THE CANCER LETTER

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J&J, Amgen Settle Lawsuit Over ESAs As FDA Prepares Another Label Change

By Paul Goldberg

Johnson & Johnson has dropped a lawsuit claiming that a "bundling" scheme used by competitor Amgen Inc. to link the sales of its red blood cell growth factors and those of the white blood cell growth factors constituted a violation of antitrust laws.

In connection with ending the litigation, Amgen paid J&J's unit Ortho Biotech $200 million.

The settlement, which was announced July 11, comes at a time when sales of red cell growth factors also known as erythropoiesis-stimulating agents, have declined by more than a third amid safety concerns.

With sales in decline and the product's future uncertain, it's likely that J&J's original effort to slow down an aggressive competitor in a booming

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Capitol Hill:

Harkin, Specter Propose A $5.2-Billion Supplement For NIH In Current Fiscal Year

By Kirsten Boyd Goldberg

Sens. Tom Harkin (D-Iowa) and Arlen Specter (R-Penn.) introduced a supplemental funding bill on July 16 that would provide an additional $5.2 billion for NIH in the current fiscal year.

Harkin, chairman of the Senate Appropriations Subcommittee on Labor, Health, and Human Services and Education, and Specter, ranking minority member of the subcommittee, co-authored the bill that would allocate $1.2 billion to NCI and $4 billion to the other NIH institutes.

"The National Institutes of Health is the premier biomedical research agency in the world," Harkin said. "It is vital for the Congress to support our scientists as they search for treatments and cures that could provide hope to millions of Americans and I am proud to work with Senator Specter to continue our efforts toward this goal."

The $5.2 billion supplemental seeks to reestablish NIH funding at levels consistent with inflation. Harkin and Specter said they determined the figure after consulting with NIH and the cancer research community. The new legislation comes just a week after President Bush signed a $150-million supplemental funding bill for NIH and FDA (The Cancer Letter, July 11).

"This funding is critical to maintaining the important medical advances that NIH has been able to achieve," Specter said. "Funding for NIH is grossly

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Amgen's 2008 Contract Softens "Bundling" Terms

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market has lost much of its urgency.

This urgency was further eroded earlier this year as Amgen softened its marketing scheme. While in the past, the supply contracts signed by oncology clinics required doctors to meet dollar targets on the sale of red cell growth factor Aranesp, starting this February, agreements circulated by distributors were modified to express targets in percentage points.

Marketing experts say that this is an important difference, as dollar targets amounted to an inducement for doctors to increase the dosage of agents that in recent years have been suspected of causing thromboembolic events and accelerating development of disease.

Now, Amgen's supply contracts set percentage goals for Aranesp, protecting the share of the market won in competition against J&J's Procrit.

The bundling contract has been remarkably effective in steering patients to Amgen's lead supportive care products in oncology. The Amgen supply contracts cover three agents: Aranesp, Neulasta and Neupogen.

In the clinic, Proctit is usually combined with Neupogen, while Aranesp is combined with Neulasta.

Setting aggressive targets and cranking out substantial discounts on multimillion-dollar purchases, the contracts in effect limited the doctors' willingness to use Procrit and Neupogen, a combination that J&J's regulatory filings contended is less expensive than the Aranesp-Neulasta combination. According to court filings, a medium-sized practice could get back up to 21 percent on Aranesp, 17 percent on Neupogen and 16 percent on Neulasta.

While the companies argued about the economics, patients generally preferred the Aranesp-Neulasta combination, because it requires less frequent administration.

To control the use of Neupogen and Neulasta, the contract sets a "maximum" level of the growth factors that can be used for calculation of rebates. This contractual lever also discourages stockpiling of Neupogen, further limiting the market for J&J's Procrit.

After an aggressive bundling scheme was instituted in 2005, the U.S. oncology sales of Aranesp jumped by more than a third, from $2.104 billion to $2.790 billion, industry figures show. At the same time, the Aranesp oncology market share jumped from 48 percent in 2005 to 57 percent in 2006.

While bundling can be effective in an expanding market, it's less useful—and can, in fact, be burdensome—when the market begins to contract. The market for ESAs has been dropping for more than a year since early 2007 as a result of safety problems, escalation of FDA restrictions, and increasingly restrictive coverage policies.

