THE CANCER LETTER INTERACTIVE

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Sponsors Wanted: FDA Offers Incentives For Pediatric Oncology Drug Development

Over the next several weeks, pharmaceutical companies will receive requests from FDA to begin clinical trials in pediatric oncology.

The unprecedented requests are part of an effort by the agency to generate the industry's interest in pediatric exclusivity provisions of the FDA Modernization Act of 1997.

"It's a unique situation that needs unique problem-solving," said Richard Pazdur, director of the FDA Division of Oncology Drug Products, who has been grappling with pediatric oncology issues since moving to the agency from M.D. Anderson Cancer Center last fall. "If the only

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In Brief:

March Dedicated To Colorectal Cancer Awareness; New Advocacy Group Formed

PRESIDENT CLINTON proclaimed March the first annual National Colorectal Cancer Awareness Month and encouraged the health care community to raise public awareness about early detection and treatment of the disease. "New technologies are giving us more powerful tools to incease the ease and accuracy of colorectal screening," the proclamation said. "By continuing to support such research, raising awareness of risk factors for the disease, promoting the widespread adoption of regular screening, and encouraging everyone to exercise regularly, we can save thousands of lives each year and dramatically reduce the risk of colorectal cancer." . . . **NATIONAL COLORECTAL CANCER RESEARCH ALLIANCE** began an education, fundraising and media campaign on the eve of the first annual commemoration of National Colorectal Cancer Awareness Month. **Katie Couric** and **Lilly Tartikoff**, along with Entertainment Industry Foundation, the leading philanthropic trade organization, founded NCCRA. NCCRA is a collaborating partner in an initiative begun this month by the Cancer Research Foundation and 34 health organizations to unify their efforts. Working with other colorectal cancer groups, NCCRA plans to make a silver star the symbol for the disease. . . **AMERICAN COLLEGE** Of Gastroenterology, which has joined with the 34 collaborating organizations to encourage risk reduction for colorectal cancer through healthy lifestyle choices and to promote regular screenings after age 50, will provide information at a toll-free health line for consumers at 800-978-7666 and on their Web site at http://www.acg.gi.com. . . . **CANCER RESEARCH**

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FDA Seeks To "Jump-Start" Pediatric Cancer Drug Trials

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thing I did coming to FDA was to help jump-start this, then the trip from Houston was well worth it."

The challenge Pazdur is confronting is as old as pediatric oncology. Since pediatric cancer is rare, the markets are small, and drug companies are reluctant to test drugs in children. As a result, in many cases, drugs clear phase III studies in adults before they enter phase I studies in children. If Pazdur succeeds, he may enhance the role of the oncology division in the clinical trials process and improve the transparency of the agency's actions.

The requests represent just one aspect of Pazdur's approach to the problem:

—Next September, the FDA will convene the first session of a pediatric subcommittee of the Oncologic Drugs Advisory Committee. Though the subcommittee is unlikely to have any drug applications to review, it will help guide the agency through policy decisions in childhood cancer.

—FDA is compiling a "Guidance to Industry" which describes the agency interpretation of FDAMA as it relates to pediatric oncology. The law was designed to drum up interest in pediatric research by offering companies six months of additional exclusivity for conducting pediatric studies.

An earlier guidance addressed pediatrics as a whole. Over the past two years, the agency has received about 160 proposals for pediatric studies, issued over 125 requests for studies, and issued 15 extensions in pediatrics, officials said. None of those extensions was in pediatric oncology. Only five inquiries in pediatric oncology have come to the agency in the two years since the law was enacted, and just one of those inquiries has led the agency to request that the sponsor perform a study.

—In a recent "Dear Sponsor" letter, Pazdur urged pharmaceutical companies to work with the NCI-supported clinical trials cooperative groups in developing pediatric drugs.

"We suggest that sponsors discuss a pediatric development plan with a pediatric cooperative study group to utilize their expertise and resources to optimize study design and patient accrual and to determine which cancers should be studied," he wrote in the letter dated Feb. 11. The letter is posted on the agency's web site at http://www.fda.gov/cder/pediatric/pedcancerletter.htm.

