THE CANCER LETTER

Vol. 32 No. 35
Oct. 6, 2006

NCI Should Toughen Deadlines, Quality, In RAID Program, Advisory Group Says

By Kirsten Boyd Goldberg

An NCI program that helps academic investigators move new compounds into phase I clinical trials should become "tougher" about holding investigators to deadlines, checking the quality of compounds developed, and overseeing the work of contractors, according to a report by an advisory group.

Established seven years ago, NCI's Rapid Access to Intervention Development gives investigators access to the institute's preclinical development resources on a competitive basis. The program has made 28 agents available for clinical trials and filed 24 Investigational New Drug

(Continued to page 2)

Capitol Hill:

Key Cancer Legislation Remains Unfinished; Election Would Shape Lame Duck Session

By Paul Goldberg

As Congress left Washington last week, key legislation shaping this year's cancer agenda—from NCI appropriations, to NIH reauthorization, to reimbursement issues—remained unfinished.

All of this business will have to be settled at the lame duck session following the Nov. 7 election. However, last week's revelations of Florida Republican Rep. Mark Foley's pursuit of teenaged boys have plunged Congressional Republican leadership into a crisis, improving the Democrats' prospects of capturing the House and possibly even the Senate.

If Democrats win either chamber, the new majority would be able to use Senate rules to stop movement of key legislation until new Congress convenes next year, insiders say. Transition of power—which includes ironing out legislative priorities and changing professional committee staffs—would take months.

"When Republicans took control of the House in 1994, it took until May or June for them to organize," said a lobbyist involved in cancer issues. "If Republicans lose control of either house—doesn't have to be both houses—there would be no lame duck session to speak of. They will come into session to pass a continuing resolution to keep funding going until the end of February or the middle of March, letting the new majority organize and take it from there."

The spending bill covering NIH is perhaps the most important piece of

(Continued to page 4)

"Development-Centric" Will Be New RAID Mantra

(Continued from page 1)

applications, at a cost of $12 million a year, on average, the review committee said in its report.

"The track record is less impressive with regard to the actual movement of new agents into clinical trials," the report said. "This may be attributable in part to the short life of the program… but also points up the need to shift the vision from provision of new drugs for clinical exploration to actually entering new drugs into first-in-human clinical trials. This shift in vision was clearly articulated… by NCI senor leadership."

The program should shift from being "investigator-centric" to "investigator-initiated… but also development-centric," according to the review, led by M.D. Anderson President John Mendelsohn.

"NCI should be friendly, supportive, but firm," Mendelsohn said in presenting the report to the National Cancer Advisory Board at its Sept. 7 meeting.

The committee's recommendations include:

—"The criteria for accepting a RAID proposal should include a commitment by the investigator to bring a new anticancer agent into a first-in-human clinical trial, with guidance from the RAID staff or though formal collaboration. The focus needs to be less on the investigator and more on achieving a clinical trial as the endpoint.

—"RAID program oversight committees for small molecules and for biologics should perform more active progress reviews by monitoring milestones and achievement of timelines and interceding with changes in course or with 'no-go' decision when appropriate. Project managers accountable to RAID leaders and the oversight committees should proactively advise the PI on the steps necessary to move forward. Project managers should be empowered to intervene when recommendations from the oversight committees are not followed and oversee the performance of contractors who are paid to carry out specific assignments within the project.

—"Since the technologies for new drug and marker development are becoming complex and since highly qualified leadership and peer review groups are difficult to enlist, the committee strongly endorses the NCI's consideration of pursuing new drug development in its internal and extramural programs within a single oversight and portfolio management structure. Collaboration, sharing of best practices, and prioritization are critical today. Skills and expertise in the leadership and in the review committees of the extramural and intramural programs should be blended whenever this will streamline oversight, improve research quality, and enhance achievement of successful outcomes that provide new therapies for patients with cancer."

An NCI review in 1998 resulted in the separation of extramural and intramural drug development. While this restructuring "produced clarity in the chain of command and enhanced NCI support" for extramural investigators, it "may dilute the efforts and availability of the small cadre of NCI employees with expertise in drug development," the report said.