During the quarter ended March 31, Aranesp sales dropped by 38 percent to $405 million, from $654 million last year. U.S. sales of Procrit were down 22.9 percent, dropping to $346 million, from $449 million at this time last year.

Amgen and FDA are in advanced stages of negotiating the new ESA label. Many oncology insiders expected that the label would be published in the evening of July 15. However, at this writing, the label changes haven't been announced.

Several sources who have been briefed by the sponsors said the agency intends to strengthen the safety warnings, urging avoidance of using ESAs in settings where treatment is provided with curative intent. The agency apparently is not mandating withholding ESAs for specific diseases, such as breast cancer and head-and-neck cancer.

Also, the label is expected to sharpen the language on hemoglobin targets, stating that while the 10 to 12 g/dL range is an acceptable range rather than a treatment goal. Patients should be kept at the lowest level required to avoid blood transfusions, the label is expected to state.

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If these reports are correct, the changes would be consistent with those contemplated by the European authorities.

Last month, the European Medicines Agency declared that ESA labels should warn that blood transfusions should be preferred to ESAs in patients with a "reasonably long life expectancy." The agency didn't mention specific diseases, and its directives appear to apply across the board, even to diseases where no safety signals have been detected. The EMEA final label language is expected later this year (The Cancer Letter, June 27).

Sources said the current Amgen contract requires practices to use 50 percent or more Aranesp if they are to earn more than a standard rebate. However, the Neulasta threshold is still a dollar target. According to documents circulated by at least one drug distributor, to earn discounts on Neulasta, doctors have to match at least 80 percent of their last year's average quarterly sales.

In addition to filing the 2005 lawsuit in the U.S. District Court for the District of New Jersey, J&J lodged multiple complaints with Centers for Medicare and Medicaid Services (The Cancer Letter, Oct. 14, 2005). J&J's original court filing, which provides a detailed description of the bundling scheme, as well as a copy of Amgen's response are posted at www.cancerletter.com.

A J&J spokesman earlier this week said the company wouldn't comment on the settlement. Amgen spokesman Ashleigh Koss said the practice of providing discounts on the company's products was entirely appropriate. "Like many other companies, Amgen provides rebates and discounts to its customers, which results in lower costs to patients, physicians, health plans and the federal government," she said. "Past and present contracts offer base level discounts and rebates that are available to all clinics, even if they purchase only one product.

"When you combine Medicare reimburseme nt for Aranesp with the higher reimbursement rates of privately-insured patients along with rebates and discounts, the clinics on average only recover a range of approximately $35-$70 per patient per week," Koss said.

It's unlikely that the settlement has stopped the wrangling over the bundling practice.

Last spring, Amgen announced that it had received a subpoena from the New York Attorney General. The subpoena covered "documents related to promotional activities, sales and marketing activities, medical education, clinical studies, pricing and contracting, license and distribution agreements and corporate communications. " J&J said it received a similar subpoena.

The attorneys general typically don't comment on ongoing investigations.

In recent years, attorneys general have been aggressive in recovering funds from pharmaceutical industry. For example, state prosecutors spearheaded litigation that extracted over $670 million from Bristol-Myers Squibb Co. for its efforts to extend market exclusivity for Taxol and BuSpar (The Cancer Letter, March 14, 2003). Problems detected through monitoring the consent agreement by the attorneys general ultimately led to the firing of Bristol's CEO Peter Dolan (The Cancer Letter, Sept. 15, 2006).

The attorneys general aren't alone in examining the marketing of ESAs. Boxes full of materials have been delivered to the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce and to the office of Sen. Chuck Grassley (R-Iowa), ranking member of the Senate Finance Committee and a critic of the pharmaceutical industry.

These investigation, too, are continuing.

"Up In Smoke" Redux: Lancet Corrects Henschke Letters

By Paul Goldberg

The Lancet this week published two corrections to letters to the editor from the Weill Cornell Medical College radiologist Claudia Henschke and her research group, the International Early Lung Cancer Research Program.

The letters, which appeared in the medical journal in 2002 and 2003, sought to deflect criticism of I-ELCAP research.

