THE CANCER LETTER

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House Committee Asks GAO To Investigate Klausner-Era NCI Contract With Harvard

By Paul Goldberg

Two years after initiating a probe of former NCI Director Richard Klausner, the House Committee on Energy and Commerce last month asked the Government Accountability Office to conduct an investigation of conflicts of interest in procurement at NIH.

The committee's 17-page letter to GAO draws on materials the committee collected over two years since launching the investigation of NCI's decision in March 2002 to award a $40 million contract to Harvard University for a "molecular target laboratory."

The five-year contract, which at the time was larger than all but one of the cancer center core grants, was designed and awarded at a time when Klausner was under consideration for employment at a Harvard University affiliate, and, subsequently, when he was applying for the Harvard presidency.

The committee's letter was marked "confidential" and not intended

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In Brief:

Niederhuber Joins NCI As Special Advisor; Freeman To Step Down As Disparities Chief

JOHN NIEDERHUBER resigned as chairman of the National Cancer Advisory Board and has joined NCI as a special advisor to the director for translational and clinical sciences. Niederhuber is a surgical oncologist and past director of the University of Wisconsin Comprehensive Cancer Center. NCAB member **Daniel Von Hoff**, director of the Translational Genomics Research Institute, will serve as interim NCAB chairman. Niederhuber would be replacing **Karen Antman**, who resigned as deputy director for translational and clinical sciences earlier this year. . . . **HAROLD FREEMAN**, director of the NCI Center to Reduce Cancer Health Disparities since 2001, will step down from that position to serve as a senior advisor to NCI Director Andrew von Eschenbach, the Institute said earlier this week. Freeman's role will be to develop "strategies to achieve the 2015 goal in minority and underserved communities," the Institute said. Freeman also will serve as an NCI liaison to the Centers for Disease Control and Prevention and the Health Resources and Services Administration, and will continue his work on developing patient navigation programs. **Sanya Springfield**, head of the NCI Comprehensive Minority Medical Branch, will serve as acting director of the center while a search for a new director is conducted. . . . **JERRY COLLINS** was named associate director of the NCI Division of Cancer Treatment and Diagnosis. He also will lead the division's Developmental Therapeutics Program.

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Committee Probes Klausner's Compliance With Recusal Regs

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for release. The document, dated Aug. 8, circulated on Capitol Hill, at NIH and other federal agencies, and was obtained by The Cancer Letter.

Citing emails, interviews, and records obtained from NIH, Harvard, researchers involved in the MTL, and a biotechnology company started by these researchers, the letter provides factual background for GAO. The committee's letter asks the Congressional agency to conduct an audit of NIH procedures that safeguard against conflicts of interest on the part of government employees, contractors, and outside experts serving on "independent technical evaluation groups" similar to one that selected Harvard to receive the five-year contract.

The probe is particularly ominous for NIH, because investigators appear to be using Klausner's actions to open discussion of conflicts of interest in procurement at a time when the institutes are grappling with the separate issue of conflicts on the part of intramural scientists who consult with the industry.

Observers said it is extremely unusual for a Congressional committee to classify its request as "confidential."

"I've never heard of Congress doing something like that," said Peter Stockton, an investigator at the Project on Government Oversight, and a former chief investigator with Energy & Commerce.

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For reasons that seem unclear, the committee's letter didn't include any names, instead referring to individuals by their titles.

Klausner didn't return calls and an email from The Cancer Letter, but two years ago, when the investigation began, he denied impropriety. "This was a very standard, competitive, open contract review around which I had zero interaction at any point during the review and decision process," Klausner said (The Cancer Letter, Nov. 14, 2003). "To this day, I have no idea who was on the committee."

The congressional committee was casting "strange innuendos," said Klausner, who left NCI in September 2001, and is currently the executive director of the Global Health Program at the Bill and Melinda Gates Foundation. "This is not gray," he said at the time. "This is a black-and-white situation."

