THE CANCER LETTER

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FDA Seeks Support For Reorganization Of Cancer Programs, But Debate Continues

By Paul Goldberg

Top FDA officials in recent weeks have been mobilizing support for a plan for reorganization of the agency's oncology operations.

The plan, which is expected to be announced in the near future, would consolidate oncology products into a single administrative unit at the Center for Drug Evaluation and Research.

According to a plan described by agency officials, the proposed

(Continued to page 2)

In Brief:

Duke Recruits Moul As Chief of Urology; Deborah Winn Named Chief, NCI CGERB

JUDD MOUL, professor of surgery at the Uniformed Services University of the Health Sciences in Bethesda, Md., and attending urologic oncologist at the Walter Reed Army Medical Center, was named chief of the Division of Urology at Duke University Medical Center. Moul, who is retiring as a colonel in the Army Medical Corps, is also director of the Center for Prostate Disease Research, a Congressionally mandated, Department of Defense research program based at USUHS and Walter Reed. Moul is known for his work in prostate cancer in African-American men, biochemical recurrence of prostate cancer, prostate biopsy technique and nerve-sparing radical prostatectomy. While at Walter Reed, Moul developed a prostate clinical trials and care unit. He hopes to bring a similar program to Duke. "We're working on a Prostate Cancer Center that would be a home for urologists, oncologists, radiation oncologists" said Moul. He will begin at Duke Aug. 15, said **Danny Jacobs**, chairman of the Department of Surgery at Duke University Medical Center. Moul also created a U.S. military-based prostate disease research database that houses information on more than 20,000 prostate cancer patients treated at nine collaborating institutions. Moul will continue his work with the database as a consult to the Department of Defense. . . . **DEBORAH WINN** was appointed chief of the Clinical and Genetic Epidemiology Research Branch in the NCI Epidemiologic and Genetics Research Program. She was acting chief of the branch and senior epidemiologist for tobacco and cancer control in EGRP. She also served as acting associate director of EGRP prior to the appointment of **Ed Trapido**. Known for her work in smokeless tobacco and the etiology of oral cancer, Winn was

(Continued to page 8)

FDA Plans to Keep Vaccines, Gene Therapies In CBER

(Continued from page 1)

center would be headed by an oncologist who would have signatory authority over the majority of cancer therapies.

However, the plan stops short of consolidation of all of the agency's cancer programs, leaving cancer gene therapies and vaccines in the Center for Biologics Evaluation and Research, sources said. Also, one version of the organizational schema that the agency has shared with outsiders suggested splitting off cancer policy from regulatory functions, sources said.

According to supporters, the agency's plan has emerged from discussions held by NCI and FDA officials over the past year (**The Cancer Letter**, June 4). Friends of Cancer Research, a non-profit group, recently circulated a sign-on letter that described the FDA plan as the beginning of incremental change.

The Friends letter, which praised FDA for making changes, touched off disagreements among cancer groups, and was abandoned on request from agency officials.

Critics said the plan could, in fact, contribute to greater splintering of FDA's oncology functions.

FDA officials made it clear that vaccines and gene therapy would remain outside authority of the center director, sources said. Also, this official's authority could be limited by having to report to an agency administrator. In a series of meetings and conference calls held in recent weeks, FDA officials appeared to be wavering on their plan to refer policy issues to a different administrative unit, sources said. However, it is uncertain whether that plan has been abandoned.

In these discussions, senior staff members of the American Cancer Society and the American Association for Cancer Research supported the Friends position, sources said. Other groups—the American Society of Clinical Oncology and the majority of the patient groups that work through Cancer Leadership Council—declined to endorse the Friends proposal, reiterating their view that all oncology programs at the agency should be consolidated into a single unit. CLC adopted this position in February 2003, and expressed it in a letter to FDA.

As a professional society whose members are involved in clinical testing of cancer drugs, ASCO is an important constituency for the agency. ASCO Executive Vice President and CEO Charles Balch advocated an approach consistent with that of Friends, but the society's elected leadership and several prominent members took the opposing view, and prevailed, sources said.

