THE CANCER LETTER

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NCI, NHGRI Plan $100-Million, Three-Year Feasibility Test Of Cancer Genome Project

By Kirsten Boyd Goldberg

NCI and the National Human Genome Research Institute plan to move forward with a three-year, $100-million pilot study to test the feasibility of a Human Cancer Genome Project that would catalogue the genetic alterations in the most common cancers.

Each institute will provide $50 million for the pilot, which would select through peer review between one and three tumors for genomic analysis, said Anna Barker, NCI deputy director for advanced technologies and strategic partnerships.

The project would fund genome sequencing centers and genomic

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In Brief:

Ellen Gritz Is President-Elect Of SRNT; ASTRO To Honor Francis Mahoney Of NCI

ELLEN GRITZ, professor and chairman of the Department of Behavioral Science at M. D. Anderson, is president-elect of the Society for Research on Nicotine and Tobacco for the 2006-2007 term. Gritz was a contributing editor to the 2001 Report of the Surgeon General on Women and Smoking, served as author and editor of the Annual Report of the Surgeon General on Smoking and Health, and was a consultant to the Office on Smoking and Health from 1980-2001. She served from 1997-1999 on the National Cancer Policy Board of the Institute of Medicine, and has been a member of the IOM Board on Population Health and Public Health Practice since 1995. . . . **AMERICAN SOCIETY** for Therapeutic Radiology and Oncology will award honorary membership to **Francis Mahoney** at the society's annual meeting Oct. 16-20 in Denver. Since 1972, Mahoney has been program director for radiation and chief of the Radiotherapy Development Branch, Division of Cancer Treatment and Diagnosis at NCI. . . . **GEORGE CANELLOS**, senior physician at Dana-Farber Cancer Institute, the William Rosenberg Professor of Medicine at Harvard Medical School professor, and founding chief of medical oncology at Dana Farber, received the San Salvatore Foundation Award for lymphoma research at the 9th International Conference on Malignant Lymphoma in Lugano, Switzerland. He is only the second American to receive the award. . . . **HAN MYINT** was named director of the Blood and Marrow Transplant Program, and co-director of the Hematology Malignancies Program at the University of Colorado School of Medicine, and will co-direct the Hematology Malignancies Program. Myint was director of the Stem Cell Transplant Center and the Hematology

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NCI, NHGRI Chip In $50M Each For Cancer Genome Project

(Continued from page 1)

analysis centers, as well as a biospecimen resource, technology development grants, and a bioinformatics platform that would integrate with NCI's Cancer Bioinformatics Grid, Barker said to the National Cancer Advisory Board at its Sept. 20 meeting.

NCI would begin the project by issuing a Request for Information to seek nominations of biospecimen resources, Barker said. Requests for Applications and Requests for Proposals would be issued in the last quarter of 2005, following review by the Board of Scientific Advisors.

An NCAB working group proposed the HCGP and estimated that with current technologies and costs, it would take 10 years and $1.35 billion to identify the most frequently occurring genetic mutations in common cancers (The Cancer Letter, March 18). The working group said the cost could come down if the project is successful in stimulating the development of new technologies.

"What we put out there was a guesstimate," NCI Director Andrew von Eschenbach said to the NCAB. "We have no idea what the ultimate cost will be…. It's too far out there in the future. What we'd like to focus on is the pilot. It will set the stage. We think we can do this in three years…. This project will have enormous return on investment by defining what we don't know. It will open up more hypothesis-driven research opportunities."

NCAB member Jean deKernion, chairman of the Department of Urology and senior associate dean for clinical operations at the David Geffen School of Medicine at University of California, Los Angeles, said the project has been criticized for its cost. "That's the problem in the community, people have heard the '$1-point-x' billion," he said. "The concept you've given us today is a reasonable investment. We're not committing to a project that's going to cost $1 billion."

The pilot project would require "very, very direct consent" from patients for the use of biospecimens, because patients could be identified from the sequence data, Barker said. "This could lead to some policy issues," she said.

Re-consent for existing databases would be necessary, and the project would require an encrypted database, she said.

* * *

New Biospecimen Office: NCI plans to establish an Office of Biorepositories and Biospecimen Research to coordinate NCI-funded biorespositories and specimen banking research, Institute officials said.