Materials cited in the committee's letter appear to contradict these statements. Congressional investigators allege that Klausner personally recruited three of the 10 members of the review group, played a role in designing and implementing the proposal, and, according to emails obtained by the investigators, communicated informally with Harvard researchers at a time when he was technically recused from the project.

Also, the committee's letter alleges that confidentiality of the review process was violated when the director of the review group—Arnold Levine, then president of Rockefeller University—apparently told Harvard researchers that their proposal had received the highest score.

Levine and Klausner subsequently ended up serving on the board of directors and the scientific advisory board of Infinity Pharmaceuticals Inc., a Cambridge, Mass., company that was formed by several of the founders of the Harvard laboratory.

Two years ago, Klausner said there was no link between MTL and Infinity. "Infinity is a company I joined," he said. "I was bombarded with requests to join many companies. I joined it after I left NCI. I had no interaction with Infinity before. In all my time at Infinity, MTL has never even come up."

The committee letter cites documents provided by Infinity, but doesn't ask GAO to review the relationship between the Harvard lab and the company.

The questions the committee posed to GAO deal exclusively with conflict of interest rules. However, it appears that the policy questions posed to the agency cannot be answered without also addressing questions of compliance with these laws in the case of the Harvard contract. Though the congressional watchdog agency

doesn't investigate criminal cases, it does have an office of "special investigations," which focuses on such issues. Also, GAO routinely refers cases to other federal agencies, sources said.

The text of the committee's letter is posted at http://www.cancerletter.com/archives/post.html?http://www.newslettersonline.com/user/user.fas/s=292/fp=3/tp=18?T=open_article,899439&P=article.

An earlier letter on the Harvard investigation is posted at http://energycommerce.house.gov/108/letters/11102003_1127.htm.

The committee initially focused on Klausner's acceptance of lectureship awards from institutions funded by NCI, his recusals from matters that involved those institutions, and the travel arrangements he made to deliver the lectures. The committee's letter on these awards is posted at http://energycommerce.house.gov/108/Letters/06262003_991.htm.

Klausner said in the past that his acceptance of awards was proper and approved by NIH (The Cancer Letter, July 4, 2003; May 21, 2004).

The Meaning of "Cooling Off"

The scientific research in question was funded through the NCI intramural program, as a subcontract to Science Applications International Corp., a firm that has a $1 billion contract for supporting cancer and AIDS research at the NCI facilities in Frederick, Md.

According to the Congressional letter, Klausner developed the idea of funding a program for finding markers for biochemical pathways.

Klausner recused himself twice from matters that involve Harvard, the document states. His first memorandum of recusal was dated June 9, 1999, and according to the committee's letter, he was "removed from consideration" for a job with a Harvard affiliate in late November 1999.

The NIH forms require officials to agree to a "cooling down" period that lasts a full year following the end of negotiations. That would have meant that Klausner would have been barred from dealing with Harvard through November 2000, which essentially would have excluded him from participation in much of the MTL project.

Klausner's second memo of recusal was dated December 2000, when he applied for the Harvard presidency. According to the letter, he was "removed from consideration" for that job sometime in February 2001, and he left NCI that September.

The legal meaning of the one-year "cooling off" period, and the consequences of ignoring it are unclear. Though the provision is mentioned in the NIH forms, it doesn't appear in Federal law or in NIH policies, the committee's letter states.

"Under NIH's current system, if an NIH employee did not comply with the 'one year cooling-off period' of his or her recusal memorandum, would that memorandum serve as a basis on which to take any administrative or disciplinary action?" the letter asks GAO.

Letter Alleges Klausner's Participation

According to the letter, during the time of Klausner's first recusal, "documents and witness statements provide reasonable grounds to believe that [Klausner] participated personally and substantially as a government employee in matters affecting Harvard."

For example, in an internal email the committee obtained from Harvard, Stuart Schreiber, principal investigator on the project that was ultimately funded by NCI, described a phone call from Klausner. In the email dated July 3, 1999, Schreiber said Klausner had called him from home on a Saturday afternoon to reiterate "how enthusiastic he is about [ChemBank], saying 'we will bankroll this…' "

Schreiber is a founder of the Institute of Chemistry and Cell Biology at Harvard Medical School, which specializes in research in "chemical genetics."