Last week, ASCO sent a letter to FDA, in which it reaffirmed the position it took through CLC a year-and-a-half ago. CLC, too, is circulating a letter. The ASCO letter was dated July 1, addressed to Acting FDA Commissioner Lester Crawford, and signed by society President David Johnson.

The text of the letter follows:

"The leadership of the American Society of Clinical Oncology deeply values your personal involvement in the ongoing discussion with the Food and Drug Administration regarding potential reform of regulation of cancer products, as reflected in your participation in the conference call with the cancer community last Monday, June 21.

"We are writing not only to express our gratitude for your engagement but also to reiterate our view of the necessary components of reform of FDA's review and oversight of products to prevent, diagnose and treat cancer.

"First, we appreciate your understanding of the cancer community's desire to elevate regulation of cancer products to the 'Center' level in order to achieve a direct reporting relationship with the

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Commissioner.

"We are informed that creation of a new Center with the same resources as the currently existing Centers would require additional funding from Congress. The idea of a direct reporting relationship to the Commissioner is nevertheless an important one that we would like to explore further with you and your staff. You can be assured that ASCO would approach Congress to support the provision of necessary additional resources should the agency commit to creation of an oncology Center.

"Second, while we understand that there is a significant policy role that was originally discussed as a separate position, the cancer community believes that this role should not be segregated from the product review and oversight function lodged in one person as the Director of either a Center or an Office dedicated to cancer products.

"There is no doubt that there are substantial policy implications involved in implementation of the agency's critical pathway for drug development, including liaison with sister agencies like the National Institutes of Health and the Centers for Medicare & Medicaid Services within the Department of Health and Human Services and other agencies elsewhere in the federal government. However, we are convinced that the most efficient approach to the all-important policy function is to assign it to the same official who is charged with ongoing regulation of products.

"This will avoid confusion and conflict and make the position more desirable to the sort of seasoned cancer specialist that we believe to be required. Third, ASCO urges that all biologics involved in cancer diagnosis, prevention and treatment be transferred to the new Office or Center.

"We have been advised that cancer vaccines and cell and gene therapy for cancer will remain in the Center for Biologics Evaluation and Research, where they currently reside. Moving those products to join cancer drugs and other biologics involved in cancer treatment is, in our view, necessary to a complete consolidation of the entire oncology portfolio under a single entity.

"Fourth, the Director of this Office or Center should be an experienced oncologist (preferably a medical oncologist, given the central role of pharmaceutical agents in cancer therapy) with training as a clinical investigator and familiarity with the drug development process.

"Finally, we hope that these changes can be effected as expeditiously as possible. We understand that there may be limits involving adequacy of office space and differing information technology platforms among the components to be consolidated, but, for us, the critical question is leadership and coordination. It should be possible to achieve the creation of the new consolidated Office or Center and to select its leader before these largely physical limits are resolved.

"Once again, we very much appreciate your willingness to be involved in this enormously important decision. If this reform is accomplished correctly, FDA can take great satisfaction from streamlining and consolidating regulatory activities in a way that could have a profound impact on people with cancer. For the benefit of our patients, we hope the agency will take advantage of that opportunity, and we look forward to working with you to that end."

NCI Programs:

NCI To Fund Lab Testing Of "Reduced Harm" Tobacco

By Kirsten Boyd Goldberg

Advisors to NCI approved the Institute's plan to set aside $15 million over five years to fund a contract for laboratory research on tobacco products that claim to have lower levels of harmful ingredients.

The NCI Board of Scientific Advisors voted unanimously June 24 to approve the Institute's plan to release a Request for Proposals that would provide $3 million a year for the product-testing component of a larger NCI research program.

The contract would represent the second component of the NCI Tobacco Control Research Branch's effort to study reduced-exposure tobacco products. NCI issued a program announcement last May inviting extramural research on these products.

New tobacco products are being marketed with implied health claims, but little is known about how people use these products, said Mirjana Djordjevic, NCI program director in the TCRB. Earlier studies of low-tar and low-nicotine products found that their benefits were offset by the ability of users to puff more intensely to obtain the desired dose.

