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FDA, CMS Take Second Look At Drugs Given "Accelerated" Approval For Cancer

Over the past decade, an "accelerated" FDA approval for cancer drugs has been as valuable as a full approval.

Since 1992, when accelerated approval regulations were introduced, pharmaceutical companies have used them to get products on the market faster, often with less rigorous studies.

To obtain an accelerated approval for treatment of a life threatening disease, a sponsor has to demonstrate that its agent is better than an existing treatment, and that it affects a "surrogate endpoint," such as

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In Brief:

Bush Appoints Kripke To Cancer Panel; Hayward, Privalsky Win MERIT Awards

MARGARET KRIPKE, executive vice president and chief academic officer of M.D. Anderson Cancer Center, has been appointed by **President George W. Bush** to the President's Cancer Panel for a three-year term. Kripke has been a leader in understanding the role of immunologic processes in the development of cancer. She founded the Department of Immunology at M.D. Anderson in 1983, becoming the first woman to head an academic department at the center. Since 1986, she has held the Vivian L. Smith Distinguished Chair in Immunology. She has served as president of the American Association for Cancer Research and the American Society for Photobiology. . . . **NATIONAL CANCER ADVISORY BOARD** has approved two new MERIT awardees: **S. Diane Hayward**, of Johns Hopkins University, and **Martin Privalsky**, of University of California, Davis. The Method to Extend Research in Time awards provide support of up to 10 years to investigators with impressive records of scientific achievement in research areas of special importance or promise. Hayward is working on identifying and characterizing the cellular signaling pathways that are manipulated by Epstein-Barr virus to stimulate cell proliferation. Privalsky is studying how v-erb A contributes to the ability of the avian erythroblastosis virus to cause leukemia. . . . **LYMPHOMA RESEARCH FOUNDATION** has awarded $1.285 million in research grants to nine institutions, said **Joseph Bertino**, chairman of the LRF scientific advisory board. They are: University of Rochester; University of California, Los Angeles; Sloan-Kettering Institute for Cancer Research; Children's Hospital, Boston; Baylor College of Medicine; Beth Israel Deaconess Medical Center;

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FDA, CMS Scrutinize Drugs Given Accelerated Approval

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tumor shrinkage or time to progression of the disease, and is "reasonably likely" to benefit patients.

Though regulations require that post-approval studies aimed to demonstrate patient benefit should be underway at the time an accelerated approval is granted, no one knows whether such regulations would ever be enforced, and some observers doubt whether enforcement of post-marketing commitments is practical or politically feasible.

In recent months, FDA and the Centers for Medicare & Medicaid Services have been scrutinizing drugs and biologics marketed under accelerated approval.

FDA is looking for a way to improve the quality of studies presented for accelerated approval, and to coax sponsors into conducting studies that would lead to demonstration of clinical benefit—and full approval. On March 12 and 13, the agency called in seven sponsors to update the Oncologic Drugs Advisory Committee on the progress of their post-approval studies.

"There is nothing more important than the sunlight of the day and the sunlight of public opinion to keep people motivated to fulfill their commitments," Richard Pazdur, director of the FDA Division of Oncology Drug Products, said to the committee, pledging to conduct more meetings of this sort.

CMS has simple motivations: to save money. The agency has initiated "national coverage analyses" of two cancer therapies that received accelerated approval from FDA. Reviews of the two therapies could raise questions of cost and off-label use.

Accelerated approval has been an often-used Door No. 2 in drug development:

—Since the first oncology accelerated approval in 1995, FDA granted 19 such indications for cancer drugs and biologics. During the same period, the agency gave full approvals to about 70 cancer indications.

—Four of the 19 indications granted accelerated approval have been converted to full approval.

—Before accelerated approval, phase II trials rarely enrolled more than 60 patients. They established an agent's activity, as a prerequisite for randomized trials. Now that phase II studies can be used for drug approval, they frequently enroll hundreds of patients.

"The accelerated approval regulation was not meant to inspire less rigorous studies or approvals that left any doubt that the drug was safe or effective," said Carl Peck, director of the Georgetown University Center for Drug Development Science and former director of the FDA Center for Drug Evaluation and Research. "If there is a perception that this has gone in this direction, then both FDA and sponsors should hasten to work together to correct this. And that can be done by committing to adequate and well-controlled trials."

