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CMS Will Pay Oncologists To Report Adherence To Practice Guidelines

By Paul Goldberg

Centers for Medicare and Medicaid Services earlier this week published regulations that establish a year-long demonstration project designed to measure physicians' adherence to practice guidelines.

The 2005 version of the demonstration project, which paid doctors $130 to collect data on side effects of chemotherapy every time they provided treatment, was popular with oncologists because it put an estimated $300 million into their practices.

Though the value of the data is unclear, the project demonstrated

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In Brief:

UT Southwestern Cancer Center Receives Its Largest Gift, $50 Million From Simmons

UNIVERSITY OF TEXAS Southwestern Medical Center Harold C. Simmons Comprehensive Cancer Center received a $50 million gift for research programs and recruitment, the largest gift UT Southwestern has ever received, from **Harold C. Simmons**, a Dallas entrepreneur, and his wife **Annette Simmons**. Last month, the couple donated $500,000 in memory of **Charles Sprague**, the first president of UT Southwestern, for a chair in clinical oncology, said **James Willson**, director of the Simmons Comprehensive Cancer Center and associate dean for oncology programs. To date, the Simmons family and foundation has given more than $125 million to support initiatives at UT Southwestern, $97 million of which for its cancer programs. The center said it is hoping to achieve NCI designation by 2009. . . . **LEUKEMIA & LYMPHOMA SOCIETY** awarded four Specialized Center of Research grants for blood cancer therapies research. The recipients for 2005 are: **Ronald Levy**, Division of Oncology, Stanford University School of Medicine; **Thomas Kipps**, deputy director of Research, Moores UCSD Cancer Center, University of California at San Diego; **Cheryl Willman**, Cancer Research and Treatment Center, University of New Mexico Health Sciences Center; **John Byrd**, Comprehensive Cancer Center, Ohio State University. Each of the recipients will receive $1.25 million per year for five years, for a total of $6.25 million. In addition to the four new centers, the society has renewed for five years the SCORs led by **Brian Druker**, of Oregon Health & Science University, and **James Griffin**, of Dana-Farber Cancer Institute. . . . **NANCY SUMBERAZ** was named president of the Multiple Myeloma Research Foundation and the Multiple Myeloma Research

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2006 CMS Demo Project To Pay $23 Per Office Visit

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that it is possible for CMS to use its payment system for collection of information and sent the message to healthcare providers that the agency is willing to pay for data.

The 2006 version of the demonstration project, which will pay oncologists $23 for providing data at office visits, will have a lower budget of about $150 million.

"This idea came from the experts on the outside and was coordinated with people at CMS who thought about implementation a lot," said Peter Bach, senior advisor on cancer policy at CMS and the point man on the demonstration project (The Cancer Letter, June 3).

Bach, a pulmonologist and biostatistician who joined the agency last February, said the new demonstration project is designed to ask a central question in oncology: "What we can do to improve cancer care?"

"We hope to circle back to informing a scientific research agenda for the future," Bach said to The Cancer Letter. "If doctors are saying they are not following the guidelines because they don't believe them, or guidelines aren't available, then we need to ask scientific questions about that.

"We are hoping that the doctors see that long-term sustainability of the program depends on their increasingly emphasizing what they do as opposed to how much they do."

Ultimately, this could change the system from its current focus—payment for services—to payment for quality of care, Bach said.

In other highlights of the new regulations:

—Assuming that historical growth rates continue, payments to oncologists for drugs and services would increase by 6% next year, the agency said. Assuming no growth, payments would decrease by 3%.

—The agency launched a Competitive Acquisition Program intended to give office-based oncologists the option to obtain the drugs they administer in their offices. The program will become operational next July.

—The agency said it will pay for most Part B drugs and biologics administered in hospital outpatient departments based on 106% of the manufacturer's average sales price. The agency initially said it would pay 108% of ASP.

—Also, CMS gave a 3.7% inflation update in Medicare payment rates in 2006 for outpatient services under a final Outpatient Prospective Payment System rule. Sole community hospitals in rural areas will receive an additional 7.1% payment adjustment.

ASCO Analyzing New Rules

Trade associations and professional societies are still analyzing the new rules. The American Society of Clinical Oncology "remains concerned about maintaining necessary resources for oncology care and is conducting a full-scale analysis to determine all of the financial implications of the final rule," said Joseph Bailes, the society's interim CEO and co-chairman of its government relations council.