NCI's internal Biospecimen Coordinating Committee, established earlier this year, will become a standing NCI committee. The Institute also plans to establish an external advisory committee for biospecimen research.

The BCC recommended that NCI take these actions following the outcome of two workshops held over the summer to derive some guidelines for best practices in biospecimen banking.

NCI has studied biospecimen banking since 2002, Barker said. In 2003, the Institute and the National Dialogue on Cancer, now known as C-Change, developed a "blueprint" for a National Biospecimen Network. In 2004, NCI collected information on all the biorepositories it funds and identified two main issues: the lack of common standard operating procedures or quality control methods employed across the biorepositories and the absence of a common database.

The BCC recommended that NCI-funded biorepositories adopt "first-generation" collection guidelines, on a voluntary basis. These would be developed over the next few weeks based on recommendations from the workshops, and would be available for public comment, said Julie Schneider of the Office of Technology and Industrial Relations.

Eventually, NCI would require that biorepositories adopt standard operating procedures and guidelines,

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Barker said.

Also, the BCC said, NCI should: implement a quality management system; build an informatics system that records and tracks each specimen; establish guidelines for categorizing biorepositories and then evaluate them; develop a standard informed consent document; establish patient privacy protection guidelines; develop a model Material Transfer Agreement to help institutions share specimens; and address a variety of other ethical, legal, and policy issues.

* * *

NCI Management Moves: At the NCAB meeting, von Eschenbach announced that **David Elizalde**, NCI deputy director for management, has moved to the office of the Surgeon General. **John Hartinger**, associate director for budget and financial management, will serve as acting deputy director for management during a search for a replacement.

Also within the Office of Management, **Jack Campbell**, NCI associate director for business operations and development for the past two years, retired July 1. He also was chief of the Research Contracts Branch and had worked for 34 years at NCI in procurement.

Todd Cole was appointed chief of the Research Contracts Branch. He was a section chief in the branch.

Leo Buscher Jr., chief of the Grants Administration Branch since 1971, will replace Campbell as acting associate director for business operations and development. He will continue to serve as the GAB chief.

Buscher is the author of NCI's popular paperback, "Everything You Wanted to Know About the NCI Grants Process But Were Afraid to Ask," first published in 1972. An updated version of the book is due out this fall, and is better than ever, with color charts, easier-to-read text, and a section on NCI history, Buscher said to The Cancer Letter. Heavy on explanation of the NIH grants process, the book could be useful to any NIH grantee, he said.

Copies made be requested from Buscher's office, at 301-496-7753, or email buscherl@gab.nci.nih.gov.

* * *

Translational Research Review: Two cancer researchers active in the American Association for Cancer Research were named co-chairman of the NCI Translational Research Working Group, appointed by von Eschenbach to review the Institute's translational research programs.

Lynn Matrisian, Ingram Distinguished Professor and chairman of cancer biology at Vanderbilt University, and **William Nelson V**, professor of oncology, urology, pharmacology, medicine, and pathology at Johns Hopkins University, will serve as co-chairmen of the panel, said **Ernest Hawk**, director of the Office of Centers, Training, and Resources, who is leading the review.

Matrisian served as AACR president last year and is chairman of the AACr Executive Committee. She also is a member of the NCI Board of Scientific Counselors.

Nelson is chairman of the AACR Science Policy and Legislative Affairs Committee. He also serves as AACR representative to the National Coalition for Cancer Research.

The TRWG will not attempt to define translational research, but will try to "define the scope of activity" funded by NCI and develop a plan for optimal translational research program, Hawk said.

Over the next year, NCI and the co-chairmen will develop the group's membership roster, begin an evaluation of the productivity of NCI programs, and plan two "roundtable meetings." The group's recommendations would be submitted to the NCAB.

* * *

More IPAs? NCI is exploring the possibility of bringing in more outside experts under interagency personnel agreements, von Eschenbach said. "This has been an important strategy on our part," he said. Experts would be hired for "time-limited" initiatives, he said.

* * *

Hurricane Katrina: NCI has identified about 7,500 cancer patients who were enrolled on NCI-supported clinical trials and were displaced by the hurricane that devastated the Gulf Coast three weeks ago, von Eschenbach said to the NCAB.