In an opinion piece published June 15, 2002, Henschke's critics, Dartmouth researchers Steven Woloshin, Lisa Schwartz and Gilbert Welch, claimed that New York City tobacco settlement funds going to fund a single-arm study of CT screening for lung cancer were going "up in smoke."

Daring as the paper appeared at the time, critics were unaware of the fact that Henschke's research was funded by the parent company of Liggett Group Ltd., a cigarette maker. The $3.6 million donation from Liggett was placed in a non-profit foundation headed by Henschke.

Henschke's tie with Liggett was reported in The Cancer Letter and The New York Times on March 25.

The Lancet is the latest medical journal to correct the record. The New England Journal of Medicine, the Journal of American Medical Association, Nature Clinical Practice Oncology, Cancer, Cytopathology and The Oncologist similarly published corrections in recent months.

The Lancet corrections don't address the fact that Henschke and I-ELCAP collaborator David Yankelevitz are listed as inventors on patents for lung cancer screening technology, some of which have been licensed by General Electric.

The corrections, published in the July 19 issue of The Lancet, read:

—NY-ELCAP investigators. Tobacco money: up in smoke? Lancet *2002;* ***360:*** *1980–81*—In this Correspondence letter (Dec 14), the conflict of interest statement should have read: "Claudia Henschke and David Yankelevitz have received funding for projects other than NY-ELCAP from the Foundation for Lung Cancer: Early Detection, Prevention and Treatment, which in turn has received an unrestricted gift from the Vector Group—the parent company of Liggett Tobacco."

—Henschke CI. A defence of the New York Early Lung Cancer Project. Lancet *2003;* ***361:*** *1138*—In this Correspondence letter (March 29), the conflict of interest statement should have read: "I have received funding for projects other than NY-ELCAP from the Foundation for Lung Cancer: Early Detection, Prevention and Treatment, which in turn has received an unrestricted gift from the Vector Group—the parent company of Liggett Tobacco."

Capitol Hill:

Senate Committee Report Says NIH Funding At "Crisis Point"

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insufficient and Congress must do something about this scandalous situation."

"With 1 out of 2 men and 1 out of 3 women expected to get a diagnosis of cancer in their lifetime, constituents in every state and Congressional district in the country are counting on their legislators to put cancer at the top of the national priority list and make this funding proposal a reality," Smith said.

The President's request for NIH for fiscal 2009 is $29.229 billion, a decrease of $150 million below the previous year.

On June 26, the Senate Appropriations Committee approved an $875 million increase in NIH funding for FY 2009. This amount isn't enough to restore the purchasing power of NIH's budget after five consecutive years of inflationary cuts, Harkin and Specter said in a statement.

Daniel Smith, president of the American Cancer Society Cancer Action Network, said in a statement that the supplemental funding bill, if enacted, "would begin to restore necessary funding that for five years running has failed to keep up with the growing cost of medical research."

At a July 16 hearing on the NIH budget, NIH Director Elias Zerhouni testified that the current funding levels could have serious consequences on the ability of the institutes to perform research and train and recruit future scientists.

The administration's budget would funds essentially the same level of competing research project grants in 2009 as in 2008—about 9,760 RPGs at $3.5 billion, Zerhouni said. NIH plans to support a total of 38,260 RPGs at $15.5 billion, by holding down inflationary increases for existing and new grants.

"Our nation continues to lead the highly competitive biotechnology and pharmaceutical sectors," Zerhouni said. "Yet, we are also the focus of increasing competition from growing research in Europe and Asia. NIH programs produce steady streams of novel discoveries and innovative researchers that flow into our industries, making them more competitive. We must continually sustain the momentum of U.S. biomedical research, or risk losing it. Complacency is unacceptable."

NCI Director John Niederhuber testified that federal spending on cancer research "is paying dividends" by helping people live longer with a cancer diagnosis. "However, of great worry, cancer is a disease of aging, the result of a lifetime of genetic alterations, additions, and subtractions that accumulate in our genes and impact their function," he said.

"With a rapidly aging population, NCI estimates that the total economic burden of cancer in the U.S. will increase to $1.82 trillion by 2017. This clearly underscores the urgency of increasing our investment in cancer research," Niederhuber said.

Hearing testimony is available at http://appropriations.senate.gov/hearings.cfm?s=lbr.