The projects selected by RAID require the work of "many hundreds of contractors," who are selected through SAIC, which holds the contract to run NCI-Frederick. Staff from RAID and NCI's Division of Cancer Treatment and Diagnosis "appear to have little control over the selection and oversight of the contractor, the speed with which contracts are let, and the quality review of data produced by the contractor," the report said.

The review process, which results in "go/no-go" decisions, has been "relatively lenient up to now, tending to favor additional resources for projects where investigators are enthusiastic about publishing their results and exploring further," the report said. "Some projects ultimately benefited from this, but others remained unpromising in spite of repeated reinvestments."

The committee recommended that separate, two-

THE CANCER LETTER

® The Cancer Letter is a registered trademark.

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.

Subscriptions/Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724
General Information/FAQ: www.cancerletter.com

Subscription $355 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.
Founded Dec. 21, 1973, by Jerry D. Boyd.

tiered review committees be instituted for both small molecules and biologics.

As a result of the review, the extramural DCTD and the intramural Center for Cancer Research signed a memorandum of understanding to develop a clinical target assay laboratory, molecular imaging facilities, and "an enhanced structure for clinical trials at the NIH Clinical Center," the report said.

Also, NCI is developing new laboratories for preclinical molecular toxicology and pharmacodynamic assays for compounds for which NCI holds the INDs. The resources could be used by extramural investigators, the report said.

The review committee also endorsed NCI plan to use the Clinical Center for conducting "phase 0" trials, designed to reduce the requirement for preclinical experiments in animal models.

DCTD Director James Doroshow said RAID has begun to implement the report's recommendations. The two-tiered review process will start this winter, and a project management office has been formed in the division to lead in making and adhering to drug development plans. NCI and FDA are forming a RAID investigator training program.

Also, prospective go/no-go development criteria will be established for each RAID project, he said.

Pharma Wants Proof of Concept

The RAID track record "is not bad," said NCAB member Robert Ingram, vice chairman, pharmaceuticals, GlaxoSmithKline. However, pharmaceutical companies "want to see proof of concept," so just taking a compound into phase I may not be enough to attract interest, he said.

Also, strong leadership of the program is important, Ingram said. "Project management is an art, and you need talented people to do that," he said. "There is a discrepancy in pay schedules [between the] private sector and the public sector. [But] there are a lot of folks out there—pharma has downsized—who have those skills and would welcome the opportunity to really make a difference when it comes to exciting new ideas and new compounds, particularly in cancer."

RAID is a "terrific program," NCAB member Bruce Chabner said. "I think the ultimate measure of the value of this program is not how many things you've put into phase I. It may be the products you've been offered from academia are the products that are least able to get support otherwise, and, therefore, are not the best ideas.

"I'd like to see you think about a pathway for taking these things all the way to approval," said Chabner, clinical director of the Massachusetts General Hospital Cancer Center. "We really need a strategy for taking [a compound] through phase I and into phase II."

RAID is designed to take compounds into phase I, but NCI has other resources to allow it to take compounds into phase II trials, Doroshow said.

"What came out of this [review] was exactly what we wanted," said Anna Barker, NCI deputy director for advanced technologies and strategic partnerships. "What we probably learned was that there is a real culture difference between what's going on in the RAID program and what goes on in our laboratories with investigators who do R01 research. I don't think that, at least when I came here and we looked at where we were with the former manager of RAID, I didn't see our staff empowered to do very much.

"What John [Mendelsohn] and others have done here is told us clearly, if you are going to do development, program managers have to be empowered to stop projects, redirect projects, and they have to be at the table. That's going to happen now," Barker said. "Where we complement pharma is going to be critical. We shouldn't be chasing the same targets, we shouldn't be chasing the same development that pharma's going to be doing."

NCI Director John Niederhuber encouraged the NCAB to form a subcommittee on drug development to help the institute oversee RAID and other programs. He asked Ingram to serve as chairman of the subcommittee.

* * *

Cancer War Board? Niederhuber's drafting of Ingram to lead an NCAB subcommittee on drug development appeared to produce a sudden inspiration on the part of NCAB member Donald Coffey, professor of urology, oncology, pathology, pharmacology, and molecular science at Johns Hopkins University.

Coffey, known for his fiery and colorful comments advocating for funding for cancer research, said that even he was overcome by his idea: "What I'm getting ready to say is of such magnitude, I don't even know how to say it," he said.

The room erupted in laughter.

