THE CANCER LETTER

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Specter Seeks NCI Explanation Of Delay In P-4 Breast Cancer Prevention Trial

By Kirsten Boyd Goldberg

Sen. Arlen Specter (R-Penn.), asked NCI Director John Niederhuber to explain the delay in starting a large, randomized breast cancer chemoprevention trial.

"It has been two and one half years since the NCI began the review and approval process of this Study and now you have indicated, in a recent interview with the Cancer Letter, 'that it is unlikely that the trial would open this year,'" Specter, ranking member of the Senate Labor, HHS, Education Appropriations Subcommittee and a crucial congressional advocate for NIH, wrote in a letter dated May 8.

Niederhuber has blocked the Pittsburgh-based National Surgical Adjuvant Breast and Bowel Project from starting the Study to Evaluate Letrozole and Raloxifene, also known as P-4. The NCI director has raised questions about the peer review process the proposal went through, and

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In the Cancer Centers:

Druker To Direct OHSU Cancer Institute; Friends Of NLM Honor Bernard Fisher

BRIAN DRUKER, the cancer specialist who helped develop Gleevec, was named director of the Oregon Health & Science University Cancer Institute. After 15 years as the founding director of the OHSU Cancer Institute, **Grover Bagby** is retiring June 30. He will continue to focus on conducting research in his laboratory and on teaching.

"I feel very grateful to the university for its support in allowing me to build this institute, and to the clinicians and scientists who actually did the heavy lifting," Bagby said. "In the hands of my friend Brian Druker, this institute will soon set new standards for cancer centers nationwide."

Druker said he wants to make cancer a statewide priority. "If we work together, we could make Oregon's mortality rate from cancer the lowest in the nation," Druker said. "Let's eliminate the suffering from this disease through better prevention, better screening and research that delivers more effective cancer treatments. Backed by what the OHSU Cancer Institute has accomplished under the directorship of Dr. Bagby, and by reaching out to the community, I know we can reach this goal."

Oregon Gov. **Ted Kulongoski** congratulated both physicians. "Focusing on screening, early intervention and prevention is what we're trying to do

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NSABP Says P-4 Would Cost NCI $54 Million, Take 7 Years

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said the cost of the study might not be worth the result: an answer to the question of which of the two drugs is preferable for reducing the risk of breast cancer in women who are at high risk of developing breast cancer (The Cancer Letter, March 2).

Replying to Specter, Niederhuber wrote that "our goal is to ensure that we are optimizing our investments in breast cancer prevention for the benefit of all women." Chemoprevention studies, "while scientifically enlightening, have failed to change the practice of breast cancer prevention among women and their healthcare providers, perhaps because of the side effects of these drugs," Niederhuber wrote in a letter dated May 21.

Raloxifene is currently being reviewed by FDA for its efficacy in breast cancer prevention, based on data from the NSABP's previous STAR trial. It has been approved in otherwise healthy women for the prevention and treatment of osteoporosis.

NSABP's proposal went through multiple levels of review at NCI, and was approved twice by the NCI Executive Committee, first in 2005 and then earlier this year. Niederhuber cast one of two "nay" votes against the trial at the committee's Jan. 22 meeting. Although that was to have been the final vetting for the proposal, Niederhuber didn't allow the study to begin. Instead, he assigned Deputy Director Anna Barker, who also voted against the study, to form an ad hoc committee to review the trial.

The P-4 committee, formed as a working group under the purview of the National Cancer Advisory Board, met in a closed session March 23. The committee is scheduled to report its findings at a public meeting of the NCAB next month.

"Once I receive the input from the NCAB I will make the determination about how NCI can lead the research that will drive advances in the field of breast cancer prevention for all women," Niederhuber wrote to Specter. "I expect that we will have a resolution of the question of the P-4 study in the near future."

NSABP Official Disputes NCI Cost Estimate

According to Niederhuber's letter to Specter, the P-4 trial would cost "in excess of $100 million," and the trial would take 10 to 13 years. A document prepared by NCI officials and circulated prior to the P-4 committee meeting said the cost to NCI would be about $74 million.

At the March 23 meeting of the P-4 committee, an NSABP official disputed NCI's cost estimates and length of time the study would take, sources said.