Senate Report Language on NIH and NCI

The Senate Appropriations Committee released its report on the fiscal 2009 appropriations bill that funds NIH.

Following are excerpts from its remarks on NIH and NCI:

The Committee has sounded the alarm for more Federal biomedical research funding for several years, and the situation is now at a crisis point. Since the end of the 5-year doubling effort, in fiscal year 2003, funding for the National Institutes of Health has declined, in real terms, by 12.3 percent. The average researcher now has a less than 1 in 5 chance of getting an NIH grant application approved, and the average age at which researchers receive their first RO1 grant has risen to 42. It is little wonder that many young scientists are balking at a career in biomedical research, putting our Nation at risk of losing a generation of talented investigators who could pursue treatments and cures. Meanwhile, several other countries are ramping up their investments in biomedical research and threatening the leadership of the United States in this field.

Regrettably, the administration's budget ignores these warning signs and proposes to freeze NIH funding at the fiscal year 2008 level of $29,229,524,000. Under this plan, the success rate for research project grants would fall to 18 percent, the lowest level on record. In real terms, NIH funding would be reduced by more than $1,000,000,000. The Bush budget also proposes eliminating all funding for the National Children's Study, for which Congress has already appropriated approximately $212,300,000 since fiscal year 2004.

The Committee rejects the administration's approach and instead recommends an overall NIH funding increase of $1,025,000,000, for a total of $30,254,524,000. That amount would allow NIH funding to keep up with the biomedical inflation rate (3.5 percent) for the first time in 6 years. It would also increase the estimated number of new, competing research project grants to 10,471--the most ever at NIH. The recommended level includes $192,300,000, an increase of $81,400,000 over the fiscal year 2008 appropriation of $110,900,000, for the National Children's Study, to ensure that the study's implementation stays on track. The Committee also fully funds the budget request of $300,000,000 for transfer to the Global Fund to Fight AIDS, Tuberculosis and Malaria. The fiscal year 2008 transfer was $294,759,000.

The Committee recommends $568,119,000 for the Common Fund. The fiscal year 2008 level was $495,608,000, and the budget request is $533,877,000. The Committee intends that much of the increase will be used to support new investigators and high risk/high reward research, as described later in this report under the section on the Office of the Director.

NIH Office of the Director: The Committee recommends an appropriation of $1,275,281,000 for the Office of the Director. The budget request is $1,056,797,000 and the fiscal year 2008 appropriation was $1,109,099,000. The Committee has included bill language specifying the amount for the Common Fund as $568,119,000. The comparable amount for fiscal year 2008 was $495,608,000, and the budget request is $533,877,000.

Conflict of Interest—The Committee greatly appreciates the Director's efforts to produce a stronger policy for its employees regarding conflicts of interest and financial disclosure. This was an arduous task but worth the effort, as it served to reassure the public and Congress that NIH employees are meeting high standards of conduct. However, the Committee notes that the vast majority of NIH funding is awarded extramurally, to non-Federal employees and institutions. Troubling allegations that some NIH-funded investigators have flaunted their universities' conflict-of-interest rules have recently come to light, and it seems clear that the NIH currently has no ability to monitor or prevent such abuses. Moreover, up to this point the NIH leadership has not demonstrated much interest in dealing with the issue. That must change. The Committee believes that the Director has no higher priority in the coming year than to address this situation and fix it.

Data Security—The Committee was disappointed by the widely publicized reports this spring that an NIH employee had failed to encrypt sensitive patient data on a laptop computer which was stolen from his car, placing 2,500 people at risk of identity theft. While the incident served as an important reminder that all employees must comply with the Government's data-security policy, the handling of the incident by NIH officials, who delayed notification to the affected patients by almost a month, raised equally disturbing questions. The Committee expects to be updated on the NIH's efforts to institute stricter compliance of the security policy as well as clearer procedures for notifying patients immediately when their personal information is at risk of being compromised.

High-risk/High-reward Research—The Committee notes that flat budgets sometimes make review panels overly conservative when judging grant applications. The Committee therefore applauds the NIH for creating sources of funding that are dedicated specifically to research that is relatively risky but could lead to significant advances. One such program is the Director's Pioneer Awards, for which the Committee provides $45,000,000, an increase of $9,000,000 over the fiscal year 2008 level. This program makes awards to investigators with a history of doing innovative research.