"I was wondering if you might consider charging [Ingram] with a bigger issue, and that is to take a quick first look at whether we need a National Cancer Board like the War Board," Coffey said.

He went on to explain:

"So, I hear things here at this table, since I've been on this board—which has been only 48 hours—the NCI

talking about the delivery of medical care, reaching out into the community. When I looked up the formation of the NCI, it's about research. This is a great idea, but how do you reach out and deliver this to the community? It's a great big amount of money and a big problem.… At the same time, we have problems with the underserved, and inequalities that have to be corrected, and then we are hearing all these multi-agencies, the FDA, CDC, all these things, then the privacy act, and you could go on all day.

"What I'm saying is, we have to redefine the risk for cancer patients and the privacy for cancer patients, and this looks like a nightmare," Coffey said.

"So, where from the United States and the world, does some group step forward and speak for cancer in a way that is not tainted—oh, there's a bunch of profit-motive people; oh, there's a bunch of researchers?...

"It just seems that we need some special, wise group to look at how we might approach this. Now, at one time, somebody brought up the name 'Cancer Czar' about six years ago, and that set off an explosion in the NCI and elsewhere. So, I would like for somebody to take a bigger look at how we make these major societal issues for cancer, and the NCAB can't do all of that.

"Am I making sense to you, Bob, without being totally crazy? That's a hell of a yoke to hang around your neck."

[Silence.]

NCAB CHAIRMAN CAROLYN RUNOWICZ: "Bob, do you want to comment?"

INGRAM: "Let me just say, I don't think I would be the right person to do that. I think it's important that we think in those terms. Never before have we had a better capability to make a difference, but it's going to take magnitudes of money to get it done. I think your idea of getting a group—it has to be a powerful group. It doesn't have to be a big group, it has to be a powerful group—if you can make that case to the American public."

COFFEY: "I'd hoped on the [National] Dialogue on Cancer, when we had President 41, George [H.W.] Bush there, that we would be able to pull that off. That was not realized, although a lot of good effort was made. It has to be done with some big effort, with a national force behind it."

* * *

THOMAS HOOVEN, NCI deputy director for management for the past nine months, plans to step down from his position and pursue other employment.

"I feel I need to step down in order to give the maximum flexibility for Dr. Niederhuber to bring on his own management team," Hooven wrote in an email to NCI staff members on Sept. 15. "Leadership is a hallmark of NCI, and these positions require the best and brightest minds, as well as a degree of style and interaction that only personal selection can bring."

Hooven was associate director for administration at the National Institute of Child Health and Human Development for six years. Previously, he worked in various positions at NCI as a budget analyst, administrative officer, and management analyst, for seven years.

Capitol Hill:

Conferees Return $4 Billion From Labor-HHS To DOD Bill

(Continued from page 1)

legislation that is now in play.

Earlier this year, Congress subtracted about $4 billion from the defense spending bill, placing this money into the Labor, HHS and Education bill. There, at least a portion of these funds would have been applied to NIH.

However, the administration objected to this transfer, and before recess last week, the House and Senate conferees returned the money to Defense, further cementing this outcome by passing the DOD spending bill.

"This action could squeeze billions from the domestic spending bills if the President resists efforts to lift the cap he imposed on discretionary spending for FY2007," said Jon Retzlaff, director of legislative relations of the Federation of American Societies for Experimental Biology.

Sens. Arlen Specter (R-Penn.) and Tom Harkin (D-Iowa), the chairman and ranking member of the Labor-HHS appropriations subcommittee, are trying to put the money back into the bill, perhaps boosting spending to the FY 2005 level. Rep. Mike Castle (R-Del.), is also involved in this effort.

Under the President's budget proposal, the NIH budget would remain flat at $28.587 billion. The NCI budget would be cut by $40 million, to $4.754 billion. The NCI budget would drop by $72 million from the level of fiscal 2005. The institute's budget will be further reduced by inflation and taps from NIH.

Continuing erosion of support for GOP decreases the likelihood of NIH reauthorization passing during the lame duck session. The reauthorization bill, H.R. 6164, was a priority for Rep. Joe Barton (R-Tex.), chairman of the Committee on Energy and Commerce.

