THE CANCER LETTER

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Von Eschenbach A "Misguided Choice" For FDA, House Members Write To Leavitt

By Kirsten Boyd Goldberg and Paul Goldberg

NCI Director Andrew von Eschenbach is a "misguided choice" for acting FDA commissioner, three House Democrats wrote in a letter to HHS Secretary Mike Leavitt.

The letter said the surgeon's efforts to address the potential for conflicts of interest have been "inadequate," adding that the appointment would weaken both the regulatory agency and the Institute.

"This dual responsibility—which exists despite Dr. von Eschenbach's pledge to give up his 'day to day' duties at NCI—opens the door to

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In Brief:

AACI Awards To Hartwell, Feinstein, Pryce; Olopade Wins MacArthur Fellowship

ASSOCIATION OF AMERICAN Cancer Institutes will honor **Leland Hartwell**, president and director of the Fred Hutchinson Cancer Research Center, with the 2005 AACI Distinguished Scientist Award for his contributions to the cancer center and cancer research. Hartwell is the recipient of the 2001 Nobel Prize in Physiology or Medicine for his discovery of the universal mechanism that controls cell division in all eukaryotic organisms. At its annual meeting Oct. 16-18 in Washington, D.C., AACI also will present its Public Service Award to **Sen. Dianne Feinstein** (D-CA), chairman of the Senate Cancer Coalition and vice-chairman of C-Change, and **Rep. Deborah Pryce** (R-OH), co-chairman of the House Cancer Caucus. . . . **EDWARD BENZ Jr**. was elected vice-president and president-elect of the Association of American Cancer Institutes. AACI members also elected **Martin Abeloff** and **Michael Caligiuri** to the 12-member board of directors. Benz, president of the Dana Farber Cancer Research Institute, director of Dana Farber Harvard Cancer Center, and the Richard and Susan Smith Professor of Medicine at Harvard Medical School, begins a two-year a two-year term as president. Abeloff is center director of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University and a professor of medicine and of oncology at Johns Hopkins University School of Medicine. Caligiuri is director of the Comprehensive Cancer Center Ohio State University and the John L. Marakas Nationwide Enterprise Foundation Professor of Cancer Research at OSU. . . . **OLUFUNMILAYO OLOPADE,** director of the Cancer Risk Clinic at the University of Chicago, was named a 2005 MacArthur Fellow. Olopade, a professor of medicine and

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House Members: NCI Director's Recusals Are "Inadequate"

(Continued from page 1)

unacceptable conflicts of interest," the three House members wrote in the letter dated Oct. 12

"FDA and NCI each have critical and independent roles in the drug safety system," said the letter signed by Reps. Henry Waxman (D-Calif.), John Dingell (D-Mich.) and Sherrod Brown (D-Ohio) of the House Energy and Commerce Committee. "Having the same person at the helm of the NCI and the FDA violates the independent safeguards build into this system. There is no justification for merging these distinct roles."

The letter represents the first open challenge to von Eschenbach's efforts to address the conflicts of commitment and conflicts of interest. Others on Capitol Hill—on both sides of the aisle—have expressed similar reservations, but are waiting for the Administration to make its next move, insiders say.

Von Eschenbach, NCI director since 2002, was named acting FDA commissioner on Sept. 23, when Lester Crawford suddenly resigned. On Sept. 30, von Eschenbach said he would take a leave of absence from NCI. Leavitt appointed John Niederhuber as "chief operating officer" of the Institute.

"Unfortunately, Dr. von Eschenbach's responses to this conflict have been inadequate," the letter said. After an initial wave of criticism, von Eschenbach said that he would refrain from participating in approvals involving therapies that are either submitted by NCI or that list an Institute employee as a principal investigator.

This recusal doesn't go far enough, since the Institute often transfers therapies to commercial entities, the congressmen wrote. Von Eschenbach's "prior involvement" would still represent a conflict, they said.

"We are also concerned that the Administration has explicitly reserved the ability to involve Dr. von Eschenbach in FDA matters in which NCI is a party on a "case-by-case basis,'" the letter continued. "This provision negates Dr. von Eschenbach's promise to abstain from such matters. There is also no process by which the public can access information on the administration's handling of Dr. von Eschenbach's conflicts of interest as they arise."

