

## Two Former Bristol-Myers Executives Indicted As Firm Agrees To \$300M Fine

By Paul Goldberg

Two former Bristol-Myers Squibb executives were indicted earlier this week as the embattled pharmaceutical company announced its agreement to pay \$300 million to investors.

Under the deal, federal prosecutors filed a criminal complaint charging the company with conspiring to commit securities fraud, but agreed to delay  
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### In Brief:

### France's New Institut National du Cancer To Coordinate Research, Director Khayat Says

**DAVID KHAYAT** was named director of France's new Institut National du Cancer (INCa), which opened officially May 23. The Institute's budget for 2005 is 70 million Euros, of which 35 million would be distributed for research. INCa's primary emphasis will be to coordinate cancer research in France, develop alliances with European agencies and research groups, and establish quality of care measurements, Khayat said in an interview published in the May 24 issue of *Le Monde*. Khayat has been head of medical oncology at the Pitié-Salpêtrière Hospital in Paris since 1990, and active in the American Society of Clinical Oncology and the American Association for Cancer Research. . . . **AMERICAN SOCIETY for Therapeutic Radiology and Oncology** said **C. Norman Coleman** and **Allen Lichter** will receive the society's 2005 Gold Medal Awards. Coleman, director of the Radiation Oncology Sciences Program and associate director of the Radiation Research Program at NCI, has developed an expertise in medical response to radiological and nuclear terrorism. Lichter, dean of the University of Michigan Medical School in Ann Arbor, is known for the development of three-dimensional conformal radiation therapy. In 1978, he became head of the Radiation Therapy Section, Radiation Oncology Branch at NCI, where he worked on a breast cancer study that proved lumpectomy plus radiation therapy was as effective as mastectomy for many breast cancer patients. The awards will be presented Oct. 18, at the ASTRO annual meeting in Denver. . . . **SMOKING** among U.S. adults continues to decline, according to the Morbidity and Mortality Weekly report. Using data from the National Health Interview Survey, the study found that 21.6 percent of U.S. adults, over 45 million people, are current smokers. That represents a decline from 22.5 percent in 2002 and 22.8 percent in 2001. The study also found that the 46 million adults who have quit smoking outnumber the 45 million people  
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## Chairman Dolan To Step Down From Board, Remain As CEO

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prosecution, and if no new infractions occur, dismiss all charges after two years.

Though the deal amounts to probation for BMS, prosecutors indicated that the investigation continues, which would mean that the company's former and current employees could face separate charges.

The U.S. Attorney's Office in Newark, N.J., June 15 announced the indictment of Richard Lane, 54, former executive vice president and president of the worldwide medicines group, which included oncology, and Frederick Schiff, 57, former senior vice president and chief financial officer.

The two are accused of conspiracy to commit securities fraud as well as securities fraud in connection with the company's efforts to inflate its sales figures by inducing distributors to hold large inventories of drugs. Through attorneys, both denied wrongdoing.

As part of Bristol's deal with the prosecutors, company Chairman and CEO Peter Dolan was forced to relinquish his job as board chairman. James Robinson, a member of the board and former head of American Express Co., was elected non-executive chairman. Dolan retains the CEO post.

"We balanced the need for punishment with an acknowledgment that this company provides great value and that its work should continue," U.S. Attorney

Christopher Christie said in a statement. "At the same time, we have compensated the victimized shareholders and are prosecuting individuals responsible for the fraud at BMS. This approach meets the needs of justice, sends a deterrent message to others and does not cause undue harm to an otherwise outstanding company, its shareholders and employees."

### Conditions Of Settlement

Bristol, a company that was once described as the pillar of oncology, agreed to the following conditions:

—Accept and acknowledge responsibility for its conduct.

—Appoint Robinson as the non-executive chairman of the board. According to prosecutors, this was designed "to ensure BMS emphasizes openness, accountability and integrity in corporate governance."

—Cooperate fully with the ongoing investigation by the U.S. Attorney's Office.