In recent months, Barton secured support from a variety of biomedical research advocacy group and shepherded the legislation to passage by the House. The bill authorizes 5 percent per year increases for NIH through fiscal 2009. Half of these new funds would be going into a "common fund" for research that cuts across boundaries of individual institutes. Under the legislation, the common fund would be capped at 5 percent of the NIH budget.

However, the Senate hasn't introduced a corresponding bill, and insiders expect no movement on the legislation during the lame duck session. NIH hasn't been reauthorized since 1993.

Congress left town without acting on the National Breast Cancer Coalition's Breast Cancer and Environmental Research Act (H.R. 2231, S.757). The Senate bill, unanimously passed by the Health, Education, Labor and Pensions Committee, has 66 cosponsors. However, Sen. Tom Coburn (R-Oklahoma) placed a hold on the legislation, and Barton refused to bring the bill forward for a vote by his committee.

"The women of America and their families are outraged that the House of Representatives and the Senate have chosen to ignore women's demand to find the causes of breast cancer and did not act on this meaningful legislation, which could lead to answers and save women's lives," NBCC president Fran Visco, said in a letter to her group's supporters. "As Members of Congress wear pink ribbons for October breast cancer awareness month, NBCC's campaign will let the country know about Congress' inaction, and will hold its members accountable for failing to do something meaningful. As millions of women and their families prepare to go to the voting booth, they will be reminded that this Congress chose to leave women's health in the dark."

The bill would authorize NIH to fund peer-reviewed grants to collaborative centers to study environmental factors that may be related to breast cancer. Altogether, NIH would spend $30 million per year for fiver years on this research.

The National Coalition for Cancer Survivorship sees an opportunity in the uncertain political situation.

"Recent polls have indicated that many seats in Congress, once thought secure, are actually up for grabs," NCCS wrote in a letter to supporters this week. "Republicans are fighting to maintain their majority while Democrats can almost taste victory. All members of Congress are listening carefully to the wishes of voters as they begin an intense month of campaigning. Cancer advocates now have a terrific chance to press the case for quality cancer care."

NCCS is trying to find cosponsors for the Comprehensive Cancer Care Improvement Act, H.R. 5465, introduced by Reps. Lois Capps (D-Calif.) and Tom Davis (R-Va.) The bill would provide for Medicare to cover cancer care planning that involves patients and care providers working together to coordinate all aspects of care. Also, the bill would provide coverage for management of cancer symptoms and side effects from treatment.

The American Society of Clinical Oncology also supports the bill.

In a letter, ASCO urged its members to contact their legislators about the following measures:

• Addressing the issue of "underwater" drugs: H.R. 5179, introduced by Rep. Ralph Hall (R-Tex.), would give CMS the authority to increase drug payments when practices and institutions cannot obtain drugs for the Medicare payment rate. It would also remove prompt-pay discounts that are not passed on to practices and institutions from the average sales price formula, to better reflect available market prices.

• Delaying the impending imaging cuts: H.R. 5704/ S. 3795, the Access to Medical Imaging Act, introduced by Rep. Joe Pitts (R-PA) in the House and Sen. Gordon Smith (R-Ore.) in the Senate, would delay deep cuts in reimbursement for medical imaging scheduled to go into effect in 2007. If passed, this legislation would protect access to these essential services that enhance patient care while a study is conducted on the potential access issues associated with the cuts.

• Reversing the physician fee schedule cut: CMS is estimating a 5.1% cut to physician payments due to the flawed Sustainable Growth Rate (SGR) formula. ASCO is lobbying Congress to pass legislation to reverse this cut and provide physicians with a positive update.

In Brief:

Kornberg Wins Nobel Prize In Chemistry For RNA Work

ROGER KORNBERG, of the Stanford University School of Medicine, will receive the 2006 Nobel Prize in Chemistry for his studies of how genetic information is transcribed into RNA, which is translated to make proteins. Kornberg's work has been supported by the National Institute of General Medical Sciences, the National Institute of Allergy and Infectious Diseases, and NCI. Over 37 years, NIH provided more than $24 million to support Kornberg's research. "Illnesses like cancer, heart disease, and various other kinds of inflammation