At a time when public confidence in FDA is lagging, "appointing a commissioner who faces a variety of potential conflicts of interest is a misguided choice that will seriously weaken both agencies," the letter said. The congressmen called for the nomination of a permanent FDA commissioner "at the earliest possible moment."

The letter is available at http://www.henrywaxman.house.gov/pdfs/Leavitt_10_12_05.pdf.

Congress Offers Symbolic Support

Von Eschenbach's boosters haven't been idle.

Last month, they orchestrated sign-on letters from House and Senate members praising the Administration for its goal to "eliminate suffering and death due to cancer by 2015."

In identical letters dated Sept. 29, 280 House members and 92 Senate members thanked the White House for "the Administration's goal of eliminating death and suffering caused by cancer by the year 2015."

Surely, the White House could use an outpouring of praise in the midst of a long-running war, the growing federal deficit and accusations of cronyism, which have been extended to include placing the Bush family friend von Eschenbach, who has no regulatory experience, in the top role at an agency that regulates a quarter of the U.S. economy.

However, it's not at all clear that the Bush White House, HHS, or NIH share von Eschenbach's vision for making cancer into a chronic disease within the next 10 years. Also, it's unknown whether the Administration supports von Eschenbach's plan to change the drug approval procedures at FDA, and some observers say that his role at the agency could be limited to keeping the Plan B morning-after pill off the market.

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The Administration has had ample time to embrace the 2015 goal, which von Eschenbach announced in February 2003. NIH Director Elias Zerhouni took three years to formulate a cautious acknowledgement of this goal. Making it clear that the goal wasn't his, Zerhouni described it in an interview with Science as NCI's "way to energize the field."

The Administration's apparent determination to avoid the subject is evident even now. On Oct. 11, HHS Secretary Michael Leavitt wrote a "guest commentary" for the Institute's house publication, the NCI Cancer Bulletin. Leavitt praised half a dozen of NCI programs, but didn't get around to acknowledging the 2015 goal. Tommy Thompson, Leavitt's predecessor at HHS, similarly made no public endorsement of von Eschenbach's promise.

The Congressional letters in support of the 2015 goal weren't entirely spontaneous. They follow a Sept. 21 press conference sponsored by the Cancer Caucus and 2015 Caucus, a group of House members that was formed two years ago to push for the goal. The press conference featured von Eschenbach and the American Cancer Society CEO John Seffrin, a non-profit that first formulated a 2015 for controlling cancer.

In addition to sending letters, the House is considering a non-binding resolution in support of von Eschenbach's goal. Similarly, the reports that accompany the House and Senate appropriations bills contains language that supports the NCI 2015 goal.

These symbolic expressions of support haven't translated into tangible benefits for NCI.

Work has stalled on the Labor, HHS & Education spending bills for fiscal 2006, and Capitol Hill insiders say the process will likely conclude with the passage of gigantic omnibus spending bills in December. Also, many on the Hill fear that funding of relief efforts for hurricanes Katrina and Rita would lower increases for biomedical research by as much as 5 percent.

Also, the House Energy and Commerce Committee in late August released a new version of a draft bill that would give the NIH director more authority, possibly even to set the budgets of each institute, including NCI. The reauthorization bill would create a "common fund" for trans-NIH initiatives—taking funds from the institutes—and group institutes into funding clusters.

Legislators Express Faith in the "Cure"

In statements that accompanied the letters to the White House, Members of Congress lavished praise on the Administration for the plan it is yet to endorse:

—"Cancer research has made great strides, and we can continue this progress by supporting the NIH's goal of eliminating cancer death and suffering by 2015," said Sen. Sam Brownback (R-Kan.), demonstrating that NIH Director Zerhouni hasn't been entirely successful in separating himself from von Eschenbach's promises.

—Rep. Deborah Pryce (R-Ohio) thanked the Administration for "spurring hope into action and making the impossible possible."

—Rep. Sue Myrick (R-NC) said she had "great faith" that "in 10 years, cancer will be a manageable disease, and we will find a cure…. As a cancer survivor, I thank the Bush Administration and my colleagues for their support of the 2015 goal."

