THE CANCER LETTER

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FDA, NCI United In Pursuit Of 2015 Goal, Von Eschenbach Tells Center Directors

By Paul Goldberg and Kirsten Boyd Goldberg

The Food and Drug Administration and NCI have a common goal: to eliminate suffering and death due to cancer by the year 2015 and usher in the era of molecular medicine, said Andrew von Eschenbach, who heads both the regulatory agency and the research institute.

"In the end, when those two agencies… are successful, then we will see a world in which no one will suffer and die from cancer, a world in which the full fruits of the era of molecular biology and molecular medicine are made available to patients and to the public in a safe and effective, rapid and cost-effective manner, and we will not only have changed the future of cancer, but we will have changed and improved the health care for the entire nation and for our world," von Eschenbach said at the annual meeting of the Association of American Cancer Institutes Oct. 18.

"There cannot be a higher calling than that."

In a variation of his motivational speech on the "radical and unbelievable

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In Brief:

Duke, Ohio State Cancer Center Core Grants Renewed; SWOG Trains Young Investigators

DUKE COMPREHENSIVE CANCER CENTER received a five-year, $35.7-million Cancer Center Support Grant from NCI to expand programs in cancer research and patient care. Duke also received one of only three NCI-funded SPORE grants for its Brain Tumor Center and one of 10 SPORE grants to fund breast cancer research. **H. Kim Lyerly** is the center director. NCI recently awarded Duke a planning grant to create collaborative partnerships to develop cancer treatments and clinical trials. Also, Lyerly was elected chairman of the American Society of Clinical Oncology Grant Selection Committee. . . . **OHIO STATE UNIVERSITY** Comprehensive Cancer Center–Arthur G. James Cancer Hospital and Richard J. Solove Research Institute will receive a five-year, $19.2 million Cancer Center Support Grant from NCI. The grant represents a 51-percent increase in money awarded in 2000, the last time NCI reviewed the center, said **Michael Caligiuri**, center director. . . . **SOUTHWEST ONCOLOGY GROUP** recognized four cancer researchers for completing the SOG Young Investigators Training Course: **Cathy Eng**, assistant professor of gastrointestinal medical oncology at M.D. Anderson Cancer Center; **Rami Komrokji,** assistant professor of medicine at University of Cincinnati Medical Center; **Melanie Palomares**,

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Von Eschenbach Continues To Speak For NCI As FDA Head

(Continued from page 1)

transformation in both biomedical research and health care," von Eschenbach, who is both NCI director and acting FDA commissioner, misspoke repeatedly, describing NCI as an "agency," FDA as an "institute," and, in one instance, referring to "F-NCI."

Von Eschenbach said he has been overseeing cancer research from "60,000 feet, like an AWAC airplane" and witnessing "an incredible change process."

"When I began, and well into my career at M.D. Anderson, the only way I had of being able to diagnose the most common cancer that occurs—prostate cancer—was what I could feel with the tip of my finger," he said, raising his right hand and wiggling the index finger in a simulation of a digital rectal exam. "That's, in fact, how primitive we were only 20 years or so ago."

Von Eschenbach's appearance in his capacity as NCI director indicates that he intends to play a key role in running the institute and to remain its public face. Though he said he has taken an administrative leave from NCI, von Eschenbach has been making speeches and public appearances as NCI director, and on some days, his quotes have appeared in unrelated press releases issued by the institute and the regulatory agency.

By juggling hats, von Eschenbach is fueling controversy over conflict of commitment, which was first noted in letters Sens. Charles Grassley (R-Iowa) and Edward Kennedy (D-Mass.) wrote to the administration last month. Other members of Congress who publicly criticized the dual appointment soon after it was announced Sept. 23 included Sens. Barbara Mikulski (D-Md.), Christopher Dodd (D-Conn.) and Ron Wyden (D-Ore.) (The Cancer Letter, Sept. 30).

Also, critics point out that von Eschenbach now heads the agency that regulates clinical trials sponsored by his institute. On Oct. 12, Reps. Henry Waxman (D-Calif.), John Dingell (D-Mich.), and Sherrod Brown (D-Ohio) wrote a letter to HHS Secretary Michael Leavitt saying that von Eschenbach's attempts to address potential conflicts have been "inadequate" (The Cancer Letter, Oct. 13).

