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FDA Approves Tamoxifen For "Reduction In Incidence," Avoids Word "Prevention"

FDA last Thursday approved Nolvadex (tamoxifen citrate) for the "reduction in breast cancer incidence in high-risk women."

The label does not allow the drug's sponsor, Zeneca Pharmaceuticals, to claim that the drug "prevents" breast cancer in high-risk populations, a claim requested by the company in the supplemental New Drug Application.

However, in a move that benefited the company, FDA did not follow its advisory committee's recommendation that the drug be approved for

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In Brief:

UC Irvine Wins Grant For Trial Of One-Visit Cervical Cancer Screening, Treatment

UNIVERSITY OF CALIFORNIA at Irvine College of Medicine received a $2.7 million grant from NCI to study a new approach for the early detection and prevention of cervical cancer that involves screening, diagnosing, and treating patients all in one visit. Because the study will include as many as 3,500 women, researchers also will examine whether environmental and genetic factors increase the risk of getting cervical cancer. **Alberto Manetta**, senior associate dean at UCI College of Medicine and a researcher on the project, estimated that 20 to 40 percent of patients with abnormal Pap smear readings do not return for further testing and treatment. Since cervical cancer affects 500,000 women worldwide each year, "an enormous number of women are missing needed treatment because they don't return for followup care," Manetta said. Manetta and colleagues **Hoda Anton-Culver,** head of cancer epidemiology, and **Alan Hubbell**, head of primary care, will conduct the five-year study. Half of the 3,500 women will undergo Pap smear screening and receive diagnosis and treatment, if necessary, during the same visit. The other half will receive traditional care with multiple visits. . . . **PETER SCHULTZ** was appointed head of the Novartis Institute for Functional Genomics, effective Jan. 1. Schultz is professor of chemistry at University of California, Berkeley, and investigator, Howard Hughes Medical Institute. He is widely recognized for his pioneering work at the interface of chemistry and biology. The institute, announced last April, is to be located in La Jolla, CA. "By bringing together a group of highly creative chemists, biologists, and engineers, and equipping them with

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Label Expanded To Include Contralateral Breast Cancer

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the "short term" reduction of the incidence of breast cancer.

"[The label] does not specifically say 'short-term,'" Susan Honig, medical officer in the FDA Division of Oncology Drug Products, said in a conference call that announced the approval to patient advocacy groups. "We felt that it was more descriptive and helpful to list all of the factors that actually occurred in the study. That provided more information than just saying 'short-term.'"

FDA also expanded the tamoxifen label to include the reduction in the incidence of contralateral breast cancer. The FDA Oncologic Drugs Advisory Committee was not asked to comment on the contralateral indication, which was based in part on the results of the B-14 trial. That trial provided the intellectual justification for conducting the P-1 prevention trial. Both trials were conducted by the National Surgical Adjuvant Breast and Bowel Project.

In another change, the label now includes data that support five years of adjuvant therapy with tamoxifen for patients with breast cancer.

The Oct. 29 approval of new indications had the appearance of a last-minute deal. Since Zeneca filed the SNDA for prevention of breast cancer on April 30, the six-month deadline imposed by law was running out.

However, until the last moment, the agency and the sponsor were locked in negotiations over labeling, Zeneca officials said.

Just in case no agreement would be reached, the agency made preparations to return to ODAC to seek additional guidance. In mid-October, FDA anounced that at a regular meeting Nov. 17, ODAC would be asked to help settle some fundamental disagreements:

"The committee will discuss... whether the indication should be 'for reducing the short term incidence of breast cancer' in women at high risk of developing the disease or 'as a preventative agent for the reduction of breast cancer in women at high risk for developing the disease. The term prevention indicates a reduction in the incidence (risk) of invasive breast cancer over the period of the NSABP P-1 trial, and does not necessarily imply that the initiation of breast cancer has been prevented or that the tumors have been permanently eliminated.'"