—Rep. Steve Israel (R-NY) also spoke about "the cure." "I am pleased to be standing with my Democratic and Republican colleagues in announcing our commitment to curing cancer by 2015," he said.

—"I would like to applaud NCI for its hard work," said Rep. Lois Capps (D-Calif.). "Thanks to NCI's unparalleled accomplishments, there is a real hope that we can realize the goal of beating cancer by 2015. Now Congress needs to step up and give NCI the resources and tools necessary to achieve this goal and bring hope to millions."

—"The most immediate step Congress can take to help achieve the goal of eliminating cancer in 10 years is to maintain $29.4 billion in funding for the NIH in the next fiscal year that is pending in the Senate," said Sen. Dianne Feinstein (D-Calif.) "This increase of $1 billion over the previous year for NIH will advance promising research into cancer treatments and cures."

—"Congress and the Administration have done a good job recognizing the need for increased funding when it comes to research and development for cures of fatal diseases," said Rep. Clay Shaw (R-Fla.). "But, I think we can do more for cancer. I co-founded the 2015 Caucus with my friend and colleague, Congressman Collin Peterson. Collin and I are committed to the goal of ending cancer death and suffering in the next 10 years. The 2015 Caucus believes that with the right resources and scientific developments, we can make great strides in treating cancer as a manageable disease, instead of a life-threatening one, and ultimately finding a cure. But, we need to act now."

—"The 2015 goal is not only about dedicating more research dollars towards cancer treatments and cures, but it's also about increasing support for the health infrastructure so patients have access and can afford the testing and the treatments closer to home," said Rep. Collin Peterson (D-Minn.). "This letter shows we can and will manage this deadly disease before 2015."

Drug Pricing:

Amgen's "Bundling" Violates Antitrust Laws, J&J Suit Says

By Paul Goldberg

A unit of Johnson & Johnson filed a suit alleging that competitor Amgen Inc. is violating antitrust laws by using "bundling" contracts to increase its share of the nearly $3 billion U.S. market for cancer-related anemia drugs.

In a suit filed Oct. 11 at the U.S. District Court for the District of New Jersey, Ortho Biotech Products, a J&J company, claims that Amgen is coercing oncologists to buy higher amounts of the Amgen anemia medication Aranesp in order to get a better price on the white-blood-cell growth factors Neulasta and Neupogen.

J&J, which markets Procrit, a competing version of EPO, claims that the contract represents an anticompetitive business practice and violates the Sherman Anti-Trust Act. The 34-page complaint seeks an injunction against Amgen as well as treble damages from the shrinking market on Procrit.

"Amgen believes the allegations in the lawsuit are without merit and we intend to vigorously defend our position," said Mary Klem, an Amgen spokesman.

Under the Amgen bundling agreement, an oncologist who wants to receive the manufacturer's rebates on Neulasta and Neupogen—two agents that have a combined 98 percent market share of white blood cell growth factors—has to meet a threshold on the use of Aranesp, the document states.

Amgen has been bundling Aranesp with Neulasta and Neupogen for some time, but over the past year, the terms of the supply contracts have been getting "considerably more coercive." The suit was triggered by the contract that became effective Oct. 1.

"Amgen has now imposed steeper pricing penalties on Amgen monopoly WBCG drugs when oncology clinics don't purchase 75 percent of their [red blood cell growth factor] drugs from Amgen," the complaint states. "In fact, if a clinic wishes to continue to receive the same level of rebates it had been receiving under pre-Oct. 1 contract, the clinic must increase its Aranesp share up to 90 percent."

Under the current pricing structure, Amgen's pre-rebate price of Neulasta and Neupogen is substantially higher than the reimbursement paid by Medicare, the complaint states.

"The clinic can only gain access to the rebates on Amgen's monopoly WBCGF drugs when they purchase virtually all of their RBCFG drugs requirements from Amgen," the document states.

A clinic that fails to meet Amgen's volume requirements on Aranesp would lose $296 every time it administers Neulasta to a Medicare patient, the complaint states.

NCI Programs:

NCI Awards $26.3M To Fund Nanotechnology Centers

NCI announced the implementation of a major component of its $144.3-million, five-year initiative for nanotechnology in cancer research.