"There is no convincing evidence that changes in cigarette design between the 1950s and the 1980s have resulted in an important decrease in the disease burden caused by cigarette use either for smokers as a group or for the whole population," according to a recent NCI review of low-tar and low-nicotine

products. Low-yield cigarettes may have played a role in promoting smoking initiation and impeding cessation, studies said.

Now there is a new generation of tobacco products being aggressively promoted as less harmful. The products purportedly deliver lower amounts of some carcinogenic agents than conventional cigarettes. Little is know about what is in these products, how they are used, or whether they increase or decrease exposure to harmful tobacco and smoke constituents, Djordjevic said.

The Federal Trade Commission has asked NCI to provide guidance on its testing method for cigarettes and the scientific basis for advertising claims for these products, especially smokeless tobacco.

"This is much-needed and essential to keep up with the tobacco industry," said BSA member David Abrams, director of the Center for Behavioral and Preventive Medicine at Brown University. "This work is absolutely critical for them not to end-run us."

The tobacco industry spends $12 billion a year on marketing. If "safer cigarettes" caught on, "the public could rationalize its addiction," Abrams said.

BSA member Robert Young, president of Fox Chase Cancer Center, said smoking cessation is preferable to use of these products, "but it would be beneficial if those who smoke had access to less carcinogenic tobacco products. Let's get [smoking]to zero, but if we can't, let's reduce the risk."

"It still boggles my mind that we have a 100-percent defective product, but we can't get it off the market completely," Abrams said. "We know why, in terms of culture, politics, and American economics. We are a bit more addicted as a society to the economics and politics of tobacco than we care about saving individual lives."

Congress passed legislation soon after reports surfaced of an excess of 100 deaths above the expected level when Ford Explorers overturned with defective tires, Abrams said. "All heck broke loose, and legislation was implemented to protect the public health, and voluntary mandates were recalling the defective product on a massive scale, within three months," he said.

"The government can act to protect the public health without blinking when it wants to," Abrams said. "How come it won't with 450,000 deaths, which is something like a 9/11 terrorist attack every three days, every single year? I still don't understand that, and that would make this discussion moot, because it's a defective product. You could argue [that] we don't want it turned into a safe product, really. It should be off the market. "

Excerpts of the text of the concept statement approved by the BSA follow:

Laboratory Assessment of Tobacco Use Behavior and Exposure to Toxins Among Users of New Tobacco Products Promoted to Reduce Harm. Concept for a new RFP, first-year set-aside $3 million; estimated total over five years, $15 million. Program director: Mirjana Djordjevic, Division of Cancer Control and Population Sciences.

The purpose of this contract is to conduct research on laboratory assessment of new tobacco products promoted with harm reduction claims and users' associated behaviors and exposure levels. While the specific research objectives of this contract are outlined in this document, the scope of work will also be guided by recommendations of the Expert Consulting Committee (described below) and by evolving scientific and public health needs.

The mission of the Tobacco Control Research Branch, Division of Cancer Control and Population Sciences, National Cancer Institute is to lead and collaborate on research and to disseminate evidence-based findings to prevent, treat, and control tobacco use. Because the Branch is located within the Behavioral Research Program, the emphasis of this contract will be on understanding human tobacco use behavior and how it influences exposure to harmful constituents and risk for tobacco-related diseases. This contract addresses elements throughout the discover, development, and delivery continuum, including the discovery of information about human smoking behavior and its relation to tobacco toxin exposures, the development and validation of laboratory methods and biomarkers, and the delivery of scientific tools and information to the scientific community, regulatory agencies, and the public.

While individual scientists and research institutions are addressing a range of particular questions and applying specific methods, NCI is in a unique position to integrate information across disciplines and to develop, standardize, and validate novel methods to the point where the research community can use them. Moreover, this contract will enable NCI to provide guidance to government agencies on tobacco products. For example, the current FTC machine-smoking testing method for tar, nicotine, and CO does not account for variation in

human smoking behavior. Thus, this method does not offer smokers meaningful information on the amount of smoke toxins they will receive from a cigarette. With the data gathered from this contract, NCI will be able to provide expert advice to the scientific community, government agencies and the public regarding product testing methods and their relevance to actual human smoking behavior.