Von Eschenbach's vision of how drugs should be developed and approved is controversial, too. In the past four years at NCI, he has promised that technologies that remain to be validated, or for that matter, invented, will soon usher in the era of "personalized medicine." After receiving the FDA appointment, von Eschenbach said he would "streamline and accelerate" the drug approval process (The Cancer Letter, Oct. 7).

HHS Deputy Assistant Secretary Christina Pearson said the administration stands behind von Eschenbach. "I know we are supportive of the work Dr. von Eschenbach has been doing out there and the goal he has laid out," Pearson said. "I don't think there has ever been a question about that."

HHS Secretary Leavitt and his predecessor Tommy Thompson haven't publicly acknowledged the 2015 goal. NIH Director Elias Zerhouni took two years to acknowledge the existence of the goal, but made it clear that it was set by NCI, not NIH. The White House, too, has been silent.

Pearson said von Eschenbach has been "focusing his energies" on FDA. "He is working a very full schedule at FDA, full days out there, and he is very busy right now," she said. "He retains the NCI director title and continues to be involved in the high-level strategic directions of the institute. He has handed over day-to-day management of the institute."

The AACI speech was a "long-standing commitment," Pearson said, adding that it's unclear whether von Eschenbach would continue to make speeches as NCI director. "He may still be on some press releases," Pearson said.

"Maintain The Momentum" at FDA

Addressing AACI, von Eschenbach provided further detail about his FDA appointment following Lester Crawford's resignation.

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"I was asked by the President to play a very important and special role" as acting commissioner, because "it was critically important that we maintain the momentum of the FDA," he said.

"It was critically important not only to the FDA, but critically important to everyone else who is dependent upon and is looking forward to the kind of future that we have been discussing and wanting to create at the NCI," von Eschenbach said.

"Because of the close collaboration and relationship that we have been fortunate to have with the FDA, and our interactions being extremely familiar with many of the initiatives and programs at the FDA, it was, for me, an important and significant opportunity to not only contribute to that institute and that agency in its particular time of need, but also an opportunity to continue to nurture and foster the collaborative, interactive, cooperative relationships that have been so core and so central to all of our important success," he said.

NCI's "agenda" and programs "would continue to move forward," von Eschenbach said.

"As I have taken an administrative leave from my daily administrative responsibilities and turned those over to John [Niederhuber] as the chief operating officer appointed by the Secretary, I am confident, I am certain, that the NCI is, and will continue to maintain, the important and essential pace of progress," he said.

"Nothing will change.

"In the meantime, for as long as I am the acting commissioner of the FDA, I will give that role the full energy and full commitment of leadership that it requires and it needs," he said.

"It's important that this agenda move as rapidly and as aggressively forward as the agenda of the National Cancer Program."

Indeed, control over FDA would be a crucial element of the controversial agenda von Eschenbach is pursuing at NCI. As a gate-keeper, the agency applies science-based criteria to regulate clinical trials and approve therapies. Von Eschenbach and his allies want to depart from many of these criteria and allow greater reliance on surrogate endpoints for treatment and prevention of cancer (The Cancer Letter, May 30, 2003, Aug. 5, 2005).

Von Eschenbach often describes his meeting with Mark McClellan in 2002, the morning after the Senate confirmed McClellan as FDA commissioner. "I kind of barged into his office, and immediately expressed my excitement for the opportunities that we have now available to us, based on the progress that has been made in biomedical research, and how important it was for us to translate that progress into interventions," von Eschenbach said at the 2003 American Society of Clinical Oncology annual meeting (The Cancer Letter, June 6, 2003).

At the AACI meeting, von Eschenbach told a more restrained version of the story: "When Mark McClellan was first confirmed as commissioner of the FDA, on a Thursday night at 10 o'clock, the following morning, we had our first one-hour meeting" to establish joint programs between the agency and the institute, he said.

Last year, von Eschenbach chose McClellan to be the first speaker for the "NCI Director's Lecture Series: Progress With A Purpose."

Instead of applauding von Eschenbach's 2015 goal, McClellan said that science is far from making cancer a manageable chronic disease.

New technologies such as "proteomics, genomics, microarrays, [and] information technology" so far have "added to the cost of discovery and development, without making the process faster or more certain," McClellan said in his remarks Feb. 2, 2004.