—Pay \$300 million in additional restitution to shareholders. With this settlement, Bristol will have paid about \$840 million as a consequence of accounting irregularities and matters related to ImClone Systems Inc.

—Adopt internal controls and remedial measures "to prevent and deter potential violations of the federal securities laws."

—Engage an independent monitor, Frederick Lacey, a former U.S. Attorney and federal judge, to monitor the company's conduct and report to Justice.

—Endow a business ethics and corporate governance chair at Seton Hall University Law School. The position would include conducting at least one seminar on business ethics and corporate governance annually that members of the BMS executive and management staff as well as other corporate executives would attend. The law school is located in Newark. Prosecutor Christie, who was appointed by President Bush, is one of its graduates.

—Hold a meeting within 30 days of the agreement for BMS senior executives and senior financial personnel and other BMS employees, to be conducted by Christie and others from his office to communicate the goals of the agreement.

—Appoint an additional non-executive director acceptable to the U.S. Attorney's Office and the BMS board within 60 days.

### "Co-conspirators" Noted In Indictment

Though the indictment of Lane and Schiff focuses on events that occurred in 2000 and 2001, the period



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Founded Dec. 21, 1973, by Jerry D. Boyd.

when Dolan was assuming control from his predecessor Charles Heimbold, court documents do not explicitly note that either of these top executives played a role in financial improprieties.

During this time, Heimbold, who retired from BMS in September 2001 to become the U.S. Ambassador to Sweden, received sizable bonuses as the company met the goals of its ambitious growth program called Double-Double and instituted another ambitious program called Mega-Double. Insiders say Dolan was picked to replace Heimbold in part because of his commitment to these targets.

According to Forbes, Heimbold was the 20<sup>th</sup> highest paid chief executive in the U.S. in the year 2000. That year, he earned \$44 million. He was paid \$34.8 million in 1999, and \$29.3 million the previous year. According to Forbes, most of this compensation came from stock sales ([www.forbes.com/2004/04/21/04ceoland.html](http://www.forbes.com/2004/04/21/04ceoland.html)).

Meanwhile, at the U.S. wholesalers, excess inventory of BMS drugs grew from \$139 million in the beginning of 2000 to \$1.95 billion in late 2001. At the time Heimbold retired, Bristol's stock price hovered above \$50 per share. Now, the price is around \$25. The company's market capitalization has dropped by about \$50 billion.

Heimbold was a top-tier Republican donor. According to nonpartisan Center for Responsive Politics, in 1999 and 2000, prior to his appointment, Heimbold gave \$259,850 to Republican candidates and party committees and another \$100,000 to the Bush-Cheney inaugural fund ([www.opensecrets.org/bush/ambassadors/heimbold.asp](http://www.opensecrets.org/bush/ambassadors/heimbold.asp)).

Last year, his contributions included \$25,000 to the Republican National Committee. His wife Monika gave another \$25,000. Also, the Heimbolds gave \$2,000 each to the George W. Bush campaign. Heimbold has left his post in Stockholm and was recently treated for cancer.

According to Forbes, Dolan earned \$3.3 million last year and holds \$7.7 worth of company shares. He is 265<sup>th</sup> highest paid CEO of a publicly traded company in the U.S.

#### **Attorney: "Others" Knew Of Lane's Conduct**

The indictment of Schiff and Lane notes that the two acted in conjunction with "co-conspirators," who were not identified in the document.

"[Defendants] Schiff and Lane and other senior executives pressured lower level employees to meet... budget targets," the indictment states. "Certain employees who suggested that the company's budget targets were too aggressive or expressed doubts that

they could make the numbers were transferred or demoted."

Attorneys for Schiff and Lane said the two executives would be vindicated. "Mr. Schiff did not operate in a vacuum," said David Zornow, of Skadden, Arps, Slate, Meagher & Flom. "His conduct was appropriate at all times and known to many others both inside and outside the company."

Zornow said the prosecutors have "overreached in this case." Last April, a judge at the U.S. District Court for the Southern District of New York threw out a civil case claiming, in part, accounting fraud by BMS officials, including Schiff, Lane, Dolan and Heimbold.

