

NIH Review Finds 44 Scientists Violated Ethics Rules On Industry Consulting

By Kirsten Boyd Goldberg

Results from an internal NIH review found that “dozens” of government scientists have consulted for drug companies, indicating that ethical violations at the Institutes are greater than previously believed, a House committee chairman said July 13.

The review, conducted in response to a request by House Energy and Commerce Committee Chairman Joe Barton (R-Tex.) and ranking member John Dingell (D-Mich.), examined whether 81 scientists had worked for drug companies between 1999 and 2004 without NIH permission.

Of the 81 scientists, 37 were cleared of ethical violations and 44 were found to have violated one or more existing ethics rules, NIH Director Elias Zerhouni wrote in a July 8 letter to the committee. The violations included failure to report income on financial disclosure forms, failure to take personal leave to do private work, and failure to seek prior approval for the arrangements.

Eight of the scientists are no longer employed at NIH, and 36 have
(Continued to page 2)

Senate Labor-HHS Finds An Extra \$1 Billion For NIH; Appropriations Committee Approves

By Kirsten Boyd Goldberg

The Senate Appropriations Committee approved a bill providing NIH \$29.42 billion for fiscal 2006, an increase of \$1.05 billion, or 3.7 percent, over the fiscal 2005 funding level, and \$905 million more than the President’s request.

The bill, approved by the committee on a vote of 27-0 on July 14 and by the Labor-HHS Subcommittee on July 12, provides \$909 million more than the measure passed by the House on June 16.

NCI would receive \$4.96 billion under the Senate bill, \$119 million more than the House measure and \$135 million over the FY 2005 appropriation.

The subcommittee came up with additional money by delaying Supplemental Security Income payments due at the end of September 2006 until Oct. 1, 2006, moving them to the FY 2007 budget.

“We were extremely pleased and grateful to Subcommittee Chairman Arlen Specter (R-Penn.) for showing once again his support of the NIH,” said Jon Retzlaff, director of legislative relations for the Federation of American Societies for Experimental Biology. “He has been one of the strongest supporters NIH has ever had.”

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been referred for possible disciplinary action. Nine of those 36 also have been referred to the HHS Office of Inspector General for investigation of possible criminal violations. The scientists were not identified by name in the committee's statement.

NIH spokesman Don Ralbovsky said officials had no comment on the committee's statement.

Drug companies submitted information on moonlighting deals with scientists after the committee was unable to get this information from NIH in 2004. In one example that the committee cited in its statement earlier this week, Pfizer Inc. said its agreements with scientists provided from \$500 to \$517,000 over the five-year period.

Zerhouni announced new ethics rules on Feb. 1, but NIH has delayed implementing them, because scientists and others say the rules are too severe. Barton commended Zerhouni for his effort to adopt a more stringent ethics policy.

"The NIH is home to many of the best and brightest scientific minds the world has to offer," Barton said in the July 13 statement. "Congress has advanced their work to fight disease and save lives by doubling their budget in recent years. But, along with financial backing, the NIH must have the support of the American people.

"These findings indicate that the ethical problems

are more systemic and severe than previously known," Barton said. "They also demonstrate the need for NIH to issue the final ethics rule as soon as possible. I wholeheartedly support the work of Dr. Zerhouni to root out any conflicts of interest—real or apparent—while ensuring that scientists can collaborate with the private sector to advance public health. Dr. Zerhouni is to be commended for handling a difficult matter with great skill."

Dingell also praised Zerhouni. "Dr. Zerhouni has provided extraordinary leadership at the NIH during an ethical crisis that was not of his making," he said. "He analyzed the mounting evidence of misconduct among a minority of NIH employees, determined the systemic basis of the problem, moved carefully to identify those involved, and revised the rules to uphold proper ethical standards."

The committee's Oversight and Investigations Subcommittee held three hearings in May and June 2004 on NIH ethics.

NIH Reauthorization Hearing July 19

In the July 13 statement, Barton also urged Congress to reauthorize NIH this year. "The director should have the authority to direct and the flexibility to move dollars among institutes and centers to encourage promising research," he said. "We must recognize that expanding biomedical research in the 21st century requires the NIH to function efficiently."

The House Energy and Commerce/Health Subcommittee has scheduled a hearing for July 19 on legislation to reauthorize NIH. Biomedical research advocates said they haven't seen any bill language yet, but a draft version would be available for the hearing.