McClellan spoke for nearly an hour about the difficulties in bringing new products to the market, particularly "targeted" therapies for inhibiting complex signaling pathways. Careful research must take place to validate whether these new tools can predict a therapy's benefit or harm to patients, he said (The Cancer Letter, Feb. 6, 2004).

At the end of McClellan's remarks, von Eschenbach presented him with a massive glass trophy as a "token of our appreciation" and reminder of "our enduring friendship relationship, and commitment to change the world." Later, the FDA commissioner had to return the trophy to NCI, since gift-giving is precluded by government ethics rules.

"Cancer Is Well-Positioned"

Now, von Eschenbach finds himself sitting at McClellan's old desk, presiding over both cancer research and drug approval, vowing to revise the drug approval process and making plans for radical changes in the practice of medicine.

Meanwhile, McClellan once again finds himself downstream from von Eschenbach. As head of the Center for Medicare and Medicaid Services, he has to pay for the therapies FDA approves.

"Cancer is… extraordinarily well-positioned to not only make major progress with regard to our ability to deal with the disease itself, but in the process of doing

so, the kind of infrastructure that we have created, the kind of momentum that we have provided—we are, in fact, positioned to lead the entire future of biomedical research from this molecular perspective, as well as lead the transformation of our entire health care system, that will be adapted to and embracing that molecular reality," von Eschenbach said at AACI.

"We are not just about eliminating the suffering and death due to cancer. We are about the transformation in health care and the transformation in biomedical research."

If the speech is an indication, von Eschenbach would make fundamental changes at FDA.

"Change is a process, that I'm fond of saying, the only human organism that really likes change is a six-month-old with a dirty diaper," von Eschenbach said. "[It] is… a process that causes a great deal of anxiety, because it opens up for us risk and it opens up for us the unknown. But change can also be an unbelievable time of opportunity, and without it, there is no growth, there really is no future."

Von Eschenbach describes cancer as an engineering problem that can be solved with "targeted, mechanistic-based interventions."

"One of the most intriguing transformations in the new molecular era with regard to delivery is the very fact that we now have within our grasp, for the first time perhaps, to be able to deal with the complexity of the human problem of cancer in the clinical setting," von Eschenbach said at AACI. "We now have tools that will enable us to see biology of disease, not just simply phenotypic, anatomic representations. The imaging tools, and the arrays, and the tools that are available to us now, will enable us to make the delivery of these interventions in itself become a discovery platform for understanding the biology of cancer."

A transcript of von Eschenbach's remarks is posted at http://www.cancerletter.com/archives/post.html?http://www.newslettersonline.com/user/user.fas/s=292/fp=3/tp=18?T=open_article,903650&P=article.

F-NCI? NCI-2? FDANCI? Speech Puzzles Staff

On Oct. 20, two days after addressing AACI, von Eschenbach made his first speech to FDA employees. The 20-minute speech was carried over a closed-circuit television system, and reporters were not permitted to cover it.

According to Dickinson's FDAWebview, the acting commissioner called for faster approval of cancer drugs, apparently failing to mention other therapeutic areas. The led one field manager to comment: "Looks like we're NCI-2!" (http://www.fdaweb.com).

Von Eschenbach's plans raise questions about conflicts of interest. In his memo to FDA staff on Sept. 30, he wrote that, "As a prudential matter," he would not take part in "certain FDA matters in which NCI is a party, unless the Department requests that I participate on a case-by-case basis."

This would include:

—"Approval applications affecting drugs, devices, and biologics submitted by NCI or where an NCI employee was a Principal Investigator;

—"FDA oversight/observation of adverse event reporting in NCI clinical protocols;

—"Other matters involving NCI as a party in which FDA is exercising its regulatory authority."

Von Eschenbach's dual role is reflected in NCI's rhetoric. "My step is faster, my enthusiasm and optimism never greater," NCI's new Chief Operating Officer John Niederhuber wrote recently in the NCI Cancer Bulletin, the institute's official publication.

"While the challenges for NCI and FDA are clearly significant, the opportunities have never been better to make a real difference for cancer patients," he wrote. "I hope all of you share in this enthusiasm and have confidence in our leadership."

The melding of NCI and FDA may have the opposite effect.

NIH Programs:

New Clinical Science Grants To Replace GCRC Awards

NIH has established a new grants program to support clinical and translational research.

The Institutional Clinical and Translational Science Awards program would fund four to seven grants for a total of $30 million, and up to 50 planning grants for $11.5 million in FY 2006.