Lawrence Wickerham, NSABP associate chairman, said the NCI Special Emphasis Panel that reviewed the study more than a year ago recommended a five-year budget of $66 million. Since then, NSABP found ways to reduce the budget to $54 million over five years, Wickerham told the committee, according to sources.

The NSABP Foundation would pay for collection and storage of tissue and blood for the trial's participants, at a cost of $1 million a year. The sponsors of the drugs, Eli Lilly and Novartis, would provide the drugs at no charge, and Novartis agreed to donate $30 million for recruitment.

Wickerham also noted that last February, the NCAB approved NSABP's grant for its Community Clinical Oncology Program research base, which included five years of funding for the P-4 trial. The grant went through competitive peer review and received a priority score of 131, the highest the cooperative group has ever received.

The study accrual of 12,900 women would take place over four years, and NSABP would be able to analyze the data three years after completion of accrual, Wickerham told the committee.

Wickerham declined to comment for this story.

Last month, NSABP Chairman Norman Wolmark objected to the closed-door meeting that he and members of NCI's Division of Cancer Prevention were not

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allowed to attend. He called it an "aberrant process" that is "delaying activation of this important study" (The Cancer Letter, April 20).

In the Federal Register notice of the meeting, no reason was given for closing the meeting to the public.

The text of Specter's letter follows:

Dear Dr. Niederhuber:

I am writing to inquire about the delay in starting the P-4 breast cancer prevention clinical trial which will examine a drug that could show promise in preventing breast cancers in postmenopausal women.

I understand that the P-4 Study has been extensively reviewed and fully approved by every NCI committee and panel that has considered the Study to date. The Study initially was reviewed and approved by the NCI's Executive Committee in October 2005. In May 2006 the Study was approved by both the NCI Clinical Trials Oversight Committee and a special emphasis panel. In October 2006 the study was approved by the NCI's Division of Cancer Prevention. Finally, on January 22, 2007 the Study was given final approval by the NCI Executive Committee. Notwithstanding all of these approvals, the National Surgical Adjuvant Breast and Bowel Project was notified on January 23, 2007 that the NCI Director had placed the P-4 Study on hold. On March 23, 2007, you called another meeting of the National Cancer Advisory Group to further discuss the P-4 trial.

It has been two and one half years since the NCI began the review and approval process of this Study and now you have indicated, in a recent interview with the Cancer Letter, "that it is unlikely that the trial would open this year."

I would appreciate your prompt reply in explaining the delay in the start of this trial and why it takes more than two years for the NCI to approve such trials.

Following is the text of Niederhuber's response:

Dear Senator Specter:

Thank you for your letter dated May 8, 2007 and for your continued support of the National Cancer Institute (NCI) and interest in research that promises to accelerate progress and change the course of cancer.

As you know, NCI is currently reviewing the proposed "P-4" clinical study. Our goal is to ensure that we are optimizing our investments in breast cancer prevention for the benefit of all women. We have a deep interest in cancer prevention and believe, based on recent scientific advances that we can do more to intervene in the course of this disease as early as possible—hopefully before clinical disease is ever apparent. For example, we are working in whole genome scanning of a large cohort population to identify inherited genetic changes that determine a woman's risk of developing breast cancer. We have already found one region on chromosome 8 which is associated with increased risk of breast cancer and we fully expect to find more. The identification of these regions will enable not only identification of women at high risk of developing the disease, but will help diagnose breast cancer earlier and hopefully prevent it all together.

Chemoprevention is of course only one aspect of NCI's research portfolio directed at the prevention of breast cancer. Previous chemoprevention studies have yielded valuable information relative to the effects of selective estrogen receptor modulators (SERMs) and nonsteroidal aromatase inhibitors on breast cancer prevention. Unfortunately these studies, while scientifically enlightening, have failed to change the practice of breast cancer prevention among women and their healthcare providers, perhaps because of the side effects of these drugs. A major challenge remains in developing accurate methods to identify women at high-risk for breast cancer who would benefit from these drugs. Drugs such as tamoxifen, letrozol, and raloxifene carry risks and produce side effects that can be life threatening.

