THE CANCER LETTER INTERACTIVE

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# Bush Proposes 16 Percent Increase For NIH, To Complete Budget Doubling

President Bush will propose an increase of $3.7 billion, or nearly 16 percent, for NIH in fiscal year 2003, bringing the Institutes' budget to $27.3 billion, the Department of Health and Human Services said last week.

The proposal, which will be submitted to Congress on Feb. 4, will fulfill Bush's campaign promise to complete the five-year budget doubling cycle for NIH. In fiscal year 1998, the NIH budget stood at $13.6 billion.

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*In Brief:*

## Ad Council, ACS Begin Ad Campaign To Promote Colon Cancer Screening

**THE ADVERTISING COUNCIL** and the American Cancer Society began a national public service advertising campaign to promote colon cancer screening. The campaign includes television, radio, Internet, and print advertising, developed by the Campbell-Ewald agency. The 15- and 30-second television PSAs depict doctors apprehending "Polyp Man"—a pesky character dressed in a large, red polyp suit. The ads convey the message that men and women age 50 and older should discuss early detection methods with their physician. Each spot concludes with the campaign tagline, "Get the test. Get the polyp. Get the cure." . . . **JOANN SCHELLENBACH**, national director of media relations for the American Cancer Society for more than 20 years, has been named director of medical and scientific communications for the society. **Shawn Steward** was appointed director of national media relations, based at ACS headquarters in Atlanta. Supporting Steward in media relations are **Susan Islam**, in the New York office, and **Lee Ann Broussard**, in Atlanta. In a memo to health media, ACS said Steward is the contact for general information about ACS, while public policy communication is being handled by **Unice Lieberman**, director of advocacy communications, and **Rachel Tyree**, manager of advocacy communications, both in the Washington, DC, office. . . . **SCOTT WADLER** was appointed the first incumbent of the Richard T. Silver Distinguished Professorship of Hematology and Medical Oncology at Weill Medical College of Cornell University. He was previously professor of medicine and obstetrics and gynecology and director of the gastroenterology program at Albert Einstein College of Medicine. . . . **H. LEE MOFFITT** Cancer Center and Research Institute has opened a Brain

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# President Proposes $5.5B For Cancer Research In FY03

(Continued from page 1)

"The President could not be clearer about his commitment to medical research, the scientific enterprise and the value of NIH and its work," said HHS Secretary Tommy Thompson. "The proposed NIH budget will support nearly 36,000 research project grants, an all-time record for the agency."

Cancer research funding would increase by $600 million, or 12.2 percent, from $4.9 billion in FY 2002 to $5.5 billion in FY 2003.

Bush promised in a September 2000 campaign speech to raise the NCI budget to $5.1 billion. Specific funding levels by institute were not available.

Advocates for cancer research generally were pleased with the proposal, but some were concerned that Bush has yet to appoint an NIH director. Acting Director Ruth Kirschstein has served in that position for two years following the departure of Harold Varmus.

"The patient community is concerned about the extended period of no NIH director," Ellen Stovall, executive director of the National Coalition for Cancer Survivorship, said to **The Cancer Letter**. "That's not consistent with the Administration's support of NIH."

In addition, FDA lacks an appointed commissioner, and several institute directorships at NIH remain vacant.

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**Bioterrorism Research**

About $1.5 billion of the increase for NIH would be devoted to proposed bioterrorism research, based on NIH recommendations. The research would include sequencing the genome of potential bioterrorism agents, accelerating development of anthrax vaccines, and improving diagnostic tools.

The bioterrorism research will be overseen by Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases. Fauci, increasingly visible in recent months as the Administration's bioterrorism expert, has been rumored as a candidate for NIH director.

**Increase For Cancer Screening**

The Administration also will propose a $9 million increase for the National Breast and Cervical Cancer Early Detection Program administered by the Centers for Disease Control and Prevention, Thompson said.

The increase would bring the program's funding to $203 million.

The program provides screening services to underserved women. It also funds post-screening diagnostic services, such as surgical consultation and biopsy, to ensure that women with abnormal results receive timely and adequate referrals.