The program would eventually replace the General Clinical Research Center awards, but there would be no decrease in funding, NIH officials said at a Oct. 12 press conference.

"This program will give research institutions more freedom to foster productive collaboration among experts in different fields, lower barriers between disciplines, and encourage creative, new approaches that will help us solve complex medical mysteries," NIH Director Elias Zerhouni said in a press release. "Ultimately, patients will be better served because new prevention strategies and treatments will be developed, tested, and brought into medical practice more rapidly."

The grants will encourage institutions to propose new approaches to clinical and translational research, including new organizational models and training programs at graduate and post-graduate levels. They will foster original research in developing clinical research methodologies, such as clinical research informatics, laboratory methods, other technology resources and community-based research capabilities.

NIH expects to increase the number of awards annually so that by 2012, 60 CTSAs will receive a total of approximately $500 million per year. The CTSA program is an NIH Roadmap for Medical Research initiative and will be administered by the National Center for Research Resources. Funding for the new initiative will come in part from the Roadmap budget and existing clinical and translational programs. This will be accomplished entirely through redirecting existing resources, including Roadmap funds.

"We are taking great care to preserve the investigator-initiated research support pool in these times of constrained budgets," Zerhouni said.

For the purposes of this initiative, NIH is defining clinical research as studies and trials that involve human subjects. Translational research is to include two segments of the research continuum. The first is the process of applying discoveries made in the laboratory, testing them in animals, and developing trials and studies for humans. The second concerns research aimed at enhancing the adoption of best treatment practices into the medical community.

The program will allow for local flexibility so that each institution can determine whether to establish a center, department, or institute, or other interdisciplinary structure, depending upon local and regional circumstances, NIH said.

The Request for Applications calls for submissions by March 27 (see Funding Opportunities, page 6). Initial awards are expected to be made by fall 2006. The RFA is available at www.ncrr.nih.gov.

WiCell Wins Stem Cell Bank Award

NIH has awarded $16.1 million over four years to fund a National Stem Cell Bank and $9.6 million to fund two new Centers of Excellence in Translational Human Stem Cell Research for four years.

The National Stem Cell Bank, awarded to the WiCell Research Institute in Wisconsin, will consolidate many of the federally-funded eligible human embryonic stem cell lines in one location, reduce the costs that researchers have to pay for the cells, and maintain quality control over the cells, NIH said.

Derek Hei is the principal investigator and James Thomson is the scientific director.

The two Centers of Excellence were awarded to the University of California, Davis, with Alice Tarantal as principal investigator, and Northwestern University, John Kessler, principal investigator.

The centers will bring together stem cell experts, disease experts, and other scientists to explore ways human stem cells may be used in the future to treat a wide range of diseases such as blood cancers and blood disorders, kidney disease, and neurological disorders.

NIH Buys Access To Knockout Mice

NIH awarded contracts that will give researchers access to two private collections of knockout mice, providing models for the study of human disease and laying the groundwork for a public, genome-wide library of knockout mice.

Under terms of three-year contracts jointly funded by 19 NIH institutes, centers and offices, Deltagen Inc. of San Carlos, Calif., and Lexicon Genetics Inc. of The Woodlands, Texas, will provide NIH and its scientific partners with access to extensively characterized lines of mice in which a specific gene has been disrupted. In the first year of the contract, NIH will expend about $10 million to acquire about 250 lines of knockout mice.

For each mouse line, the contractors will provide not only the mouse line itself, but also data on the impact of the specific gene deletion on the mouse's phenotype, which includes appearance, health, fitness, behavior, ability to reproduce, and radiological and microscopic data. Such comprehensive information on such a large group of mice has never been available to public sector researchers.

The contracts provide NIH with irrevocable, perpetual, worldwide, royalty-free licenses to use and distribute to academic and non-profit researchers these lines of knockout mice. The mouse lines, which will be stored in the form of frozen embryos, frozen sperm and frozen embryonic stem cells, will be delivered to NIH-funded mouse repositories and made available to researchers who request them.

All data on the mice will be made available to researchers worldwide without restriction in publicly available databases on the Web.

Under the license agreements with Deltagen and Lexicon, researchers who receive the knockout mice lines are free to publish any results from research involving the line and also to seek patent or other intellectual property protection for any of inventions or discoveries resulting from such research.