The demonstration project CMS will launch on Jan. 1 recognizes ASCO's practice guidelines and the guidelines developed by the National Comprehensive Cancer Network as the standards of care in oncology. "We believe CMS' emphasis on cancer care quality guidelines in the demonstration project will help improve care for all cancer patients," Bailes said in a statement.

Ellen Stovall, president and CEO of the National Coalition for Cancer Survivorship, said the demonstration is a step toward greater accountability in oncology.

"This new demo will benefit patients, ultimately, because it will make the system more transparent and more beneficial," Stovall said. "It will cause some physicians to reorient their practices to accommodate a more systematic use of guidelines."

Some oncologists have come to view the 2005

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demo—and the funds in provided—as an entitlement. Community Oncology Alliance, a group that represents a minority of U.S. oncologists, has been advocating for a bill to keep the 2005 version of the demonstration project unchanged.

The bill, HR 4098, was sponsored by Rep. Jim Ramstad (R-Minn.). It seeks to continue to pay oncologists to collect data on pain, nausea and vomiting, and fatigue. The text is posted at http://thomas.loc.gov/cgi-bin/query/D?c109:1:./temp/~c1097vyNCx.

COA has clashed with ASCO in the past, accusing the larger association of becoming entrenched in Washington and accepting less than optimal deals for oncologists.

"This evening, we should ask the question—should we consider the continuation of the demonstration project at a lower level of funding a victory worth celebrating while we move forward for 2006?" COA's Co-Executive Director Steve Coplon wrote in an email Nov. 3.

"Such celebration and self-adulation is incredulous—especially to those oncologists, nurses, and staff who will look cancer patients in the eyes tomorrow knowing that our dedication to excellence in quality, cost, and access is threatened—not only by policy makers in Washington, but even by the continued compromise of those who claim to represent us," Coplon wrote.

"It was clear in 2003 that we needed ASP rightly defined plus 12% and $550 million—some mishandled, telegraphed, and ultimately negotiated a lower rate—that put us all at risk. Thankfully, the grass roots made a difference on the essential service side—and we survived. It was clear, last year that we must make the difference ourselves—and we succeeded with the demonstration project—while others had no answer—preferring to play to their future organizational status—rather than the concerns that we all have for our patients. Much can be said along the same line—this year."

CMS Sends Message on Quality

The CMS strategy is to focus on quality as a way of improving beneficiary outcome and controlling costs, Bach said.

"The belief is that a lot of spending growth is due to inefficiency and lack of coordination of care," he said. "As we continue to focus through our payment system and claims system on doctors being compensated or rewarded for providing high quality, efficient care that's well coordinated, we will get a better result and save costs.

As CMS starts the new demonstration project, it will eliminate the G-codes it used to collect data—and reimburse—for the 2005 demonstration project and institute new G-codes designed to gather more specific information on treatments and adherence to the ASCO and NCCN guidelines.

Reporting will no longer be specific to chemotherapy administration services, but instead will be associated with physician evaluation and management visits for cancer patients, the agency said.

The demonstration will cover level 2 through 5 visits for patients with to one of the following thirteen diagnostic categories: invasive cancer of the breast, colon, rectum, prostate, lung, stomach, esophagus, pancreas, ovary, head and neck, as well as chronic myelogenous leukemia, multiple myeloma, and non-Hodgkin's lymphoma.

To qualify for the $23 payment, oncologists would submit one G code from each of the following three categories:

—The primary focus of the evaluation and management service. The physician will be asked to identify the primary focus of the visit from one of several categories, including for instance, supervision of therapy and attendant toxicity management, palliation and pain control, or surveillance for disease recurrence.

—The current disease state. The physician will report the status of the patient's cancer, for example, characterizing the extent of spread of the cancer as best understood clinically at that time.

—Adherence to clinical guidelines. The physician may report that the guidelines are being followed, or are not followed, for example, where there was an alternative treatment due to patient preference, or where the physician did not agree with the guidelines.

"I spent last year going around the country talking with oncologists, and all I heard over and over is, we are paid through chemotherapy," Bach said. "This is an arcane system that incentivizes the chemo and deemphasizes everything else we do for cancer patients, some of whom are very sick, some of who need a lot of care outside chemotherapy and some who are better off in some clinical situation getting palliative care rather than chemotherapy."