The following are research needs that can be effectively addressed through this contract:

1. Assessment of tobacco product emissions under varying behavior conditions.

—The contractor will review existing methods for measuring biologically and pharmacologically relevant constituents of both smoked and smokeless tobacco products. Cigarettes will be tested employing different machine-smoking methods for a comparative assessment of the emissions of selected agents under varying smoking intensity.

—The contractor will use the above methods to evaluate how emissions relate to product design characteristics. For example, changes in filter ventilation of the product may influence, via increased puffing intensity and blocking of filter vents, the combustion/pyrolysis process and, in turn, the product's emissions to the smoker.

—The contractor will assess individual behaviors/topography of use of new products and establish their relationship with actual delivered dosages of nicotine and select panel of toxic and carcinogenic agents to the user.

2. Standardization and validation of laboratory methods and biomarkers.

—The contractor will review the state of knowledge regarding existing as well as emerging biomarkers and laboratory methods, including new technologies such as proteomics and metabolomics, and advise NCI on their promise for further development and validation.

—The contractor will conduct appropriate laboratory tests to validate candidate biomarkers and tests for use in evaluating tobacco products.

—The contractor will apply validated tests to new potential reduced-exposure tobacco products to generate data that will inform the scientific community and regulatory agencies about the properties and potential impact of these products compared with conventional products.

3. Communication of major findings.

The contractor will create and maintain a public use Web-based database of laboratory methods for ascertaining product emissions and actual exposures and relevant findings for use by the scientific community, regulatory agencies, and the public. The contractor will work with NCI's Tobacco Harm Reduction Network and WHO's International Network for Tobacco Testing and Research for Regulation, which are currently under development. The contractor will also work with NCI to synthesize findings in formats for peer-reviewed publication, scientific presentations, and public dissemination.

4. Expert consulting committee, consisting of 10-15 members, will be asked to meet twice each year to provide specific recommendations to NCI on critical issues and establish priorities to be addressed through this RFP. The contractor will coordinate and support activities of the committee.

Advisors Approve Partnerships Of Minority Institutions, Centers

The NCI Board of Scientific Advisors approved the Institute's plan to continue a three-year-old program that provides funding for cancer centers and minority-serving institutions to create partnerships for cancer research, training, education, and outreach.

On a 16-0 vote, with three members abstaining due to conflicts of interest, the BSA on June 24 approved the set-aside of $42.5 million over five years to fund about 22 grants for these partnerships.

Excerpts of the concept statements follow:

Planning Grant for Minority Institution Cancer Center Partnership. Concept for a reissued RFA, 12 awards, first year set-aside $2.5 million, total $12.5 million over four years. **Cooperative Planning Grant for Comprehensive Minority Institution Cancer Center Partnership**. Concept for a reissued RFA, 8 awards, first year set-aside $3 million, total $15 million over five years. **Comprehensive Minority Institution Cancer Center Partnership**. Concept for a reissued RFA, 2 awards, first year set-aside $3 million, total $15 million over five years. Program director: Sanya Springfield, Office of the Deputy Director for Extramural Sciences.

The MI/CCPs target four areas:

1. Cancer research: Joint pilot research projects may be in any area of basic, clinical, prevention, control, behavioral, or population research. Research projects conducted primarily at the MSI may be in any area of cancer research, but research projects conducted primarily at the cancer center must

specifically address areas of cancer disparity in minority and underserved populations. The expectation is that successful pilot research projects will become full research projects and that full research projects will become competitively funded grants.

2. Cancer training. Cancer training is the most productive way to sustain a long-term effective partnership. These programs must place an emphasis on the training of minority scientists and on educating majority trainees to appreciate the issues and problems associated with cancer disparities in minority populations. NCI particularly encourages training of minority scientists in basic, clinical, behavioral, and population research; there is a huge deficit of minority scientists engaged in these research areas, which are highly dependent for their success on the cultural sensitivity of the researchers. These training programs must represent true collaborations that function seamlessly across the institutional boundaries of the MSI and the cancer center. Successful activities in this area may lead to the submission of a competitive training grant application as well as individual predoctoral fellowships, career development awards, and research supplements for trainees.