A Present for Henry Friedman

The agency's grappling with the FDAMA provisions in pediatric oncology are illustrative of unique challenges of the specialty that functions differently from both general pediatrics and adult oncology.

It is a field where nearly all patients are treated on protocols, nearly all drugs are used off label, and more than half of the patients are cured with first-line regimens. While the rest of oncology is Balkanized, pediatric oncology is shattering the barriers between principalities to organize a single clinical trials cooperative group by early 2001.

The unification of two principal NCI pediatric cancer cooperative groups is intended to help pediatric oncologists cope with the extraordinary pressure on the clinical trials system. First—fortunately—patients are scarce. Fewer than half of the estimated 13,000 patients a year need second-line therapy.

While patients are scarce, drug candidates are more so. "Pediatric groups are saying they have more patients than agents," said Steven Hirschfeld, a pediatric oncologist and medical officer at the FDA Center for Drug Evaluation and Research. "The availability of agents is the limiting factor. Any previously approved agent that has had a hint of being useful has generally been studied."

Though pediatric oncologists often speak of multiple "disconnects" in incentives for sponsors, an

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argument can be made that the profit motive in pediatric oncology works perfectly: Drug companies see no gain in developing drugs for populations of a few hundred children.

"Pediatric cancer is a relatively small problem," said Gregory Reaman, chairman of the division of hematology and oncology at Children's National Medical Center, vice chairman for scientific affairs of Children's Cancer Group, and the group's associate chairman for new agent studies. "Developing agents and testing agents in children doesn't do a whole lot from the financial incentivization perspective for pharmaceutical sponsors."

CCG Chairman Archie Bleyer said that in the 1960's and 1970's, most of the antitumor agents used in adult patients were first discovered to be effective in children. However, since 1980, only one drug was approved for use in childhood cancers, compared with 34 approved for use in adults.

Fed up with having to beg for agents, Duke University pediatric oncologist Henry Friedman decided to expand his translational research to adults five years ago.

"Most companies see rationale in doing adult brain tumors," said Friedman, co-chairman of the new agents subcommittee of the Children's Oncology Group brain tumor committee, and chairman of committee on new agents for the Pediatric Brain Tumor Consortium.

Conducting about 20 company-sponsored brain tumor trials in adults puts Friedman in good position to convince drug companies to let him conduct as many as five trials in children.

"I am treated by the drug companies as a good customer, so my Christmas present, in lieu of a ham, is the opportunity to do pediatric trials," Friedman said to **The Cancer Letter**. "It's a good will contribution. They truly believe at a scientific and a clinical investigation level that the trials are sound. At the commercial level, it's a write-off."

Generally, FDA has tried to put as much information about a drug as possible on the package insert. In pediatric oncology, where drugs are almost always used off-label and in multi-drug regimens, that's not useful.

"Many of the obstacles that FDA has previously put in place for pharmaceutical companies to test new agents in children relate to the fact that the studies need to lead to labeling indications," Reaman said to **The Cancer Letter**. "In pediatric oncology, using labeling as an endpoint is definitely wrong. It's nice to have labeling, but competent specialists who treat the overwhelming majority of children with cancer in this country don't use package inserts as a replacement for peer-reviewed literature."

What To Do?

After FDAMA was enacted, the agency spent months writing a guidance document covering all pediatrics.

FDA medical officer Hirschfeld spent two frustrating years trying to interest sponsors and investigators in pediatric oncology incentives. Hirschfeld took his message to cooperative groups, NCI-sponsored phase I meetings, and meetings of the American Association of Pharmaceutical Scientists. "Every time a sponsor came in to FDA, they left with information packet on pediatric exclusivity," Hirschfeld said to **The Cancer Letter.**

Yet, all the slides, letters, information packets, and postings on the CDER web site were no match for confusion reinforced with a lack of interest.

People who are generally accustomed to dealing with complex issues became hopelessly bewildered by the distinction between the 1997 FDAMA pediatric exclusivity provision, and the 1998 Pediatric Rule, which mandates that drug companies undertake pediatric studies if diseases they seek to treat are the same in children and in adults, Hirschfeld said.