The new project will provide a broader scope of data, Bach said.

"Let's say they are in a palliative mode and not getting chemotherapy, the 2005 demo was turned off," he said. "The oncologists couldn't participate, because they weren't giving chemo. We are asking what the focus of the visit is. What that's intended to do is not only to

scrutinize the visit, but better capture the spectrum of care that oncologists deliver."

Also, the agency would be able to analyze the physicians' statements on compliance with the practice guidelines.

"We want to understand more about how frequently PET scans are being ordered and CT scans and lab tests, and compare those to what the recommendations are," Bach said. "This is an area where the evidence isn't necessarily strong in all cases, but it sure would be useful to figure out whether oncologists agree with the guidelines. And because we have the claims data, we can also assess what they are saying what they are actually doing.

"Program costs in oncology for cancer patients are rising faster than they are for medical patients in general," Bach said. "And the costs on imaging and lab tests are rising faster than the costs of chemotherapy. These are astronomical numbers, and part of it is due to more intensive surveillance. If it's appropriate, that's great. If there is variation that will lead us to doing new studies or shoring up the practice guidelines, that should lead to more efficient care."

ACCC: Reimbursement Will Hurt Hospitals

The Association of Community Cancer Centers said the rule "will have significant consequences for Medicare patients and the hospitals that treat them.

"Hospitals are often the providers of last resort for patients who need advanced cancer care or other essential treatments, and inadequate reimbursement will have serious consequences for patient care," the association said.

"Inadequate Medicare payment rates for drugs and related handling and administration services may make it difficult for many hospitals to continue to offer critical cancer therapies. Should hospitals decide to close their infusion units entirely, the added strain on physician offices could be dire for patients."

ACCC comments are posted at http://www.accc-cancer.org/MEDIA/alerts/media_alerts_nov03_05_mcarehosp.htm.

A summary of the Competitive Acquisition Program is posted at http://www.cms.hhs.gov/media/press/release.asp?Counter=1713.

A summary of the hospital outpatient rates is posted at http://www.cms.hhs.gov/media/press/release.asp?Counter=1711.

A summary of the physician fee schedule is posted at http://www.cms.hhs.gov/media/press/release.asp?Counter=1709.

FDA News:

Von Eschenbach To FDA Staff: "While I Am Here, I Will Lead"

By Kirsten Boyd Goldberg

In a closed telecast accessible only to FDA employees, Acting Commissioner Andrew von Eschenbach said he would be a hands-on leader for the agency.

"I will make my time here count, even though I am fully aware that the final decision on my tenure at FDA rests with the President and with the Senate," von Eschenbach said. "But you should also know that I did not come here to be a figurehead, to merely warm the commissioner's seat, or to be a ceremonial leader. While I am here, I will lead. I will make decisions. I will serve you and I will be your commissioner."

Von Eschenbach said he plans to address three areas immediately: "the well-being of our staff," the development of a senior leadership team, and efforts to make progress in several "strategic objectives," including the Critical Path initiative.

Von Eschenbach, appointed by President Bush to lead the agency on Sept. 23, made the remarks in an Oct. 20 telecast recently posted on the FDA intranet. In the speech, von Eschenbach acknowledged the unusual events that led to his appointment.

"The circumstances that brought us together were abrupt, and as unexpected for me as they were for you," von Eschenbach said in the telecast. The resignation of Lester Crawford "was difficult for all of us." Crawford is "among my special friends, on both a personal and professional level," he said.

Von Eschenbach said he will turn attention to three areas:

—"First, will be the well-being of our staff.… My first area of focus will be on you, working to get the resources you need to get your work done, and trying to make certain you are rewarded and satisfied. I will be working with senior leadership to define priorities and resource allocations, along with strategies to leverage resources and procure additional ones. I intend to be your advocate and strong supporter, because you, the talented and dedicated people of FDA, are the most important reason for its success."

—"The second area that is related to the first is executive leadership," ensuring that top officials work together as a "more effective and integrated team." Von Eschenbach would form a "senior leadership team" that will "help organize and lead many of the cross-cutting activities that require close collaboration."