Anyone who had attended the original ODAC debate of the definitions would have seen that the committee debate was exhaustive and its rejection of the term "prevent" unanimous. No special insight would have been required to see that the prospect of watching the committee do the same thing again could not possibly have been relished by Zeneca.

The wording of the final label appears to show a softening of the two positions described in the meeting announcement. The words "short term" were eliminated. However, the claim to the word "prevent" was abandoned, too.

After announcing the drug's approval and releasing the new text of the label, FDA cancelled the Nov. 17 meeting.

Defining The P-Word

The most significant of the changes—the downgrading from "prevention" to "reduction of incidence"—occurred after ODAC in its Sept. 2 meeting voted unanimously that the data from the Breast Cancer Prevention Trial (P-1), on which the Zeneca application was based, was insufficient to support the claim to prevention.

In the trial, women treated with tamoxifen had 44 percent fewer breast cancer cases than women on the placebo arm.

However, ODAC members said the "prevention" indication could not be justified.

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Committee members said follow-up was insufficient and it was unclear which subsets of patients stood to benefit the most from tamoxifen (**The Cancer Letter**, Sept. 11).

"The concern I have is with the word 'prevention,'" said George Sledge, a consultant to ODAC at the Sept. 2 session. "This is a trial of very short follow-up. Everything we know about breast cancer is that it is a disease that takes a long term to go from a premalignant to an invasive, malignant state.

"Here, we are seeing effects within a year of starting the drug. While those may be beneficial effects in and of themselves, they are not prevention in the way that scientists understand the word prevention.

"While I would be comfortable saying that we have demonstrated risk reduction with this very well-controlled, very well-performed trial, I don't think it has met the bar of what a scientist would consider a chemopreventive effect," said Sledge, an oncologist at the University of Indiana.

The committee's decision was entirely unexpected by the company, NCI, and the investigators, sources said. ODAC had reviewed the breast cancer trial protocol on three occasions. The committee approved the concept in 1990, signed off on the protocol in 1991, and recommended protocol modifications in 1994.

However, at the Sept. 2 session, ODAC voted 11-0 against approval of tamoxifen for prevention of breast cancer. Once the offending word was replaced with "short-term reduction of incidence," the committee recommended approval in a 9-0 vote, with two members abstaining.

The question of the definition of the word "prevention" goes beyond linguistic hairsplitting. Different FDA committees have used criteria of varying stringency as they defined prevention of heart disease and osteoperosis.

A transcript of the ODAC attempt to translate the findings of the P-1 trial into the language of a drug package insert is available on the FDA web site, http://www.fda.gov/cder/news/tamoxifen/.

The Fate of a Fine Distinction

In mid-October, shortly after the ODAC meeting, Mark Krueger, a consultant to Zeneca, wrote letters to several patient groups in an apparent effort to orchestrate their support for the drug.

"Although the [Breast Cancer Prevention Trial] represents a significant breakthrough in the prevention of breast cancer, tamoxifen is not appropriate for every woman at risk," Kreueger wrote in a letter to one of the groups, cleverly stringing together the p-word, "breakthough," and a caveat.

Krueger had a little proposition to the advocacy group:

"Enclosed is a...camera-ready article on the results of the trial for possible inclusion in your newsletter."

The brief article described the paper on the P-1 trial publised in the Sept. 16 issue of the Journal of the National Cancer Institute, adding that FDA "is considering whether to approve tamoxifen...for use in preventing breast cancer in healthy women considered at high risk.

"In August, a panel of doctors who advise FDA voted to recommend this use," the proposed article states.

Actually, the panel did nothing of the sort. It voted 11-0 against the use of the word "prevent."

"I see where that could be confusing," acknowledged Mary Lynn Carver, a Zeneca spokesman. "We did not clearly state specifically what ODAC was discussing in-depth. What we were trying to do was to get this information to the advocacy community."

The materials Krueger sent out were first reviewed by the company, Carver said to **The Cancer Letter**.