One Drug, Two Examples

Oddly, FDA and CMS may be using the same chemotherapy agent to make two different points.

FDA's Pazdur frequently singles out Eloxatin (oxaliplatin), approved last year for second-line treatment of advanced colorectal cancer, as an example of excellent use of the accelerated approval program.

The drug's sponsor, Sanofi-Synthelabo, enrolled 821 patients in a randomized three-arm phase III trial, and after the first 150 patients received four months of treatment, conducted an analysis of surrogate endpoints, demonstrating a statistically significant difference in response rates favoring a combination of Eloxatin with infusional 5-fluorouracil and leucovorin.

Though a response rate for Eloxatin was relatively small—9 percent—it was statistically

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significant. Also, trial data suggested an advantage in time to progression. The agency approved Eloxatin in record time, within 46 days of the company's submission of the New Drug Application (**The Cancer Letter**, Sept. 6, 2002).

While Eloxatin appeared on the market under an accelerated approval, the data from the registration trial continued to mature. These data—including survival—are expected to be presented at the upcoming annual meeting of the American Society of Clinical Oncology.

The Eloxatin clinical development program meets the criteria similar to those used by FDA for accelerated approval of anti-viral drugs in the treatment of AIDS.

Usually, sponsors of AIDS drugs conduct two randomized trials. Accelerated approval is granted based on the surrogate endpoint of a decrease in viral load at 24 weeks, and full approval is granted based on the same endpoint with a longer duration, at 48 weeks.

"A similar approach has already been discussed for oncology trials," said Pazdur, referring to the Eloxatin trial. "Accelerated approval can be granted by the improvement in response rate and time to progression in an interim analysis of a randomized trial. Full approval may be based on a survival advantage observed by continuing the study."

To CMS, Eloxatin may be a landmark of a different sort: it's a cancer chemotherapy agent that obtained approval based on a surrogate endpoint.

In hospital outpatient prospective payment system regulations that went into effect on Jan. 1, the agency reserves the right to deny Medicare coverage for any drug or biologic if it "represents a novel, complex, or controversial treatment, may be costly to the Medicare program, may be subject to overutilization or misuse, or received marketing approval based on the use of surrogate endpoints."

The regulation specifically denies "pass-through" payment to the monoclonal antibody-based Zevalin (ibritunomab tiuxetan) therapy for non-Hodgkin's lymphoma.

Like Eloxatin, Zevalin, an agent sponsored by IDEC Pharmaceuticals Corp., received an accelerated approval from FDA last year. Zevalin is being reimbursed as a radiopharmaceutical.

Under normal circumstances, the pass-through program pays Medicare hospital bills for drugs and biologics during their first two or three years on the market.

"National Coverage Analysis"

In addition to withholding pass-through payments for Zevalin and Eloxatin, CMS has initiated "national coverage analysis" of the two agents.

The stakes are high: if the agency determines that a therapy is not eligible for reimbursement, no Medicare contractor would be able to pay for it, CMS sources say.

Since instituting this process in 1999, CMS has used it primarily to review surgical procedures, diagnostics, and devices. Only one therapy that involved a drug has gone through such review, Ocular Photodynamic Therapy with the drug verteporfin for macular degeneration.

According to documents posted on the CMS Web site, the agency staff decided to initiate the review of both Zevalin and Eloxatin.

The agency appears to be interested in two issues: Eloxatin's "impact" on Medicare and the appropriateness of its off-label use in early stage disease.

The document, posted at http://www.cms.gov/ncdr/ncdr_index.asp , states:

"Oxaliplatin is an antineoplastic agent (a platinum analogue) approved by the FDA under the trade name Eloxatin, for use in combination with 5-fluorouracil (5-FU) and leucovorin in patients with colorectal cancer whose disease has recurred or has become worse following initial therapy with a combination of irinotecan with 5-FU and leucovorin. It is not approved for patients with newly diagnosed colorectal cancer. Given the potential impact of this treatment on the Medicare program, CMS has internally generated a national coverage determination to evaluate when oxaliplatin is reasonable and necessary in the Medicare population."