NIH is permanently authorized to receive funding from Congress, but the purpose of reauthorization would be to alter priorities or reorganize the Institutes. NIH was last reauthorized in 1993.

In a hearing last March, Barton said the committee had three priorities for NIH reauthorization: to expand the NIH director's authority to move funding between Institutes, improve budget efficiency in the allocation of funding that currently requires 26 line items, and create a more transparent reporting system to Congress to track research progress in broad scientific areas rather than specific diseases.

In a 2003 report, the Institute of Medicine concluded that Congress should enhance the NIH director's influence over the 27 institutes and centers through a larger budget for the director's office, funding for trans-NIH initiatives, and the authority to hire and



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

fire all institute directors (The Cancer Letter, Aug. 1, 2003, Vol. 29 No. 31).

The NCI director is appointed by the President, under the special authorities granted to the Institute through the National Cancer Act of 1971. Congress should “reassess” those special authorities, because they may result in an “unnecessary rift... between the goals, mission, and leadership of NIH and those of NCI,” The IOM report said.

The report, “Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges,” can be read at <http://search.nap.edu/books/0309089670/html/>.

Advisors to NCI have submitted letters to Barton urging the committee to preserve the Institute’s special authorities under any NIH reauthorization bill. The advisory groups maintained that these measures have allowed cancer research to expand and prosper in ways that otherwise wouldn’t have been possible.

The National Cancer Advisory Board sent the following letter to Barton on June 2. The letter was signed by NCAB Chairman John Niederhuber, professor of oncology and surgery, University of Wisconsin-Madison:

The National Cancer Advisory Board, whose members are appointed by the President of the United States, has noted the House Energy and Commerce Committee’s intent to draft legislation that would reauthorize the National Institutes of Health. The NIH is world renowned for its scientific accomplishments and its leadership in all areas of biomedical research and disease intervention. The NCAB believes strongly that these outstanding accomplishments and the NIH’s envied international position of scientific leadership have evolved from its structure as a confederation of truly outstanding specialized Institutes. The significant degree of Institute autonomy has historically insured a focused scientific mission for each Institute and even more importantly been a major factor in the NIH’s ability to attract outstanding scientists for Institute leadership. The NCAB firmly believes this confederated model has been singularly responsible for the scientific accomplishments of the NIH, has been the underpinning for significant inter-institute collaboration in discovery and as a result has generated a sum of accomplishment far greater than would have occurred in a single NIH Institute model.

It is certainly appropriate that the House Committee on Energy and Commerce carefully assess and consider all opportunities to further enhance and strengthen the

position of the NIH as the world leader in biomedical research. The NCAB, however, urges you to use your position as Chair to strongly oppose any changes in a reauthorization bill that would compromise the special authorities granted to the National Cancer Institute. Further more, we strongly encourage you to consider opportunities to strengthen these authorities at this extremely critical time in our fight to conquer this disease. The special authorities granted through the National Cancer Act of 1971 are largely responsible for the tremendous recent advances in genomics and proteomics that have placed our scientists on the verge of achieving the NCI’s “2015 Goals” of eliminating the suffering and death due to cancer.

The National Cancer Act of 1971 also established for the first time a much needed National Cancer Program. The authorities granted to the NCI elevated the position of NCI Institute Director to that of a Presidential appointment. The Act established the President’s Cancer Panel as a method of keeping the President and the NCI Director apprised of public concerns and the needs of the scientific community; put in place an advisory board, the NCAB, also appointed by the President. Elevating the Director position to be a Presidential appointment in 1971 was viewed by Congress and the public as a way to provide strong leadership, not only within the Institute, but across a diverse group of government, public and private organizations struggling to work effectively to make more rapid progress against cancer.

Such a strong position of national leadership for the cancer community in this country has never been more important than it is in 2005. Today we are entering a new era of discovery in biomedical research and in cancer medicine. As indicated above, much of this tremendous opportunity is the direct result of scientific accomplishment within the NCI and through its extramurally funded research programs. Within the next decade we will truly revolutionize our approach to the detection and characterization of cancer. In this new era each patient’s tumor will be characterized on the basis of the genetic alterations present within the tumor’s cancerous cells as well as the specialized tissue cells supporting its growth. The patient’s cancer will be defined as to the resultant changes in cellular signaling pathways that cause these cells to grow abnormally so as to become lethal to the patient.