The website of Schreiber's lab describes ChemBank as "a collection of data about small molecules" that is being developed "to assist biologists who wish to identify small molecules that can be used to perturb a particular biological system and chemists designing novel compounds or libraries, and serve as a source of data for cheminformatic analyses."

According to the committee's letter, on Oct. 1, 1999, Klausner attended a meeting at Schreiber's lab.

"The meeting was held to learn about the research being performed under the NCI grant," the letter states. "The Harvard principal investigator was seeking supplemental funding from NCI for the grant. At the meeting, the Harvard principal investigator and his associate described their research vision and provided a tour of the laboratory. According to a witness, the NCI director was an active participant in the meeting."

The letter states that ChemBank was among projects discussed at the meeting.

The committee said there is no evidence that Klausner received a written authorization to participate in matters involving Harvard after conclusion of his employment negotiations.

During the "cooling off" period, "reasonable grounds exist to believe [that Klausner] personally and

substantively participated in the MTL program (that included ChemBank), because he conceived the MTL initiative, authorized the financial support for the MTL initiative from the NCI director's reserve funds, directed NCI management and SAIC during the launch of the MTL program, selected the NCI Source Selection Officer, helped to develop the evaluation factors and the scoring weight according to the evaluation factors, helped to develop the timetable, and decided on the inclusion of a Determination of Exceptional Circumstances in the subcontract," the letter states.

According to the letter, Klausner also served as the "source selection officer" for the Frederick contract, which was modified to include the MTL program.

"Moreover, there is evidence reflecting that [Klausner] personally interacted with Harvard during the launch phase of the MTL program," the letter states.

For example, in an April 20, 2000, email to the Harvard Dean of the Faculty of Arts and Sciences, Schreiber wrote: "[The] molecular target laboratory (mtl) contract will provide considerable resources to support iccb-like research aimed at basic cancer biology (not cancer drug development). i estimate $8-10m/y1, 10-18m/y2, eventually reaching up to 50m/year in year 5. you may not be surprised that I have been working closely with [NCI director] on this project over the past three years; it was my major assignment as a member of the nci's board of scientific advisors. I have met with [NCI director] probably 10 times in Washington during this period, and have had regular phone discussions while it evolved. A turning point was a meeting with [NCI director] in Bethesda with [Harvard scientist] and me where we discussed the concept of 'CHEMBANK,' an analog of GENBANK that we proposed to be the public database of phenotypic assays and small molecules, among others."

Previous NIH Investigation Described as Flawed

The question of Klausner's compliance with the recusal "raises the issue of accurate monitoring and recordkeeping by NCI," the letter states.

According to the letter, this flawed recordkeeping apparently misled an earlier internal investigation by NIH. "[Klausner] signed an NCI Ethics Office Annual Reconciliation for CY 1999 Disqualification Update… that included a handwritten notation that stated June 19, 1999, as the date of cancellation for the disqualification from matters involving Harvard," the letter states.

After the committee initiated the investigation of Klausner in 2003, NIH assigned its Office of Management Assessment to review the former NCI Director's compliance with the ethics regulations in his dealings with Harvard.

"The signed disqualification update misled internal NIH investigators into concluding that the NCI Director was no longer discussing job opportunities with Harvard after June 19, 1999, and that, therefore, there was no potential criminal conflict of interest," the letter states.

According to the committee, Klausner's negotiations with Harvard lasted until around Nov. 30, 1999. With the "cooling off" period included, he would have been recused through Dec. 1, 2000.

In December 2000, Klausner submitted a second letter of recusal from matters involving Harvard, apparently because he was applying for the job as president of the university. He was removed from consideration sometime in February 2001, the letter states.