—"My third area of focus will be to accelerate progress in several strategic objectives: Critical Path, pandemic flu, communication, bioinformatics, and globalization. Each of these important areas have been a part of our strategic plan. Each of them provide enormous opportunities for us to focus and leverage our contributions to our health care agenda." Von Eschenbach said he has asked each of the deputy commissioners to "play a direct role in guiding and developing these initiatives."

Also, von Eschenbach said he would work to strengthen FDA's collaboration with other agencies, including NIH, CMS, CDC, and the Agency for Healthcare Research and Quality.

"As we begin our time together, I want you to know how honored and excited I am to be part of the FDA's future," von Eschenbach said.

Goals of NCI and FDA "Closely Aligned"

Von Eschenbach said he was aware that many FDA employees "perhaps wondered about my commitment" to the agency, "especially since I have retained my title as director of NCI," a post he has held for almost four years.

"I trust you'll understand, in the hours and days after the President asked me to become acting commissioner, my concerns were also for the National Cancer Institute," he said. "I care greatly for, and I treasure, the professionals who dedicate themselves to NCI…. Together, we have been pursuing an ambitious and bold goal. We challenged ourselves and this nation to eliminate the suffering and death due to cancer, and to bring that about by the year 2015. It is a challenge that has been made possible by the exponential growth in biomedical science. We dedicated ourselves to doing what was necessary in discovery, development, and delivery, to be able to use that progress to achieve our goal.

"As I considered the possibility of being your commissioner, I needed to be certain that the well-being of NCI and its staff would be assured," he said. "Fortunately, I've been privileged to have an NCI with superb leadership, and although I will retain the title of director, I have taken a leave of absence administratively…. enabling me to focus my full attention here at the FDA."

The "goals and purposes of NCI and FDA" are "closely aligned," von Eschenbach said. "Many of you here at FDA have stood alongside NCI and other agencies of NIH in your understanding that there is immense lifesaving potential in our capacity to preempt the disease process like cancer….

"By discovery of cancer's genetic and molecular mechanisms, we are developing interventions based on progress in molecular medicine," he said. "We now have within our grasp the real possibility of delivering interventions that will make cancer and many other diseases manageable conditions that no more will result in suffering and death. FDA's… role in the discovery, development, and delivery continuum has been an essential part of all of that excitement and all of that opportunity."

FDA is "America's gold standard of professionalism and protection," von Eschenbach said. "Millions of families can sleep each night, secure in the knowledge that the food they ate was safe, and the medicine they gave their children was effective. That must never change."

However, the new "molecular perspective" will require the agency to change, von Eschenbach said. "We need to imagine and create the role of the Food and Drug Administration around that new reality. In an era of molecular medicine, as we move from public health to a system of personal health and personalized medicine, the FDA, a strong, science-based regulatory agency, will be challenged to become a science-led regulatory agency…. The pace of discoveries and technologies will quite certainly demand an FDA that rapidly and efficiently enables the fruits of progress to be available to patients and the public."

Von Eschenbach the agency "must continuously earn" the trust of the public. "I will strive to set a tone for the kind of FDA we all wish to continue to build, an agency that cares about people," he said. "Together, we have the opportunity and the obligation to put the patient, the public, and the person at the center of all that we do…. We will not rest until we can assure that the fruits of discovery, development, and delivery are available to all Americans."

Two days prior to his speech to FDA employees, von Eschenbach told the Association of American Cancer Institutes that FDA and NCI had a common goal: to eliminate suffering and death due to cancer by the year 2015 and usher in the era of molecular medicine (The Cancer Letter, Oct. 21).

NCI Programs:

AIDS Malignancy Program Gets New Director, Authority

By Kirsten Boyd Goldberg

NCI has appointed a new director of the AIDS Malignancy Program and has enhanced the program's status by giving its head the authority to report to an institute deputy director, rather than a division director.

Kishor Bhatia was named director of the program, and will report to Mark Clanton, deputy director for Cancer Delivery Systems. Bhatia has been program director for the Cancer Diagnosis Program in the Division of Cancer Treatment and Diagnosis since 2004. He succeeds Jody Black, who left NCI.