We believe an effective breast cancer prevention effort must build on what we have learned from these chemoprevention trials and from the increasing application of molecular sciences and new technologies—advanced imaging techniques, new biomarkers, genome characterization on various technology platforms, etc. Moreover, it is imperative that we provide women with real alternatives that do not ask them to trade breast cancer risk for an increased risk of endometrial cancer, stroke, and venous thromboembolic disease or cancer of the uterus or colon, or in the case of aromatase inhibitors, increased risk of cardiovascular disease and osteoporosis and fractures.

I fully understand your concern about the P-4 breast cancer prevention trial. I want to assure you that the steps we are taking are being done to ensure that this trial will produce the best outcome for women. In response to the significant concerns expressed by the scientific community and several advocacy groups I asked that a Working Group of the Clinical Investigations Subcommittee of the National Cancer Advisory Board (NCAB) review this trial in the broad context of cancer prevention research overall, with

broad input from various cancer research and advocacy communities. As you have noted, the P-4 study has been extensively reviewed by a variety of NCI mechanisms. However, each reviewed the study from a different perspective and many of these reviews pointed out key concerns that led us to seek further input from a wide range of experts. While these reviews resulted in the continued consideration of the P-4 proposal, none of these steps were an official approval of the project with a commitment of funds. Given our increasing understanding of cancer at the genomic and proteomic levels, as well as the magnitude of this investment (total costs are estimated to be in excess of $100 million), the length of the trial (results are expected in 10-13 years), and concerns of breast cancer advocates and others, I believe that this project demands the highest level of consideration. Therefore, I asked the NCAB to undertake this task as part of work that they routinely do, providing the final external review and advice for the majority of all grant applications. The NCAB is composed of leaders from all areas of the cancer community and is an important partner in determining the direction of the National Cancer Program.

The Working Group report will be presented to the full National Cancer Advisory Board at the next meeting (June 14-15, 2007). The report will be presented and discussed in open session and the Board has a formalized mechanism to receive additional input and comment. Once I receive the input from the NCAB I will make the determination about how NCI can lead the research that will drive advances in the field of breast cancer prevention for all women.

It is my sincere desire to provide women with the real means and information to reduce their risk for breast and all other types of cancer. I hope that you appreciate that I am doing everything possible to ensure that this very important, highly visible project and indeed every project that we undertake will not only maximize our return on investment in terms of outcomes, but will also fully consider the time and the health of the thousands of women who participate. It is my responsibility to ensure that the best science is brought to bear on this important endeavor.

This is an exciting time in cancer research that promises to enable the development of unprecedented advances in science into better prevention methods, enhanced early detection techniques, and more targeted therapies. However, to realize these benefits for those living with the risk of cancer, it is imperative that we evaluate the opportunities presented to us. I believe this will inform the best way forward for all efforts in the prevention of breast and other cancers.

I expect that we will have a resolution of the question of the P-4 study in the near future. My staff will continue to work with your office to keep you informed. I also remain available should you have any questions.

Cooperative Groups:

SWOG To Increase Payment For Patient Accrual To Studies

By Kirsten Boyd Goldberg

NCI's largest cancer clinical trials network, the Southwest Oncology Group, said it plans to increase the payments it makes to medical centers to enroll, treat, and monitor trial participants—if NCI restores earlier budget cuts.

NCI sets the payments, called the capitation rate, at $2,000 per person, an amount that has remained the same for many years. The payment doesn't cover the actual costs of participation. According to a 2005 study commissioned by the Coalition of Cooperative Groups, the median cost in a federally-sponsored phase II study was $6,266, while the median cost for a phase III study was $3,427.

"We have cancer centers now refusing to do cooperative group studies because of this funding inadequacy," SWOG Chairman Laurence Baker said at the group's annual meeting in Chicago recently. "We will not succeed without the greater participation of our cancer centers."

Last year, the Jonsson Comprehensive Cancer Center at University of California, Los Angeles, dropped out of SWOG over the capitation rate, he said.

The group plans to raise the capitation rate by about $300 to $400 per patient, which is a symbolic increase, Baker said.

"We are doing this to call attention to this problem and challenge others to do something about it," Baker said. "Cancer centers which should be at the forefront of doing publicly funded trials are opting out to do company-sponsored studies. That can't be in the best interests of the American public."

Pharmaceutical company-sponsored trials pay as much as $14,000 to $15,000 per participant, said Bruce Redman, an executive officer of SWOG and professor of medicine at the University of Michigan.