Funding Opportunities:

AJCC Invites Proposals For Staging Algorithms

Improving AJCC/UICC TNM Cancer Staging: Developing and Validating New Algorithms for Cancer Prognosis, Staging, and Predicting Response to Therapy.

Letters of Intent Due Date: Dec. 15.

Application Receipt Date: Jan. 16.

American Joint Committee on Cancer invites proposals to develop and evaluate improved staging algorithms for cancer sites and types. The results will be used by the AJCC Disease Site Task Forces to recommend revision of the AJCC Cancer Staging Manual for the 7th Edition due for publication in 2009.

Research objectives include:

1. define alternative cancer staging algorithms that improve prognostic information for a cancer site or group of cancer sites using existing anatomic information as defined in the Collaborative Staging System. 2. define alternative cancer staging algorithms that improve prognostic information for a cancer site or group of cancer sites using existing anatomic elements as define in the CSS supplemented with modified anatomic information, additional anatomic information, or non-anatomic information. 3. define algorithms to predict response to therapy based on anatomic information as collected in the CSS, new or modified anatomic factors, and nonanatomic tumor or patient characteristics. 4. provide validation for proposed new schemas and prognostic factors.

Inquiries: Valerie Vesich, ajcc@facs.org or phone 312-202-5313.

Bayer Accepting Applications For Oncology Surgery

Application Due Date: April 3

Bayer HealthCare Pharmaceuticals is accepting applications for its fellowship program traditionally open to cardiothoracic surgeons and anesthesiologists only. The program will now be open to other surgeries that could conserve or manage blood use, including orthopedic and oncology surgery.

Program information and application forms are available at www.trasylol.com/grants.htm.

Inquiries: Bayer Fellowship Program coordinator, Bruce Leeb & Co., phone 201-703-6100; info@blc1.com.

Radiation Therapy Grants Available For Institutions

American Society for Therapeutic Radiology and Oncology and the American Society of Radiologic Technologists Education and Research Foundation will award four one-time program development grants to colleges, universities or medical institutions in the U.S., interested in opening radiation therapy programs.

Each radiation therapy development program grant is $12,500, for a total of $50,000.

Inquiries: http://www.astro.org/about_astro/awards/.

RFAs Available

RFA-RM-06-001: Planning Grants for Institutional Clinical and Translational Science Awards.

Letters of Intent Receipt Date: Feb. 27.

Application Receipt Date: March 27.

The RFA is developed as an NIH Roadmap Initiative. All institutes and centers participate in Roadmap Initiatives and will be administered by NCRR on behalf of NIH. The goal of the Institutional CTSA program is to provide resources for institutions to develop a plan for the content, governance, administration and evaluation of a CTSA, and to manage the organizational and cultural changes needed to implement the program.

Objectives include: flexibility for institutions to integrate the components in ways that best provide an academic home for clinical and translational science; development of clinical and translational methodologies; enhancement of tools, services, and intellectual discipline used to design, perform, and analyze high-quality and ethical research studies; applicability to the whole spectrum of clinical and translational science including studies of different sizes and specialties; career development of clinical and translational research professionals; a policy of collaboration, cooperation, and sharing; higher-degree granting programs that disseminate the knowledge required for the rigorous discipline of clinical and translational science; a forum to address national impediments to clinical and translational science across institutions. The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-06-001.html.

Inquiries: Bernard Talbot, National Center for Research Resources, phone 301-435 0793; talbotb@mail.nih.gov.

RFA-RM-06-002: Institutional Clinical and Translational Science Award.

The initiative would help institutions forge a integrative academic home for clinical and translational science that has the consolidated resources to: 1) captivate, advance, and nurture a cadre of well-trained multi- and inter-disciplinary investigators and research teams; 2) create an incubator for innovative research tools and information technologies; and 3) synergize multi-disciplinary and inter-disciplinary clinical and translational research and researchers to catalyze the application of new knowledge and techniques to clinical practice at the front lines of patient care. The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-06-002.html.

Inquiries: Anthony Hayward, phone 301-435 0790; haywarda@mail.nih.gov.

Program Announcements

PA-06-006: Small Business Innovation Research Program Parent Announcement

Application Submission Date: Dec. 1

NIH, CDC, and FDA invite small business concerns to submit SBIR phase I, phase II, and Fast-Track grant applications through Grants.gov in response to identified topics. See http://grants.nih.gov/grants/funding/sbirsttr1/2005-2_SBIR-STTR-topics.doc.