The Committee also includes up to $50,000,000 for Transformative Research Project Grants, a new program that will provide grants for potentially transformative investigator-initiated projects, and $108,027,000, an increase of $51,853,000 over the fiscal year 2008 level, for New Innovator Awards, which are directed to young investigators.

New and Early-stage Investigators—The Committee encourages the NIH to continue its commitment to maintaining the pipeline of new and early-stage investigators, who tend to fare more poorly during tight financial times than their veteran counterparts. Through programs such as the NIH Director's New Innovator Awards, the NIH Director's Bridge Awards, and the Pathway to Independence Awards, as well as individual programs undertaken by the Institutes and Centers, the NIH has made significant investments to attract and support the researchers of the future. The Committee was pleased to note that in fiscal year 2007, the NIH set a policy to support its 5-year historical average of first-time and early-stage investigators at about 1,500, and that the NIH exceeded this target. The Committee encourages the NIH to continue these efforts, and to seek to support 1,750 new investigators in fiscal year 2009.

National Cancer Institute

Much progress has been made in the fight against cancer, yet the disease continues to exact an enormous toll. In 2008, it is estimated that cancer will claim over 565,000 Americans—1,500 a day. The annual costs for cancer care in this country exceed $200,000,000,000. And while cancer death rates have declined for each of the past 3 years, cancer remains the leading cause of death for Americans under the age of 85. Therefore, the Committee recommendation for the NIH includes a special emphasis on cancer research.

The Committee recommends an appropriation of $4,958,594,000 for NCI. The budget request was $4,809,819,000. The fiscal year 2008 appropriation was $4,805,088,000.

Bone Cancer—NCI is encouraged to enhance its research program in osteosarcoma biology through exploratory and other grant mechanisms emphasizing the following priorities: development of suitable genetic and orthotopic models, studies on the role the tumor microenvironment plays in tumor progression, the identification of tumor progenitor cells and the biology of tumor invasion. NCI is also urged to support research on the development of clinically relevant experimental models of tumor dormancy, studies on dormant tumor cells and their interaction with the microenvironment, and identification of factors that trigger dormancy of invasive tumor cells or activation of dormant cells.

Decisionmaking—The Committee applauds the NCI for supporting research on decisionmaking processes as they relate to cancer, which will help people make better informed choices about cancer prevention and screening.

Health Communication—The Committee encourages the NCI to continue its investment in the Health Information National Trends Survey [HINTS], and to consider expanding the survey to track how public information campaigns may influence attitudes about cancer screening and vaccines.

Liver Cancer—The Committee continues to urge the NCI to develop a comprehensive research program to slow the incidence of primary liver cancer and to develop viable treatment options that will improve survivability. The Committee urges more programs aimed at the discovery of new interventions for the early detection, management and treatment of cancer associated with hepatitis. The Early Detection Research Network continues to be an impressive and productive programmatic model.

Lung Cancer—The Committee encourages the NCI to expand its research to improve lung cancer diagnosis and treatment and undertake additional research to better understand the role gender plays in this disease.

Melanoma—The Committee is aware of the ongoing dialogue between the NCI and the advocacy and extramural research community on prioritizing NIH-funded melanoma research, most recently with the 2007 Community-Oriented Strategic Action Plan for Melanoma Research. The Committee encourages the NCI to better target its funds in three categories: targeted therapies in melanoma; host response in melanoma; and prevention, including exploring the feasibility of a randomized trial of screening for melanoma.

NCI Community Cancer Centers Program—The Committee commends the NCI for launching the NCI Community Cancer Centers Program early in 2007. The NCCCP, now in a 3-year pilot phase, seeks to bring more Americans into a system of high-quality cancer care, increase participation in clinical trials, reduce cancer healthcare disparities, and improve information sharing among community cancer centers. The program encourages collaboration of private-practice medical, surgical, and radiation oncologists as well as providing links to NCI research and the NCI-designated Cancer Centers. The Committee supports these goals

and encourages the NCI to continue supporting this program.