As a result, we will be able to prescribe a “therapy” unique for each patient’s tumor. We will have new technologies that will allow us to monitor this treatment in ways never before imagined. These advances will not only provide new technologies for

monitoring treatment but also methods for screening and early detection. Prevention of cancer will become more realistic and an integral part of everyday medicine. These tremendous advances will dramatically impact our national health care system. They will also present significant challenges to the FDA in terms of evaluation and approval processes for multidrug therapy regimens and to our health care system in terms of managing costs as well as the ethical issue surrounding the management of such knowledge.

With this new era of personalized cancer “therapy,” comes new and unique responsibilities for the NCI Director. The NCI Director must have the national stature to be able to work effectively and collaboratively with the leaders of the FDA and CMS, as well as with the heads of other key federal agencies. The Director must be a force within the private as well as the public sectors. The Director must be seen as the broker of the National Cancer agenda by those in the private sector involved in the development of new drugs and new devices and by the academic community where much of very basic discovery occurs.

The NCAB is citing these examples of the NCI Director’s increasing responsibilities to emphasize the importance of this single position as a leader in the shaping of the country’s future health care agenda. The NCAB believes the discoveries and changes in health care that occur related to cancer will be the model for management of other chronic diseases in this new era of genomic and proteomics derived medicine.

When the public in 1971 lobbied Congress aggressively for the creation of the National Cancer Program, it did so knowing the tremendous burden this disease placed on the people of our country. To meet this challenge Congress provided important special authorities to the NCI. One of these, known as the “NCI bypass budget,” required the NCI to perform a yearly assessment of progress and of scientific opportunity and to use that assessment to develop a professional judgment plan and budget for the upcoming fiscal year. This annual exercise provides the President, Congress and the public with a carefully vetted action plan and an estimate of cost for implementing important high priority research opportunities that would provide meaningful progress against cancer. The NCAB believes this annual process of strategic planning has been a significant factor in accelerating progress in research and is a major reason we are in fact entering this new era of genetic based discovery.

The National Cancer Act of 1971 provided another important authority for the NCI, perhaps the most

important in terms of national impact at the level of the patient and their loved ones. This authority provided for the novel creation of a National Cancer Centers Program. Over the ensuing years this program has grown to include 60 NCI supported cancer centers spread across the United States. The program has been so successful that another 20 or so centers have been developed at other academic medical centers. Although unfunded by the NCI, these 20 cancer centers have believed this NCI program so important to improving their research in cancer and their ability to deliver outstanding cancer care that they have invested their own institutional resources to have a major cancer center. The NCI designated cancer centers have become the focus for multidisciplinary cancer research, are the base of support for our country’s clinical trials research, and continue to foster excellence in patient care.

The high standards established for successful competition to achieve designation as an NCI supported cancer center has leveraged significant University resources in terms of dollars and space, and greatly enabled philanthropic support to achieve an average four fold multiplier of the federal investment in each center. The Cancer Centers program has been unbelievably successful and new centers under development at several universities are being considered for funding by the NCI in areas of the country currently underserved by this program.

Critical to the ability of the NCI to achieve its 2015 goals of eliminating the suffering and death due to cancer, and for the NCI to continue to provide broad leadership for the national cancer agenda, is the special authority to maintain the flexibility of a portion of the NCI budget. Because the NCI is responsible for providing multi-year grant awards (3-5 years) to external scientists, only a small portion (approximately 5%) of the NCI’s annual budget can be considered flexible and available to the Director to support novel areas of high priority science. If the House Committee on Energy and Commerce were to propose in the reauthorization of NIH a shift of even 1% of the current NCI budget to the NIH, the impact on funding of research programs both intramural and extramural would be devastating. In fact, the existing set asides already in place for the NCI budget severely impact the scientific agenda of the NCI. Additional redistribution of resources would require the NCI to severely cut existing programs and would eliminate any opportunities for timely response to exciting new scientific opportunities in nanotechnology, proteomics and genomics.

The special authorities provided to the NCI by the

1971 National Cancer Act have proven highly effective. The vision and strong leadership of those individuals who crafted the authorities deserves tremendous credit. The accomplishments of the NCI have had a direct impact on many other diseases and many of the authorities have been adopted by other Institutes of the NIH including the very successful cancer centers model. Special authorities for education and training in cancer and the International authority have also been adopted by other Institutes.