In addition to the stated topics, applicant SBCs may also propose any other areas of research within the mission of the identified awarding components and submit an investigator-initiated SBIR application. The FOA will use the SBIR R43/R44 mechanisms.

The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-06-006.html.

Inquiries: For NCI, Michael Weingarten, phone 301- 496-1550; mw498z@nih.gov.

PA-06-007: Small Business Technology Transfer Program Parent Announcement

The PA will use the STTR R41/R42 funding mechanisms. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-06-007.html.

In Brief:

SWOG Selects Richard Fisher As Deputy Group Chairman

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assistant professor of medical oncology at City of Hope National Medical Center; and **John Strother**, fellow of hematology and medical oncology at Oregon Health & Science University. . . . **RICHARD FISHER** was named deputy chairman of the Southwest Oncology Group. Fisher is director of the University of Rochester Medical Center James P. Wilmot Cancer Center, director of cancer services for Strong Health, and chief of the Hematology/Oncology Unit in the Department of Medicine. He was a senior investigator at NCI from 1972 to 1984. . . . **MICHAELE CHRISTIAN**, head of NCI's Cancer Therapy Evaluation Program, received a 2005 Presidential Rank Award for Meritorious Executive from HHS. . . . **MARY ANN GUERRA** was named chief operating officer of Translational Genomics Reasearch Institute. She has been vice president of operations since joining TGen in 2004. Guerra will oversee the TGen business and administrative management operations, including business development and strategic partnerships, communications, outreach, human resources, and facilities, said **Jeffrey Trent**, president of Tgen. From 1994 to 2001, Guerra was deputy director for management at NCI. . . . **TGen FOUNDATION** received $100,000 to establish the Advancing Treatments for Adrenocortical Carcinoma Fund for genetic research in adrenocortical carcinoma. The gift came from **Troy Richards**, a Scottsdale philanthropist. The study is analyzing 100 ACC tumor samples and comparing their genetic signatures to 20 benign adrenal cortex samples, said **Michael Demeure**, senior investigator and lead scientist on the project. Demeure, along with **Daniel Von Hoff**, director of Translational Research Division at TGen, are to collaborating with the American Association of Endocrine Surgeons and Mayo Clinic to obtain ACC tumor samples. . . . **CEDARS-SINAI** Medical Center Division of Neurosurgery established a neurosurgical training program to produce neurosurgeons who are as skilled in the research laboratory as they are in the operating room. "We've always had an emphasis on quality patient care and research. Now, the third component of the triad, our teaching mission, is complete with the introduction of the residency program," said **Keith Black**, director of the Division of Neurosurgery, the Cedars-Sinai Maxine Dunitz Neurosurgical Institute. **Moise Danielpour** will direct the training program. . . . **ARKANSAS CANCER** Research Center at University of Arkansas for Medical Sciences made two additions to its Department of Otolaryngology-Head and Neck Surgery, said **James Suen**, director of ACRC. **Brendan Stack**, who holds the Suen endowed chair, was named director of the Divisions of Head and Neck Oncology and Clinical Research. Stack was professor and director of head and neck oncology and director of research in the Division of Otolaryngology-Head and Neck Surgery at Pennsylvania State University College of Medicine. **Paul Spring** was appointed associate professor and director of basic research. He was assistant professor in surgery and otolaryngology at University of Kentucky College of Medicine and chief of otolaryngology-head and neck surgery at the Veterans Administration Medical Center in Lexington. . . . **ST. JUDE CHILDREN'S** Research Hospital appointed three department chairmen, said **William Evans**, director and CEO. **Douglas Green** will head the Department of Immunology. For the past 15 years Green was head of the Division of Cellular Immunology at the La Jolla Institute of Allergy and Immunology. **Rodney Guy** will head a new Department of Chemical Biology and Therapeutics, which will study the molecular basis of childhood catastrophic diseases.