Another source of confusion was a "priority list" of drugs eligible for exclusivity extension under FDAMA. That list includes drugs for diseases believed to be the same in children and in adults.

"People come to an understanding that you can only get exclusivity if the disease is the same," Hirschfeld said. Actually, FDA can consider proposals for drugs that are not on the priority list. "We maintain the priority list to comply with the law, but eligibility for an extension is not restricted to the priority list."

Some sponsors expressed an interest, but there was little follow-up, Hirschfeld said.

"I've had a dozen conversations with sponsors who say they are interested, and they are doing something, but they are not far enough along, and when I check with them—I check with two or three regularly—they say, 'We are working on it,'" Hirschfeld said.

The questions asked in the five studies proposed by sponsors to the oncology division were far from visionary.

"When I looked at the five proposals, I understood the difficulties that the companies had,"

Pazdur said to **The Cancer Letter**. "There was no evidence of a clear-cut plan of how to develop the drug. They were trying to answer one question—what is the dose? The sponsors were reluctant to jump into a full development plan in pediatrics, which was what would be needed."

Hirschfeld and Pazdur were not alone in their frustration.

"Two years have passed without any benefit to children with cancer," Susan Weiner, president of the Children's Cause, a pediatric cancer advocacy group, said to **The Cancer Letter**. "The law sunsets in another two years."

Exclusivity for Negative Data

Last summer, Weiner and Washington attorney Samuel Turner challenged the agency on its implementation of the pediatric exclusivity provisions of FDAMA.

Turner, whose clients include the Children's Cause, the American Society of Clinical Oncology, National Coalition for Cancer Survivorship, and Bristol-Myers Squibb, approached many members of Congress as well as Pharmaceutical Research and Manufacturers of America and the American Academy of Pediatrics.

Weiner and Turner were interested in two issues: obtaining exclusivity for new drugs, as well as for drugs currently on the market.

"The questions related to the new age of molecular medicine can't be put off for kids," Weiner said to **The Cancer Letter**. "We have to get new agents here, and while we wait for these, we have to make sure that the child who is diagnosed with a brain tumor who is getting treated with currently available treatments is getting state-of-the-art care."

On Feb. 3 and 4, AAP held a meeting of clinicians, drug development experts, advocates, and regulators to determine why FDAMA was having no impact on pediatric oncology. At the meeting, Murray Lumpkin, CDER Deputy Center Director for Review Management, announced that the agency would offer new ways for sponsors to qualify for six-month exclusivity.

These included exclusivity extensions to sponsors who conduct phase I trials and determine that the therapies are inappropriately toxic for children. Under FDAMA, six month-extensions can also be granted for negative results in phase II trials.

"What we want is a good-faith effort," Pazdur said. "This is a unique situation in regulatory medicine, because the sponsor is obtaining an extension of exclusivity even if clinical trials data would not support approval."

However, information has to be new and generated through prospective commitment. "We are not looking to reward people for dredging up old information," Hirschfeld said. "We are willing to reward people for undertaking a relative limited investment and assuming a limited risk in order to provide new information that would be of value to practitioners and to their patients."

Many drugs that are currently on the market for adult oncology and previously tested in children are unlikely to benefit from the extension. "We can have sympathy, but we can't do anything about someone who has already done the studies," said Hirschfeld. "It's as if you just bought last year's car, and they come out with a fancier new model that's cheaper and better. Legislation is applied prospectively, not retroactively."

The AAP meeting concluded that access to new agents should be given the highest priority.

"The old drugs aren't the issue," Malcolm Smith, head of the pediatric section of the NCI Cancer Therapy Evaluation Program, said to **The Cancer Letter**. "The drugs that are of most concern to us are the drugs that are in the pipeline."

Unable to rely on the invisible hand of the market, AAP meeting participants decided to settle for the next best thing: developing a plan for frequent communications between all players.