Loretta Preska, the judge, said the plaintiffs in the class action suit failed to demonstrate intent to commit fraud. However, in July, the company agreed to pay \$300 million to settle the claims without admitting wrongdoing.

"The main focus of what is alleged in this indictment has not even met the standards of civil litigation, as it was dismissed as legally insufficient in a civil action by a Federal District Judge," Zornow said in a statement on behalf of Schiff.

Lane's attorney Richard Strassberg also cited Preska's decision.

"The government is attempting to prosecute Rick Lane for innocuous, cautious statements made during routine telephone conference calls with professional Wall Street analysts," Strassberg, an attorney with Goodwin Procter, said in a statement. "Indeed, a federal judge rejected nearly identical claims in a civil case in New York just one year ago.

"The government's actions today seek to create a new, untested, and unfair theory of criminality that could broadly apply to almost any corporate executive who speaks with the public," Strassberg said. "Anyone closely examining these charges will see a frightening example of government overreaching that sends the clear message that executives should not speak to the public. This is the wrong message to send to corporate America, and it is fundamentally unjust for Mr. Lane."

The deal between BMS and the prosecutors was expected to be announced last week, but was apparently delayed after news stories describing it appeared in The New York Times and The Wall Street Journal (The Cancer Letter, June 10).

The criminal complaint against the company, the deferred prosecution agreement, and the indictment of Schiff and Lane are posted at [www.usdoj.gov/usao/nj/publicaffairs/NJ\\_Press/break.html](http://www.usdoj.gov/usao/nj/publicaffairs/NJ_Press/break.html).

### Capitol Hill:

## House Panel Gives NIH Exact Amount White House Sought

By Paul Goldberg

A House appropriations subcommittee marked up the 2006 spending bill, giving NIH an increase that matches the President's budget proposal.

The Labor, HHS Appropriations Subcommittee last week provided the institutes with \$28.5 billion, about \$142.3 million over the current budget. This amounts to a 0.5 percent increase.

If the markup level holds, NCI would get \$4.842 billion, a \$16.515 million increase over fiscal 2005. This amounts to a 0.3 percent boost over the current year.

Most of the proposed increase for NIH is slated to go into the Office of the Director, which would receive \$482.2 million, a \$124.2 million—nearly 35-percent—increase over the current year. However, most of that increase—\$97 million—is slated to go to biodefense measures.

Subcommittee Chairman Ralph Regula (R-Ohio) said this year's allocation was reduced by \$1.5 billion because of the new requirements to pay for the Medicare Prescription Drug Program. Ranking Member David Obey (D-Wisc.) said the NIH increase would be the smallest in 36 years.

"This year, projections indicate NIH will be able to fund only one in five proposals submitted by researchers," Paul Kincade, president of the Federation of American Societies for Experimental Biology, said in a statement. "With such low chances of funding, scientists will shy away from experiments that seem risky or have uncertain outcomes. Yet these are exactly the types of projects that yield the greatest innovations."

The Senate is expected to have a higher allocation for the Labor/HHS subcommittee, which would set the stage for a last-minute reconciliation in the House-Senate conference.

## Senate Committee Confirms Lester Crawford For FDA

The Senate Committee on Health, Education, Labor and Pensions approved Lester Crawford's nomination for FDA Commissioner earlier this week.

After Crawford was approved by voice vote June 15, two Senate Democrats and one Republican placed holds on the nomination as it advances to consideration by the full Senate.

Sens. Patty Murray (D-Wash.) and Hillary Rodham Clinton (D-N.Y.) opposed the vote until FDA makes a

final decision on Plan B, a contraceptive pill. An FDA advisory committee voted overwhelmingly that the pill should be available for over-the-counter sales, but the agency is yet to approve it.

Sen. Tom Coburn (R-Okla.) also placed a hold on the nomination, arguing that FDA should revise the labeling of condoms.