Guy was head of the Center for Chemical Diversity at the University of California in San Francisco. **Leslie Robison**, associate director of the University of Minnesota Comprehensive Cancer Center and associate chair of the Children's Oncology Group, will head the new Department of Epidemiology and Cancer Control. Robinson, a pediatric cancer epidemiologist, is the principal investigator of the Childhood Cancer Survivor Study. . . . **MOORES CANCER CENTER** at University of California, San Diego, received a $1.8 million UC Discovery grant from the University of California through its Industry-University Cooperative Research Program to study skin sampling to detect prostate cancer. DermTech International, a San Diego firm, is the industry partner on the grant. The Veterans Affairs San Diego Healthcare System will also play a role in the project. The study will compare the gene expression profiles of skin from men with and without the disease, to create a set of representative biomarkers that can be used as a tool to screen for prostate cancer. **William Wachsman**, associate professor of medicine at UCSD, member of the cancer center and a staff physician in hematology and oncology with the VA San Diego Healthcare System, is principal investigator. . . . **JULIE ROSS**, professor and childhood cancer epidemiologist, was named associate director for population sciences at the University of Minnesota Cancer Center, said **John Kersey**, center director. She also holds the Children's Cancer Research Fund Chair in Pediatric Cancer Research and is the director of the Division of Epidemiology and Clinical Research in the Department of Pediatrics at the University of Minnesota Medical School. In both positions, she succeeds **Les Robison**, who has accepted a position outside of Minnesota. . . . **ELLEN STIFLER**, director of principal gifts for divisional programs at Johns Hopkins University, was named director of development for the Johns Hopkins Kimmel Cancer Center. . . . **ROSWELL PARK** Cancer Institute appointed neurosurgeon and radiation oncologist **Dheerendra Prasad** director of neuro-and pediatric radiation medicine and co-director, gamma knife unit in the Department of Radiation Medicine. He was member of the Department of Neurosurgery at the University of Virginia for 12 years. . . . **UNIVERSITY OF PENNSYLVANIA School of Medicine** was named a Breast Cancer Center of Excellence by the Department of Defense Breast Cancer Research Program. The designation includes a five-year, $10 million grant to **Lewis Chodosh**, principal investigator. The center will study breast cancer progression using state-of-the-art non-invasive imaging techniques and genetically engineered mouse models to develop therapies. **Mitchell Schnall,** vice chairman of Radiology at Penn**,** and **Ruth Muschel**, former Abramson Cancer Center member**,** are co-principal investigators of the grant. The center includes two dozen investigators at Penn, the University of California Davis, Albert Einstein College of Medicine, McGill University, and the Children's Hospital of Philadelphia. . . . **PURDUE UNIVERSITY** formed the Oncological Sciences Center, an interdisciplinary cancer research facility. The center, along with three other centers in the Purdue Discovery Park, will receive $10 million over three years from Lilly Endowment. "We will now have the means to exploit Purdue's considerable strength in engineering to achieve our collective national goal of eliminating cancer as a cause of suffering and death by the year 2015," said **Marietta Harrison**, interim director of the center. The existing Purdue Cancer Center will function as a cornerstone of the Oncological Sciences Center. . . . **ONCOLOGY NURSING** Certification Corporation received accreditation of its Advanced Oncology Certified Nurses and Certified Pediatric Oncology Nurse Programs from the National Commission for Certifying Agencies, for a five-year period. ONCC first received NCCA accreditation in 2000. Also, **Janice Nuuhiwa**, staff development specialist in hematology/oncology at Children's Memorial Hospital in Chicago, was selected 2005 Certified Pediatric Oncology Nurse of the Year for her work in pediatric oncology nursing, oncology nursing service, education, and for supporting and promoting oncology nursing certification. . . . **ASCO FOUNDATION** Hurricane Relief Fund has raised more than $500,000, including a contribution from Amgen Inc. The donations will be disbursed through Cancer Care for people with cancer from southern Louisiana, Mississippi, Alabama, and Texas, who have been affected by the hurricanes and are in need of critical support services, ASCO said. . . . **AMERICAN SOCIETY** Therapeutic Radiology and Oncology has begun RT Answers, a patient Web site that provides information on radiation therapy treatment for cancer, at www.rtanswers.org. . . . **CMS** released an interim final rule announcing selection criteria for a program to provide loans to hospitals providing cancer care. Funds from this program are to be used for improvements in the hospital's infrastructure such as construction or renovation.Qualifying hospitals must be "engaged in research in the causes, prevention, and treatment of cancer" and either an NCI-designated cancer center or an official cancer institute of the state. Application is posted at http://www.cms.hhs.gov/providers/hipps.

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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