To involve drug companies, meeting participants identified pediatric cancer drug development experts working in the industry. This led to the instant formation of a pediatric oncology work group within PhRMA.

"The group will be crucial in furthering the cause of pediatric oncology drug development," said Stephen Spielberg, vice president, pediatric drug development, at Janssen Research Foundation. "Critical to timely study of new drugs is having pediatric oncologists within industry who can act as liaison with children's oncology cooperative groups, NCI, and FDA, and as advocates for pediatric development within their companies."

Discussion at the AAP meeting gave Wiener the idea of creating an independent forum for all the pediatric oncology constituencies. "It needs to be a working group or a task force where people examine the challenges and have the standing to bring about solutions," she said.

Recognizing Existing Structures

On Feb. 11, eight days after the AAP meeting, FDA sent out the "Dear Sponsor" letter that urged the pharmaceutical companies to work through cooperative groups in designing pediatric programs.

"To expedite this initiative, we suggest that sponsors discuss a pediatric development plan with a pediatric cooperative study group to utilize their expertise and resources to optimize study design and patient accrual and to determine which cancers should be studied," the letter said.

Though FDA cannot mandate how sponsors test drugs, the agency decided to point out that participation in clinical trials is the standard of care in pediatric oncology.

"To develop a pediatric drug development program without enlisting the cooperation of industry, NCI, the academic pediatric community, and cooperative groups would not work," Pazdur said in an interview.

Also, by suggesting that sponsors involve cooperative groups, the agency would in effect endorse reliance on the existing system for prioritizing trials, said CTEP pediatrician Smith.

"The benefit of that is that these are the people who have to prioritize among the many agents that could be studied and select the ones that are most promising for the limited number of children," Smith said to **The Cancer Letter**.

"The concern is that decisions not be based on financial considerations, but simply on the science and the potential benefit. Children's cooperative group investigators are the best people to judge that benefit."

The approach outlined in Pazdur's "Dear Sponsor" letter seems to be on the right track, said Sharon Murphy, chairman of the Pediatric Oncology Group and chief of hematology and oncology at Children's Memorial Hospital in Chicago.

"It's a bold statement, and the correct one, I might add," Murphy said to **The Cancer Letter**. In pediatrics, the standard of care is protocol-based, center-based treatment. It's a unique opportunity and a responsibility to work in partnership with NCI and FDA to make these studies happen."

CCG Chairman Bleyer agrees. "My colleagues and I applaud this specific effort of the agency to incentivize the industry," said Bleyer, professor of pediatrics at M.D. Anderson Cancer Center. "It's now up to the industry to respond. The companies have little reason not to include pediatric patients in the development of their agents."

If the incentives work, everyone would benefit, Hirschfeld said.

"Using cooperative groups lowers the sponsors' costs dramatically, because they don't have to spend resources on the infrastructure or patient recruitment," he said. "The advantage to the patients is that they are dealing with physicians who are the most experienced in the field. The advantage to cooperative groups is that they would have access to agents. The advantage to FDA is that we would be comfortable with the quality of the data. And NCI would be assured that the cooperative group mechanism would be strengthened by this type of an arrangement."

The entire spectrum of FDAMA issues will be revisited at the meeting of Children's Cancer Group and Pediatric Oncology Group April 12-16, in Tampa. CCG and POG are in the process of uniting into a single Children's Oncology Group, and have merged their new agents committees. The groups plan to elect new leadership by early 2001.

NCI Programs:

Project Expands Group Studies To Community Oncologists

NCI earlier this week began a pilot project that has the goal of enabling more patients and physicians to participate in phase III cancer clinical trials.

Traditionally, only physicians who are members of NCI cooperative groups have had the opportunity to place patients on large-scale cancer clinical trials. The Expanded Participation Project is designed to extend clinical trials privileges to other qualified oncologists, NCI officials said.

The project will offer oncologists a menu of studies with simplified administration and direct reimbursement for the additional time and effort involved in enrolling patients and collecting research data, NCI said.

The cooperative group system, established in 1955, enrolls about 20,000 patients in NCI-supported multi-institutional clinical trials each year. The 12 groups receive over $140 million in annual funding from NCI and conduct several hundred clinical trials at any given time.