First-year awards totaling $26.3 million were provided to establish seven Centers of Cancer Nanotechnology Excellence (CCNEs).

Each of the CCNE awardees is associated with one or more NCI-designated cancer centers, affiliated with schools of engineering and physical sciences, and partnered with not-for-profit organizations or private sector firms. The CCNE awards and principal investigators are:

—Carolina Center of Cancer Nanotechnology Excellence, University of North Carolina, Chapel Hill, Rudolph Juliano.

—Center of Nanotechnology for Treatment, Understanding, and Monitoring of Cancer, University of California, San Diego, Sadik Esener.

—Emory-Georgia Tech Nanotechnology Center for Personalized and Predictive Oncology, Shuming Nie and Jonathan Simons.

—MIT-Harvard Center of Cancer Nanotechnology Excellence, Robert Langer and Ralph Weissleder.

—Nanomaterials for Cancer Diagnostics and Therapeutics, Northwestern University, Chad Mirkin.

—Nanosystems Biology Cancer Center, California Institute of Technology, James Heath.

—Siteman Center of Cancer Nanotechnology Excellence at Washington University, St. Louis, Samuel Wickline.

NCI Funds Energetics Research Centers

NCI awarded funds for the Transdisciplinary Research on Energetics and Cancer initiative, a five-year, $54 million project to study diet, weight, and physical activity and their effects on cancer.

Four research centers and a coordinating center will conduct research on energy balance and energetics (the study of the flow and transformation of energy through living systems). The centers also will provide training opportunities for scientists.

The centers and principal investigators are:

—Case Western Reserve University, Nathan Berger.

—Fred Hutchinson Cancer Research Center, Anne McTiernan.

—University of Minnesota, Robert Jeffery.

—University of Southern California, Michael Goran.

The Fred Hutchinson Cancer Research Center will serve as the coordination center, led by Mark Thornquist.

Eight Centers Study Imaging Response

NCI awarded administrative supplements to eight NCI-designated cancer centers to establish Imaging Response Assessment Teams. NCI will provide almost $6 million in total funding to eight awardees over three years to establish IRATs as formal shared resources.

The eight awardees are the Arizona Cancer Center, University of Arizona; Comprehensive Cancer Center Ohio State University and Arthur G. James Cancer Hospital & Richard J. Solove Research Institute; Holden Comprehensive Cancer Center at University of Iowa; Memorial Sloan-Kettering Cancer Center; Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University; Alvin J. Siteman Cancer Center, Washington University School of Medicine; University of California, Davis Cancer Center; and University of Pittsburgh Cancer Institute.

The IRAT awards are intended to advance the role of imaging in assessment of response to therapy and increase the application of quantitative anatomic, functional, and molecular imaging endpoints in clinical therapeutic trials. IRATs are designed to provide enhanced involvement in quantitative analysis, interpretation, and integration of imaging data in response to therapy trials, as well as regular dissemination and communication of these methods with IRATs at other institutions.

The concept for IRATs grew out of discussions within the Association of American Cancer Institutes and between AACI and NCI. Three years ago, AACI established the Cancer Imaging Initiative to explore how cancer centers could partner more effectively with the NCI, private industry, and other cancer research entities to develop new research and clinical trials opportunities in imaging. The initiative was chaired by Robert Gillies, director of cancer imaging and molecular imaging at the Arizona Cancer Center and professor of biochemistry and molecular biophysics and radiology at the University of Arizona.

AACI partnered with the American College of Radiology Imaging Network, a cooperative group sponsored by NCI's Cancer Imaging Program to co-sponsor a special imaging workshop for cancer center directors and chairs of radiology. The workshop identified barriers to productive collaboration by cancer centers and radiology departments and developed recommendations for the promotion of imaging studies in cancer research. Their recommendations included the short-term goal of establishing "radiology response assessment teams" comprised of radiologists and imaging scientists to participate in the initial design of therapy-based clinical trials.

Leischow To Leave NCI For Arizona

Scott Leischow will resign from NCI as of Oct. 31 to become a deputy director of the Arizona Cancer Center.