are linked to disturbances in the transcription process," said NIH Director **Elias Zerhouni**. "Understanding this process in more detail may provide researchers with the needed tools to develop new treatments for diseases." Kornberg's father, **Arthur Kornberg**, was also an NIH grantee and shared the 1959 Nobel Prize in medicine for studies of how genetic information is transferred from one DNA molecule to another. The Kornbergs are the eighth parent-child pair to win Nobel Prizes. "I am most pleased that Roger Kornberg has been recognized for his critical contributions to our understanding of the fundamental process of transcription," said NCI Director **John Niederhuber**. "Cancer is a disease of genetic alterations, and Roger's research is essential to the development of a new era of highly targeted cancer therapy." . . . **ANDREW FIRE AND CRAIG MELLO** will receive the 2006 Nobel Prize in Physiology or Medicine for their discovery of RNA interference, a mechanism for silencing genes. Fire, of Stanford University School of Medicine, and Mello, of the University of Massachusetts Medical School, published their findings in 1998. "The unanticipated discovery of a basic biological process that can silence genes took the biomedical research community by storm," said **Jeremy Berg**, director of National Institute of General Medical Sciences, which funded their research for many years. "RNAi is both a powerful tool for studying gene function and a promising approach to treating a host of human diseases, from macular degeneration and cancer to flu and other infections." NIGMS began supporting the work of Fire in 1987 and Mello in 1999 and has provided $8.5 million to support the two scientists. National Institute of Child Health and Human Development also provided more than $3 million toward Mello's research. . . . **2006 ALBERT LASKER AWARD** for Basic Medical Research medical science is shared by **Elizabeth Blackburn** (University of California, San Francisco), **Carol Greider** (Johns Hopkins University School of Medicine) and **Jack Szostak** (Harvard) for the prediction and discovery of telomerase, an RNA-containing enzyme that synthesizes the ends of chromosomes, protecting them and maintaining the integrity of the genome. The 2006 Albert Lasker Special Achievement in Medical Science Award was presented to **Joseph Gall**, of the Carnegie Institution, for his 57-year career as a founder of modern cell biology and the field of chromosome structure and function, his invention of in situ hybridization, and for being an early champion of women in science. The 2006 Albert Lasker Clinical Medical Research Award was presented to Aaron Beck, of University of Pennsylvania, for the development of cognitive therapy, which has transformed the understanding and treatment of many psychiatric conditions, including depression, suicidal behavior, generalized anxiety, panic attacks, and eating disorders. . . . **ASSOCIATION OF AMERICAN CANCER INSTITUTES** will present its Public Service Award to **John Edward Porter** and its Distinguished Service Award to **Margaret Foti** during the association's annual meeting Oct. 22-24, in Chicago. Porter, partner in the law firm Hogan & Hartson, of Washington, D.C., and chairman of the Board of directors for Research!America, was a Democratic U.S. Congressman from Illinois for 21 years and chairman of the Subcommittee on Labor, Health and Human Services, and Education, where he was a strong supporter of increased funding for NIH and NCI. Foti is CEO of the American Association for Cancer Research. . . . **AMERICAN CHEMICAL SOCIETY** recognized three oncology researchers as Heroes of Chemistry for discovering and developing Altima, the first drug approved for malignant pleural mesothelioma: **Homer Pearce**, former vice president of cancer research at Eli Lilly and Co., **Chuan Shih,** a research fellow at the company, and **Edward Taylor,** professor emeritus, Department of Chemistry, at Princeton University. . . . **AMERICAN SOCIETY for Therapeutic Radiology and Oncology** announced election results for positions on its board: President-elect—**Patricia Eifel**, of M.D. Anderson Cancer Center. Education council vice-chairman—**Minesh Mehta**, University of Wisconsin, Madison. Government relations council vice-chairman—**Maria Kelly**, University of Virginia School of Medicine. Also, three employees were promoted and one new appointment made. **Terry Karras Jr**. was named chief financial officer. He was director of finance and administration. **Kathy Thomas** was named senior director of education. She began her career in education at ASTRO in 1991. **Emily Wilson** was named director of government relations. She was government relations representative at ASTRO. **Robyn Watson** was appointed director of research. Watson worked in health services management at Telecare Corp. and Alameda County Employees' Retirement Association of Northern California.