In summary, the special authorities provided to the NCI by Congress have proved immensely successful in the efforts of this country to change the outcomes associated with this very complex disease we call cancer. The authorities have provided benefits to the NIH community at large in terms of AIDS research, collaborative inter-institute research programs and as a model for the development of extramural centers of excellence for other diseases and for prevention of disease. Abandoning these authorities would be extremely devastating to the mission and goals of the NCI. Consideration by your committee to strengthen these authorities especially in ways to facilitate more collaborative efforts between the NCI and the private sector would be extremely timely in moving the 2015 goals toward reality. The many who suffer from this disease and their families would be forever grateful to you and your colleagues.

Finally, the NCAB is extremely concerned that diverting resources from individual NIH institutes would do irreparable damage to these institutes in terms of scientific leadership and the ability of the institutes to achieve their respective scientific missions. It is precisely the presence of flexibility in Institute budgets and the responsibility for setting the scientific agenda that attracts our best scientists to Institute leadership positions. Without the creativity and diversity of such talented individuals the NIH itself will be seriously compromised.

The membership of the NCAB appreciates very much the excellent leadership you provide the House Committee on Energy and Commerce and your desire to insure a sound and even more successful future for the National Institutes of Health.

The NCI Board of Scientific Advisors sent the following letter to Barton on May 24. The letter was signed by BSA Chairman Robert Young, president of Fox Chase Cancer Center:

The Board of Scientific Advisors of the National Cancer Institute, a 33 member external advisory

committee comprised of national experts in all aspects of cancer research, has noted the House Energy and Commerce Committee's intent to draft legislation that would reauthorize NIH.

Careful consideration of strategies to increase the efficiency of the NIH is certainly appropriate. However, the NCI has long held certain authorities that have aided not only cancer research, but the entire spectrum of biomedical research conducted and supported by the NIH. We strongly urge you to preserve the NCI's special authorities that allow the Director to exercise creative and flexible approaches to the complex cancer problem. We fear that the loss of these special authorities of the NCI will dampen the creativity within the field and slow the progress being made at this particularly critical juncture.

The National Cancer Act of 1971 established the National Cancer Program, and provided essential authorities to NCI that strengthened its ability to lead the effort to conquer the disease that was taking a heavy toll on Americans. In doing so, cancer became recognized as a national priority. Those authorities are equally important in 2005 if the momentum of today's cancer research is to carry forward. The progress in cancer research has significant value to the American public, extending far beyond cancer. The lessons learned through cancer research have had far-reaching impact on diseases such as AIDS, heart disease, autoimmune disorders, and various degenerative diseases.

The special authorities of the National Cancer Institute has allowed the creation of a novel Cancer Centers Program with 60 centers across the country and others currently being considered for states and locales where such centers do not currently exist. The NCI designated Cancer Centers Program would not have been created without this special authority. Another special authority requires the yearly development of the professional judgment or bypass budget that provides the President, Congress and the cancer community with an action plan and a cost estimate for high priority opportunities for accelerating the pace of cancer research. Furthermore, the National Cancer Act also created the President's Cancer Panel whose role is to advise the President directly on the opportunities for progress.

These NCI authorities have allowed the Cancer Institute to be creative with its research dollars and to respond rapidly to unique opportunities. The dividends have been substantial. The age-adjusted mortality from cancer nationally began to decline in 1990 and this decline has continued incrementally every year for the

past fifteen. Death rates have declined from the four most common cancers—lung, breast, prostate and colorectal. Dramatic progress has also been made in addressing childhood cancer, and eight out of ten children diagnosed with cancer are now living into adulthood.

Research into the fundamental biology of cancer is just now yielding substantial dividends. We are entering the age of targeted drug therapy where treatments are more specific, less toxic and more effective. Physicians now use image-guided surgery and radiation therapy to improve outcomes while reducing morbidity and improving quality of life for cancer patients.