"The timing of when [the letter] went out is very important here," Carver said. "It was after ODAC, but before any decision was made by FDA. There was still a great deal of ongoing discussion between all parties—NCI, NSABP, FDA, ourselves, the advocacy groups—over whether this was still going to be called 'prevention' or 'reduction of incidence.'"

Recently, a federal judge ruled that the First Amendment applies to drug companies seeking to distribute unedited reprints from peer-reviewed journals. However, this protection does not apply to materials generated by the drug companies (**The Cancer Letter**, Aug. 14).

The materials did not benefit Zeneca. After obtaining a copy of Krueger's letter and article, Cindy Pearson, executive director of the National Women's Health Network, said her group was "concerned that the company has already sent misleading letters that describe the drug as preventing breast cancer."

Krueger did not return repeated calls from **The Cancer Letter**.

P-Word Survives Approval

After FDA approved the new indication for Tamoxifen, Zeneca and HHS issued press releases that were consistent with the language of the label.

However, not all press releases were sensitive to approved semantics. "The Pennsylvania Breast Cancer Coalition applauds FDA for approving tamoxifen as the first drug to help prevent breast cancer in healthy women who are regarded at very high risk of developing the disease," proclaimed the coalition.

The word "prevention" appeared throughout press coverage of the approval. Even when reporters understood the significance of the terminology, headline writers appeared to ignore them.

The lead of the Reuters story said simply that tamoxifen was approved for preventing breast cancer in healthy women. High risk was not mentioned until the fifth paragraph. The New York Times and Los Angeles Times similarly used "prevention" in the lead and the headline. The New York Times worked in the offending word by saying that tamoxifen could "help prevent or delay" the disease in high-risk women.

While oncologists and epidemiologists may be able to understand the subtle concepts in the tamoxifen label, women who will want to consider the drug and general practitioners who will prescribe it may have a harder time discerning a reasonable risk from one that is gratuitous.

"The focus that was set from Day One is that it is an educational campaign around risk assessment," said Zeneca spokesman Carver. "We definitely have a lot of education to do as to what the risk factors are."

Zeneca said it plans to distribute a breast cancer risk assessment model to health care professionals nationwide. The model—called the "Gail Model"—was developed by NCI and used to determine eligibility for the P-1 trial. Now NCI is adapting the model for broader use.

Patient advocacy groups could prove to be the most reliable sefeguard against overuse of the drug.

Nearly all groups are urging patients and physicians to use caution in requesting and prescribing the drug. "The National Breast Cancer Coalition is concerned that despite the fact that tamoxifen was not approved for prevention, many women concerned with developing breast cancer will view this as a new wonder drug," the coalition said in a statement.

"In deciding whether to take tamoxifen, women need to consider their age, personal and family history, and other known breast cancer risk factors," the Susan G. Komen Breast Cancer Foundation said in a statement. "Further, the drug's side effects, some of which may be life threatening, must be taken into account."

Early next year, the American Society of Clinical Oncology is expected to issue a "technology assessment" of tamoxifen and the Eli Lilly & Co. drug Evista (raloxifene hydrochloride).

"No one has yet undertaken an independent assessment of the data to determine who would benefit most from these drugs," said Rowan Chlebowski, a medical oncologist from the Univ. of California at Los Angeles Harbor Medical center, co-chairman of the ASCO working group developing the recommendations.

"Oncologists are seeing more and more healthy women who think they are at risk of breast cancer and want to do everything possible to prevent it," Chlebowski said. "But these drugs are not for everyone, and may in fact only be appropriate for a select group of women."

The assessment, which will attempt to define the risks and benefits of the two drugs, will be published in the society's Journal of Clinical Oncology.

NCI Programs:

NCI Plans At Least $20M Raise For Cooperative Groups

SAN ANTONIO—The NCI-supported clinical trials cooperative groups can expect their funding to increase by 20 to 25 percent this year, Institute Director Richard Klausner said to members of the Southwest Oncology Group.