Leischow served as chief of the Tobacco Control Research Branch and later as acting associate director of the Behavioral Research Branch in the Division of Cancer Control and Population Sciences. Since 2004, Leischow has been on detail to the HHS Secretary's office, serving as senior advisor for tobacco policy.

Before joining NCI five years ago, Leischow was co-director of the Arizona Cancer Center's Biobehavioral Oncology Research Program.

Funding Opportunities:

Program Announcement

PA-06-001: Mentored Research Scientist Development Award (K01)

The NIH MRSD award provides support and protected time, three, four, or five years, for an intensive, supervised career development experience in the biomedical, behavioral, or clinical sciences leading that leads to research independence. The application may be submitted on behalf of the principal investigator by any domestic for-profit or non-profit institution/organization, or public or private institutions, such as universities, colleges, hospitals and laboratories. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-06-001.html.

See http://grants.nih.gov/grants/guide/contacts/pa-06-001_contacts.htm for information regarding each IC's scientific/research contacts for the K01 program.

NCI RFPs Available

RFP N02-CM-67000-28: Collection, Storage, Advertisement, and Distribution of Biological Response Modifiers. Response Due Date: Oct 31.

NCI Biological Resources Branch is soliciting sources to support to provide high quality biological research reagents and biological standards to investigators for preclinical and

laboratory studies. The contractor would provide the facilities and personnel to operate a computerized inventory system and repository for the acquisition, receipt, storage and distribution of biological reagents and standards. The RFP is available at http://www.fbodaily.com/archive/2005/09-September/16-Sep-2005/FBO-00894753.htm.

Inquiries: Drake Russell, phone 301-496-8620; russeldr@mail.nih.gov.

RFP: N01-PC-55049-40: Cancer Genetics Network. Response Due Date: Dec. 6.

NCI Division of Cancer Control and Population Sciences is seeking a Data Coordinating Center to manage the Cancer Genetics Network that will provide data coordinating services and manage subcontracts for up to 15 CGN Centers. CGN is an NCI-sponsored research infrastructure comprising a multi-site registry of persons with cancer or at high risk of cancer and their families. CGN and its database are a research resource for investigations on the genetics of cancer and other related issues. DCC will maintain the CGN enrollee database and provide research support for its use in a high-quality, timely, and cost-efficient manner. The RFP is available at http://www.fbodaily.com/archive/2005/09-September/25-Sep-2005/FBO-00902545.htm.

Inquiries: Dorothy McMillan, contracting officer, phone 301-435-3828; dm308v@nih.gov.

Other Funding Notices

NOT-CA-05-029: Notice of Intent to Publish an RFA for the Clinical Proteomic Technology Assessment Consortia for the Clinical Proteomic Technologies Initiative. CPTI is an integrated approach to develop and enhance proteomic technology capabilities to discover and measure cancer-associated proteins from readily accessible biological fluids. RFA, to be published in the late Fall, would support multiple 5-year awards to establish the consortia through use of the NIH U24 cooperative agreement funding mechanism. The goal of the consortia will be to optimize and standardize proteomic technology platforms, with an emphasis on mass spectrometry-based and affinity capture-based approaches. Multidisciplinary teams will address technology engineering, statistical design, and quantitative pathological assessments as applied to furthering our understanding of basic and clinical mechanisms of cancer. A component of the consortia will be the development of interlaboratory protocols and analysis of biological samples from both mouse models and clinical specimens. The notice is available at http://grants.nih.gov/grants/guide/notice-files/NOT-CA-05-029.html.

Inquiries: Gregory Downing, phone 301-496-1550; downingg@mail.nih.gov.

NOT-CA-05-030: Notice of Intent to Publish a Request for Applications for Advanced Proteomic Platforms, Analytical Methods, and Computational Sciences for the Clinical Proteomic Technologies Initiative. The notice is available at http://grants.nih.gov/grants/guide/notice-files/NOT-CA-05-030.html.