As our society ages, cancer threatens to be an even greater burden. Cancer disproportionately strikes older and minority populations—whose numbers will grow in the next 10-20 years. Close to 60% of all new cancers and 70% of deaths from cancer are in persons older than 65. African Americans and Alaskan Natives are minority populations that experience a higher incidence of colorectal and lung cancers than any other ethnic group. Older and minority Americans will need tailored prevention strategies and cancer interventions. Additionally, today's 9.8 million cancer survivors will require longer term, comprehensive approaches to meet their unique needs. All of these facts make clear why cancer continues to require significant national attention and resources. Advanced technologies such as nanotechnology, genomics, and proteomics are now being harnessed in the fight against cancer. Cancer researchers and engineers are teaming up to develop ways to intervene in the cancer process earlier to produce more successful outcomes. We are at a time of unprecedented opportunity, where basic scientific research is creating so many exciting opportunities for a meaningful and lasting impact on the care we can provide to patients. In order to expedite the development of these opportunities, NCI needs the ability to enter into flexible, dynamic collaborations that will promote the rapid development of preventive agents, diagnostic tools, and targeted therapies—precisely those flexibilities inherent in the NCI's special authority.

The authorities granted to NCI by the National Cancer Act of 1971 are still heavily relied upon to remove barriers to progress by forging partnerships, opening access to datasets and tissue resources, and more fully utilizing emerging technologies to apply them to efforts in genomics, proteomics, communications, and delivery of clinical and public health interventions. The ability of NCI to provide leadership, coordination, effective communication, and visionary strategies for the planning and budget of the National Cancer Program—

all made possible by authorities enacted in 1971—will be critical in the years ahead in providing care to the millions of people yet to be diagnosed with cancer along with the millions of new cancer survivors.

The utility of the NCI's authority also rests on the flexibility of a portion of the NCI budget. Because many aspects of critical cancer research require multi-year funding, only a small portion (approximately 5%) of the NCI's yearly budget is easily shifted to areas of high priority for new initiatives. The shift of substantial amounts of the NCI's vital flexible funds to the NIH would constrain the creativity of the cancer effort.

Finally, the special authorities provided the NCI have proved to be so useful that they have been subsequently utilized by other institutes. For example, the Cancer Centers model has been utilized by many other institutes including the National Heart Lung and Blood Institute, the National Institute of Allergy and Infectious Diseases as well as seven other institutes. Certain special authorities such as support for Education and Training Programs and the International authority have also been extensively used by others.

In summary, the special authorities provided the NCI by the Congress have been creative, productive and successful. They have allowed the National Cancer Institute to create novel mechanisms that have accelerated the pace of cancer research. There appears to be little evidence that abandoning these special authorities would be helpful to other areas of biomedical research and we would strongly urge that the special authorities provided the NCI by the National Cancer Act of 1971 be preserved.

NCI Programs: **BSA May Expand Reach Of "NCI Listens" Program**

By Kirsten Boyd Goldberg

NCI needs to reach out to scientists not involved directly in cancer research, such as imaging experts and pathologists, members of an Institute advisory group said.

The NCI Board of Scientific Advisors appointed a subcommittee at its June 27 meeting to develop a proposal for sending cancer representatives to meetings of professional societies in a variety of fields. The proposal would continue the board's 10-year-old "NCI Listens" program, in which BSA members and NCI staff hold information sessions at annual meetings of cancer professional societies.

The board began NCI Listens to help former

NCI Director Richard Klausner, a molecular biologist, communicate with cancer researchers, BSA Chairman Robert Young said. "Klausner was unknown in cancer and there was concern about where NCI was going," said Young, president of Fox Chase Cancer Center.

Attendance at these sessions has been dwindling in recent years.

At the annual meeting of the American Association for Cancer Research earlier this year in Anaheim, Calif., about 140 participants, out of an overall attendance of 15,000, showed up for the NCI Listens session, said board member William Hait, director of the Cancer Institute of New Jersey.

Board member Jane Weeks reported that about 40 people attended the NCI Listens session at the Society of Behavioral Medicine annual meeting. The discussion centered around "anxiety about funding for behavioral scientists," Weeks said.

In the past 10 years, NCI has increased efforts to bring society and advocacy representatives to the Institute for half-day or full-day meetings with the director and staff, Young said.

The American Society of Clinical Oncology discontinued the NCI Listens session at its annual meeting several years ago.

Despite the low turnouts, several board members spoke in favor of continuing the program.

"It's very good public relations for NCI," said board member Hedvig Hricak, chairman of the Department of Radiology at Memorial Sloan-Kettering Cancer Center. "I would reach out to other communities. ASCO is already involved in cancer." By attending meetings of imaging societies, NCI might find new investigators, she said.