The HELP committee voted on the Crawford nomination after the HHS Office of the Inspector General found no evidence of an extramarital affair between the acting commissioner and an agency employee.

### NCI Programs:

## Cancer Genome Project Meeting Planned For July

By Kirsten Boyd Goldberg

NCI and the National Human Genome Research Institute plan to hold a public meeting in July to seek "broad input" on a pilot project to test the feasibility of the proposed Human Cancer Genome Project, an NCI official said last week.

"Very few people agree on how to do this," Anna Barker, NCI deputy director for advanced technologies and strategic partnerships, told the National Cancer Advisory Board at its June 7 meeting.

Earlier this year, an NCAB working group proposed the Human Cancer Genome Project as a 10-year, \$1.35 billion effort to identify the most frequently occurring genetic mutations in common human cancers. The report outlined the steps NCI should take to begin the project, with a three-year pilot phase (The Cancer Letter, March 18).

Barker said NCI and NHGRI have formed a "management group" to develop the pilot project. The plans will be developed in August and brought for discussion to the fall meetings of the NCAB and the NCI Board of Scientific Advisors, she said.

Requests for Applications for the pilot project would be released in the last quarter of 2005, and applications would be reviewed in early 2006, Barker said. "Everything the Cancer Institute does is going to be competitive," she said.

"It's an extremely major undertaking for all of us," Barker said. "We're talking about sequencing these genes. It's not a Human Genome Project. It's about 150 Human Genome Projects. It's big."

The project promises to be "the largest and most important paradigm-shifting initiative that anyone's going to do in cancer," Barker said.

—Eric Lai contributed to this report.

## *Medicare:* **One-Year License Suspension, Fine, For CMS Chief Physician**

*By Paul Goldberg*

Medicare's chief physician accepted a one-year suspension of his Maryland medical license and agreed to pay a \$20,000 fine for having submitted inaccurate reports of completion of continuing medical education courses.

Sean Tunis, chief medical officer and director of the Office of Clinical Standards and Quality at Centers for Medicare and Medicaid Services, signed a consent order with the Maryland Board of Physicians Chairman, accepting the penalties for "willfully making false report" in seeking medical licensure or in the practice of medicine.

It's unclear whether Tunis would be allowed to return to his job at CMS, where he was placed on paid administrative leave after the disciplinary proceedings were announced. A CMS spokesman said there has been no change following the resolution of the case, declining to elaborate.

Tunis directed all National Coverage Determinations at the agency, including those that affected cancer therapies. These included the decisions on treatments for colorectal cancer, radiopharmaceuticals for the treatment of lymphoma, as well as the diagnostic use of PET scans. In these decisions, CMS formulated its new reimbursement strategy of demanding outcomes data as a condition of providing coverage for new technologies (The Cancer Letter, Feb. 4).

Tunis and the medical board completed the consent order on May 25. In a separate statement released through a spokesman, Tunis attributed the matter to "careless recordkeeping" on his part.

"I wish to emphasize that my mistake in failing to properly document the CME credits I continuously earned never had any bearing on the quality of care I provided to my patients or on my ability to fulfill my professional obligations to those I treated," he said. "In nearly 20 years of medical practice, I have never been the subject of any complaint related to patient care, and I have been diligent in maintaining my knowledge of clinical medicine."

Tunis said he was eager to resume his career. "I decided to sign this order because I acknowledge that I made a mistake and I wish to accept responsibility for it," he said. "Now that this order is signed, I look forward to continuing my public service and my career in public health policy."

Under the agreement with the board, Tunis would have to earn the disputed CME credits, take a course in ethics, pay the fine, and accept a one-year suspension of his license followed by a two-year probation.

According to the consent order, the inquiry into Tunis's CME credits began three years ago, as a result of an anonymous written complaint. In addition to working for CMS, Tunis practiced medicine at the emergency room of Mercy Medical Center in Baltimore.

As a physician practicing at Mercy, Tunis had to earn 50 credit hours of CME during each of the two-year periods of renewal of credentials. He was reappointed at the hospital in 1998, 2000, and 2002. After signing the consent order and agreeing to a suspension, he resigned from the hospital.