During the one-year "cooling off" period pledged in his first recusal memorandum, Klausner made decisions concerning the timing of the meetings of a panel of outside scientists who reviewed the competing applications for the MTL contract, the letter states.

The contract proposals were evaluated by an Independent Technical Evaluation Group of scientists, who were convened by SAIC. However, Klausner "claimed in an email that he personally recruited three of the 10 members of the panel, according to records and interviews," the letter states.

"Moreover, there is evidence showing the NCI Director was involved in the decision not to increase the available funding for the MTL program on Feb. 12, 2001."

At that time, Harvard was one of six competitors for the contract.

"If in fact the NCI Director did not know he had been removed from consideration for the Harvard presidency on Feb. 12, 2001, while personally and substantially participating in a funding decision on the MTL when Harvard was a member of a discrete class of six MTL competitors, then he would not have been in compliance with his recusal for an actual conflict of interest," the letter states.

Conflicts and Disclosures

According to the letter, SAIC officials told the committee that they were unaware of Klausner's recusal from matters that involved Harvard.

"They first became aware of the recusals in connection with this committee's investigation," an SAIC lawyer wrote to the committee.

Also, the ITEG included two members affiliated with Harvard. One was employed by a Harvard cancer center, and another was in the midst of negotiating employment with the university. These scientists apparently were not given waivers of conflict of interest, the letter said. Though they didn't review Harvard's proposal, they scored the other five.

Conflict of interest rules that apply to scientists who serve on ITEGs are unclear, the letter said.

Levine, the ITEG chairman, too, had a connection to Schreiber. The Harvard scientist served on the Rockefeller board of trustees.

"The ITEG chairman told the committee staff that the Harvard principal investigator in his role as trustee did not have control over the ITEG chairman's hiring or salary, but served as a scientific and faculty evaluator," the letter states. "As a result of this disclosure to the NCI, the ITEG chairman stated that he did not participate as a primary or secondary reviewer of any of the proposals, but did preside over the meeting and scored the proposals based on the discussions at the meeting.

"The committee staff found no documentation for the NCI's or SAIC's handling of the ITEG chairman's issue."

Members of the review panel had to sign confidentiality agreements that prohibited disclosure of information related to the review. Yet, according to the letter, Levine apparently revealed the final scores to one of the top scientists involved in the Harvard lab.

On July 1, 2001, this scientist noted in an email that he had spoken with Levine earlier that day. "He mentioned (indiscretely) [sic] that [Schreiber's proposal] got the top score. Good news! Now we need to get them as neighbors!"

In an interview with the committee investigators, Levine said he had no specific recollection of making the disclosure, but said it would have been "inadvertent," and expressed regret to the committee staff, the letter states.

"Offer Standard 100,000-Share Package"

At the time Levine's group was evaluating the MTL proposals, top scientists involved in the Harvard lab were forming Infinity.

From the start of the investigation, the committee focused on potential links between the lab and the company. Since the government-funded lab didn't claim ownership of intellectual property, its findings could be available for commercialization by private entities.

On July 6, 2001, five days after Levine apparently revealed the scores, Steven Holtzman, president and CEO of Infinity, sent an email to the scientists involved in the company.

"[Levine]: go for him/get him on board; offer standard 100,000 share package," the email read.

A day later, Holtzman sent an email to formally invite Levine to join the company, and Schreiber, in a separate email, added: "It would be really terrific working with you… I think you will find it stimulating and fulfilling. Please come work your magic with us!" Levine accepted the invitation, the letter states.

"Because of previous personal and business relationships, these individuals may have been interacting separately from what occurred with the MTL project," the letter states. "Indeed, [Levine] told the committee staff that these interactions were separate.

"However, the timing of events outlined raises questions of whether the board invitation was at all intended in part to be a possible reward for sharing sensitive information," the letter states.

"Furthermore, even if the board invitation was not related at all to the disclosure of confidential information, the nature of the relationship of the ITEG chairman and the Harvard principal investigator was such that it could risk an inadvertent disclosure of confidential information in an otherwise innocent contact and put the contact into a questionable light.