The increase would allow the program to provide an additional 29,000 diagnostic tests, as well as increasing education and outreach programs, improving quality assurance measures, and improving access to screening and follow-up services, HHS said.

"Together, breast and cervical cancer took the lives of more than 45,000 American women in 2001," Thompson said. "These deaths occurred disproportionately among low-income women and women who belong to racial or ethnic minorities. By increasing screening rates for at-risk women, we can save lives."

HHS has approved requests from 34 states to expand Medicaid to cover cancer treatment for women without health insurance who are diagnosed with cancer through the CDC program.

*Professional Societies:*

# FASEB Seeks $27.3B For NIH, Increases For Research, Training, And Infrastructure

The Federation of American Societies for Experimental Biology recommended an appropriation of $27.3 billion for NIH in fiscal 2003.

The recommendations, developed by scientists at FASEB's annual Federal Funding Consensus Conference, would complete the doubling of the NIH budget from fiscal 1998.

FASEB recommended increases in three areas: investigator-initiated research, training for young scientists, and investment in research inftastructure.

"Rapidly approaching scientific and medical opportunities argue for increased support for patient-oriented research for translating laboratory breakthroughts in molecular medicine into new therapies," the report states.

This will require collaboration between scientists trained in a variety of disciplines.

"Cross-disciplinary teams are required to understand cellular function by mining molecular, proteomic, and genomic databases to create tools for information management and integration, the report states.

**"Backlog of Opportunity"**

According to FASEB, advances in understanding the genetic basis of disease have created a "backlog of opportunity."

"A new cadre of biomedical scientists with expertise in molecular technologies, bioinformatics and novel clinical laboratory capabilities is needed to translate basic information into clinical strategies," the report states.

Additional investment in the infrastructure would give scientists access to the latest research tools. "A shared core resources facility program, perhaps administered by the National Center for Research Resources, is needed to fund and manage today's advanced research technologies in a cost-effective way," the report states.

Altogether, about $400 million would be needed for construction of "cutting-edge, multi-technology centers and shared instrumentation."

The anthrax attacks draw attention to another requirement of science today: the need for security of research facilities at academic institutions.

"Currently, there is no funding mechanism to provide for new security measures at the many institutions where NIH-supported research is performed," the report states.

**Support For Bioinformatics**

Other recommendations involving NIH funding include:

—Increased support for interdisciplinary graduate programs that emphasize bioinformatics.

—Resources for standardization, archiving, and dissemination of bioinformatics data.

—Establishment of a repository for human embryonic stem cell lines. "Such a repository, established at NIH or an independent entity under NIH supervision, would greatly increase access to research materials by centralizing the collection, characterization, maintenance and distribution of such cell lines," the report states. "FASEB assumes that at least some derivers of stem cell lines would contribute their stem cell lines on a voluntary basis in a manner similar to the way that other tissue and culture repositories currently operate. Such a repository would distribute cell lines to researchers under negotiated material transfer agreements and licensing agreements, greatly accelerating the dissemination of these cell lines and assuring rapid development and adoption of best practices for their use.

—Establishing a new program to help institutions add research space. FASEB recommends $250 million in grants for improving existing facilities and $750 million in loan guarantees.

—Increasing funding for Research, Management and Support at NIH. From fiscal 1993 to fiscal 2001, spending on RM&S declined from 4.8 percent to 3.3 percent of the budget. "NIH is budgeting a doubling research portfolio with resources that are being reduced as a percentage of the budget," the report states.

**FASEB also recommended:**

—a 15-percent increase for the NSF, bringing that agency's budget to $5.5-billion;

—increased funding for the USDA's National Research Initiative Competitive Grants Program to at least $200 million;

—an increase of $100 million for NASA's Office of Biological and Physical Research;

—a budget of $3,668 million for DOE's Office of Science;

—a $33.5-million increase for the VA's biomedical research programs; and

—a budget of $664 million for the EPA's Office

of Research and Development.