The medical board's investigation found irregularities in all three reappointment applications that were on file at the hospital. In some cases, Tunis claimed more credits than the sessions allowed, or wasn't registered to take the sessions he claimed to have attended. In one case—Grand Rounds at the Johns Hopkins School of Medicine—Tunis wasn't registered to obtain certification and didn't complete sign-in sheets.

Despite requests from the medical board, Tunis was unable to produce original CME certificates. According to the document, Tunis initially admitted having altered two CME documents in 2001.

"I was fully confident that I was reconstructing records for CME credit I had legitimately obtained (albeit through activities for which I did not have documents at the time)," he wrote in response to a letter from the board in 2002.

In that letter, Tunis said that even though he altered the documents, he didn't submit them to the hospital.

"It is my belief that the documents were faxed by a disgruntled CMS subordinate, whom I had chosen not to promote to a management position several months earlier," Tunis wrote. "This person vowed at the time to 'make me regret ever having known him.' This person had a cubicle adjacent to my office, and I now realize that he regularly eavesdropped on my phone conversations and entered my office to search my files in an attempt to find some information that might harm my reputation."

The 19-page consent order is posted on the Maryland Board of Physicians website, <https://www.mbp.state.md.us/bpqapp/PProfile3.asp>.

While Tunis is on leave, Barry Straube, the chief medical officer for CMS Region IX in San Francisco, has taken his place at the agency.

### Drug Development:

## **Court Rules Exemption Protects Early Research**

By Kirsten Boyd Goldberg

An exemption to patent law allows drug companies to ignore the patents of rivals when beginning research on competing therapies, the Supreme Court ruled June 13 in a unanimous decision.

The ruling in *Merck KGaA v. Integra Lifesciences* set aside a lower-court ruling for Integra, which owns a patent on a short, 3-amino acid peptide called the RGD peptide, important for cell adhesion.

Integra filed the patent-infringement suit in 1996 against Merck, a German company, after Merck declined to license the patents after funding research at Scripps Research Institute by David Cheresch.

“The use of patented compounds in preclinical studies is protected... at least as long as there is a reasonable basis to believe that the compound tested could be the subject of an FDA submission and the experiments will produce the types of information relevant to an [Investigational New Drug] or [New Drug Application],” Justice Antonin Scalia wrote.

The U.S. Court of Appeals for the Federal Circuit, in a divided decision in 2003, sided with Integra, ruling that the “safe harbor” provision of patent law only protects research used for an FDA regulatory decision proving that a drug is safe and effective, not early-stage research. In appealing the decision to the Supreme Court, Merck argued that the appeals court defined the safe harbor provision too narrowly.

The Supreme Court rejected the lower court’s “unduly narrow interpretation.” The Bush Administration had sided with Merck, arguing that drug development would slow and drug prices would increase if the lower court ruling stood.

The ruling is available at <http://www.supremecourtus.gov/opinions/04pdf/03-1237.pdf>.

—Eric Lai contributed to this report.

## **Editor Wins Journalism Award**

Paul Goldberg, editor of *The Cancer Letter*, received an award from the Society of Professional Journalists Washington, D.C., Professional Chapter in the chapter’s annual journalism awards competition.

Goldberg won first place for reporting by a Washington-based newsletter for his story, “Patients Sue Milken, Cancer Centers, Over Prostate Cancer Remedy PC-Spes,” published in the Feb. 20, 2004, issue of *The Cancer Letter*.

### NIH Roadmap:

## **NIH Awards \$89M To 9 Centers To Screen For Small Molecules**

NIH is awarding \$88.9 million in grants to nine institutions over three years to establish a collaborative research network called the Molecular Libraries Screening Centers Network that will use high-tech screening methods to identify small molecules that can be used as research tools.