Klausner said the new funding, about $20 million to $30 million, would go partly towards correcting past underfunding of the cooperative groups. NCI allocated $93.9 million to the cooperative groups in fiscal 1998.

"The clinical trials system, and particularly the cooperative group system, is the most underfunded component of all that is funded by the NCI, and I have made a commitment to correct that," Klausner said in a speech at the plenary session of the SWOG Fall Meeting on Oct. 23.

Klausner said the promise of a more effective cancer clinical trials system was important in making

a convincing argument before Congress to increase funding for NCI.

In his remarks, Klausner described the Institute's plans for making cooperative groups more effective. The key component of this new program will be a competitive system that allows "idea generators" in the field to feed ideas into disease-specific concept review committees. The new system will be tested in pilot studies (**The Cancer Letter**, Oct. 9).

"We want to have a trials system open enough and large enough so that any patient has the opportunity to consider a high quality clinical trial," he said.

Also critical is NCI support and participation in developing an informatics infrastructure to set common standards for cooperative groups, he said.

"We must demand that all the clinical trials systems that we support move towards an integrated, paperless informatics system, so that SWOG can talk to everyone else, including industry, and that we can integrate that with the expectations of regulatory agencies," Klausner said.

NCI's spending on the pilot studies and informatics will be in addition to the 20 to 25 percent increase in funding for the cooperative groups, he said.

CALGB To Test Centralized Review

Centralized institutional review boards will be another feature of a streamlined system, Klausner said.

After more than two years of negotiations between NCI and the Office for Protection From Research Risks, the OPRR has approved a demonstration project with the Cancer and Leukemia Group B to determine the value and utility of a central IRB for multicenter trials, he said.

"If this works, it will take away an extremely important impediment to rapidly initiating trials, especially across multiple centers," Klausner said.

To spare cooperative groups from some of the "nuts and bolts" work of organizing future trials, Clinical Trials Support Units will be formed to coordinate and integrate administrative tasks for all 12 cooperative groups.

"The originating site of a trial will, in essence, be transparent, and anyone within the network will be able to participate in any of the available trials," Klausner said.

A pilot study using CTSUs will be implemented this year for genitourinary and lung cancer trials, he said.

In remarks after his speech, Klausner said the pilot projects are consonant with what the cooperative groups have asked for, and should serve to strengthen them rather than to lessen any group's autonomy.

"These pilots are going to make it more attractive for many people to participate in clinical trials," Klausner said. "The one thing cooperative groups say they want is an open and streamlined system, and streamlining means not having to do the 'stuff' that drives all of us crazy."

"To the extent that the entire research enterprise sees the cooperative group system as the network of collaborators to bring ideas to, that is a way we can expand the world of interactions across the cancer community," Klausner said.

SWOG Chairman Charles Coltman Jr. said that a streamlined system would open registration to physicians who have not historically been involved in clinical trials, and also increase cooperation between groups.

"We are long overdue for commonality in forms, in protocol format, in endpoints, and in statistical methodology," Coltman said. "The absence of those have been major impediments for interacting across groups."

But even if all these aspects are the same for all investigators, Coltman said, individual groups would still benefit from their own commitment and intellectual property in the clinical trial designs, methodology and correlative studies.

Other innovations Klausner described include NCI's Cancer Genome Anatomy Project, whose object is the molecular classification of genes expressed in all stages of tumor development; the web-based Cancer Chromosome Aberration Project to describe the cytogenetics of cancer; the Gene Annotation Index of naturally occurring genetic variations; and a series of chemistry-biology centers to create natural product libraries and link them to high-throughput drug discovery centers.

Also, all NCI training programs are being revamped, Klausner said. The Institute will create a new K22 transitional award for investigators just becoming independent, K30 awards for institutions to create didactic frameworks for clinical research, and a K24 program for training mid-level and senior clinicians. The K24, which will provide annual salaries of up to $75,000, begins funding this year.