NCI ordered the cooperative groups to cut their 2007 budgets by 10 percent or more late last year. For SWOG, the cut was about $1.1 million, Redman said. Congress has since voted to restore some funding to

the institute, but it's not clear whether funds will be reallocated to the cooperative groups, or how much each group will receive.

The group's scientific advisory board approved the proposal to raise the rate for 2007, if NCI's funding cuts to SWOG are restored.

"These are small amounts of dollars to make up for what is a real shortfall in funding phase III and phase II trials," Redman said. "One of the hopes is that it will stimulate discussion. Also, some centers that may be saying, 'Gee, we just can do this anymore,' hopefully will see this is a move in a positive direction and continue to participate."

SWOG had proposed to increase the capitation rate to $3,620 in a 2003 grant renewal application to NCI. While institute officials said the increase was justified, they kept the amount at $2,000, citing funding restrictions.

SWOG is a network of more than 5,000 physicians at nearly 550 institutions in the U.S., including 16 NCI-designated cancer centers.

In another development, SWOG has closed enrollment in a trial comparing a standard therapy, dexamethasone, with a combined therapy of the same drug plus lenalidomide (Revlimid, Celgene Corp.) for newly diagnosed with multiple myeloma.

SWOG recommended that participants in the study, S0232, be given the choice of switching to lenalidomide with dexamethasone if they are taking dexamethasone alone. SWOG also recommends using a lower dose of dexamethasone based on preliminary results of an Eastern Cooperative Oncology Group study which showed that lenalidomide is highly effective when combined with either high doses of dexamethasone (as used in S0232) or lower doses. The ECOG study also showed in preliminary analysis that low-dose dexamethasone plus lenalidomide may result in better one-year survival rates and fewer cases of side effects compared to high-dose dexamethasone plus lenalidomide in newly diagnosed patients.

The SWOG data and safety monitoring committee based its recommendation to permanently close enrollment on the preliminary results from the ECOG clinical trial, announced in early April. Also, a number of clinical trials have suggested that dexamethasone in combination with thalidomide, a drug very similar to lenalidomide, is superior to dexamethasone alone in terms of response rates and progression free survival. The group had temporarily suspended enrollment in its trial, S0232, on April 2 following the ECOG announcement.

The double-blinded phase III trial began in October 2004 to compare progression-free survival in 500 participants. To date, 198 participants were enrolled. The ECOG study, E4A03, set out to test the same combination, but with two different doses of dexamethasone, in 445 people newly diagnosed with multiple myeloma. ECOG closed its study in April, based on its preliminary findings that participants who received a low dose of dexamethasone plus lenalidomide had superior results in terms of one-year survival rate and toxicity.

Pharmaceutical Industry:

NY Subpoenaes Amgen, J&J Over ESA Promotion, Trials

By Paul Goldberg

The New York attorney general has subpoenaed the files of Amgen Inc. and Johnson & Johnson, the companies said.

According to Amgen's May 22 filing with the Securities and Exchange Commission, the company received a subpoena seeking "documents related to Amgen's promotional activities, sales and marketing activities, medical education, clinical studies, pricing and contracting, license and distribution agreements and corporate communications." The company said the subpoena was received on May 10.

A J&J spokesman said her company received a subpoena that covers the sales, marketing, medical education, and clinical trials of Procrit.

The New York attorney general's office declined to comment on the subpoenas or the investigation.

State prosecutors are a potent force in pursuing improper promotion and anticompetitive practices by pharmaceutical companies. In the case of Bristol-Myers Squibb Co., the attorneys general spearheaded litigation that extracted over $670 million from the company for its efforts to extend market exclusivity for Taxol and BuSpar (The Cancer Letter, March 14, 2003). Problems detected through monitoring by the attorneys general ultimately led to the firing of Bristol's CEO Peter Dolan (The Cancer Letter, Sept. 15, 2006).

The attorneys general can proceed with discovery immediately and can pursue their claims in federal and state courts. By contrast, plaintiffs in the shareholders suits that are being filed against Amgen have to wait for certification of their cases as class action suits before they proceed with discovery.