The institutions and principal investigators receiving grants are:

Columbia University Medical Center, James Rothman; Emory University, Raymond Dingleline; Southern Research Institute, Gary Piazza; The Burnham Institute, John Reed; The Scripps Research Institute, Hugh Rosen; University of New Mexico Albuquerque, Larry Sklar; University of Pennsylvania, Scott Diamond; University of Pittsburgh at Pittsburgh, John Lazo; Vanderbilt University, C. David Weaver.

### Cancer Prevention:

## **Spit Tobacco Use Associated With Heart Disease, Stroke**

Two large prospective studies from the American Cancer Society find men who use spit tobacco have a higher risk of death from heart disease, stroke, and all causes combined compared to non-users. The studies are the largest to date on the subject and challenge the claim that smokeless tobacco might be an acceptable alternative to smoking.

Surveys show more than 7.7 million Americans used spit tobacco in 2003, including about 4 percent of middle school students and 7 percent of high school students. Companies that manufacture these products have attempted to position them as a way to quit smoking, but there is no evidence smokeless tobacco is as safe or effective as nicotine replacement products for smokers attempting to quit, ACS said.

“These studies point to a significant potential danger of spit tobacco,” said Michael Thun, head of epidemiology for ACS and co-author of the report. “The smokeless tobacco industry should not be allowed to claim that these products are suitable for tobacco cessation, since there is absolutely no evidence these products are either as safe or as effective as standard nicotine replacement treatment.”

For the studies, S. Jane Henley and colleagues from the ACS department of epidemiology and surveillance research used two large prospective cohorts, the ACS

Cancer Prevention Studies I and II (CPS-I and CPS-II) to investigate patterns of disease and death among men who reported current use of smokeless tobacco at the time they were enrolled in the study. Together, both cohorts comprised nearly 1 million men, nearly 10,000 of them smokeless tobacco users.

Men who reported spit tobacco use (either snuff or chewing tobacco) at the time they enrolled in the study had higher death rates from all causes combined and from cardiovascular diseases compared to men who reported never using any tobacco product. Associations with other diseases were less clear. In CPS-I but not CPS-II, use of spit tobacco was associated with higher death rates from chronic obstructive pulmonary disease and increased risk of malignant and non-malignant diseases of the digestive system. In CPS-II but not CPS-I, men who used chewing tobacco or snuff had higher death rates from all cancers combined and lung cancer.

“The higher risk of cardiovascular disease that we found among spit tobacco users could reflect a toxic effect of tobacco, or may represent confounding from other factors, like the lower socioeconomic status of men who used chewing tobacco or snuff,” said Henley. “Regardless, the tobacco industry should not be allowed to promote these products as a cessation aid. The appropriate comparison is between smokeless products and nicotine replacement therapy, not between these products and smoking.”

### Funding Opportunities:

## **NCI Seeks RAID Proposals**

**NOT-CA-05-022: Rapid Access to Intervention Development.** Receipt Due Dates: Feb. 1 and Aug. 1.

NCI requests project proposals in response to RAID. The program will make available to academic investigators, on a competitive basis, the preclinical development contract resources of the NCI Developmental Therapeutics Program. The goal of RAID is the rapid movement of novel molecules and concepts from the laboratory to the clinic for proof-of-principle clinical trials. RAID would provide any (or all) of the preclinical development steps that may be obstacles to clinical translation. Possible tasks may include production, bulk supply, good manufacturing process manufacturing, formulation, and toxicology. Suitable agents for RAID will include small molecules, biologics, or vaccines. The notice is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-CA-05-022.html>. For information on the procedure for requesting RAID resources, see <http://dtp.nci.nih.gov/>.

Inquiries: RAID, Developmental Therapeutics Program, NCI Division of Cancer Treatment and Diagnosis, phone 301-496-8720; fax 301-402-0831; e-mail [raid@dtpax2.ncifcrf.gov](mailto:raid@dtpax2.ncifcrf.gov).