In the Cancer Centers:

MEMORIAL SLOAN-KETTERING Cancer Center has established the Geoffrey Beene Cancer Research Center, with an initial commitment of $44 million from the estate of the fashion designer. The center will support the Cancer Biology and Genetics Program, which is based in the Sloan-Kettering Institute,

and the Human Oncology and Pathogenesis Program, based in Memorial Hospital. When fully in place, the Geoffrey Beene Cancer Research Center will fund a range of activities, including endowed senior and junior chairs, graduate fellowships, core research labs, and a lectureship, in addition to providing substantial direct support for research. Work supported through the center will be housed in the new Mortimer B. Zuckerman Research Building, a 23-story research facility that doubles the size of the MSK research enterprise. **MSKCC** announced the following awards and appointments. **Dennis Dowdell Jr.**, was named vice president for human resources. He comes from The Executive Leadership Council of Washington, D.C. **Michael La Quaglia**, chief of the pediatric surgical service, was elected chairman of the surgical executive committee of the Children's Oncology Group. **Peter Smith-Jones** of the nuclear medicine service received the Society of Nuclear Medicine 2006 Berson-Yalow Award for significant contributions to basic/clinical radioassay. . . **SEATTLE CANCER Care Alliance** announced development of SCCA Proton Therapy Center, a state-of-the-art facility that makes radiation treatment available in Washington, Oregon, Idaho, Alaska, Montana and Wyoming, said **Fred Appelbaum**, executive director and president of SCCA. Only four proton-therapy centers are operating in the U.S., the nearest in southern California. "Proton beams deliver precise doses of charged particles to tumors, thereby minimizing damage to surrounding healthy tissue and are used today to treat many solid-tumor cancers such as those of the eye, skull base, head and neck, and prostate," said **George Laramore**, chairman of the Department of Radiation Oncology, University of Washington. "The potential exists to treat many more types of tumors, including those of the lung, breast and abdomen," he said. The center continues a partnership between members of the Seattle Cancer Care Alliance: Fred Hutchinson Cancer Research Center, Children's Hospital & Regional Medical Center, and UW Medicine. The center will begin accepting patients in 2010. . . . **INDIANA UNIVERSITY Cancer Center** has established the Indiana University Cancer Center Translational Research Acceleration Collaboration, or ITRAC. The initiative would use a portfolio management methodology to target and accelerate high potential research, which would include: roadmaps to inventory and map research activity toward increasing patient diagnosis, treatment and care; metrics to evaluate, prioritize and determine support for research activity; inventory of assets to better leverage resources, build capacity and determine strategic partnerships; governance to provide oversight, strategic direction, scientific review and mentorship; and project management to facilitate ITRAC application, said **Mark Kelley**, associate director of research who engineered and began the ITRAC model. **Mary Murray** is the project manager. . . . **RICHARD GOLDBERG**, associate director of clinical research for the University of North Carolina Lineberger Comprehensive Cancer Center, was named physician-in-chief of the North Carolina Cancer Hospital, a facility of UNC Health Care. Goldberg will lead the continued development of an integrated, comprehensive system for cancer care, translational research, multidisciplinary patient care, and educational opportunities. He is chairman of the gastrointestinal cancer committee for the Cancer and Leukemia Group B cooperative group, professor of medicine and chief of the division of hematology and oncology in department of medicine at UNC. . . . **ROBERT FIGLIN** was named chairman of the Division of Medical Oncology and Experimental Therapeutics and associate director for clinical research at City of Hope. Figlin is the Henry Alvin and Carrie L. Meinhardt Chair in Urologic Oncology and professor of medicine and urology, at the David Geffen School of Medicine at the University of California, Los Angeles.

Funding Opportunities:

Komen Offers $13 Million For Focused Areas of Study

Susan G. Komen Breast Cancer Foundation announced the availability of $13 million in grants for its new Focused Areas of Study Grant Program. Research proposals are being accepted in four specific areas of breast cancer:

Ductal Carcinoma in Situ—Applications are being accepted for basic, clinical and translational research initiatives that examine DCIS initiation, progression, and invasion, as well as underlying biological processes for each. Proposals ranging from $300,000 to $1.5 million for a funding period of two to three years will be considered.

Experimental Model Systems. Proposals in this category should catalyze the development and refinement of laboratory methods that are surrogates of human biology. Funding may be granted to proposals of merit for the development of tools that facilitate the testing and generation of hypotheses that advance the understanding of breast cancer initiation, growth, progression or metastasis. Proposals ranging from $300,000 to $1.5 million for a funding period of two to three years will be considered. Proposals involving mouse models will not be considered for funding through the Focused Area Program, but should be directed to the Komen Foundation Research Grant Program.