Review Group Report:

NCI Role In Drug Development Seen As Information Provider

The NCI Developmental Therapeutics Program should provide more information and resources to cancer researchers working in drug development, fund new "centers of excellence," and cut back its 60-cell line screen to just three cell lines, a review committee advised in a report to the Institute.

The program, founded in 1955, has made major contributions to the development of cancer drugs, but now needs to be reconfigured and, in some areas, expanded to meet the needs of rapidly changing science and technology, said the report by the Developmental Therapeutics Review Group.

"An important role of DTP should be to assume a leadership position in informatics to facilitate the development of cancer therapeutics," the report said. "Resources such as the natural products repositories, select chemical libraries, engineered cell lines, hybridization assay technology, standardized reagents for cancer immunotherapy, and information databases useful in the determination of protein structures, should be made available by DTP to qualified investigators."

In other recommendations, the review group said:

—NCI should limit the intramural portion of the DTP budget to 15 percent of the program's total budget. Extramural funding, 85 percent of the budget, should be used to fund cooperative groups such as the National Cooperative Drug Discovery Groups, Natural Products Discovery Groups, contracts, and centers of excellence.

—NCI should form an oversight committee of five to eight scientists from DTP, academia, and industry to evaluate and fund projects that are submitted to DTP through the extramural program or proposed by DTP staff. The committee should have a budget of $50 million.

—The Decision Network Committee, responsible for prioritizing drugs for clinical development, should be opened to representatives from academia, cancer centers, and other NCI staff.

—NCI should establish a review mechanism to continuously evaluate the status of screening assays.

"There are three areas in which NCI and DTP can have a major impact on cancer therapeutics development in addition to carrying out a reconfigured screening program: a) in providing public access to its repository of compounds, research tools, and information databases; b) in working with the academic and industrial communities to develop, evaluate, and deploy new assays in both the internal and external scientific communities; and c) in fostering a more collaborative approach to screening by serving as a matchmaker between chemists and biologists for the analysis of novel agents," the review group's report said.

The report was presented to a recent meeting of the NCI Board of Scientific Advisors.

Other recommendations of the report:

—NCI should support a chemical diversity program with the explicit goal of finding small molecules that can manipulate the function of all proteins or processes relevant to cancer.

—NCI should undertake a major new interdisciplinary initiative to acquire structural information on cellular targets that are potentially relevant to cancer. This would include establishment of an instrumentation and education resource dedicated to making X-ray crystallography broadly accessible to members of the cancer research community, in addition to vigorous participation in efforts to determine the structure of all proteins encoded in the human genome—alone and in complex with interacting cellular partners—that may be involved in the malignant process.

—NCI should reconfigure its program for screening compounds for anti-tumor activity to ensure responsiveness to changes in science and technology. The current 60-cell-line screen should be reduced to 3 cell lines focused on the identification of lead compounds based on inhibition of cell proliferation. NCI should establish a network of extramural sites that have expertise in the development of new assays to assess the effects of compounds on the biochemical, cell biological, and tissue physiological parameters that govern cancer cell pathogenesis and pathophysiology.

—NCI should establish Centers of Excellence in a variety of scientific areas, for example, pharmacology/toxicology core facilities with the technology in place to do state-of-the-art drug metabolism, pharmacokinetics, and drug absorption studies and simulations. NCI should develop methods to allow more accurate a priori determination of the potential for metabolism and/or toxicity.

—NCI should expand the scope of the Biologic Resources Branch by augmenting the categories of biological reagents that are currently being produced,

and developing capabilities for production of recombinant vectors and novel production technologies.

"Report of the National Cancer Institute Developmental Therapeutics Review Group," is available on the NCI website at the following address: http://deainfo.NCI.nih.gov/advisory/bscdevtherprgmmin.htm.

NCI Offers Simplified Language For Informed Consent Forms

NCI has recommended simplified language for informed consent documents to make the forms more understandable to people considering participation in a cancer clinical trial.