### In Brief:

## **Former Smokers Outnumber Current Smokers, Study Finds**

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who continue to smoke, the second straight year this has happened. The study is available at the MMWR Web site: [www.cdc.gov/mmwr](http://www.cdc.gov/mmwr). . . . **UC DAVIS Cancer Center** has received \$4.48 million from NCI to reduce cancer disparities in Asian Americans. The grant builds on a previous project, the Asian American Network for Cancer Awareness, Research and Training, funded through the NCI Special Populations Network. The new project, funded through the NCI Community Networks Program, will bring together cancer-control experts from the California Department of Health Services, UCSF, UCLA, University of Hawaii in Honolulu, Fred Hutchinson Cancer Research Center/University of Washington in Seattle, and Dana-Farber Cancer Institute/Harvard University, with two community groups, the Sacramento-based Hmong Women’s Heritage Association and the San Francisco Medical Society Foundation/Chinese Community Health Plan. UC Davis and other project participants are contributing \$400,000 to the project. **Moon Chen Jr.**, professor of public health sciences, is the principal investigator. . . . **BARBARA ANN KARMANOS Cancer Institute** and the Wayne State University Institute of Gerontology received a \$2.5 million grant from NCI to study the link between minorities and the underserved, and the incidence of cancer, through the Community Networks Program. The program will help community-based research and research-training projects promote secondary prevention behaviors in older African-Americans, including detection, treatment seeking and routine surveillance. **Terrance Albrecht**, program leader for the Communication and Behavioral Oncology Program at the Karmanos Cancer Institute is the principal investigator. . . . **JANET HARRIS**, of the U.S. Army Nurse Corps, was named director of Congressionally Directed Medical Research Programs, where she had been deputy director for one year. She is in charge of the Department of Defense breast cancer, prostate cancer, ovarian cancer, neurofibromatosis, and other peer-reviewed medical research programs for the U.S. Army Medical Research and Materiel Command, which controls \$3 billion in programs. Harris is associate professor of nursing at the University of Texas Health Science Center Houston and the Uniformed Services University of the Health Sciences. Before coming to CDMRP, Harris was chief of the Department of

Nursing Science at Fort Sam Houston. She also was chief of Nursing Research Service at Walter Reed Army Medical Center and was consultant to the Army Surgeon General for Nursing Education/Enlisted Training and Development. She received her B.S. in nursing from the University of Nebraska Medical Center in Omaha, her M.A. in nursing from the University of Washington in Seattle, and her Ph.D. from the University of Maryland, Baltimore. She has served in the U.S. military for 27 years. . . . **MARSHALL HORWITZ**, 68, the Leo and Julia Forchheimer Professor of Microbiology and Immunology and professor of pediatrics and of cell biology at the Albert Einstein College of Medicine, died March 31 at the North Shore University Hospital on Long Island, of undetermined causes. He was known for his work with adenoviruses, and in particular, how the adenovirus could be a vehicle in cellular and gene therapy. Before HIV was discovered, he and a team of international researchers suggested an association between an adenovirus and AIDS. He is survived by his wife, **Susan Band Horwitz**, the Rose C. Falkenstein Professor of Cancer Research and co-chairman of the Department of Molecular Pharmacology at Albert Einstein College of Medicine; two sons, Joshua, of Arlington, Va., and Bruce, of Lexington, Mass.; a sister, Toba Hausner, of Silver Spring, Md., and two grandchildren. . . . **FOX CHASE** Cancer Center staff news: **Elizabeth Henske** was elected to the American Society for Clinical Investigation for her work on tuberous sclerosis complex. **Gary Freedman**, radiation oncologist, was promoted to member of the medical science division, clinical investigator track, in the Department of Radiation Oncology. Freedman is associate director of the Breast Evaluation Center. He also is director of the residency and fellowship training program in radiation oncology. **Baruch Blumberg**, Fox Chase Cancer Center Distinguished Scientist and Nobel Laureate, was honored with a scientific symposium for his 80<sup>th</sup> birthday. Blumberg won the 1976 Nobel Prize in medicine for his 1967 discovery of the hepatitis B virus, which led to the development of the hepatitis B vaccine at Fox Chase and FDA approval in 1981. The symposium took place June 16. Also at Fox Chase, **James Greenwood** was elected to the extramural activities committee on the board of directors. He is president of the Biotechnology Industry Organization. . . . **ROCKEFELLER UNIVERSITY** received a \$100 million gift from **David Rockefeller**, honorary chairman and life trustee. The gift will be used for biomedical research in areas including genomics, stem cell research, aging, and the brain, said **Paul Nurse**, president of