Staff from NCI's Cancer Centers Program, Cancer Therapy Evaluation Program, and Cancer Information Service, worked with cancer centers, the American Society of Clinical Oncology, and community oncologists to find patients and send them to Baton Rouge, San Antonio, Houston, Alabama, and Florida, where their treatments can continue, he said.

"It was, for me, an incredibly proud and gratifying moment to see NCI personnel respond as a team," von Eschenbach said.

* * *

Fiscal Year End: NCI is "on target" to fully allocate its $4.82 billion budget by the end of the fiscal year on Sept. 30, von Eschenbach said. Congress hasn't approved a budget for FY 2006, and NIH expects to be operating under a continuing resolution during the first part of the new fiscal year.

Capitol Hill:

House Panel Investigates Misuse Of NIH Grant Funds

By Paul Goldberg

The House Committee on Energy and Commerce has started yet another investigation of NIH, this time focusing on misuse of research grant money by university scientists and the apparently related issue of compensation of research assistants.

The latest probe was announced in two separate letters from the committee's Republican leadership to the HHS Office of the Inspector General. The two letters, dated Sept. 20, indicate that House investigators aren't running out of either interest or material in scrutinizing NIH, and that they are broadening the probe.

The House investigation of NIH initially focused on conflicts of interest on the part of intramural scientists and administrators, and last month it was expanded to include potential irregularities in contracting at NIH.

In one of the recent letters to OIG, Energy and Commerce Chairman Joe Barton (R-Tex.) and Oversight and Investigations Subcommittee Chairman Ed Whitfield (R-Ky.) called for an investigation of what may be the practice of institutions obtaining NIH research grants and diverting the funds to different research or other uses.

The letters are based on a whistleblower's suit against Cornell Weill Medical College. That action, which was joined by the Department of Justice, concluded as the institution reimbursed the government $4.4 million, but admitted no wrongdoing. "There were no issues about the quality or integrity of the research," the institution said in a statement acknowledging the settlement. "None of the researchers were the subject of individual sanctions or additional administrative actions."

The case and the settlement was reported by The Wall Street Journal Aug. 16.

In the second letter to OIG, Barton and Whitfield asked the office to investigate whether "federal taxpayer dollars have been used by state universities to compensate graduate research assistants for tuition remission rather than for their actual work on programs funded by the NIH."

The issues of misuse of grant funds and compensation of research assistants are related, Barton and Whitfield wrote to OIG.

"Some of the misconduct alleged in [the Cornell case] involved the billing of the NIH for salaries and expenses unrelated to the NIH grants," the letter said. "Prior to publication of the article, the Committee on Energy and Commerce separately received allegations involving a university misusing NIH grant money to unreasonably compensate graduate research assistants."

Last year, the committee requested documents on NCI's safeguards against overdrafts by a grantee institution (The Cancer Letter, Dec. 3, 2004). At that time, the committee focused on the Institute for Cancer Prevention, which overdrew its NCI grant accounts by $5.7 million before declaring bankruptcy (The Cancer Letter, Oct. 1, 2004).

The committee's investigation of contracting and conflicts of interest are at least in part focused on former NCI Director Richard Klausner, who last week stepped down from his job as director of the Global Health Program at the Bill and Melinda Gates Foundation. One aspect of the House probe is based on Klausner's alleged role in NCI's decision to award a $40 million contract to Harvard University at the time when he was applying for jobs with that institution (The Cancer Letter, Sept. 9, 16).

Committee Asks for Audit of Grantee Institutions

The letter on the Cornell case states:

"[In] a complaint-in-intervention filed June 15, 2005, the U.S. Attorney's Office for the Southern District of New York alleged that a university grantee failed to comply with NIH guidelines for clinical research programs and made false statements in applications to NIH for renewal of its General Clinical Research Center grant.

"In particular, the U.S. Attorney's office highlighted the disparities between the number of research activities projected by the grantee in its grant applications or grant continuation applications to NIH, and the actual number of research activities performed by the grantee after receiving the NIH grant money, as reflected in the grantee's internal data, and to some extent, the grantee's annual progress reports submitted to NIH.

"For example, one year the university grantee projected an increase in the number of in-patient days awarded under the grant based on four protocols pending that would require the availability of additional bed days. One of these protocols was never used. Another protocol never had any patient admissions under it.