The report, titled Federal Funding for Biomedical and Related Life Sciences Research, is available on the Web: http://www.faseb.org/opar/fund2003/fedfund03.pdf.

*Generic Paclitaxel Saga:*

## Ivax Paclitaxel To Remain On Market In Deal With BMS

A series of court rulings, corporate deals, and regulatory decisions have resulted in generic paclitaxel remaining on the market.

In the tradition of extreme complexity of all matters involving the agent, recent developments proceeded along several tracks.

First, FDA corrected the regulatory problems that were pointed out by an appeals court. The U.S. Court of Appeals for the District of Columbia earlier this month reaffirmed its position that the agency failed to justify approval of generic paclitaxel marketed by Ivax Corp. (AMEX: IVX) of Miami (**The Cancer Letter**, Nov. 9, 2001).

In a seemingly odd maneuver that's likely to satisfy the court, on Jan. 24 the agency withdrew its approval of the Ivax paclitaxel, then—immediately—returned to Square One, and approved the Abbreviated New Drug Application for the agent once again.

This revolving-door move was made possible by a series of rulings and deals that concluded in recent weeks.

On Jan. 11, the U.S. District Court for the Central District of California issued a partial summary judgment which threw out the patent infringement claims by American BioScience Inc. against Bristol-Myers Squibb, the sponsor of Taxol, the branded paclitaxel (**The Cancer Letter**, Jan. 18).

Santa Monica-based ABI claimed that the packaging used by BMS for its branded Taxol infringed its patent and sought to sought to keep the generics off the market to protect the value of its claim against Bristol.

Farfetched of not, patent disputes listed in the FDA Orange Book, can extend the pharmaceutical companies de-facto market exclusivity by as much as three years.

In fact, generics claimed that the ABI-Bristol patent spat was in fact an effort to obtain additional exclusivity on Taxol.

For more that a year, the court rulings have gone back and forth on validity of the Orange Book listing of the ABI patent (**The Cancer Letter**, Oct. 20, 2000). Finally, on Jan. 17, Bristol "delisted" the ABI patent.

According to Ivax, the delisting followed an agreement between Ivax and Bristol to settle all pending Taxol-related litigation.

Under the deal, Ivax agreed to dismiss the claims pending in the U.S. District Court in New Jersey and in the Florida State Court. In return, Ivax receives a royalty-free license to some of the BMS patents related to Taxol.

Separately, Ivax will continue to pursue its counterclaims against ABI in the U.S. District Court in Los Angeles, claiming antitrust violations and anti-competitive conduct.

"Our paclitaxel product is on the market to stay," said Neil Flanzraich, Ivax vice chairman and president. "Ivax's invalidation of the ABI patent claims combined with the delisting of the ABI patent from the Orange Book and the renewed FDA approvals secure the future of our paclitaxel product."

*NCI Programs:*

## Shared Specimen Resource Needed, GYN Review Finds

NCI should develop and make available to the cancer research community a "virtual shared specimen resource" to support gynecologic cancer research, an advisory group formed to review the Institute's gynecologic cancer research programs has concluded.

In a report accepted by the Advisory Committee to the NCI Director, the Gynecologic Cancers Progress Review Group said it had identified timely access to high quality samples of human tissue and body fluids as the greatest need of researchers.

The full report of the Gynecologic Cancers Progress Review Group is available at http://prg.nci.nih.gov/gyno/finalreport.html.

Excerpts of the report follow:

**Essential Research Priority: The Virtual Shared Specimen Resource**

Priority: Develop and make available to the cancer research community a Virtual Shared Specimen Resource (VSSR) to support gynecologic cancer research.

To make significant progress, the gynecological cancer research community needs to exploit emerging genomics, proteomics and informatics technologies to identify precursor lesions, markers of risk and early

detection, molecular disease classifications, prognostic indicators, and new targets for prevention and treatment. Despite a wealth of opportunities, progress is impeded by the dearth of high-quality, fresh-frozen, annotated specimens available to the gynecologic research community. In part because technologies are developing so rapidly, cutting-edge research requires specimens that are obtained at critical points in the disease process, processed and stored in evolving ways, and associated with high-quality clinical and follow-up data.