Neuroblastoma—The Committee urges the NCI to significantly expand its research portfolio on neuroblastoma, with a focus on clinical trials for high-risk patients. Given the poor survival rates for children with advanced disease, the Committee encourages the NCI to prioritize support for all promising neuroblastoma research in this population, both inside and outside of the Children's Oncology Group.

Pancreatic Cancer—The Committee notes that less than 2 percent of NCI's budget is devoted to pancreatic cancer research, even though this form of cancer is the fourth leading cause of cancer-related death. The Committee strongly urges the NCI to assign more resources to launch a pancreatic cancer-specific research and training initiative, including the establishment of a prioritized research plan that includes exception funding for grants that are pancreatic cancer focused, strengthening and expanding the SPOREs, and instituting training mechanisms designed to stimulate clinical and translational career development. The Committee expects the NCI to be prepared to provide a detailed accounting of resources targeted principally on pancreatic cancer research before the fiscal year 2010 budget hearing.

Pediatric Cancer—The Committee urges the NCI to expand and intensify pediatric cancer research, including laboratory research to identify and evaluate potential therapies, preclinical testing, and clinical trials through cooperative clinical trials groups. Such research should include research on the causes, prevention, diagnosis, recognition, treatment, and late effects of pediatric cancer.

Prostate Cancer Imaging—The Committee is aware of the potential of prostate imaging to improve early diagnosis and minimally invasive treatment of prostate cancer, and it encourages the NCI to provide additional funding for research and the development of technologies for prostate cancer detection and treatment, comparable to state-of-the-art mammograms.

Vaccine Research—The Committee recognizes that aspects of science surrounding an HIV vaccine and cancer vaccines contain many similarities and synergies. Therefore, the Committee urges the NCI to incorporate the development of an HIV vaccine into cancer vaccine research efforts. The Committee also supports new partnerships between the NCI and Institutes that are capable of supporting a joint HIV/cancer vaccine program. In addition, the Committee urges the OAR to increase HIV/AIDS funding at the NCI.

Senate Passes Bill Authorizing $30M For Pediatric Cancer Clinical Trials Research

The Senate on July 16 passed the Conquer Childhood Cancer Act, authorizing $30 million annually over five years for pediatric cancer research.

The bill, introduced in the Senate by Sens. Jack Reed (D-R.I.) and Norm Coleman (R-Minn.), passed without amendment by unanimous consent, echoing the 416-0 vote June 12 in the House.

The act authorizes funding for collaborative pediatric cancer clinical trials research, to create a population-based national childhood cancer database, and to further improve public awareness and communication regarding available treatment and research for children with cancer and their families.

"Too many young people's lives were cut short by cancer, but their hopes were not," said Reed. "We have made great advances in treating cancer, but there is still much more to be done. The Conquer Childhood Cancer Act will deliver much needed hope and support to children and families battling cancer and more resources for vital pediatric cancer research programs."

"Passage of the Conquer Childhood Cancer Act in the Senate is a monumental step in the fight against childhood cancer," said Coleman. "I am proud that my colleagues were able to come together and pass legislation that will provide the resources to not only support children and families with childhood cancer, but also find a cure."

President Bush is expected to sign the bill into law.

"The Conquer Childhood Cancer Act allows for translation of the very best research discoveries into clinical evaluation and practice, in order to improve the cure rates for all children with cancer," said Gregory Reaman, chairman of the Children's Oncology Group. "On behalf of my colleagues in the Children's Oncology Group and the children with cancer and their families who are our partners in clinical research, we thank our leaders in the Senate. Only research cures childhood cancer."

In the Cancer Centers:

CITY OF HOPE and **California Institute of Technology** have established the Caltech/City of Hope Medical Research Fund, which will support collaborative biomedical and bioengineering research programs to develop treatments for cancer, diabetes and other diseases. Also, the two institutions established the