"Another protocol never used any in-patient days in the next fiscal year and only one day was ever used under this protocol in the following fiscal year. The fourth protocol had no in-patient visits under the protocol 'ever' and according to the U.S. Attorney's

office, 'it is highly unlikely that any in-patient visits the [next fiscal year] were truly anticipated.'

"In light of concerns such as those alleged by the U.S. Attorney's office and your office's jurisdiction and past activity in this area, we request that the Office of Inspector General examine whether there are widespread disparities between the numbers of research activities grantees projected to obtain taxpayer funds from the NIH and the numbers of research activities actually performed with these funds.

"To that end, we further request that the OIG conduct an audit of some of the largest NIH clinical research center grants to review the number of research activities each respective institution projected to the NIH and what research activities these institutions actually performed.

"The OIG may also want to consider designing this audit to capture other kinds of discrepancies, such as false statements, improper accounting, improper charges to NIH grants, and even fraudulent double-billing of the Medicaid program for in-patient fees charges incurred in connection with protocols performed under these clinical research center grants."

Compensation of Graduate Students Questioned

The letter on compensation of graduate students states:

"Universities conduct a great deal of biomedical research funded by the NIH, and often employ graduate students to assist with the research. The Office of Management and Budget permits graduate student research assistants to be reimbursed 'reasonable compensation for work performed,' in the form of salaries and tuition remission under OMB Circular A-21. An Oct. 26, 1994, OIG report entitled, `Audit of Graduate Student Compensation at Selected Universities,' found that three particular universities charged more than $5.7 million in unreasonable compensation. The report further concluded that the OMB Circular provided 'inexact guidance and the selected universities used a liberal interpretation of reasonableness . . . [which] resulted in less than prudent actions.'

"As a result of this report, in 1996 the NIH published an explicit statement that it is unreasonable to charge more for a graduate student (salary plus tuition remission) than the equivalent compensation of a first-year postdoctoral scientist performing comparable work and effort at the same institution. In 1999, at the request of this committee, the Government Accountability Office examined compensation paid to graduate students at the University of California under Federal research grants. The GAO found that the university charged federally sponsored research $19.3 million for student compensation in excess of what it paid first-level postdoctoral researchers at a comparable level of work and effort. However, because of a pending lawsuit related to these issues, the GAO did not think it appropriate to reach a conclusion on whether these practices were inconsistent with the OMB Circular.

"The committee staff has recently learned that these compensation practices not only may have continued, but that the University has a salary scale in which it can bill the taxpayer for student compensation at rates approaching six times the salary of postdoctoral researchers. According to the salary scale information effective Oct. 1, 2002, posted on the University of California-Davis website, resident and non-resident graduate student researchers can receive salaries and tuition remissions equivalent to hourly rates of $75 to $89, which is roughly proportional to an annual salary range of $150,000 to $180,000.

"Nonresident students' compensation would be generally higher since they are charged much higher non-resident tuition rates and would receive full tuition remission from the university. By contrast, the starting salary for a post-doctoral scholar at the University is a little more than $31,000. Such a wide discrepancy between salary rates for current graduate students and those who have attained their doctorates raises questions of unreasonableness, particularly since both contribute similar amounts of work, time, and effort. Additionally, universities use tuition remission as a recruitment tool for foreign students, who may be tax exempt from such payments."

NCI-Sponsored Research:

Digital Vs. Film Mammograms: Study Finds No Difference

Preliminary results from an NCI-sponsored trial of digital vs. film mammography show no difference in detecting breast cancer for the general population of women in the trial.

However, those women with dense breasts, who are pre- or perimenopausal, or who are younger than age 50 may benefit from having a digital rather than a film mammogram, the study concluded.

In those women, the types of lesions that were found by digital mammography and not by film were invasive cancers without evidence of metastasis to axillary lymph nodes at the time of diagnosis and medium and high-grade *in situ* lesions (DCIS).

The results were released Sept. 16, by the New England Journal of Medicine and at a meeting of the American College of Radiology Imaging Network.

The trial was conducted by a network of researchers led by ACRIN.

"These results will give clinicians better guidance and greater choice in deciding which women would benefit most from various forms of mammography," said senior author, Etta Pisano, of the University of North Carolina at Chapel Hill.