3. Cancer education: Cancer education programs could focus on any effort to augment existing or create new curricula in the MSI and the cancer center. These programs would apprise and culturally sensitize graduate, postdoctoral, and medical students in research, medicine, and public health of the need to reduce disproportionate cancer burden in minority and underserved populations. A successful effort may result in the submission of competitive NCI education grant application and later to institutional commitments to make these curricula an inherent component of their educational systems.

4. Cancer outreach: Cancer outreach programs may be defined as proactive efforts to help minority communities develop and manage their own culturally sensitive programs for educating their populations about cancer risk, early detection, screening, prevention, and treatment. MSIs and cancer centers would be expected to combine their expertise in working with minority leaders and community organizations to develop outreach programs that effectively reach individuals and physicians and that increase the recruitment and retention of racial and ethnic minorities into clinical trials and prevention protocols.

Applications would be submitted in one of three ways:

1. As planning grants (P20s) for the development of partnerships. These would be for up to four years of support and up to $275,000 in direct costs per year. They are to be focused on identifying and developing areas of collaborative opportunity that have the highest potential for success. Each pilot project requires co-principal investigators, one from the MSI and one from the cancer center. Each pilot project would not exceed $120,000 in direct costs per year or duration of more than three years.

2. As cooperative planning grants for comprehensive partnership (U56). This would be for up to five years and up to $550,000 in direct cost per year. The U56 MI/CCP is the first step to the U54.

3. As full partnerships supported by the Specialized Center-Cooperative Agreement (U54) mechanism. These will provide up to five years of support and up to $2.5 million in direct costs per year. To be eligible for a U54, applicants must demonstrate clearly that the application is based on previous comprehensive planning activities (whether supported by a U56 cooperative planning grant or not).

Funding Opportunities:

Mesothelioma Foundation Offers Developmental Funds

Mesothelioma Research Grant: $100,000

Application Deadline: Aug. 15, 2004

Mesothelioma Applied Research Foundation is accepting applications for developmental projects advancing pleural or peritoneal mesothelioma treatment. Projects may related to benchwork or clinical research, must not be presently funded or pending review, and may be conducted through any not-for-profit academic, medical or research institution, in the U.S., or abroad. The $100,00 grants are for two years. The application is available at www.marf.gov.

Inquiries: Christopher Hahn, executive director, MARF, 1609 Garden St., Santa Barbara, Calif., 93101, phone 805-560-8942; fax 805, 560-8962.

Program Announcement

PA-04-121: Understanding Mechanisms of Health Risk Behavior in Children and Adolescents

National Institute of Child Health and Human Development, NCI, National Heart, Lung, and Blood Institute, National Institute on Alcohol Abuse and

Alcoholism, National Institute on Drug Abuse, the Office of Behavioral and Social Sciences Research, and Office of Dietary Supplements invite research grant applications looking into factors and processes that influence the initiation, continuation, and/or cessation of one or more of the following health risk behaviors: (1) substance abuse, (2) inadequate exercise and poor dietary practices as they relate to being overweight or obese, and (3) intentional and unintentional injuries. The majority of all American adult deaths results from cardiovascular disease and cancer, with many of the associated risk factors being initiated during adolescence. Interdisciplinary research is sought to explore the biological, genetic, physiological, psychological, and social/environmental factors and mechanisms that influence health risk behavior change in children and adolescents.

One complication of obesity is type II diabetes mellitus. Other complications likely to follow the increase in obesity and type II diabetes include increases in cardiovascular disease, kidney failure, and blindness. Besides type II diabetes, overweight and obese children and adolescents are at risk of becoming overweight adults with problems of coronary artery disease, hypertension, stroke, respiratory problems, gallbladder disease, osteoarthritis, sleep apnea, and some forms of cancer. The PA will use the NIH Research Project Grant R01 and Exploratory/Developmental Grant R21 award mechanisms. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-04-121.html.