Caltech/City of Hope Endowed Funds, an endowment that will support a series of public educational forums highlighting new developments in biomedicine and therapies. The interdisciplinary research programs and educational forums are funded by a $1.5 million seed gift from an anonymous donor. The Caltech/City of Hope Medical Research Fund received $1 million. The remaining $500,000 will establish the Caltech/City of Hope Endowed Funds at Caltech and City of Hope, and will be administered by **Richard Jove**, director of the Beckman Research Institute at City of Hope, and **Stephen Mayo**, vice provost of research and Bren Professor of Biology and Chemistry at Caltech. "The grants allow Caltech and City of Hope to share our knowledge with the community and, hopefully, inspire more people to study science and further our collective efforts," said **Michael Friedman**, president and CEO, City of Hope. . . . **INDIANA UNIVERSITY** Melvin and Bren Simon Cancer Center patient care building will open in August, with a public viewing of the $150 million, 405,000-square-foot structure at open houses this month. The expansion of the cancer center is a partnership between the Indiana University School of Medicine and Clarian Health. "The new building's private patient rooms and other amenities will provide an outstanding environment for the delivery of state-of-the-art inpatient and outpatient care," said **Stephen Williams**, director of the IU Simon Cancer Center and the HH Gregg Professor of Oncology with the IU School of Medicine.

Funding Opportunities:

NIH Roadmap Initiatives

RFA-RM-08-017: Epigenomics of Human Health and Disease. NIH Roadmap Initiatives. R01. Letters of Intent Receipt Date: Sept. 28. Application Due Date: Oct. 28. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-RM-08-017.html. Inquiries: Brenda Weis, 301-451-2067; weis@mail.nih.gov.

RFA-RM-08-020: Molecular Libraries Screening Instrumentation. NIH Roadmap Initiatives. R01. Letters of Intent Receipt Date: Sept. 2. Application Due Date: Oct. 2. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-RM-08-020.html. Inquiries: Ajay, 301-496-7531, ajaydr@mail.nih.gov.

RFA-RM-08-021: Renewal of the National Technology Centers for Networks and Pathways Program. NIH Roadmap Initiatives. U54. Letters of Intent Receipt Date: Sept. 28. Application Receipt Date: Oct. 28. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-RM-08-021.html. Inquiries: Douglas Sheeley, 301-594-9762; sheeleyd@mail.nih.gov.

RFA-RM-08-026: Development of New Technologies Needed for Studying the Human Microbiome. NIH Roadmap Initiatives. R01. Letters of Intent Receipt Date: Sept. 2. Application Due Date: Oct. 2. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-RM-08-026.html. Inquiries: Jeffery Schloss, 301-496-7531; schlossj@exchange.nih.gov.

RFA-RM-08-027: Development of New Technologies Needed for Studying the Human Microbiome. NIH Roadmap Initiatives. R21. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-RM-08-027.html.

Other Funding Opportunities

RFA-GM-09-012: Research on Causal Factors and Interventions that Promote and Support the Careers of Women in Biomedical and Behavioral Science and Engineering. R01. Letter of Intent Receipt Date: Sept. 21. Application Submission/Receipt Date: Oct. 22. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-GM-09-012.html. Inquiries: Juliana Blome, 301-594-2762; blomeju@mail.nih.gov.

RFA-DK-08-003: Implementation Planning Grants for Educational, Behavioral, or Social Studies for Translation of Genetic Factors in Common Diseases. U34. Letters of Intent Receipt Date: Oct. 24. Application Due Date: Nov. 25. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-DK-08-003.html. Inquiries: Paul Kimmel, 301-594-1409; pk77g@nih.gov.

RFA-DK-08-004: Translation of Common Disease Genetics into Clinical Applications. R21. Letters of Intent Receipt Date: Oct. 24. Application Due Date: Nov. 25. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-DK-08-004.html. Inquiries: Paul Kimmel, 301-594-1409; pk77g@nih.gov.

RFP RFQ-NCI-80117-MM: TIRF Microscope. Full text: http://www.fbodaily.com/archive/2008/07-July/16-Jul-2008/FBO-01613757.htm. Inquiries: Melissa Marino, 301-402-4509; marinome@mail.nih.gov or Caren Rasmussen, 301-402-4509; cr214i@nih.gov.

RFP N02-CM-91000-16: Cancer Therapy Evaluation Program's Informatics and Computer Support. Full text: http://www.fbodaily.com/archive/2008/07-July/05-Jul-2008/FBO-01607476.htm. Inquiries: Annmarie Keane, 301-435-3814; ak155a@nih.gov or Richard Hartmann, 301-496-8620; hartmari@mail.nih.gov.

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