"This example is illustrative of the need for a strong ethics program to avoid the appearance of conflict of interest. In addition, because the ITEG chairman was not an NIH employee, an SAIC employee, or a special government employee, the question is raised whether NIH and/or SAIC lack the ability to enforce the confidentiality agreement on ITEG members who are not NIH employees or NIH contractor employees."

The letter doesn't pose questions about Klausner joining the Infinity board of directors and scientific advisory board after he left NCI.

Infinity's Holtzman said the company is not under investigation. "Basically, everything was above board in terms of Infinity's relationships with Klausner and with Levine, and they had nothing to do with any of their government services," he said to The Cancer Letter. "To my knowledge, the investigation was thoroughly undertaken, and there were no conflicts found. There was nothing inappropriate or illegal done. There may have been some appearances because of coincidences, but that's about it, as far as I know."

The company's relationship with the Harvard scientists is entirely appropriate, Holtzman said.

The government encourages technology transfer

from the public sector to the industry, he said, adding that Infinity hasn't commercialized any government-funded research.

"If you look at Infinity's pipeline of products, which you can by going out to our website, none of them have any relationship or anything to do with anything that came out of the academic labs," Holtzman said. "They were all homegrown and invented. So, the relationship with those individuals has been as individuals, not with respect to their work in their laboratories."

Holtzman said he has known Levine since 1987. "The reason he is on my board of directors is that he is a close friend and he is a world-class cancer scientist, as you know, Holtzman said. "I had no idea that he was on the ITEG, and he never put the two and two together, the relation of that with the company."

Levine, who is now a professor in the School of Natural Sciences at the Institute for Advanced Study, was traveling and could not be reached for comment.

NIH News:

NIH Consulting Ban Retained, Divesture Limited To Top Jobs

By Kirsten Boyd Goldberg

Final ethics rules released by NIH after six months of review continue the ban on agency scientists earning consulting fees from drug companies, but allow most employees to keep their industry stock holdings.

Senior NIH employees, of which there are about 200, and their spouses and minor children, are required to divest of holdings worth more than $15,000 in "substantially affected organizations," including pharmaceutical, biotechnology, or medical device manufacturing companies, health care providers or insurers, and supported research institutions.

The senior employees include the NIH director and deputy director; all direct reports to the NIH director; all Institute/Center directors, deputy directors, scientific directors, and clinical directors in each IC; extramural program officials who report directly to an IC director; and other employees designated as such because they possess equivalent levels of decision-making responsibility.

Other employees may be required to divest if, after review, a potential conflict resulting from their holdings would impede their ability to do their government job, the regulations said.

"We have a balanced set of conflict of interest rules that protect the integrity of NIH and its ability to provide the American public with an unbiased and trusted source of scientific and health information, while preserving our ability to recruit and retain world class scientists and staff," NIH Director Elias Zerhouni said in a prepared statement on Aug. 25.

The regulations also address awards and activities with professional organizations:

—Monetary awards will be contingent upon prior approval and limited to awards that have been determined to be bona fide. Senior employees will not be allowed to receive cash awards offered by donors who have matters pending under their official responsibility.

—Employees who file either a public or a confidential financial disclosure report, and those non-filers who serve as clinical investigators on an NIH clinical study, are required to report their interests in substantially affected organizations, as well as those of their spouse and minor children, and to indicate the amount held in such investments.

—With prior approval and review by ethics officials, employees may engage in outside activities with professional or scientific organizations, including service on data and safety monitoring boards, Grand Rounds lectures, and scientific grant review.

—NIH scientists are permitted, to the extent allowed under existing government-wide rules and with prior approval, to engage in compensated academic outside activities such as teaching courses at universities, writing general textbooks, performing scientific journal reviews or editing, and providing general lectures to physicians and scientists as part of a continuing professional education program. NIH scientists can also engage in the practice of medicine and other health professions with prior approval and in accordance with existing rules. Outside activities that involve hobbies, sports, civic organizations or interests unrelated to the NIH mission are permissible, generally without prior approval.