If the New York case involves antitrust matters, the prosecutors would be able to draw on evidence

from a civil suit filed by Johnson & Johnson. That litigation claims that Amgen's practice of "bundling" its erythropoiesis stimulating agent Aranesp with the white blood cell growth factors Neulasta and Neupogen constitute an anticompetitive strategy (The Cancer Letter, Oct. 14, 2005).

The New York investigation is part of a wave of legal challenges facing Amgen. The company's failure to disclose the results of a Danish study in head and neck cancer earlier this year has triggered an inquiry from SEC as well as at least three shareholders suits.

In the SEC filing, Amgen disclosed that one such suit was filed on May 11 in the U.S. District Court for the Central District of California. The complaint alleges that Amgen and its executives "made false statements that resulted in a fraudulent scheme and course of business operated as a fraud or deceit on purchasers of Amgen publicly traded securities."

Amgen said also that on May 14 it was served with a shareholder demand on the board of directors to establish a "special litigation committee" to investigate potential breaches of fiduciary duties by current or former officers and directors of the company.

Shareholders allege that these individuals violated core fiduciary duties, causing Amgen to suffer damages, the company said. According to the filing, shareholders seek to recover from the individuals damages resulting from their breach of fiduciary duties, monies and benefits improperly granted to them, insider trading proceeds, and all costs associated with the inquiry by the SEC. Shareholders also demand that the board make a claim under the company's errors and omissions policy in the amount of the damages and that the board commence an action within 90 days.

Congress is investigating, too. In addition to an investigation by the House Committee on Energy and Commerce, the Senate Committee on Finance has issued a letter to Amgen requesting documents and a briefing to discuss the marketing and safety of ESAs.

In a letter dated May 16, Sen. Chuck Grassley (R-Iowa), the committee's ranking Republican, requested documents related to the ESA controversy.

The text of the letter, addressed to Amgen Chairman and CEO Kevin Sharer, follows:

The U.S. Senate Committee on Finance has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage under those programs to oversee the proper administration of the programs, including the payment for prescription drugs regulated by the Food and Drug Administration.

Last Thursday, FDA's Oncologic Drugs Advisory Committee met to discuss the use of erythropoiesis-stimulating agents in cancer patients. As you know, the Advisory Committee recommended new restrictions on prescribing information for ESAs and additional clinical trials to assess the drugs' safety. In addition, on May 14, 2007, the Centers for Medicare and Medicaid Services released its proposed coverage decision memorandum regarding the clinical conditions for Medicare reimbursement for ESAs.

Several news articles have raised concerns not only about Medicare's payment system creating incentives for using higher doses of ESAs than are necessary, but also the impact of marketing and supply contracts between ESA manufacturers and dialysis providers on the utilization of ESAs. The Wall Street Journal reported that Amgen Inc. may have promoted the use of Aranesp and Epogen for improving a patient's quality of life without sufficient evidence for the claim. The New York Times reported on profits that doctors make through rebates they may receive from purchasing the drugs from Amgen and Johnson & Johnson and collecting payments from Medicare and private insurers, which are often above the purchase price.

In addition, I read with great concern the Los Angeles Times article, dated May 11, 2007, which noted that some members of the Advisory Committee suggested that Amgen "was not being upfront about all the drug's risks." What further troubled me was a Bloomberg article, also dated May 11, 2007, which reported that the FDA was given limited access to results from company studies and Amgen did not provide complete responses to the FDA's requests for data. It is essential that the FDA receive complete and accurate information in order for the agency to take appropriate and timely actions in response to emerging safety concerns.

Accordingly, I am requesting that Amgen arrange a briefing for my Committee staff by May 31, 2007, to discuss the issues and concerns that have been reported in the media over the last several weeks regarding the marketing and safety of ESAs. In addition, please be prepared to address the following questions:

Please describe the types of data that the FDA requested from Amgen. Were the data related to the safety and/or efficacy of the ESAs?

Did Amgen provide complete responses to FDA's data requests? If not, please provide an explanation for submitting incomplete responses.

In its proposed coverage decision memorandum,

CMS expressed concern that a number of trials of ESA treatment have been terminated, suspended, or otherwise not completed. Has Amgen sponsored any trials of ESA treatment that have been terminated, suspended, or otherwise not completed that showed evidence of serious adverse effects? If so, have the results from those trials been made available to the FDA? If not, please explain why study results were withheld from the FDA.

