an unmet medical need for a life-threatening or otherwise serious illness.

Therefore, as FDA strives for a consistent efficacy standard between cancer drugs and biologics, we believe there should be a consistent approach to facilitating expedited reviews of cancer drugs and biologics.

Using Special Protocol Assessments for the design of the registration study or studies makes sense, yet has only been employed once by CBER. The design of a well-controlled study agreed to by the sponsor and the agency in advance of the conduct of a pivotal trial appears to be particularly important when the study employs surrogate endpoints and/or is done in a very small population. Both of these limitations characterized the studies at the heart of the expedited approval, fast-track submission by ImClone.

Funds have been provided under PDUFA III for management review aimed at, among other goals, coordination of the review processes at CBER and CDER. It would appear that instituting common “best practices” procedures for drugs slated for accelerated approval, at least in the area of protocols for clinical studies and evaluation of the clinical data flowing there from, for cancer drugs and perhaps other vital medications could and should be done without extensive study or delay.

It is important that we understand what, if any, obstacles prevent the implementation of the common-sense use of Special Protocol Assessments approach to protocol development and clinical review in CBER.

Accordingly, we request that center directors Janet Woodcock and Kathryn Zoon, together with such supporting personnel as they may need, meet with committee staff to discuss the administrative steps that the centers are prepared to take to assure that protocols of registration studies are properly designed and that the presentation format and content requirements are clear to sponsors and consistent among centers (including CDRH for combination products that have a device component).

Dr. Pazdur’s testimony also showed there are different approaches between CDER and CBER relating to the communications with sponsors about refusal-to-file letters or other negative decisions. We also request that the center directors discuss the merits of instituting a best practice procedure regarding communications with sponsors. It appears that early and frequent communications with sponsors result in better decision-making at FDA.

The committee must also evaluate what, if any, legislation might be necessary or helpful in promoting coordination of the centers to assure that innovative therapies for unmet medical needs reach desperate patients quickly. Hence, it is important that directors Woodcock and Zoon be prepared to discuss all aspects of the accelerated approval process.

NCI Programs: **Advisors Approve Concepts For Three New Grant Programs**

The NCI Board of Scientific Advisors approved the Institute’s plan to spend \$25 million over the next five years to fund the development of integrated aging and cancer research programs at NCI-designated cancer centers.

The board also approved concepts for an institutional pre-doctoral research training award that would bring students to the NCI Intramural Research Program, and for studies to determine how diet and dietary factors impact DNA methylation processes involved with cancer prevention.

The board’s actions took place at its June 24 meeting.

Following are excerpts of the concept statements for the new grant programs:

Integrating Aging and Cancer Research in NCI Cancer Centers. Concept for a new RFA, first-year set-aside \$5 million, length of award 5 years, estimated total cost \$25 million for five awards. Program director: Patricia McCormick, Office of Centers, Training and Resources.

The purpose of this RFA concept is to promote the development of interdisciplinary programs (or other equally effective models) in NCI-designated cancer centers to conduct and build a competitive research base in collaborative and translational research at the aging/cancer interface.

Mobilizing cancer centers to conduct research on cancer in older persons is a strategy that has the most potential to result in real progress. The requirement of NCI-designated cancer centers to take advantage of all of the potential resources of the institution and their unique infrastructure and experience in integrating diverse scientific disciplines make them ideal research settings for meeting the challenges inherent in research on cancer in older persons. NCI-designated cancer centers have proven track records of creating interdisciplinary programs



that meet the current needs of scientific inquiry. Organized research structures in cancer centers will bring together basic scientists, gerontologists, oncologists, nurses, social support personnel, and other health professionals and promote collaborative and translational research at the aging and cancer interface. Many institutions already harbor NIA aging research centers and NCI cancer centers, but the scientists frequently are not being integrated optimally. We have every reason to believe that the interdisciplinary enrichment offered by cancer center institutions and cancer center consortiums can achieve these goals and objectives, effectively breaking down past barriers to progress.

All NCI-designated cancer centers would be eligible to apply for planning grants or P20s to establish interdisciplinary research programs as defined in the Cancer Center Support Grant (P30) Guidelines or develop new models for creating a lasting, effective, interdisciplinary effort in the cancer center. Funds could be used to support program leaders and/or co-leaders; retreats and other means of creating cross-disciplinary dialogue; recruitments to strengthen interdisciplinary capability; and pilot projects to generate the preliminary data necessary for building a comprehensive research base.

Planning efforts would be required to focus on two or more of the following areas: 1) biology of aging and cancer; 2) treatment efficacy and tolerance; and 3) effects of comorbidity on cancer.

Applicants would be allowed to apply for up to \$500,000 in direct costs (estimated \$750,000 total costs) for up to five years. Approximately five P20s are expected to be competitive based on the known scientific composition of institutions that currently are NCI-designated cancer centers. Estimated total costs in the first year would be \$5 million, with \$2 million from NIA and \$3 million from NCI. Total costs for the five-year period of this initiative would be \$25 million (\$10 million from NIA and \$15 million from NCI).