Secondary goals measuring the relative cost-effectiveness of both digital and film technologies, and the effect on participant quality of life due to the expected reduction of false positives, are still being assessed and will be reported at a later date.

Starting in October 2001, the Digital Mammographic Imaging Screening Trial enrolled 49,528 U.S. and Canadian women who had no signs of breast cancer. Women in the trial were given both digital and film examinations. Examinations were interpreted independently by two different radiologists. Breast cancer status was determined through available breast biopsy information within 15 months of study entry or through follow-up mammography 10 months or later after study entry.

General Electric Medical Systems, Fuji Medical Systems, Fischer Imaging, and Hologic digital mammography systems were tested in the trial. Of these, all except for the Fuji system are FDA-approved.

NCI and other organizations didn't change their recommendations for mammograms based on the results of this study. NCI continues to recommend that:

—Women in their 40s should be screened every one to two years with mammography.

—Women aged 50 and older should be screened every one to two years.

—Women who are at higher than average risk of breast cancer should seek expert medical advice about whether they should begin screening before age 40 and the frequency of screening.

Cancer Training:

NCI, NSF Award Grants For Nanobiotechnology

NCI and the National Science Foundation awarded grants worth a total of $12.8 million over the next five years to four institutions to conduct interdisciplinary training in nanoscience and technology research with applications to cancer.

The awards, granted through the NSF Integrative Graduate Education and Research Traineeship Program, will support about 30 students at each institution.

The awardees are:

—Integrative Nanoscience and Microsystems, University of New Mexico, Albuquerque, principal investigator Diana Huffaker.

—NanoPharmaceutical Engineering and Science, Rutgers University, PI Fernando Muzzio.

—Nanomedical Science and Technology, Northeastern University, PI Srinivas Sridhar.

—Building Leadership for the Nanotechnology Workforce of Tomorrow, University of Washington, Seattle, PI Marjorie Olmstead.

The award program will be jointly overseen by NSF and by NCI through the NCI Alliance for Nanotechnology in Cancer, a $144.3-million, five-year initiative begun last September.

Hurricane Relief:

NIH Expands Phone Service For Medical Consultations

The National Institutes of Health expanded its telephone medical consultation service previously available to health care providers to all patients affected by Hurricane Katrina.

Medical experts at NIH, academic medical centers and medical professional societies are available 24 hours a day, 7 days a week, to provide medical consultations on a wide array of medical problems. The toll-free number is 1-866-887-2842.

"The medical needs of those in the Gulf Coast region are enormous and we mobilized immediately to offer this service for our colleagues providing care in often difficult situations," said NIH Director Elias Zerhouni. "Our goal is to match national experts with care providers dealing with difficult or complicated medical cases. We also want to help patients in the affected area who were on clinical trials and receiving treatment."

Consultations are available in environmental/toxic concerns, infectious diseases, tropical/geographical medicine, ophthalmology, oral medicine, psychiatry, cardiac/pulmonary diseases, genetic diseases, pediatric endocrinology, pediatric metabolism, obstetrics/gynecology, cancer and adult endocrinology.

Physicians caring for patients on NIH-sponsored clinical trials that have been interrupted because of the Katrina disaster-or clinical trial patients themselves-can call the consultation line for options on continuing therapy under a clinical trial.

Funding Opportunities:

RFA Available

RFA-HG-05-007: Completion of a Comprehensive Mouse Knockout Resource. Letters of Intent Receipt Date: Oct. 20. Application Receipt Date: Nov. 22.

NIH institutes and centers, including NCI, invite applications for trans-NIH program research projects for the production of a comprehensive resource of mouse mutants in which every gene in the mouse genome has been knocked out by a null mutation marked with a reporter system of high utility. The primary focus will be on construction of the mutations, and a secondary focus will be on the choice of mouse stain. Applications that propose approaches to the cost-efficient generation of the mutations directly in strain C57BL/6 will be given preference for funding. Awards will be made using the Cooperative Agreement U01 mechanism. The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-HG-05-007.html.