Board member Richard Schilsky, associate dean for clinical research in the Biological Sciences Division, University of Chicago, suggested reaching out to pathologists for help with the issue of biospecimen collection.

Board member Hait said there could be negative publicity if NCI ended the program. "You can just imagine: 'The NCI Stops Listening,'" he said.

Shelton Earp, director of the UNC-Lineberger Comprehensive Cancer Center, said the information sessions may be particularly important for communicating with trainees.

Board member Mack Roach III, professor of radiation oncology, University of California, San Francisco, said politics necessitates increased communications among scientists. "As the budget gets tighter, we may need the support of the community," he

said. "We need a louder voice."

NCI Director Andrew von Eschenbach said the Institute is "looking comprehensively" at its communications, has formalized its conferences with professional and advocacy groups, a program led by NCI Deputy Director Alan Rabson, and has expanded its exhibit program.

Young appointed a subcommittee to develop a proposal for "NCI Listens II."

Philanthropy: **Brain Cancer Foundations Form Funders' Collaborative**

By Eric Lai

Eight organizations have formed a collaboration to promote new ways of conceptualizing translational research in brain cancers.

The American Brain Tumor Association, the Brain Tumour Foundation of Canada, the Brain Tumor Society, the Children's Brain Tumor Foundation, the Goldhirsh Foundation, the James S. McDonnell Foundation, the National Brain Tumor Foundation, and the Sontag Foundation said they will fund collaborative projects to develop effective brain cancer treatments.

The groups named the effort the Brain Tumor Funders' Collaborative.

The collaboration came about after a series of workshops the foundations held with researchers and clinicians. The groups concluded that the key component for bridging the translational gap is collaboration among investigators from various disciplines.

The BTFC will provide up to three \$2 million multi-year grants for brain tumor research teams, preferably comprised of researchers and clinicians from different institutions. Proposals will be accepted in early August, and the awards are to be announced in mid-January.

The BTFC is looking for teams to develop novel and innovative approaches for moving pre-clinical research into clinical applications for brain tumor patients.

"Only pre-proposals from new collaborative teams with the requisite skills needed for designing and testing new research systems will be seriously considered. Pre-proposals packaging old wine into new bottles will be rejected early in the review process," the BTFC proposal eligibility guidelines said.

Further information is available at: http://www.braintumorfunders.org/index.php?option=com_frontpage&Itemid=1.

In the States:

Texas Cancer Council Updates State Cancer Plan

By Eric Lai

The Texas Cancer Council, a state agency charged with promoting cancer awareness, recently finished the 2005 edition of the Texas Cancer Plan.

Last revised in 1998, the plan provides a blueprint for reducing the cancer burden in the state. Taking into account the health disparities among various populations throughout the state, the plan provides information on reducing the unequal burden of cancer in specific population groups and geographically defined groups.

“Thousands of Texans every day are in the battle for their lives because of cancer,” said Texas Cancer Council Chairman James Dannenbaum. “We have the potential to dramatically reduce cancer incidence and mortality rates throughout the state.”

For the first time, the plan addresses cancer survivorship issues such as the physical, psychosocial, spiritual, and economic problems that cancer survivors often face. Cancer is the second leading cause of death among Texans, all ages combined, and the leading cause of death among adults younger than 85 in the state.

“The fight against cancer is one of Texas’ top health concerns,” said Texas Governor Rick Perry. “The Texas Cancer Plan sets the foundation for a fight we can win.”

The plan is available at www.tcc.state.tx.us.

Funding Opportunities:

Training Grants Available

NOT-DK-05-015: NIDDK and NCI Career Development Program Urologic Surgeons

Division of Kidney, Urologic, and Hematologic Diseases of the National Institute of Diabetes and Digestive and Kidney Diseases and the Office of Centers, Training and Resources Cancer Training Branch of NCI invite urologic surgeons to apply for K08 grants, and the K23, with a less than 75 percent effort. This is part of a pilot program to address the concerns that urologic surgeons are unable to devote more than 50 percent of their time to research activities and still maintain their surgical skills. The notice is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-DK-05-015.html>.

Inquiries, for NCI: David Eckstein, (for K08), Cancer Training Branch, Office of Centers, Training and Resources, phone 301-496-8580; fax 301-496-4472; e-mail de47n@nih.gov. Lester Gorelic, (for K23), program director, Cancer Training Branch, phone 301) 496-8580; fax 301-402-4472; e-mail le2h@nih.gov.