The P20 grants would not be renewable as they are expected to generate a competitive research base for the cancer center program and the program is expected to become part of the Cancer Center Support Grant in the future. All P20s will receive an interim peer review for progress at the end of three years based on the goals, objectives, and timetables established by the cancer center; continued funding for the last two years will be contingent upon achieving credible progress.

NCI Institutional Pre-doctoral Research Training Partnership Award. Concept for a new RFA (cooperative agreements), first-year set-aside \$1 million, length of award 5 years, estimated total cost \$3 million for five awards. Program director: Lester Gorelick, Office of Centers, Training and Resources.

The purpose of this RFA concept is to encourage the development of new pre-doctoral training programs that are partnerships between extramural institutions and specific components of the NCI Intramural Research Program (IRP). Specific components in the Division of Cancer Epidemiology and Genetics and the Center for Cancer Research were selected because they represent unique research strengths of NCI and are nationally recognized as areas of high priority for training. Participation in this initiative is anticipated to expand opportunities for students and faculty at the respective institutions, to provide greater access of the extramural community to unique aspects of the NCI IRP and to result in important new scientific collaborations between extramural and intramural scientists.

The TU2 cooperative agreement funding mechanisms will operate according to the policies of the National Research Service awards and will support didactic, research training, travel and other program expenses while graduate students are at the extramural institution (one to three years). Cancer Research Training Awards will be used to support predoctoral candidates for their research training while at NCI (two to four years). The total project period may not exceed five years, and total support (NRSA plus CRTA) for an individual trainee may not exceed five years. Only domestic, non-for-profit public or private universities or academic institutions that offer the Ph.D. and/or equivalent health professional degrees may apply for grants to support this research training. Candidates must satisfy all eligibility requirements for an NRSA award, including requirements related to U.S. citizenship. Candidates must satisfy all eligibility requirements for an NRSA award, including requirements related to U.S. citizenship.

Applications will be accepted by the extramural NCI Cancer Training Branch only in the following areas of research training:

- Division of Cancer Epidemiology and Genetics:
 - Environmental, occupational, nutritional, radiation, viral, genetic, and molecular epidemiology.
 - Biostatistics and methodological research.



Center for Cancer Research:

—Chemistry, bioinformatics, and computational biology.

NCI will commit \$3 million or less in extramural funds (approximately \$1 million per year) to support the training and training-related expenses of 16 predocs per year (six to be aligned with DCEG and 10 to be aligned with CRC) in the extramural phase for up to three years. Existing CRTAs will be used to support the training and related expenses of up to 16 candidates in the intramural phase for up to three years.

Support in the extramural phase will be provided for stipends; tuition, health insurance and fees; supplies (at the extramural position); travel of trainees, including attendance at scientific meetings; and training-related expenses not to exceed \$20,000 per candidate. Support also will be provided for travel costs for Steering Committee members and for purposes of advertising the new training programs nationally.

Due to the small number of trainees proposed for this pilot phase of the program and the need for a minimum critical mass of trainees for a training program, the maximum possible number of grant awards would be two for partnerships with DCEG and three for partnerships with CCR.

DNA Methylation, Diet and Cancer Prevention. Concept for a new RFA, first-year set-aside \$2.5 million, length of award 4 years, estimated total cost \$10.3 million for seven to 10 awards. Program director: Sharon Ross, Division of Cancer Prevention, Nutritional Science Research Group.

The purpose of this RFA concept is to invite applications for grants proposing innovative, preclinical, and clinical research to determine how diet and dietary factors impact DNA methylation processes involved with cancer prevention. Although evidence exists that dietary components are linked to cancer, the specific nutrients and site of action remains elusive.

The focus of this concept is to link phenotypic changes to epigenetic alterations induced by specific essential and non-essential nutrients. The resulting information will be critical for optimizing effective dietary intervention strategies for cancer prevention. Investigators may choose from the full range of clinical and preclinical approaches. The focus should be on how individual dietary components influence DNA methylation and how this correlates with

phenotypic change. A variety of technologies to assess DNA methylation sequences may be utilized. These can be broadly classified into techniques that measure the overall content or distribution patterns of 5-methylcytosine (i.e., methylated CpG island amplification, methylation-sensitive restriction fingerprinting, differential methylation hybridization, and Restriction Landmark Genomic Scanning) and those that examine known gene sequences (i.e., methylation-sensitive single nucleotide primer extension, and combined bisulfite restriction analysis). The use of genetically engineered animal models including transgenic or gene knockouts are appropriate. The efficient utilization of molecular resources such as gene databases and bioinformatics may also be used to expedite identification of gene-specific methylation targets.