"Cooperative groups have contributed enormously to cancer research," said Richard Ungerleider, EPP project officer and chief of the NCI Clinical Investigations Branch. "Unfortunately, 97

percent of U.S. cancer patients still never participate in a clinical study. The reason is that real or perceived barriers prevent widespread physician participation in cooperative groups."

Sixteen clinical studies for the four most common cancers—breast, lung, prostate, and colorectal—are currently open to EPP physician partners, with more available later this year, NCI said. Each of the studies is still open to its originating cooperative group, which will analyze and publish the results.

The EPP's Internet-based data entry system will allow patient information and study data to be entered directly from physicians' computers.

Because caring for patients in clinical studies requires additional time and effort by the physician and staff, EPP partners are provided $1,500 per patient to cover research-related costs.

The EPP is pilot testing what NCI officials said they hope will become a national network of physicians with access to NCI-sponsored clinical trials. Once under way, this network would allow any oncologist to enroll patients in cooperative group studies via an Internet-based system. By granting wider access to clinical trials, the network should reduce the time it typically takes each phase III study to accrue the hundreds or thousands of necessary patients.

"Trimming the amount of time it takes to complete these studies will speed answers to important treatment questions and quicken advances in cancer care," said Ungerleider.

The EPP is one component of a large-scale plan to restructure and strengthen the NCI clinical trials system. The concept for the EPP grew out of a two-year effort by NCI, its advisory boards, and cooperative group chairmen to study the clinical trials system and develop methods for broadening physician and patient access to trials and completing studies faster.

In 1997, an NCI advisory group, chaired by James Armitage of the University of Nebraska Medical Center, made nearly four dozen recommendations for improving the clinical trials system, including increased funding to the cooperative groups, uniform data collection standards, and improved informatics systems (**The Cancer Letter**, Oct. 3, 1997).

A second panel, the Clinical Trials Implementation Committee, deliberated for nine months about specific ways to improve the system (**The Cancer Letter**, Oct. 9 and June 12, 1998).

So far, 12 organizations have joined EPP:

APN/Impath Research Co., LLC (Fort Lee, NJ), Cancer Research for the Ozarks (Springfield, MO), Coastal Cancer Center (Myrtle Beach, SC), Green Mountain Oncology Group (Bennington, VT), Hematology & Oncology Associates of Eastern Idaho, PLLC (Idaho Falls, ID), Howard University/ PCM (Washington, DC), Kaiser-Permanente Mid-Atlantic (Kensington, MD), Kaiser-Permanente of Northern California (Vallejo, CA), Montgomery & Warmuth M.D., P.A. (St. Augustine, FL), North Idaho Cancer Center (Coeur d'Alene, ID), North Country Oncology/Hematology (Glen Falls, NY), and VA Medical Center (Buffalo, NY).

The EPP Web site is available at: http://light.emmes.com/epp/.

For an overview of NCI's clinical trials restructuring, see http://cancertrials.nci.nih.gov/researchers/restructuring.

A history of NCI's Cooperative Group Program is posted at: http://ctep.info.nih.gov/CoopGroup/_new/_Coop%20Group%20Prog.html.

Science Policy:

Agencies Announce Plans To Monitor Gene Therapy Trials

FDA and NIH earlier this week announced two initiatives to strengthen the safeguards for individuals enrolled in gene therapy clinical trials.

FDA said it will implement a "Gene Therapy Clinical Trial Monitoring Plan," requiring that sponsors of gene therapy trials routinely submit their monitoring plans to the FDA. The agency said the new requirement "addresses emerging evidence that the monitoring by study sponsors of several recent gene therapy trials has been less than adequate.

FDA also said it will conduct surveillance and "for cause" inspections of clinical trials to assess whether the monitoring plans are being followed and whether monitoring has been adequate to identify and correct critical problems. The sponsors will also have to address such issues as the experience and training of the monitors and the adequacy of the monitoring in their plans.