Inquiries: Jane Peterson or Mark Moore, National Institute of Human Genome Research, phone 301-496-7531; e-mail jane_petersoon@nih.gov; mmoore3@mail.nih.gov

Program Announcement

PAR-05-145: Established Investigator Award in Cancer Prevention & Control

The NCI Established Investigator Award in Cancer Prevention and Control would provide researchers in cancer prevention, control, behavioral, and/or population sciences with protected time for research and mentoring. The award provides partial salary support for up to 5 years and for up to 50 percent effort. It is renewable for one additional 5-year period. The PAR is available at http://grants1.nih.gov/grants/guide/pa-files/PAR-05-145.html.

Inquiries: Scientific/Research Contacts: Mary Blehar, Cancer Training Branch, phone 301-496-8580; e-mail mblehar@mail.nih.gov.

RFP Available

RFP: N02-CM-67000-28 Collection, Storage, Advertisement and Distribution of BRMs

NCI Biological Resources Branch is soliciting sources to provide high quality biological research reagents and biological standards to qualified investigators for preclinical and laboratory studies. The contractor would provide the facilities and personnel to operate a computerized inventory system and repository for the acquisition, receipt, storage and distribution of biological reagents and standards. Facilities must include sufficient, well-monitored and appropriately controlled space for -70 degree C, -20 degree C, 4 degree C, and liquid nitrogen storage. Aseptic facilities should also be available to sterilely aliquot and label new products.

The RFP is posted at http:/rcb.nci.nih.gov/.

Inquiries: Drake Russell, russeldr@mail.nih.gov or Carolyn Barker, cb123d@nih.gov; phone 301-496-8620.

Other Funding Notices

NIH Grantees Affected by Hurricane Katrina

NIH is participating in a number of activities to address the immediate medical needs of those affected and is committed to the support of our investigators, fellows and trainees. We have made contact with several senior officials of institutions affected by hurricane Katrina and have started to discuss with them their plans for assessment of the damage and recovery. We will be flexible in devising mechanisms for facilitating the continuity of investigators' research, and understand that research projects may be relocated temporarily to other locations as each organization rebuilds from the hurricane. Additional details about this issue will be provided directly to affected organizations, and answers to Frequently Asked Questions will be posted on the NIH website dedicated to post-Katrina information for investigators and grantees: http://grants.nih.gov/grants/katrina/index.htm.

Notice of Extension: PAR-04-096 Paul Calabresi Award for Clinical Oncology (K12) . NCI has extended the expiration date to June 2, 2006. Letters of intent should be received by May 2, 2006. Inquiries: Lester Gorelic, phone 301-496-8580; e-mail gorelicl@mail.nih.gov.

Notice of Extension: PAR-03-148 Cancer Education and Career Development Program. NCI has extended the expiration date to July 5, 2006. The application receipt dates for the extended period are the standard receipt dates. Inquiries: Mary Blehar, Cancer Training Branch, phone 301-496-8580; e-mail mblehar@mail.nih.gov.

Small Business Innovation Research Program Contract Solicitation. Proposal Receipt Date: Nov. 4.

The SBIR program provides support for biomedical and behavioral research and development of new or improved technologies and methodologies that could succeed as commercial products. In accord with the intent of the SBIR program to increase private sector commercialization of innovations derived from federal R&D, scientists at research institutions can play an important role in an SBIR project by serving as consultants and/or subcontractors to the small business concern. The notice is available at http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-060.html.

Inquiries: For NCI--Mary Landi-O'Leary, phone 301-435-3807; e-mail ml186r@nih.gov .

NIH $35,000 Annual Student Loan Repayment. Program Close Date: Dec. 1. NIH offers five Loan Repayment Programs, which include the Clinical Research LRP, Clinical Research LRP for Individuals from Disadvantaged Backgrounds, Contraception and Infertility Research LRP, Health Disparities LRP, and Pediatric Research LRP.

Through the programs, NIH would repay up to $35,000 annually of the qualified educational debt of health professionals in biomedical and behavioral research. The

programs also cover federal and state tax liabilities. To qualify, applicants must have a doctoral-level degree, devote 50 percent or more of their time (20 hours per week based upon a 40-hour work week) to research funded by a domestic non-profit organization or government entity (federal, state, or local), and have educational loan debt equal to or exceeding 20 percent of their institutional base salary. Applicants must also be U.S. citizens, permanent residents, or U.S. nationals to be eligible.

Application information: http://www.lrp.nih.gov.