In Brief:

David Baltimore To Step Down As Caltech President In June

(Continued from page 1)

human genetics, was selected for "translating findings on the molecular genetics of breast cancer in African and African-American women into innovative clinical practices in the United States and abroad." Olopade will receive $500,000 over the next five years from the John D. and Catherine T. MacArthur Foundation. . . . **DAVID BALTIMORE** said he plans to resign as president of the California Institute of Technology on June 30, after serving eight years in that position. He will remain at Caltech to pursue HIV research. He recently received a $13.9 million grant from the Bill & Melinda Gates Foundation for his Grand Challenges in Global Health proposal, "Engineering Immunity Against HIV and Other Dangerous Pathogens." Baltimore, 67, received the 1975 Nobel Prize for his research on the genetic mechanisms of viruses. . . . **VANDERBILT UNIVERSITY** appointments: **David Carbone** was named the Harold L. Moses Chair in Cancer Research and **Carlos Arteaga** was named the Vice Chancellor's Chair in Breast Cancer Research. Carbone is professor of medicine and cancer biology at the medical center and director of the Experimental Therapeutics Program at Vanderbilt-Ingram Cancer Center. Arteaga is professor of Medicine and Cancer Biology and member of the Division of Hematology-Oncology. . . . **ROBERT DICKSON** was named the first recipient of the Cecilia Fisher Rudman Distinguished Professorship in Breast Cancer Research at the Lombardi Comprehensive Cancer Center at Georgetown University. He is professor and vice chairman of the Department of Oncology with a secondary appointment in cell biology and pharmacology. . . . **DONALD MORTON** received the National Cancer Fighter Award at the annual convention of the Commission on Cancer of the American College of Surgeons. He is CEO of John Wayne Cancer Institute and Professor Emeritus of Surgical Oncology, University of California, Los Angeles. . . . **QIN YU** was appointed chief of the nuclear medicine section of the Department of Diagnostic Imaging at Fox Chase Cancer Center. Yu is known for his work in PET/CT fusion. . . . **CHARLES SHAPIRO**, director of breast medical oncology at the Ohio State University Arthur G. James Cancer Hospital and Richard J. Solove Research Institute, was named chairman of a new Cancer and Leukemia Group B committee for cancer survivorship, the Symptom Intervention Committee. The new subcommittee of the