On April 10, 2007, The Wall Street Journal reported that Amgen conducted some studies related to the use of Aranesp and Epogen to improve a patient's quality of life. When did Amgen inform the FDA of those studies? Has the FDA requested data regarding those studies? If so, did Amgen submit the data as requested?

The Wall Street Journal also reported $500 million a year in sales from doctors who prescribed Aranesp "off label" to treat anemia in cancer patients who were no longer receiving chemotherapy. In light of the increased risk of serious adverse effects, including death, associated with the use of ESAs in this patient population, what actions, if any, has Amgen taken to ensure that doctors and patients are informed of the new safety risks?

Any documents responsive to the issues and questions to be discussed at the briefing should be sent to the Committee prior to the briefing via electronic transmission in PDF format. In cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

In the Cancer Centers:

Druker To Lead OHSU Center; Bernard Fisher Wins Award

(Continued from page 1)

throughout the entire health care system, and by bringing in a renowned expert in the field of cancer, we have an opportunity to accelerate our efforts in the area of breast cancer—where Oregon has the second highest incidence of breast cancer in the nation," he said. Oregon's cancer mortality rates are about in the middle of the pack in the country, but for women, Oregon ranks 39th.

"Research is critically important to this effort. The more we understand about cancer the faster we will create better therapies," Druker said.

Druker's goal is to attract nationally recognized researchers and clinicians to the OHSU Cancer Institute, which has 138 members and more than 200 clinical trials underway at any one time.

Druker holds the JELD-WEN Chair of Leukemia Research at the OHSU Cancer Institute. He is an investigator with Howard Hughes Medical Institute and a professor of medicine (hematology and medical oncology), cell and developmental biology, and biochemistry and molecular biology in the OHSU School of Medicine.

Under Bagby's leadership, the OHSU Cancer Institute became an NCI-designated cancer center. Bagby first came to OHSU in 1970 to complete his residency and fellowships in hematology/oncology. In 1976, he returned to OHSU as an assistant professor. He also served as a professor of medicine in the Department of Molecular and Medical Genetics. Bagby will continue his work with the OHSU Cancer Institute after his retirement. He will focus on leukemia and cancer research programs with a special emphasis on Fanconi anemia and continue to mentor younger researchers.

* * *

BERNARD FISHER, Distinguished Service Professor of Surgery at the University of Pittsburgh School of Medicine, received a Distinguished Medical Service Award from the Friends of the National Library of Medicine for his contributions to the treatment and understanding of breast cancer. Fisher, a 1943 graduate of the Pittsburgh School of Medicine, is known for conducting clinical trials demonstrating that breast-conserving surgery was as effective as radical mastectomy for treating the disease. In subsequent trials, he established the effectiveness of using chemotherapy and/or tamoxifen. In more recent studies, he was the first to demonstrate that tamoxifen could reduce the risk of breast cancer in high-risk women. He received the award May 8 at an event and dinner at the National Museum of Women in the Arts in Washington, D.C. . . . **M. D. ANDERSON** Cancer Center and **UNIVERSITY OF TEXAS** Southwestern Medical Center each received a $50 million gift from the T. Boone Pickens Foundation for health care, research and education. Under the agreement, the gifts will create special funds at the institutions, requiring that each one grow to $500 million within 25 years from earnings on the original principal or from new outside donations solicited by the institutions. When the goal is reached, the institutions will be able to distribute the funds as they deem fit. In recognition of the gift, a recently completed 800,000-square-foot medical research and education facility on the UT Southwestern campus will be named the T. Boone Pickens Biomedical Building. M. D. Anderson will name its new 21-story, 730,000-square-foot academic building the T. Boone Pickens Academic Tower, which is scheduled to open