NIH and FDA also said they plan to convene a conference of investigators to review appropriate monitoring practices.

Clinical trial monitors would be selected by and report to the sponsor or the sponsor's designee, such

as a contract research organization. Monitors verify that the rights and well-being of human subjects are protected; that the conduct of the trial is in accordance with the protocol, regulatory requirements, and good clinical practices; and that data reporting (including safety reporting to IRB, FDA, and NIH) is accurate and complete.

Also, in those instances where the gene therapy trial has an independent data and safety monitoring board, the board's findings and recommendations regarding patient safety are shared with the IRB, FDA, and NIH. In some gene therapy trials, one or more of the investigators is also the sponsor or a member or employee of the sponsoring organization. NIH said it will develop procedures to further assure appropriately independent oversight of the conduct of such trials.

"Clinical trial monitoring and responsible reporting must be taken seriously by all parties involved in gene therapy trials," said FDA Commissioner Jane Henney. "Our plan will help restore the confidence in the trials' integrity that is essential if gene therapy studies are to be able to fulfill their potential."

In the second initiative, a series of Gene Transfer Safety Symposia, NIH and FDA will enhance patient safety by providing critical forums for the sharing and analysis of medical and scientific data from gene transfer research.

The symposia, which are expected to take place about four times a year, will bring together leading experts in gene transfer research and give them an opportunity to publicly discuss medical and scientific data germane to their specialties.

The first symposium took place this week during a meeting of the Recombinant DNA Advisory Committee. Scientists and physicians discussed the safety and future clinical applications of a new class of adenoviral vectors that have been extensively altered with the aim of improved safety.

Subsequent symposia will be held at the RAC, FDA's Biological Response Modifier Advisory Committee, and other venues. These symposia will address such gene transfer topics as monitoring of data safety; cardiovascular complications of vector administration; good clinical practice in research; cell and gene therapy guidance development for product quality control and assurance; entry criteria and informed consent for participants in gene transfer research; and use of drugs to control promoters in gene therapy vectors. Future symposia also will focus on topics such as the use of a particular vector, a specific disease for which gene transfer is an experimental therapeutic approach or a specific population of patients enrolled in gene transfer studies, such as newborns, children, the elderly, or normal volunteers.

FDA and NIH also will provide support for professional organizations and academic centers interested in holding safety conferences focused on gene therapy.

"The knowledge and understanding gained through these safety symposia and educational outreach efforts will guide the conduct of current trials and enhance the design of future gene transfer trials to maximize patient safety," said NIH Acting Director Ruth Kirschstein.

FDA also announced it is notifying sponsors of gene therapy trials to supply additional information about cell banks, viral banks, and other gene therapy products produced or generated in their facilities for potential use in human gene therapy studies. Among other gene therapy related information, FDA is asking the sponsors to provide quality control information for each lot of products produced in their facilities or used in their clinical trials.

Funding Opportunities:

RFAs Available

Minority Institution Cancer Center Collaborations Planning Grant

The purpose of this initiative is to help researchers and educators in minority-serving institutions and NCI-designated cancer centers (or other institutions with highly organized, integrated research efforts focused on cancer) plan and initiate, through formal interactions and pilot projects/programs, focused collaborative activities in the areas of cancer research or research training and career development that can successfully compete for support through traditional NCI-sponsored grant mechanisms such as, R01, P01, P50 SPORE, T32, K12, R25.

Comprehensive Minority Institution Cancer Center Partnership Cooperative Agreement

The purpose of this initiative is to implement comprehensive partnerships between minority-serving institutions and NCI-designated cancer centers in cancer research (a required component) and at least one of the following targeted areas: cancer research training and career development, education and outreach to minority communities that will achieve the following general objectives: (1) build and stabilize the independent, competitive research and research training capabilities to MSIs. (2) create a stable, long-term collaborative

relationship between MSI's and NCI-designated cancer centers (or groups of centers) in the areas that focus on problems and issues relevant to the disproportionate cancer incidence and mortality in ethnic minority populations. (3) improve the effectiveness of cancer center research, education and outreach programs designed to benefit ethnic minority populations in the region the cancer center serves. (4) export successful approaches in addressing disproportionate cancer incidence and mortality rates in ethnic minority populations to all NCI cancer centers, as well as other key networks supported by NCI.