The VSSR will allow us to perform molecular profiling to identify the molecular signatures of gynecologic cancers. It will facilitate the discovery of markers of gynecologic cancer risk, premalignant and malignant disease, and new approaches of preventing and treating progressive disease. Specifically, it will enable us to achieve answers to the following questions, which have been elusive in the past:

·How can women at high risk for gynecologic cancers be identified?

·How can ovarian and endometrial cancers be detected early?

·What strategies can be developed to prevent gynecologic cancers?

·What new approaches can be developed to better treat gynecologic cancers?

Various tissue collection initiatives have been proposed and many exist, but they are limited in their usefulness for one or more of the following reasons:

·Banked specimens were not processed or stored appropriately for current scientific needs.

·Banked specimens were not obtained at the appropriate time in the course of disease, or do not represent the needed tissue types.

·Informed consent obtained from tissue donors was not adequate for current scientific needs.

·Specimens were not linked to adequate clinical data, including demographics, risk factors, therapy, and follow-up.

·Lack of incentives to share specimens inhibits widespread use.

As a result, specimens are not currently available in a timely fashion to a large group of researchers addressing the critical scientific questions in gynecologic cancer research.

Nearly every GYN PRG breakout group cited the critical need for quality samples of tissue and body fluids for research in gynecologic cancer. The groups also pointed out that these specimens must be collected in a manner to allow adequate preservation of DNA and RNA for research use. They further listed the need for these specimens to be linked to adequate patient data, including demographics, risk factors, therapy, and follow-up. Where possible, these specimens should be serially collected: before treatment, during treatment, and at any recurrence. Specimens from women without gynecologic cancer are needed as well, including women with benign gynecologic conditions and women with no evidence of gynecologic or malignant disease. Finally, these specimens and their associated clinical data must be collected with appropriate informed consent to allow for their use in all future research, including techniques yet to be developed and questions yet to be asked.

The VSSR will enable the gynecologic cancer research community to realize the promise of exciting new technologies to identify gynecologic cancers early in the disease process and to discover new targets for their prevention and treatment. To make significant progress, a cooperative effort is needed to ensure that the best scientists have access to the right specimens. Although the scientific community has made efforts to this end, it is very difficult. NCI has an opportunity to facilitate the scientific community efforts and in fact, have already begun the process through the definition of common data elements to describe the specimens.

Features of the VSSR would include specific scientific goals, a coordinating center, and an advisory committee to ensure efficiency, equity, quality, and inventory control in specimen collection, management, and distribution. The VSSR is "virtual" in the sense that although information describing the specimens is managed centrally, the specimens themselves reside in various institutions.

The VSSR will surmount existing barriers to effective specimen banking and distribution in the following ways:

·Its virtual design will overcome the reluctance of institutions that collect specimens to have their specimens stored centrally.

·Its central coordination will provide equitable access to banked specimens as well as providing a means of prospective collection of specimens when banked specimens are inadequate.

·Its scientific oversight will ensure that appropriate policies are developed regarding consortia members' rights and responsibilities, with attention to structuring incentives to promote collaboration.

**Recommended Actions:**

NCI should provide the resources needed to

facilitate development of a VSSR for gynecologic cancer research.

An advisory committee composed of leaders in gynecologic cancer research, such as members of the GYN PRG, should monitor and oversee the progress of the resource and the research it supports.

Multiple institutions should collaborate in the development and use of the VSSR, with a long-term goal of serving the specimen needs of the larger gynecologic cancer research community.

**Resources:**

The VSSR would probably involve multi-institutional consortia addressing one or more of the critical scientific questions identified by the GYN PRG, including identification of precursor lesions; biomarkers of risk, early-stage disease, and prognosis; molecular signatures of malignant and premalignant lesions; and targets for prevention and therapy. Each consortium would develop a specimen repository to support its own research needs as well as those of the larger gynecologic research community.