Very little information currently exists about gene-specific changes in DNA methylation as influenced by bioactive food components, as well as how such changes impact cell vulnerability in cancer development or cell responsiveness to cancer prevention. This concept is aimed at encouraging innovative research leading to the elucidation of mechanisms by which dietary factors influence DNA methylation processes as well as increasing our understanding of these processes in cancer prevention. At this point very little information exists to adequately evaluate the specificity of individual nutrients, the impact of intakes/exposures, and any acclimation with time and/or tissue specificity.

Funding Opportunities:

RFA Available

Mouse Models of Human Cancers Consortium (U01)

The objective is to maintain the MMHCC, which was initiated by NCI in 1999. The intent for the next phase of the consortium is to promote technologic innovation to derive models that reflect human cancers with increased fidelity; to encourage substantial in-depth characterization of existing and new mouse cancer models for comparison to human diseases; to exploit mouse cancer models for a greater range of translational applications; and to attract additional research disciplines to the Consortium to leverage significant advances in bioinformatics, chemistry, other areas of human research, and systems biology and modeling.

U01 grants and NIH Intramural Projects will



support the continuation of the MMHCC, a cooperative group designed to advance innovation in mouse cancer modeling, credentialing, and translational application. In addition, the MMHCC will continue to collaborate with NCI to implement and sustain research infrastructure that enables mouse cancer model research and testing, and access to existing models. NCI anticipates that augmenting the mouse modeling expertise of the MMHCC with a broader base of perspectives in the future will enable the Consortium to design and generate additional mouse cancer models and modeling strategies, employ existing methods and invent new ones to characterize the models more thoroughly for cross-comparisons to human cancer, and substantially expand the repertoire of approaches to apply them to the diverse aspects of human cancer research. The RFA is available at <http://deainfo.nci.nih.gov/concepts/CA-03-014.htm>.

Inquiries: Cheryl Marks, Division of Cancer Biology, NCI, phone 301-594-8778; e-mail cm74v@nih.gov

Program Announcements

PA-02-116: Age-Related Prostate Growth: Biologic Mechanisms (R01 and R21)

National Institute on Aging, NCI, National Institute of Diabetes and Digestive and Kidney Diseases, and National Institute of Environmental Health Sciences invite research applications addressing biologic mechanisms related to aging processes that underlie the initiation and progression of prostate growth processes in middle-age, and the pathophysiologic connections of that growth process with the prostate diseases prevalent in older men, benign prostatic hypertrophy and prostate cancer. NCI has a special interest in receiving applications that address the role of aging tissue microenvironment (stromal cells) in prostate carcinogenesis and/or progression. Examples include 1. studies that focus on tumor cell-stroma interactions in prostate cancer and in progression and metastasis, 2. the role of aging host stroma and the extracellular matrix, and growth factors in the acquisition of androgen independent prostate cancer and in organ specific metastasis, and 3. the cooperation among oncogenes, tumor suppressor genes and growth factors and their interactions with prostatic stromal cells during carcinogenesis and tumor progression. The PA will use the NIH R01 and R21 award mechanisms. The PA is available at <http://grants1.nih.gov/grants/guide/>

pa-files/PA-02-116.html.

Inquiries: Suresh Mohla, Division of Cancer Biology, NCI, 6130 Executive Blvd., Rockville, MD 20892, phone 301-435-1878; fax 301- 480-0864; e-mail mohlas@mail.nih.gov

In Brief:

Univ. of Pennsylvania Renames Center After Major Donors

(Continued from page 1)

UNIVERSITY OF PENNSYLVANIA Cancer Center, an NCI-designated comprehensive cancer center, has been renamed the Abramson Cancer Center of the University of Pennsylvania. The name change was made to honor the generosity and support of Leonard and Madlyn Abramson and their family. In 1997, the Abramsons announced a \$100 million gift to establish The Leonard and Madlyn Abramson Family Cancer Research Institute at the cancer center. "We want to recognize the Abramson family and acknowledge the significant research and clinical accomplishments made possible through their magnificent gift," said **John Glick**, director of the Abramson Cancer Center. . . . **JOHN HOWARD** was named director of the U.S. Centers for Disease Control and Prevention National Institute for Occupational Safety and Health, effective July 15. Howard served as chief of the Division of Occupational Safety and Health in the California Department of Industrial Relations since 1991. He began his career in occupational health as internist in the University of California, Los Angeles School of Medicine Pulmonary Fellowship Program at Cedars-Sinai Medical Center in Los Angeles in 1979. He studied asbestos-exposed shipyard workers and published research findings related to workplace asbestos exposure and occupational lung disease. **Kathleen Rest**, who has served as NIOSH acting director since June 2001, will resume her duties as NIOSH deputy director. . . . **NATIONAL HUMAN GENOME Research Institute** has renamed and redesigned its Web site, www.genome.gov. Information sections include research, health, policy and ethics, educational resources, careers and training and grants. This is the first overhaul of the NHGRI Web site since 1997. . . . **JOSEPH HOGAN**, president and CEO of GE Medical Systems, received the CancerCare Human Services Award recently, for exceptional dedication and leadership for the benefit of people with cancer and their families.



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.