Inquiries for both of the above initiatives: Sanya Springfield, Comprehensive Minority Biomedical Branch, Office of Centers, Training and Resources, ODDES, NCI, phone 301-496-7344; e-mail ss165i@nih.gov

In Brief:

NCI Plans Progress Review In Lymphoma This Year

(Continued from page 1)

FOUNDATION OF AMERICA, founding organization of the National Colorectal Cancer Awareness Month initiative, reports that new research reveals Americans are woefully unaware of the warning signs and treatment for colorectal cancer. African Americans and Hispanics/Latinos are twice as unaware of the disease as Caucasians, even though they are more likely to die from colorectal cancer. The survey also found that physicians are not discussing colorectal cancer screening tests with patients at high risk. (For information visit the National Colorectal Cancer Awareness Month's web site at: http://www.preventcancer.org/colorectal.htm). . . . **NCI PLANS** to convene a **Progress Review Group** in lymphoma this year to review the Institute's lymphoma research portfolio, examine scientific opportunities, and recommend methods to speed progress. PRGs in breast and prostate cancer completed their reports to NCI last year (**The Cancer Letter**, Feb. 26, 1999). In a statement, the Lymphoma Research Foundation of America said its advocacy work "resulted in a commitment from" NCI to convene the lymphoma PRG. NCI sources said the PRG was in the works, but the efforts of advocacy groups brought greater attention to the issue. **Reps. Patrick Kennedy** (D-RI) and **John Doolittle** (R-CA) and **Sens. Dianne Feinstein** (D-CA) and **Barbara Boxer** (D-CA) wrote letters to NCI Director **Richard Klausner** encouraging formation of the PRG. . . . **AMERICAN CANCER SOCIETY** and Discovery Health Media have signed a two-year agreement to produce cancer education programming for distribution on the Discovery Health Channel and discoveryhealth.com., a consumer health portal, beginning this spring. A poll, commissioned by the partnership, found that cancer is the number one health concern for Americans. The partnership will incorporate survey data into two television programs and a dozen health minutes to target behavioral change. . . . **ACS** has begun **Stakeholders,** a program that will train locally nominated cancer survivors, family members, ACS volunteers and other non-scientist volunteers to review research grant applications and serve as members of one or more of the 17 peer review committees in the ACS extramural grants division. **David Ringer** is the scientific program director heading the initiative. . . . **FIRST-EVER DECLINE** in overall male cancer deaths was reported by the ACS Department of Epidemiology and Surveillance Research annual cancer statistics update. The decrease is attributed to reductions in deaths from leading cancers among men, namely lung and bronchus, prostate, and colon and rectum cancers, according to the ACS report, published in the Jan/Feb. issue of CA—A Cancer Journal for Clinicians (http://www.ca-journal.org).The statistics also show the beginning of a decline in the number of deaths among women from breast and colorectal cancers, although the number of overall female cancer deaths continues to climb because of a sustained increase in deaths from lung and bronchus cancer. . . . **GEORGE DAHLMAN** was named vice president, public policy, for the Leukemia and Lymphoma Society. Dahlman was former press secretary to former Sen. Alan Dixon (D-IL) in the 1980's and until his appointment at LLS, served as assistant executive director, public affairs, for the Regional Transportation Authority of Chicago. . . . **UNIVERSITY OF CALIFORNIA AT IRVINE** received $2.2 million for breast cancer research expansion and to establish diagnostic and treatment programs for low income and medically underserved women. The gift was from the Avon Breast Cancer Crusade. . . . **PURCHASE BOOKS**, videos, music, toys, electronics, and home improvement items through **The Cancer Letter's** Web site, in association with Amazon.com. **The Cancer Letter**, as a member of the Amazon Associates Program, will receive 5 percent of the sale price of purchases made through the Amazon.com search function posted at http://www.cancerletter.com.

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