Fresh tissue and fluids would be obtained at critical points in the disease process from large numbers of women (hundreds to thousands, depending on the research focus), including those with and without gynecologic cancer. Rates of specimen accrual for rare types of gynecologic cancer (such as Type II endometrial, Stage I serous ovarian, and invasive cervical cancers) and other conditions of interest (such as prophylactic oophorectomy and precursor lesions) would be important in selecting consortia.

Also important would be quality control of collection, processing, storage, and characterization, as well as the ability to collect data on risk factors, clinical aspects, follow-up, and outcome by using common data elements agreed upon by the major NCI networks (Cancer Therapy Evaluation Program, Specialized Programs of Research Excellence, Early Detection Research Network, etc.). Plans for specimen collection and processing would be based on the specific research questions to be addressed, as well as on the development of a more generally useful repository. Expertise in genomics, proteomics, and/or informatics would be needed within each consortium to support specific research goals. Consortia would provide access to banked specimens in the virtual repository and would initiate prospective specimen collection to meet the specific goals of new studies for which banked specimens were unavailable or inadequate.

The VSSR coordinating center would:

·facilitate specimen access by the greater research community;

·manage specimen inventory and data;

·develop policies and systems to provide equitable access to the resource, as well as a plan for managing specimen inventory, including rapid prospective collection of tissue to meet research needs for which banked specimens are inadequate;

·coordinate the work of the collection sites across consortia so that the "spigot" can be turned on as needed to collect specimens of a particular type, to be appropriately processed and characterized to maintain inventory and/or to meet specific scientific objectives;

·monitor and control the inventory of banked specimens to ensure the adequate availability of banked specimens to meet the needs of the research community;

·oversee a Specimen Allocation Committee, composed of investigators at the collection sites, which would approve applications for prospective collection of unique specimens to meet particular scientific research objectives, as well as the use of stored specimens;

·provide data collection forms and a specimen inventory control and tracking system (such as the Biological Specimen Inventory), to ensure the use of CDEs, facilitate specimen and data sharing, and avoid unnecessary investment in computer systems at each institution and consortium site;

·provide a website (clearinghouse) to support communication with the greater research community regarding the ability of collection sites to accrue numbers of specimens of different types within a year, and availability of specimens banked already in the repository.

While the GYN PRG hopes that all or many of the priorities in this report will be addressed, we also believe that there can be little progress in gynecologic cancer research unless this essential priority is implemented. The absence of a dedicated specimen resource will preclude timely scientific progress in gynecologic cancer research. Human specimen resources are required to meet the critical scientific needs identified in the 2002 NCI Plans and Priorities for Cancer Research (http://planning.cancer.gov), as well as those identified in this report. If successful, the VSSR could become a model for a resource that covers tumor types beyond gynecologic cancers.

**High-Impact Research Priorities:**

Drawing on the discussions of Roundtable

participants, the PRG leadership identified three areas of research:

·the identification of markers of risk, early detection and targets for treatment;

·the development of human papillomavirus vaccines;

·research to improve patients' quality of life; reduce disparities related to care.

These areas were selected because of their importance to the science of gynecologic oncology in terms of both the state of the science today and the potential for benefit over the next 5 years. Two of these priorities are relevant to all three gynecologic tumor types and encompass areas of the science of oncology that also apply to other types of cancer. The other priority (HPV vaccines) is included as a high-impact priority because it has the potential to nearly or completely eliminate cervical cancer and thus would have a major effect on women's health throughout the world.

**The group also identified six scientific opportuntiies:**

—Characterize the hormonal, immunologic, and epithelial/stromal interactions that result in the development of gynecologic cancers.

—Develop imaging techniques to evaluate tumor biology, molecular signatures, and therapeutic response.

—Develop relevant preclinical models for gynecologic cancers.

—Find ways to overcome resistance to chemotherapy and radiotherapy.

—Develop individualized and optimized radiation therapy techniques in conjunction with other treatment modalities.

—Encourage increased participation in clinical trials in gynecologic cancer.