Inquiries: For NCI—Louise Mâsse, NCI, Division of Cancer Control and Population Sciences, phone 301-435-3961; fax 301-480-2087; e-mail massel@mail.nih.gov.

RFPs Available

RFP N02-CM-57000-28A: Operation and Maintenance of the Biological Data Processing System

Proposals Due: Approximately Aug. 18

NCI Developmental Therapeutics Program is seeking a contractor to operate and maintain its Biological Data Processing System. Experience is required in the following areas: planning and designing scientific information systems; implementing large and complex biological and chemical databases; various hardware/software environments such as VAX/VMS, Oracle, TCP/IP, C, PL/SQL, Jbuilder 9, Java Server Page, Entensible Markup Language, Java 2 Enterprise Edition, HTML, and postscript. Bidder must demonstrate proficiency designing and developing browser-based and J2EE solutions and establishing database connectivity between such solutions and an Oracle database. The offerer may not be a pharmaceutical, chemical or biological firm. It is anticipated that a single, cost-reimbursement, cost-plus-award-fee, performance based service contract will be awarded on or before Feb. 1, 2005, for a base period of three years plus two one-year options. The RFP will be available electronically at http://rcb.nci.nih.gov/.

Inquiries: Carolyn Baker, contract specialist, phone 301-435-3815; fax 301-402-6699; e-mail cb123d@nih.gov.

RFP N02-CM-57001-28: Synthesis of Non-GMP Compounds for Screening

NCI Developmental Therapeutics Program is soliciting organizations with expertise in organic synthesis to perform synthesis of compounds needed for biological evaluations as anti-cancer agents. The contractor shall synthesize non-GMP target compounds as prioritized by NCI and deliver the synthesized compounds in amounts pf 0.1 to 100.0 grams to the NCI repository. The synthesis assignments may on rate occasions include parallel synthesis or de-convolutions of small combinatorial libraries, and syntheses of a few selected analogs of known compounds. Synthesis and delivery of 10 to 25 target compounds per years are anticipated depending upon complexity and amounts. The contractor shall prepare the Material Safety Data Sheets for all single compounds and libraries which are delivered, and check the purities of previously synthesized or purchased compounds when requested. Mandatory qualification criteria: as many of the compounds assigned for synthesis may be of a hazardous nature, the offeror must possess the necessary licenses required by the local, state, and federal governments to handle, synthesize, store, and ship such compounds and dispose of toxic waste. It is anticipated the one single reward will be made for a five-year period beginning on or about Feb. 1, 2005. The RFP will be available at http://rcb.nci.gov/.

Inquiries: See preceding RFP.

RFP N02-CM-42400-96: Primary Rodent Production Center

Biological Testing Branch of the NCI Developmental Therapeutics Program is seeking an organization with the capabilities and facilities for producing pathogen-free rodents. The following Mandatory Qualification Criteria must be met at the time of proposal submission to the contracting officer: a) in accordance with the NIH policies, administered by the Veterinary Resources Program, all laboratory animals delivered to the NIH campus, NCI at Frederick, and NIH contract laboratories within the Washington, DC metropolitan area must be delivered in environmentally-controlled vehicles that are used exclusively for transporting animals. Contractor must be capable of obtaining proper paper/clearances when requested to make foreign shipments. Shipping boxes used must be escape proof and properly filtered to protect the animals from pathogens. All proposers must have documented experience in this procedure/practice; b) colonies maintained under this contact shall be housed in a maximum barrier environment. If the animals are housed in the same room as commercial animals they must be labeled and identified in a manner that clearly separates

the government and commercial animals. The task must also be performed at more than one location in order to prevent the total loss of all colonies should a contamination or any type of disaster occur; c) animal monitoring shall be performed by in-house professional staff capable of monitoring all animal colonies for their health status at all locations where the contract would be performed. The in-house staff must also have the ability to test mice by means of biochemical markers and be capable of performing pathology/histology services. Additionally, the PI and other key personnel should have experience and expertise with rodent breeding procedures of inbred, outbred and hybrid colonies and with the production of the highest quality rodents and a willingness to participate in grantee reimbursement collection for surplus animals. The government anticipates awarding the five-year, cost-reimbursement contract by May 1, 2005. The RFP is available at http://web.ncifcrf.gov/about/mosb.asp.