In Brief:

Deborah Dunsire Named President, CEO, Of Millennium

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and Oncology Fellowship Program at Rush University Medical Center in Chicago. . . . **DEBORAH DUNSIRE,** head of the Novartis Pharmaceuticals Corp. North American Oncology Operations, was named president and CEO of Millennium Pharmaceuticals Inc. She succeeds **Mark Levin,** co-founder and CEO. . . . **JEFFREY HUMPHREY** was named vice president for U.S. Oncology Medical and Scientific Affairs at Bayer Pharmaceutical Corp. in West Haven, Conn. In his former job, Clinical Exploratory Head at Pfizer Inc., Humphrey directed phase I and phase II clinical development at that company's research site in New London, Conn. . . . **JAMES HOLLAND** received the gold medal of N.N. Blokhin Cancer Research Center of Moscow for his contributions to oncology. He is Distinguished Professor of Neoplastic Disease at Mount Sinai School of Medicine. . . . **LINDA TOLLEFSON** was appointed assistant commissioner for science at FDA. Tollefson was deputy director of the Center for Veterinary Medicine. In her new position, she will also serve as Coordinator for Commissioned Corps Affairs at FDA and direct the FDA Offices of Women's Health and Orphan Products Development. . . . **SUSAN WOOD,** assistant FDA commissioner for women's health, resigned on Aug. 31 in protest against the agency's decision to delay once again a ruling on expanded use of the Plan B contraceptive, by Barr Laboratories Inc. "I can no longer serve as staff when scientific and clinical evidence, fully evaluated and recommended for approval by the professional staff here, has been overruled," she wrote in an e-mail to FDA colleagues, according to The Washington Post. Wood joined FDA in 2000. She was director for policy and program development at the HHS Office on Women's Health. . . . **SYED KASHMIRI** of the Laboratory of Tumor Immunology and Biology in the NCI Center for Cancer Research, died on July 19 of cancer. Before coming to NCI in 1987, Kashmiri worked at Rockefeller University, Johns Hopkins University, and the University of Pennsylvania. He was known for his work in modifying immunoglobulin genes to render them more applicable and effective in targeting tumors. He was 68. . . . **UNIVERSITY OF NEVADA Medical Center** received a five-year, $9 million grant from NCI for lymphoma research using microarray technology. The technology uses a specialized Diagnostic Lymphdx Array chip to study cancerous genes. **Wing Chan**, professor of pathology and co-director of the Center for Lymphoma and Leukemia Research at UNMC is the principal investigator. Besides UNMC, the study is also being conducted at NCI and in New York, Arizona, Ohio, Canada, Spain, the U.K., Germany and Norway. The group was funded in 1999 for a $4.2 million grant to launch the project, said **Ken Cowan**, director of the UNMC Eppley Cancer Center. . . . **DENVER CLINIC For Extremities at Risk** is the new name for the Institute for Limb Preservation in Denver. The clinic, which is located within HealthONE-Presbyterian/St. Luke's Medical Center, is a multi-specialty group of orthopedic, micro-vascular and vascular surgeons, oncologists, pediatric specialists and other healthcare professionals who treat patients with extremities in jeopardy from trauma, cancer, infections, non-healing bones and dying joints, said **Ross Wilkins**, co-founder of the organization. The daily work of the clinic is more often dealing with bone and soft tissue tumors; infection and healing problems including osteomyelitis and non-union healing issues; and osteonecrosis, he said. . . . **TENNESSEE COMPREHENSIVE CANCER CONTROL PROGRAM** coalition has developed a cancer control plan for the state. "The prevalence of cancer in Tennessee is far too high and causes a tremendous burden to patients, families and our health care system," said **Debra Wujcik**, acting chairman of the coalition. "Our coalition was formed to coordinate various state and local health and policy organizations and the leading health care groups to develop a strategic plan to lower the rate of cancer in the future." During the first of the three-year implementation phase beginning in 2005-06, the coalition decided to focus initially on tobacco-related cancers, prostate cancer, colorectal cancer, and melanoma/skin cancers. The coalition was formed through collaboration among the Tennessee Department of Health, the American Cancer Society, the Centers for Disease Control and Prevention, the American College of Surgeons' Commission on Cancer, and NCI. The coalition has a Web site at http://www2.state.tn.us/health/CCCP/.

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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