In Brief:

Tomaszewski Named Deputy For NCI Treatment Division

JOSEPH TOMASZEWSKI has been named deputy director of the Division of Cancer Treatment and Diagnosis at NCI. Since May 2004, he has served as acting associate director of the DCTD Developmental Therapeutics Program while also overseeing the Toxicology and Pharmacology Branch, where he served as chief for the past 14 years. **James Doroshov** is the current director of the division. . . . **TRANSLATIONAL Genomics Research Institute** received a \$7.1 million grant from NIH to continue the Neuroscience Blueprint, a project researching the genetic causes of neurological and mental health disorders. The award is part of a \$25 million grant TGen will share with other NIH microarray centers supported by the Neuroscience Microarray Consortium, including Duke University and the University of California, Los Angeles. . . . **CHRISTINE CHUNG** received the Damon Runyon Cancer Research Foundation award for clinical investigation. She is assistant professor of medicine, Division of Hematology/Oncology, at Vanderbilt-Ingram Cancer Center. Her mentor is **David Carbone**, Ingram Professor of Cancer Research and investigator in the Vanderbilt SPORE Program of Research Excellence, for whom she is the second protégé to receive the Damon Runyon Research Foundation/Lilly Clinical Investigator Award. Her research interests are in head and neck cancers. The award provides \$750,000 over five years and also will retire up to \$100,000 in medical school debt. . . . **OFFICE OF RESEARCH on Women’s Health** named five experts to its Advisory Committee: **Luther Clark**, chief, Division of Cardiovascular Medicine, State University of New York Health Science Center; **Ponjola Coney**, senior vice president for health affairs and dean, School of Medicine, Meharry Medical College; **Andrea Dunaif**, chief, Division of Endocrinology, Metabolism, and Molecular Medicine, Northwestern University; **Linda Kaste**, associate professor and director of Predoctoral Dental Public Health, University of Illinois-Chicago College of Dentistry; and **Carmen Zorilla**, professor in obstetrics/gynecology, University of Puerto Rico. . . . **UNIVERSITY OF COLORADO** Cancer Center received \$1 million from the Avon Foundation Walk for Breast Cancer in Denver June 28. The funds will be used for indigent care and pilot research programs on the relationship between hormones and breast cancer metastasis. The foundation also awarded \$90,000 to Children’s Treehouse Foundation.

A Notch-Signaling Pathway Inhibitor in Patients with T-cell Acute Lymphoblastic Leukemia/Lymphoma (T-ALL)

An investigational study for children, adolescents and adults with relapsed and refractory T-cell acute lymphoblastic leukemia/lymphoma is now accruing patients at various centers around the country.

This study's goal is to evaluate the safety and tolerability of a Notch inhibitor as a rational molecular therapeutic target in T-ALL, potentially uncovering a novel treatment for these cancer patients.

Eligibility criteria and treatment schema for the study include:

Notch-Signaling Pathway Inhibitor in Patients with T-ALL	
Eligibility Criteria	<p>Patient must be \geq 12 months with a diagnosis of T-cell acute lymphoblastic leukemia/lymphoma AND must also have:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Relapsed T-ALL <input type="checkbox"/> T-ALL refractory to standard therapy <input type="checkbox"/> Not be a candidate for myelosuppressive chemotherapy due to age or comorbid disease <p>ECOG performance status \leq 2 for patients $>$16 years of age OR Lansky performance level $>$50 for patients 12 months to \leq16 years of age</p> <p>Fully recovered from any chemotherapy and $>$2 weeks from radiotherapy, immunotherapy, or systemic steroid therapy with the exception of hydroxyurea or intrathecal therapy</p> <p>Patient must be $>$2 months following bone marrow or peripheral blood stem cell transplantation</p> <p>No treatment with any investigational therapy during the preceding 30 days</p> <p>No active or uncontrolled infection</p>
Treatment Plan	<p>Open label and non-randomized, this study is conducted in two parts. Part I is an accelerated dose escalation to determine the maximum tolerated dose (MTD), and Part II is a cohort expansion at or below the MTD. MK-0752 will be administered orally. Plasma concentrations will be measured at defined time intervals.</p>

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

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