in spring 2008. . . . **H. LEE MOFFITT** Cancer Center & Research Institute will receive a $20.4 million gift from **Donald Adam**, chairman and CEO of American Momentum Bank of Tampa, for the Donald A. Adam Comprehensive Melanoma Research Center. **Jeffrey Weber** is director of the Donald A. Adam Comprehensive Melanoma Research Center. The leadership team includes **James Mule**, translational scientist, and **Vernon Sondak**, melanoma surgeon. The gift funds the first five years of research and development. During that time, the research and medical team plan to recruit melanoma researchers, conduct clinical trials on new cancer drugs and pursue the Melanoma Genomics Project, which maps the development of the diseases on a molecular level. . . . **CANARY FOUNDATION** and **STANFORD UNIVERSITY** are collaborating on the Center of Excellence for Cancer Early Detection. Canary Foundation is a nonprofit organization that funds research in early cancer detection. The creation of the center formalizes a joint interest of the foundation and the Stanford University Department of Radiology to advance molecular diagnostics with an emphasis in molecular imaging for early cancer detection. The foundation pledged $7.5 million, with $4 million to be matched by the Department of Radiology, totaling $11.5 million dollars. **Sanjiv Gambhir**, professor of radiology and bioengineering, and director of the molecular imaging program at Stanford, is head of the Center of Excellence for Cancer Early Detection. . . . **WISTAR INSTITUTE** has established the Wistar Institute Vaccine Center to address global public health needs. **Hildegund Ertl** is founding director of the vaccine center and professor and immunology program leader at Wistar Institute. She is overseeing a development program for new or improved vaccines against diseases including HIV, influenza, rabies, human papillomavirus, and colorectal cancer. The center will draw on the expertise of researchers in the Wistar Immunology Program who serve as founding faculty members: **Andrew Caton**, **Jan Erikson**, **Luis Montaner**, and **E. John Wherry III**. Funding that supports the center members include a $10.1 million NIH contract and a $4.2 million Pennsylvania Department of Health grant for development of a universal influenza vaccine. . . . **UNIVERSITY OF NEW MEXICO** Cancer Center began the first phase of construction on the UNM Cancer Treatment and Clinical Research Facility, a 190,000-square-foot, $90 million ambulatory cancer treatment and clinical research center scheduled to open in 2009. **Cheryl Willman** is director and CEO of the UNM Cancer Center. . . . **FOX CHASE CANCER CENTER** researchers received recognition: **Melvyn Goldberg**, vice chairman of surgery and chief of thoracic surgery, was named the first holder of the $1.5 million Gloria and Edmund M. Dunn Endowed Chair in Thoracic Surgical Oncology. Goldberg also is professor of surgery at Temple University School of Medicine and Hahnemann University Medical Center. **Elizabeth Henske**, member of the Division of Medical Science, received the second annual Society for Women's Health Research Medtronic Prize for Scientific Contributions to Women's Health for her work in sex differences research and women's health. She received $75,000. . . . **LINCOLN STEIN**, Cold Spring Harbor Laboratory researcher known for his work in comparative genomics, data integration, and data visualization, will lead the National Human Genome Research Institute data coordination for the modENCODE Data Center. The $57-million project will identify all functional elements in the genomes of the fruit fly and roundworm. Contributing consortium members include Lawrence Berkeley National Laboratory; Fred Hutchinson Cancer Research Center; Memorial Sloan-Kettering Cancer Center; University of North Carolina at Chapel Hill; Duke University; New York University; Yale University; University of Washington, Seattle; and University of Chicago. . . . **NATHAN BERGER**, Hanna-Payne Professor of Experimental Medicine and director of the Center for Science, Health and Society at Case Western Reserve University, is the 2007 recipient of the Frank and Dorothy Humel Hovorka Prize for his ability to bring people together. Berger, known for his work in poly polymerase, DNA repair, stress proteins, and developmental therapeutics, is professor of medicine, biochemistry and oncology at the School of Medicine.

Funding Opportunities:

RFP N02-CM-77002-21A: Storage and Distribution of Chemicals and Drugs used in Preclinical Evaluation and Development. Response Due Date: July 12. Full text: http://www.fbodaily.com/archive/2007/05-May/24-May-2007/FBO-01300123.htm. Inquiries: Drake Russell, russeldr@mail.nih.gov.

NOT-CA-07-016: Notice of Availability of Blood Samples for Validations of Lung Cancer Biomarkers. Full text: http://www.grants.nih.gov/grants/guide/notice-files/NOT-CA-07-016.html. Inquiries: Karl Krueger, Division of Cancer Prevention, 301-435-1594; kruegerk@mail.nih.gov.; Peter Ujhazy, Organ Systems Branch, 301-496-8528; jhazyp@mail.nih.gov.

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