Assembly of Scientists "Happy"

The Assembly of Scientists, a group of NIH employees formed at the height of the controversy over the ethics rules NIH proposed earlier this year, has essentially endorsed the final regulations.

"In general, we are happy and think the final regulations are much more reasonable and address many, but not all, of our concerns," Ezekiel Emanuel, chairman of the Department of Clinical Bioethics at NIH and president of the executive committee of the Assembly of Scientists, said to The Cancer Letter. "I think what the conflict of interest rules show is that when you get a lot of smart people thinking together, you come up

with something that is a lot better than if you have only a few people looking at the situation.

"As for the absolute prohibition on consulting, we don't agree with the NIH decision," Emanuel said. "If the consulting is related to your research, then you shouldn't do it, but if it's not, we don't see a reason for prohibiting it."

AOS plans to hold a membership meeting Sept. 14 and is seeking nominations for its council. The group has a Web site at http://aos.fastflag.com.

"NIH is very decentralized, but the Assembly has provided a focus and an ability to articulate the concerns of the 4,000 to 4,500 scientists on campus," Emanuel said. "The scientists feel they have a better and more articulate voice. I hope the Assembly continues and improves the atmosphere at NIH."

The Assembly needs to work with the NIH director's office on a variety of issues affecting morale in the intramural program, including limitations on travel to international scientific meetings and the centralization of human resources, Emanuel said.

Help Offered For Displaced Patients, Cancer Caregivers

By Kirsten Boyd Goldberg

Oncology organizations and NCI are helping cancer patients and oncologists displaced by Hurricane Katrina.

The American Society of Clinical Oncology is helping to coordinate treatment services. The following resources can be found at www.asco.org/katrina:

—Hurricane Katrina Message Board, searchable by keyword, is a physician/patient locator and communications tool. Messages are welcome from dislocated patients or from health care providers treating hurricane victims who need to consult with those patients' cancer doctors.

—NCI assistance: Because many displaced patients do not have internet access, ASCO and NCI are collaborating to help connect patients with alternate cancer care providers, using NCI's toll-free operators who are aided by ASCO's online resources. Live assistance is available at 1-800-4CANCER.

—List of oncology practices accepting displaced patients: ASCO is maintaining a list of oncology practices in Louisiana, Mississippi, and Texas, as well as in several other states, that have indicated their ability to care for patients in need of urgent treatment during this time. Patients can call the listed doctors' offices or cancer centers to learn more about receiving treatment while they are unable to access their primary cancer care facilities.

The American Society for Therapeutic Radiology and Oncology has a list of radiation therapy facilities around the country willing to treat patients who have been evacuated from the area. That list is available at www.astro.org/katrina.htm.

Getting medical records for these patients will be a challenge, ASTRO officials said. A consortium of providers from the Gulf Coast region have established a call center through the Western Michigan Cancer Center in Kalamazoo, Mich., where displaced oncologists can register. This will allow the new radiation oncologist to talk to the original doctor to ensure that people with cancer continue to receive the proper treatments. That number, 1-800-636-3876.

For patients enrolled on NCI-sponsored clinical trials, and doctors who are asked to treat cancer patients who have been on an NCI-sponsored trial, NCI has established a phone number, 301-496-5725.

During the emergency, NCI will send cancer investigational drugs for displaced patients to sites that had not previously participated in trials, assist with sharing of cancer drug supplies, assist with regulatory issues, and provide protocols to physicians caring for cancer trial patients in emergency situations.

Mark Clanton, NCI deputy director for cancer care delivery systems, is coordinating the NCI efforts. "Our first and foremost concern is the safety and well-being of medical personnel and patients in the area," Clanton said in a prepared statement. "We are marshalling all available communication and information resources to accomplish this, and are also working to help NIH address the needs of displaced researchers and others."

An NCI Web page, http://www.cancer.gov/katrina, includes a clinical trials search form to help displaced cancer patients on clinical trials determine what specific trial they are participating in and to help them find an alternative site to continue their treatment vital information.