CALGB Cancer Control and Health Outcomes Committee is dedicated to identifying and investigating drug and non-drug interventions that treat the side effects and symptoms of cancer or its treatment. . . . **JENNIFER MARSH** was appointed executive administrator of the James Graham Brown Cancer Center at the University of Louisville. She served as the center's associate director of research and development. . . . **JEFFERSON MEDICAL College** of Thomas Jefferson University staff appointments: **Tim Manser** was named chairman of the Department of Microbiology and Immunology. He has headed the Immunology Program at the Jefferson Kimmel Cancer Center since 2000. **Jeffrey Benovic**, professor of biochemistry and molecular biology, was named chairman of the newly restructured Department of Biochemistry and Molecular Pharmacology and professor and vice chairman in the Department of Microbiology and Immunology. He is interim deputy director of the cancer center. **Scott Waldman** was named chairman of the new Department of Pharmacology and Experimental Therapeutics. He is a member of the cancer center and director of the Division of Clinical Pharmacology. **Charles Yeo** was named the Samuel D. Gross Professor and chairman of surgery. He is chief of the Division of General and Gastrointestinal Surgery at Johns Hopkins Hospital. . . . **UNIVERSITY OF TEXAS Health Science Center** at San Antonio announced two faculty appointments at its Children's Cancer Research Institute. **Vivienne Rebel**, of Harvard Medical School and the Dana-Farber Cancer Institute, will work on molecular mechanisms that govern hematopoietic stem cell regulation, said **Sharon Murphy**, director of CCRI. She arrives in November. **Yuzuru Shiio**, who was senior scientist at the Institute for Systems Biology, is studying global protein changes underlying cancer. His research at CCRI, which began in July, is on the function of the Myc-Max-Mad/Mnt regulatory network using a combination of systematic quantitative proteomic analysis and molecular biology methodologies. . . . **DOUGLAS THROCKMORTON** was named deputy director of the Center for Drug Evaluation and Research at FDA, working with CDER Director **Steven Galson**. Throckmorton joined FDA in 1997 and has been acting deputy director of CDER since May 2004. He will continue to serve as chairman of FDA's new Drug Safety Oversight Board, the CDER liaison to the Agency's human subjects' research review board, and chairman of CDER's revitalized Research Coordinating Committee. . . . **THERESA TOIGO** was appointed acting director of the FDA Office of Women's Health. Toigo also serves as director of the FDA Office of Special Health Issues. She has held various FDA positions in CDER, CBER and the Office of the Commissioner since joining FDA in 1984. She succeeds **Susan Wood**. . . . **DAVID LONGFELLOW** was named second president and chief operating officer of the Toxicology Forum, a non-profit organization in Washington, D.C., that deals with toxicology issues in human and environmental health. Longfellow retired from NCI in 2004 after a 34-year career in extramural programs. Most recently, he was senior coordinator for chemical carcinogenesis in the Cancer Etiology Branch of the Division of Cancer Biology. **Philippe Shubik** co-founded the forum in 1974 and became its first president in 1976. Shubik, who served as a member of the National Cancer Advisory Board from 1970-1982, died last Dec. 20, at age 83. . . . **ONCOLOGY NURSING Society** will combine the nursing education provider of ONS and its for-profit subsidiary, Oncology Education Services Inc., to create the ONS Education Services Division. The division will produce all educational programs now managed by ONS and OES. The change is to maintain independence in educational programming and to comply with pharmaceutical guidelines requiring separation between marketing and educational initiatives, said ONS CEO **Pearl Moore**. . . . **MULTIPLE MYELOMA Research Foundation** received an A+ rating from the American Institute of Philanthropy, a nonprofit, independent information service that researches and evaluates efficiency, accountability, and governance of non-profit organizations. MMRF also received a four-star rating from Charity Navigator for its fiscal management and compliance with all of the Better Business Bureau's Wise Giving Alliance standards for charity accountability. . . . **F. HILL SLOWINSKI** was named senior director of publications of the American Society of Clinical Oncology. Slowinski, a lawyer, will direct the development and production of the educational and scientific publications. . . . **CORRECTION**: In the Sept. 23 issue, an item in the In Brief section should have read as follows: **UNIVERSITY OF NEBRASKA Medical Center** received a five-year, $9 million grant from NCI for lymphoma research using microarray technology. **Wing Chan**, professor of pathology and co-director of the Center for Lymphoma and Leukemia Research at UNMC, is the principle investigator. Besides UNMC, the study is also being conducted at NCI and in New York, Arizona, Ohio, Canada, Spain, the U.K., Germany, and Norway. The group was funded in 1999 with a $4.2-million grant, said **Ken Cowan**, director of the UNMC Eppley Cancer Center.

A Notch-Signaling Pathway Inhibitor in Patients with T-cell Acute Lymphoblastic Leukemia/Lymphoma (T-ALL)

An investigational study for children, adolescents and adults with relapsed and refractory T-cell acute lymphoblastic leukemia/lymphoma is now accruing patients at various centers around the country.

This study's goal is to evaluate the safety and tolerability of a Notch inhibitor as a rational molecular therapeutic target in T-ALL, potentially uncovering a novel treatment for these cancer patients.

Eligibility criteria and treatment schema for the study include:

Notch-Signaling Pathway Inhibitor in Patients with T-ALL	
Eligibility Criteria	Patient must be = 12 months with a diagnosis of T-cell acute lymphoblastic leukemia/lymphoma AND must also have: • Relapsed T-ALL • T-ALL refractory to standard therapy • Not be a candidate for myelosuppressive chemotherapy due to age or comorbid disease ECOG performance status =2 for patients >16 years of age OR Lanksy performance level >50 for patients 12 months to =16 years of age Fully recovered from any chemotherapy and >2 weeks from radiotherapy, immunotherapy, or systemic steroid therapy with the exception of hydroxyurea or intrathecal therapy Patient must be >2 months following bone marrow or peripheral blood stem cell transplantation No treatment with any investigational therapy during the preceding 30 days No active or uncontrolled infection
Treatment Plan	Open label and non-randomized, this study is conducted in two parts. Part I is an accelerated dose escalation to determine the maximum tolerated dose (MTD), and Part II is a cohort expansion at or below the MTD. MK-0752 will be administered orally. Plasma concentrations will be measured at defined time intervals.

For information regarding centers currently open for enrollment, please contact 1-888-577-8839.

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