In a recent mailing to Institutional Review Boards, hospitals, cancer centers, patient groups, and individual researchers, NCI offered specific guidelines for clarifying informed consent documents. Included with the recommendations were computer disks with a model form that investigators can use in developing their own documents.

The packet is intended to support researchers who write consent forms and assist local IRBs in reviewing the documents, the Institute said. "The ultimate goal is to increase patients' understanding of studies, and provide them with a sound foundation for decision-making," said Mary McCabe, director of the NCI Office of Clinical Research Promotion.

The guidelines were developed by the Comprehensive Working Group on Informed Consent in Cancer Clinical Trials, which included representatives of the NIH Office for Protection From Research Risks and the Food and Drug Administration, as well as research physicians and nurses, patient advocates, IRB members, communications and legal experts, ethicists, and representatives of the pharmaceutical industry.

The recommendations and model template were evaluated through a series of focus groups with patients, physicians, nurses, IRB members, and clinical research associates.

The Working Group made recommendations regarding specific elements in the consent form, such as the study's objectives, risks, and benefits. It also made general recommendations concerning readability and information access.

Some examples:

—The consent form should clearly and simply explain the research study and state why the potential research participant is eligible to enroll. The main objective of the proposed study should be placed in the context of standard care.

—Risks should be presented for the entire regimen rather than listing the risks for each specific drug or procedure that comprise the intervention.

—No investigational approach should be identified as the only chance for cure or contrasted with standard approaches that offer no chance of cure.

—Informed consent documents should be understandable to the patient population at the local facility. Documents should be written at an eighth grade or lower reading level.

—The research participant should be informed about and provided access to supplemental information during the initial decision-making process and throughout the research trial.

In addition to the recommendations, the Working Group developed sample consent forms for four current NCI-sponsored studies. The samples are included in the packet along with the guidelines and the template. The informed consent materials are available on the NCI Web site for clinical trials, http://cancertrials.nci.nih.gov.

NCI RFP Available

RFP N01-CP-91002-21

Title: **Record Linkage Studies Utilizing Resources In Population-Based Tumor Registries (Master Agreement Annual Solicitation)**

Deadline: Approximately Jan. 5, 1999

The NCI Division of Cancer Epidemiology and Genetics, Radiation Epidemiology Branch, is seeking offerors for a Master Agreement Pool for Record Linkage Studies. A MA will be awarded under this title to each acceptable offeror. NCI wishes to contract with population-based tumor registries in the US and other countries in order to collaborate in the conduct of record-linkage and subsequent analytical investigations. The duties required in support of the record-linkage studies include: develop a study plan which includes the evaluation of existing records that are potentially valuable for record-linkage, develop or apply the appropriate record-linkage procedures to link a "population file" with the cancer registry files, and provide results of the record-linkage study to the Project Officer either on computer tape or in tabulated form as requested. Offerors should have cancer incidence data for all patients diagnosed within a defined geographic locale for at least five years, and have the ability to ascertain all cancer cases within the registries' catchment area of women of all age groups and U.S. minority populations, as appropriate.

The offerors must have experience in the collection of cancer data from a variety of medical sources and multiple institutions, and must have legal authority to collect medical data within the given geographic area or be able to demonstrate the willingness of all medical facilities within that area to participate in data collection and patient follow-up activities. The current MA Pool is effective from March 15, 1996 through March 14, 2000. The RFP is available at: http://amb.nci.nih.gov/rfp.htm.

Contact: Barbara Shadrick, email: bs92y@nih.gov; fax: 301-480-0241; phone 301-435-3787.