Rockefeller University. The graduate program will be called the David Rockefeller Graduate Program. . . . **LARRY NORTON**, deputy physician-in-chief for Breast Cancer Programs and the Sarofim Chair in Clinical Oncology at Memorial Sloan-Kettering Cancer Center, will give the first Ezra M. Greenspan Memorial Lecture at the Chemotherapy Foundation Symposium, scheduled for Nov. 2-5, in New York City. . . . **MEMORIAL SLOAN-KETTERING** Cancer Center said the following staff members were named to endowed chairs. **David Kissane** was named to an Alfred P. Sloan Chair. **Pier Paolo Pandolfi** is the first Albert C. Foster Chair. **Gavril Pasternak** was named to the Anne Burnett Tandy Chair of Neurology. **John Petrini** is the incumbent of the Paul A. Marks Chair in Molecular Cell Biology. . . . **NEVADA CANCER** Institute hired four senior staff members, said **Heather Murren**, president and CEO. **Dava Gerard** was appointed chief operating officer. She was president and medical director of a regional comprehensive non-profit cancer center in Texas. A breast surgeon, she also was chairman of the Susan G. Komen Foundation Medical Advisory Board. **Philip Manno**, known for his work in lung, head and neck, coagulation and hematological cancers, was named chief of Clinical Oncology and Hematology Services at the institute. He continues in his oncology practice as part of the Nevada Cancer Institute Medical Group. **Louis Fink** has joined as director of Core Laboratory Services. He was professor and vice chairman of the Department of Pathology at University of Arkansas for Medical Sciences College of Medicine. **Richard Faircloth**, a software development specialist, was named chief information officer. . . . **WILLIAM GRADY**, assistant member, Fred Hutchinson Cancer Research Center, was one of 60 scientists to receive a Presidential Early Career Award for Scientists and Engineers from President Bush June 13. Grady, also a research associate at the Veteran's Administration Puget Sound Healthcare System, was nominated for the award by the Veterans Administration Office of Research and Development. The VA will give him research funding of \$25,000 per year for five years. . . . **ALBERT SZENT-GYÖRGYI** exhibit was added to Profiles in Science, a National Library of Medicine online museum at [www.profiles.nlm.nih.gov](http://www.profiles.nlm.nih.gov). The biochemist and 1937 Nobel Laureate in Physiology or Medicine isolated vitamin C. His later work in submolecular or quantum biology led to connections between free radicals and cancer. The exhibit includes oral histories, published articles, lectures, documentaries, and photographs from the scientist's papers.

## 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	<p>Patient must be <math>\geq</math> 12 months with a diagnosis of T-cell acute lymphoblastic leukemia/lymphoma AND must also have:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Relapsed T-ALL</li> <li><input type="checkbox"/> T-ALL refractory to standard therapy</li> <li><input type="checkbox"/> Not be a candidate for myelosuppressive chemotherapy due to age or comorbid disease</li> </ul> <p>ECOG performance status <math>\leq</math> 2 for patients <math>&gt;</math>16 years of age OR Lansky performance level <math>&gt;</math>50 for patients 12 months to <math>\leq</math>16 years of age</p> <p>Fully recovered from any chemotherapy and <math>&gt;</math>2 weeks from radiotherapy, immunotherapy, or systemic steroid therapy with the exception of hydroxyurea or intrathecal therapy</p> <p>Patient must be <math>&gt;</math>2 months following bone marrow or peripheral blood stem cell transplantation</p> <p>No treatment with any investigational therapy during the preceding 30 days</p> <p>No active or uncontrolled infection</p>
Treatment Plan	<p>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.</p>

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

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