Biomarker Identification and Validation. Proposals

should demonstrate the potential to catalyze the next generation of breakthroughs in the understanding of breast cancer causation, progression, metastatic and recurrent disease. A biomarker is defined by the foundation as any measurable biological characteristic having high fidelity relevance to breast biology and/or physiology as it applies to normal or cancer biology. Priority will be given to applicants addressing key challenges or barriers pertaining to the validation of breast cancer biomarkers. Proposals will be accepted ranging from $300,000 to $3 million for a funding period of two to three years.

Environmental Research Methods. Proposals should address current environmental research challenges in laboratory or clinical settings relevant to breast cancer. Preference may be given to proposals that address specific challenges pertaining to research methodology, measurement standards and assessment instruments, research focusing on mammary-specific models, or projects demonstrating potential to enhance clinical application or utility. Proposals will be accepted ranging from $300,000 to $5 million for a two- to five-year period.

Inquiries: Chandini Portteus, 972-855-4393; grant applications: http://www.komen.org/focusedgrants.

NIH Loan Repayment Programs

NIH offers to repay up to $35,000 annually of the qualified educational debt of health professionals in biomedical and behavioral research. The programs also provide coverage for Federal and state tax liabilities.

The five LRPs offered include the Clinical Research LRP, Clinical Research LRP for Individuals from Disadvantaged Backgrounds, Contraception and Infertility Research LRP, Health Disparities Research LRP, and Pediatric Research LRP.

Application Deadline: Dec. 1. For information and applications: www.lrp.nih.gov.

RFAs Available

RFA-ES-06-008: Manufactured Nanomaterials: Physico-chemical Principles of Biocompatibility and Toxicity. R01. Letters of Intent Receipt Date: Dec. 13, Application Receipt Date: Jan.12. Full text: http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-06-008.html. Inquiries: Sally Tinkle, 919-541-5327; tinkle@niehs.nih.gov.

RFA-CA-07-032: Improved Measures of Diet and Physical Activity for the Genes and Environment Initiative. U01. Letters of Intent Receipt Date: Dec. 11; Application Receipt Date: Jan. 11.Full text: http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-032.html. Inquiries: Amy Subar, 301-594-0831; subara@mail.nih.gov.

Distribution Policy for The Cancer Letter

Thank you for your purchase of this issue of The Cancer Letter! Because issue and subscription sales are our major source of revenue, we wouldn't be able to provide you with the information contained in this newsletter without your support. If you have any questions or comments about the articles, please contact the editors (see page 2 of your issue for contact information).

We welcome your use of the newsletter and encourage you to send articles once in a while to colleagues. But please don't engage in routine distribution of The Cancer Letter to the same people week after week, unless your organization has purchased a site license or group subscription. If you aren't sure, ask the person who is paying for this subscription. If you are sending the newsletter to an unauthorized list, please stop; your actions are against Federal law. If you received this newsletter under an unauthorized arrangement, know that you are in receipt of stolen goods. Please do the right thing and purchase your own subscription.

If you would like to report illegal distribution within your company or institution, please collect specific evidence from emails or photocopies and contact us. Your identity will be protected. Our goal would be to seek a fair arrangement with your organization to prevent future illegal distribution.

Please review the following guidelines on distribution of the material in The Cancer Letter to remain in compliance with the U.S. Copyright Act:

What you can do:

- Route a print subscription of the newsletter (original only) or one printout of the PDF version around the office.
- Copy, on an occasional basis, a single article and send it to a colleague.
- Consider purchasing multiple subscriptions. We offer group rates on email subscriptions for two to 20 people.
- For institution-wide distribution or for groups larger than 20, consider purchasing a site license. Contact your librarian or information specialist who can work with us to establish a site license agreement.

What you can't do without prior permission from us:

- Routinely copy and distribute the entire newsletter or even a few pages.
- Republish or repackage the contents of the newsletter in any form.

If you have any questions regarding distribution, please contact us. We welcome the opportunity to speak with you regarding your information needs.

The Cancer Letter
PO Box 9905
Washington DC 20016
Tel: 202-362-1809
www.cancerletter.com