NCI assessing the number of displaced researchers and laboratories to help determine how their research can be resumed in a different location, the Institute said.

The American Cancer Society said it can provide patients and caregivers information on national and state-specific resources for food, shelter, transportation, and medical assistance, is available by calling 1-800-ACS-2345 or at www.cancer.org/katrina.

NIH has deployed a medical team to a field hospital in Meridian, Miss., and has offered 100 beds at the

NIH Clinical Center for patients who may need to be transferred to the NIH campus. Further information from HHS is available at http://www.hhs.gov/katrina/.

Funding Opportunities:

ACS RFA Available

Pathogenesis and Treatment of Lymphedema Secondary to the Management of Breast Cancer. Applications Due Oct. 15.

The American Cancer Society, supported by the Longaberger Co., announces this RFA to investigate the incidence, etiology, and new treatments for secondary lymphedema in human subjects. The purpose of this RFA is to stimulate research on the modification of morbidity from lymphedema secondary to treatment for breast cancer and to gain some understanding of the natural history and effective interventions aimed at minimizing that morbidity. Inquiries: See www.cancer.org (Index of Grants/Special Initiatives) or contact Ronit Elk: ronit.elk@cancer.org.

Program Announcements

PA-05-143: Mentored Patient-Oriented Research Career Development Award (K23). Objectives of this PA are to encourage research-oriented clinicians to develop independent research skills and gain experience in advanced methods and experimental approaches needed to become an independent investigator conducting patient-oriented research and increase the pool of clinical researchers who can conduct patient-oriented studies. The PA is available at http://grants1.nih.gov/grants/guide/pa-files/PA-05-143.html.

Inquiries: For NCI--Lester Gorelic; phone 301-496-1804; fax 301-402-6251; e-mail gorelicl@mail.nih.gov.

PA-05-142: Biobehavioral Methods to Improve Outcomes Research. NIH invites applications to promote biobehavioral research and development of research designs, methods of measurement, and data analysis techniques. NCI encourages methodological and technological innovation among biobehavioral studies that use cancer as the disease paradigm and seek to improve clinical outcome, e.g., quality of life, symptom management, disease progression. The PA is available at http://grants1.nih.gov/grants/guide/pa-files/PA-05-142.html.

Inquiries: For NCI--Paige McDonald, phone 301-435-5037; fax 301-435-7547; e-mail Mcdonalp@mail.nih.gov.

PA-05-141: Basic and Preclinical Research on Complementary and Alternative Medicine. NCI is interested in basic, mechanistic, and preclinical research as it relates to the prevention, diagnosis and treatment of cancer as well as management of cancer symptoms and side effects due to conventional cancer treatment. The PA is available at http://grants1.nih.gov/grants/guide/pa-files/PA-05-141.html.

Inquiries: Wendy Smith, phone 301-435-7980; fax 301-480-0075; e-mail smithwe@mail.nih.gov.

In Brief:

Jeffrey Strathern Named Deputy For CCR-Frederick

(Continued from page 1)

Collins, a pharmacologist, has been director of the FDA Laboratory of Clinical Pharmacology for the past 17 years. He was a senior investigator with NCI. . . . **JEFFREY STRATHERN** was named deputy director for the NCI Center for Cancer Research-Frederick, CCR Director **Robert Wiltrout** said. Strathern obtained his Ph.D. from the Molecular Biology Institute, University of Oregon in 1977. He became a member of the Yeast Genetics Laboratory at Cold Spring Harbor Laboratory. In 1984, he joined the ABL-Basic Research Program at NCI-Frederick. He moved to the NCI intramural program in 1999. . . . **STEVEN ROSENBERG**, chief of the NCI Surgery Branch, was selected by NCI Deputy Director **Alan Rabson** to receive the second Alan Rabson Award for NCI Intramural Cancer Research. The award will be presented at the NCI Intramural Scientific Retreat on Jan. 11.

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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