Inquiries: Scott Drega, contract specialist, phone 301-846-1115; fax 301-846-6628; e-mail sdrega@ncifcrf.gov.

Other Funding Notices

NOT-CA-04-014: Notice of Limited Competition Request for Competitive Renewal Application: The Breast Cancer Surveillance Consortium Infrastructure Support

NCI is requesting competitive renewal applications for infrastructure support from the awardees of the Breast Cancer Surveillance Consortium http://breastscreening.cancer.gov/sites.html.

The BCSC is a collaborative network of seven mammography registries with linkages to pathology and/or tumor registries that are supported by a central statistical coordinating center. The SCC is the organization responsible for pooling and analyzing pooled BCSC data, which are used to evaluate the performance of breast cancer screening in clinical practice. The Notice is available at http://grants.nih.gov/grants/guide/notice-files/NOT-CA-04-014.html.

Inquiries: Rachel Ballard-Barbash, associate director, NCI Applied Research Program, Division of Cancer Control and Population Sciences, Phone 301-496-8500; fax 301-435-3710; e-mail barbashr@mail.nih.gov. or Robin Yabroff, program director, NCI, Health Services and Economics Branch, DCCPS, phone 301-594-1723; fax 301-435-3710; e-mail yabroffr@mail.nih.gov.

NOT-CA-04-023: Addendum—Specialized Programs of Research Excellence in Human Cancer for the Year 2004

The application receipt date for Gynecological Cancer SPOREs has been changed from Oct. 1, 2004 to Feb. 1, 2005. The Letter of Intent receipt date for Gynecological Cancer SPOREs has also been changed to Dec. 1, 2004. The Notice is available at http://grants.nih.gov/grants/guide/notice-files/NOT-CA-04-023.html.

Inquiries: Jane Fountain, program director, NCI, Organ Systems Branch, Office of Centers, Training, and Resources, Office of Deputy Director of Extramural Sciences, phone 301-496-8528; fax 301-402-5319.

In Brief:

NIH Foundation Names Carucci To Direct Grand Challenges

(Continued from page 1)

involved with the EGRP-funded Cancer Genetics Network and developing initiatives in gene-gene and gene-environmental interactions. She is NCI program coordinator for the Long Island Breast Cancer Study Project and a member of the Division of Cancer Control and Population Sciences' Health Disparities Research Coordinating Committee . . . **DANIEL CARUCCI** was named director of the Grand Challenges in Global Health initiative by the Foundation for the National Institutes of Health. The initiative is funded by a $200 million grant from the Bill and Melissa Gates Foundation. He will work with **Elke Jordan**, part-time science liaison. Carucci was director of the Malaria Program at the Naval Medical Research Center. . . . **HARVARD MEDICAL SCHOOL** and the **Johns Hopkins University School of Medicine** were awarded grants by National Human Genome Research Institute to establish Centers of Excellence in Genomic Science. The Harvard center will deveop technologies for genomic molecular imaging, while the Johns Hopkins center will advance the emerging field of epigenetics. Harvard, whose team will be led by **George Church**, will receive $2 million annually for five years. **Andrew Feinberg** of Johns Hopkins and his colleagues will establish the Center for Epigenetics of Common Human Disease at Johns Hopkins. **Eric Green**, director of the NHGRI Division of Intramural Research, and **Tamara Harris**, chief of the Geriatric Epidemiology Section at the National Institute on Aging will also participate. The center will receive $1 million annually for five years. Other participants are: **Roger Brent**, Molecular Sciences Institute, Berkeley, Calif.; **Jingyue Ju**, Columbia University; **Deirdre Meldrum** and **Maynard Olson**, both of the University of Washington, Seattle; **Michael Snyder**, Yale University; **William Talbot**, Stanford University School of Medicine; **Michael Waterman**, University of Southern California.

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