## *Funding Opportunities:*

## Program Announcement

**PAR-02-051: Cancer Therapy-Related Use Of Genetically Engineered Mice**

Application Receipt Date: April 19

The goal of this program announcement is to encourage the use of genetically engineered mouse cancer models for cancer therapy-related goals. Mouse cancer-prone models with heritable genetic alterations are usually derived to explore mechanisms that underlie basic cancer or tumor biology. Through in-depth phenotyping, these models are often discovered to have molecular genetic profiles and histopathology that are similar to the molecular signatures and tumor progression of human malignancies. Because of the similarities, the models may be appropriate to identify molecular targets for therapy or to test new molecularly targeted agents. The models may be credentialed with new agents through systematic preclinical trials to discover how well the mice mimic the clinical course of human cancer in response, or development of resistance, to therapy. Or the model strains may be used to discover the genetic determinants of response to therapeutic agents.

Where it is advisable, the applicants to this PA should include collaborators who are expert in, for example, translational research, clinical trials, imaging research, and statistical analysis. Applicants are also encouraged to consider subcontracts with companies that can provide relevant services that are unavailable at their institutions. The following are examples of topics that are responsive to this PA; however, appropriate subjects are not limited to those given below.

1. Preclinical trials of appropriate agents in relevant GEMs to determine if the timing and penetrance of the tumor phenotype limits the value of the model for this use.

2. Preclinical trials to credential appropriate GEMs for how well they reflect the observed clinical course of human cancers.

3. Appropriate experiments to determine the pharmacodynamics and pharmacokinetics of specific agents in GEMs.

4. Preclinical trials that incorporate use of high-throughput technologies or small-animal imaging to monitor delivery of agents or response to therapy.

5. Preclinical trials to determine efficacy of new single or multiple agents at different stages of tumor progression.

6. Preclinical trials that examine which aspects of trial design are appropriate for experiments with GEMs.

7. Examination of GEMs and their corresponding normal background strains for genetic determinants of therapeutic response.

The text of the PA is available at http://grants.nih.gov/grants/guide/pa-files/PAR-02-051.html.

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*In Brief:*

## Biology Societies Endorse Cloning Prohibition Act

(Continued from page 1)

Tumor Patient Education and Resource Center. Moffitt received a $35,500 grant from the American Brain Tumor Association to open the center, designed to help patients find information on their disease. . . . **HUMAN CLONING** Prohibition Act of 2001 (S1758) has been endorsed by a coalition of research organizations led by the Federation of American Societies for Experimental Biology. The groups signed a letter (http://www.faseb.org/opa/ppp/ltr_1x24x02.html) supporting the bill, which bans reproductive cloning but allows the use of somatic cell nuclear transfer for therapeutic and scientific purposes. "Any legislative ban on human cloning must not prohibit therapeutic cloning," according to the letter. "This technology employs somatic cell nuclear transfer, a technique that has enormous potential to treat human diseases and repair damaged tissues or organs." . . . **MIZZOU RATS:** A federally-funded Rat Resource and Research Center has opened at the University of Missouri-Columbia. The center will import, cryopreserve, produce, and distribute laboratory rats. Researchers from the University of Missouri-Columbia, Indiana University School of Medicine, Harlan-Sprague Dawley Inc., and Northwestern University Medical School formed the center with a $6.7 million grant from the National Center for Research Resources and the National Heart, Lung, and Blood Institute. The inventory will include various inbred, hybrid and genetically modified rats, provided by investigators who have derived them, but who do not have the resources to cryopreserve and broadly distribute them. There are more mutant rat strains than there is capacity to make them available in pathogen-free form to the research community, NCRR said. The center also will provide services include genotyping, phenotyping, and testing for and eliminating pathogens. The center also plans to conduct research to develop lower-cost methods for cryopreservation, new methods for testing for pathogens, and methods for "cloning" rats by nuclear transfer techniques. "The mouse and rat genomes are currently being mapped and sequenced, and this activity is expected to facilitate derivation of even more mutant rats in the near future," said NCRR Director **Judith Vaitukaitis**. "The RRRC should therefore markedly increase the use of specific rat strains and mutants for research and thus facilitate the use of these animals to understand problems of human health and physiology."

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