In Brief:

John Kersey Leads ASBMT

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powerful new genomic and chemical technologies, the institute will be a world-class leader in biomedical research," Schultz said. The institute will receive funding of $250 million over 10 years, according to a statement by the Novartis Research Foundation. . . . **JOHN KERSEY**, Univ. of Minnesota pioneer in bone marrow transplantation for treatment of leukemia and lymphoma, has been installed as president of the American Society for Blood and Marrow Transplantation. **Allan Eaves**, Terry Fox Laboratory, Vancouver, is president elect; and **James Armitage**, Univ. of Nebraska College of Medicine, is vice president. New directors are **Joseph Antin**, Dana-Farber Cancer Institute; **Richard Champlin**, M.D. Anderson Cancer Center; **John Hansen**, Fred Hutchinson Cancer Research Center; **Armand Keating**, Univ. of Toronto; **Elizabeth Shpall**, Univ. of Colorado; and **John Wingard**, Univ. of Florida College of Medicine. Continuing on the board are **Neal Flomenberg**, Thomas Jefferson Univ., secretary; and **Robertson Parkman**, Childrens Hospital of Los Angeles, treasurer. . . . **ASBMT** presented awards at its recent annual meeting to **Claude Lenfant**, director of the National Heart, Lung, & Blood Institute, for his contributions to medical research and public health policy that have benefited bone marrow transplant patients; and to Nobel laureate **E. Donnall Thomas**, for a lifetime of achievement in hematopoietic stem cell transplantation. . . . **DENNIS SLAMON**, director of the Revlon/UCLA Women's Cancer Research Program at Jonsson Cancer Center, received the National Breast Cancer Coalition Public Advocacy Award. Slamon was recognized for his work that led to the development of Herceptin, approved by FDA in September for use against metastatic breast cancer. . . . **UNIV. OF PITTSBURGH** Cancer Institute awards presented at its annual leadership dinner: Golf legend **Arnold Palmer**, a prostate cancer survivor, received the Spirit of Hope Award; **Robert Hannan**, former president of Thrift Drug, received the Arthur F. McNulty Civic Leadership Award; **Theresa Whiteside**, codirector of UPCI's Biological Therapeutics Program, received the UPCI Scientific Leadership Award; the late **Herbert Jacob**, who played a central role in treatment of patients with advanced breast cancer at the Magee-Womens Hospital/UPCI Breast Program, received posthumously the Leo H. Criep Excellence in Patient Care Award; **Terry Evans**, clinical assistant professor of medicine, also received the Leo H. Criep Award; and **Joyce Herschl**, director of oncology social work services at UPCI, received the UPCI Excellence in Patient Care award. . . . **LUTHER BRADY**, professor of radiation oncology at MCP/Hahnemann Univ. School of Medicine, has been awarded the Silver Medal of the Fondazione Internationale Menarini and Univ. of Pisa in recognition of scientific excellence. . . . **JOHN DIBIAGGIO**, president of Tufts Univ., has been elected president of the American Cancer Society Foundation Board of Trustees. The foundation is the capital gift and endowment arm of ACS. To date over $43 million has been raised to support cancer control programs since it was established in 1992. . . . **UNIVERSITY OF SOUTHERN CALIFORNIA** Norris Comprehensive Cancer Center hosted "Conquering Cancer in the New Millenium," a series of lectures on Oct. 29, in celebration of 25 years of cancer research at the center. Center director **Peter Jones** presented an overview of achievements at the center. USC researchers who discussed their work included **Mimi Yu, Malcolm Pike, Ronald Ross, Michael Lai, Amy Lee, Michael Lieber, W. French Anderson, Jeffery Weber, Robert Seeger, Michael Press, Donald Skinner, Alexandra Levine, Leslie Bernstein, Robert Haile, Peter Brooks, Donald Kohn,** and **Derek Raghavan**. NCI Director **Richard Klausner** wrapped up the conference with an address on the national cancer research agenda. . . .**WORMS FROM FOX CHASE** Cancer Center lab of **Eric Moss** orbited Earth on the space shuttle Discovery this week in a science project by students at Northeast High School in Philadelphia. Goal of the study was to determine whether space travel alters the life span of the *C. elegans* worms, which live about 18 days. A worm control group remained on the ground. Results are expected soon.