The AMP supports about $115 million in extramural HIV and AIDS malignancy research funded by NCI, and coordinates all AIDS and AIDS oncology efforts across NCI. Existing projects managed by the AMP include the AIDS and Cancer Specimen Resource, the Women's Interagency HIV Study, the Multicenter AIDS cohort study, and the AIDS International Training and research Program. The AMP also works with the NIH Centers for AIDS Research.

The AMP was started in the early 1990s by Ellen Feigal, who was a senior investigator in DCTD and later became the division director.

"Elevating the program is a good idea," said Feigal, who left NCI in 2004 to become vice president of clinical sciences and deputy scientific director, Translational Genomics Research Institute. "It will facilitate more effective interaction between the institutes and give a central focus for NCI that spans the spectrum of disciplines. It makes sense from a scientific front and clinical front."

Bhatia said a significant emphasis for the program is the reduction of the burden of AIDS-related cancers in African-Americans and Hispanics. The program's goals for the next few years will be to "keep it aligned to strategic priorities of NCI," Bhatia said. "We also want to make some contributions to international cancer control arena, because the AIDS epidemic is international."

Bhatia was a senior staff fellow at the NCI Pediatric Branch from 1989-1997 and as a senior staff scientist from 1997-2000. From 1999 through 2004, he served as director of the Translational Program in the International Network for Cancer Treatment and Research at the Institute Louis Pasteur in Brussels. He served as director of the research center at the Children's Cancer Center at King Faisal Hospital in Riyadh, Saudi Arabia, from 2000 to 2004, while also teaching as an adjunct professor in the Department of Pathology at the University of Nebraska.

Bhatia received a B.S. in microbiology from Pune University in Pune, India. He later received a Ph.D. in biochemistry from the University of Bombay in Mumbai, India. He became a member of the British Royal College of Pathology in 2003. Bhatia participated in the development of the Middle Eastern Cancer Society in 1994, and serves as a member of the NIH Working Group on Capacity Building for International Research.

Funding Opportunities:

Program Announcements

PA-06-041: **NIH Support for Conferences and Scientific Meetings**

NIH offers support of scientific meetings contingent on fiscal and programmatic interests and priorities. A conference grant application is required to contain a letter from the appropriate NIH staff documenting advance permission. Investigators are urged to initiate contact well in advance of the application receipt date. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-06-041.html.

Inquiries: Linda Stecklein, NIH Conference Grant Coordinator, 301-402-7989, LS41G@nih.gov.

PA-06-010: Integration of Heterogeneous Data Sources. Application Receipt Dates: New, competing continuation, revised, supplemental applications: Dec. 1, 2005; Apr. 1, Aug. 1, and Dec. 1, 2006; Apr. 1, Aug. 1, and Dec. 1, 2007. AIDS and AIDS-Related Applications (New, competing continuation, revised, and supplemental): Jan. 2, May 1, and Sept. 1, 2006; Jan. 2, May 1, and Sept. 1, 2007.

The PA encourages small businesses to develop innovative software for integrating diverse cross-disciplinary data sources into coherent knowledge bases for biomedical research. The PA is available at http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3273.

Inquiries: Margaret Grabb, mgrabb@mail.nih.gov.

PA-06-011: Integration of Heterogeneous Data Sources. The PA is available at http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3274.

Inquiries: Jennifer Couch, couchj@mail.nih.gov .

PA-06-012: **Manufacturing Processes of Medical, Dental, and Biological Technologies**

Application Receipt Dates: New, competing continuation, revised, supplemental applications: Dec. 1, 2005; Apr. 1, Aug. 1, and Dec. 1, 2006; Apr. 1, Aug. 1, and Dec. 1, 2007; Apr. 1, and Aug. 1, 2008. AIDS and AIDS-Related Applications (New, competing continuation, revised,

and supplemental): Jan. 2, May 1, and Sept. 1, 2006; Jan. 2, May 1, and Sept. 1, 2007; Jan. 2, May 1, and Sept. 1, 2008.

NIH is encouraging U.S. small business concerns to submit STTR phase I, phase II, and Fast-Track grant applications to research the manufacture of biomedical products and the implementation of new technologies in medical care. The PA is available at http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3275.

Inquiries: Greg Downing, downing@mail.nih.gov.

NIH Loan Repayment Programs

NIH is accepting applications to its five Loan Repayment Programs. Deadline for applications is Dec. 1. NIH offers to repay up to $35,000 annually for careers in biomedical and behavioral research. Applications and qualification information is available at www.lrp.nih.gov.

In Brief:

ACS Appoints Board Members; ISB Awarded $13M In Grants

(Continued from page 1)

Consortium. She will report to **Kathy Giusti**, founder of the MMRF and MMRC, who will retain her role as chief executive officer. Sumberaz headed a consulting business, Point Pharma LLC, and was global oncology director and U.S. new business development director of Bayer Corp. She worked for 11 years at Eli Lilly and Co. **Scott Santarella**, executive director of the MMRF, took on the additional role of chief administrative officer. . . . **AMERICAN CANCER SOCIETY FOUNDATION** appointed officers to its volunteer Board of Trustees. **John Boler**, founder and chairman of Boler Co. and owner of Hendrickson International, was elected chairman for a one-year term. Boler has served on the board for more than 20 years, said **Rob Mitchell**, chief development officer of the society and president of the foundation. **Robert Brown**, founder and CEO of B&C Associates Inc., and **Thomas Moran,** chairman, president, and CEO of Mutual of America, will serve as vice chairmen. **Robert Garff**, chairman and CEO of Garff Enterprises Inc., was elected secretary. **John Baity**, senior partner in the law firm Milbank, Tweed, Hadley & McCloy, was named treasurer. **Robert Ingram**, vice chairman of pharmaceuticals at GlaxoSmithKline, is immediate past chairman. . . . **INSTITUTE FOR SYSTEMS BIOLOGY** received two grants worth $13 million from the Bill & Melinda Gates Foundation and Amgen. ISB was awarded a $10 million in a challenge grant and Amgen granted ISB $3 million for endowment and operations for systems biology research, said **Leroy Hood**, president and co-founder of the Institute for Systems Biology. . . . **BRUCE BROUSSARD** was named president for US Oncology Holdings and its operating company, US Oncology, Inc. Broussard has been chief financial officer since August 2000 and has been executive vice president of pharmaceutical services since 2003. He will continue to report to **R. Dale Ross**, chairman and CEO of US Oncology. . . . **H. KIM LYERLY**, director of the Duke Comprehensive Cancer Center, was elected chairman of the American Society of Clinical Oncology grant selection committee. Lyerly will begin his term in June 2006. . . . **ELLEN GRITZ**, professor and chairman of the Department of Behavioral Science at M.D. Anderson Cancer Center, was honored by the Texas Board of Regents with the Olla S. Stribling Distinguished Chair for Cancer Research, a seven-year appointment. Also, Gritz was elevated to vice chairman of the American Legacy Foundation from her position on the board of directors. . . . **PENN MEDICINE** of the University of Pennsylvania is breaking ground for the Center for Advanced Medicine. The $232-million center will house the Abramson Cancer Center, radiation oncology, cardiovascular medicine, and an out-patient surgical pavilion. The center is scheduled to open in 2008, said **Arthur Rubenstein**, executive vice president of the University of Pennsylvania for the Health System and dean of the School of Medicine. . . . **SCOT REMICK**, director of developmental therapeutics at the Ireland Cancer Center of University Hospitals of Cleveland and the Case Comprehensive Cancer Center, was named the first incumbent to the Dr. Lester E. Coleman Jr. Chair in Cancer Research and Therapeutics. The $1.5 million Coleman chair was established in 2003, said **Stanton Gerson**, center director. The gift supports the Coleman chair holder's salary and income from the endowment fund is allocated for research and clinical program support. . . . **BRIAN DRUKER,** co-director of the Center for Hematologic Malignancies at the Cancer Institute at Oregon Health & Science University in Portland, was awarded the Robert Koch Prize for 2005, worth 100,000 Euros, by the Robert Koch Foundation. He was singled out for his discoveries in chronic myelogenous leukemia. The foundation also has awarded the Robert Koch Gold Medal to **Emil Unanue** for scientific achievement. He is Mallinckrodt Professor and chairman of the Department of Pathology and Immunology, Washington University School of Medicine, St. Louis. Unanue is known for his work on cellular immunity to bacterial disease pathogens and protein antigens. The prizes were presented on Oct. 28 by **Klaus Schroder**, Secretary of State at the Federal Ministry for Health and Social Security, at Langenbeck-Virchow House in Berlin.

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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