According to CMS, the final decision on Eloxatin is expected on May 13.

"An adverse decision by CMS could result in the denial of Medicare coverage for Eloxatin, and would be the first time in the US that an FDA-approved cytotoxic agent was not covered by the Medicare program—indeed, a dangerous precedent," Mace Rothenberg, principal investigator in the Eloxatin pivotal trial, wrote in a recent letter to physicians who took part in the trial.

"A negative decision by CMS to reimburse Medicare beneficiaries for new cancer therapies like Eloxatin would have a significant adverse effect on our ability to deliver state-of-the-art cancer care to seniors," wrote Rothenberg, a gastrointestinal

oncologist at Vanderbilt-Ingram Cancer Center.

The agency's review of Zevalin has gone beyond the projected date, Oct. 24, 2002. The text of the CMS announcement of its analysis of Zevalin follows:

"Ibritumomab Tiuxetan is a radioimmunotherapy approved by the FDA, under the trade name Zevalin, to treat certain forms of non-Hodgkin's lymphoma. The therapeutic links monoclonal antibodies that bind to malignant and normal B cells with a radioisotope that provides localized radiation. The treatment regimen consists of Rituximab, a monoclonal antibody, preceding Indium-111 Ibritumomab Tiuxetan, to determine if the patient is a candidate for therapy, followed 7 to 9 days later by a second infusion of Rituximab prior to Yttrium-90 Ibritumomab Tiuxetan, the therapeutic arm. Given the uniqueness of this treatment which employs a diagnostic with a radioimmunotherapy, the CMS has internally generated a national coverage determination to assure that Ibritumomab Tiuxetan is appropriately used in the Medicare population."

Zevalin may be facing an additional problem at FDA. Last December, ODAC recommended approval of the Corixa agent Bexxar for chemotherapy-refractory, low-grade and follicular NHL with or without transformation, an indication almost identical to Zevalin's. Bexxar and Zevalin have not been compared in head-to-head trials.

It is unclear whether FDA would follow the committee's advice, setting a precedent by granting two accelerated approvals for the same indication.

ODAC Considers Eight Indications

It's unlikely that agents that received accelerated approval would be pulled off the market, even if they are deficient in completing post-marketing studies, FDA officials said.

"The accelerated approval comes with a potential, never used to date: accelerated withdrawal," Robert Temple, director of the FDA Office of Drug Evaluation I, said at the advisory committee meeting. "Instead of the usual hearing process, it would come before an advisory committee."

FDA has never withdrawn a drug because of a lack of efficacy. All withdrawals were caused by safety problems.

"When a drug has proved active in a setting where nothing else worked, you don't likely remove it because the trial failed to show overall survival advantage," Temple said. "It's pretty obvious that you don't withdraw an active drug lightly. You try to do other studies, you think why the studies failed."

At the meeting last week, ODAC reviewed post-marketing studies of accelerated approval for eight cancer indications that received accelerated approval between 1995 and 2000:

—Doxil (doxorubicin hydrochloride) for Kaposi's sarcoma in AIDS patients with disease that has progressed on prior combination therapy or in patients who are intolerant to such therapy.

The sponsor, Johnson & Johnson, completed a post-marketing study, but FDA found its results uninterpretable because of the effect of retroviral therapy. The treatment of AIDS has changed since the approval of Doxil in 1995, and the incidence of KS has dropped markedly, making it difficult to recruit patients.

—Doxil for metastatic ovarian cancer refractory to paclitaxel and platinum chemotherapy regimens. Patients have been living longer since the indication's approval in 1999, and the company's randomized comparative study hasn't reached maturity to analyze the survival point.

—Ontak (deneluekin diftitox) for persistent or recurrent cutaneous T-Cell lymphoma in patients whose maligant cells express the CD25 component of the IL-2 receptor. The agent was approved in 1999. The sponsor, Ligand Pharmaceuticals Inc., is conducting a double-blind, placebo controlled three-arm study.

—Ethyol (amifostine) for reduction in cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced non-small cell lung cancer. The agent was approved in 1996. The sponsor, MedImmune Oncology Inc., has conducted a two-arm study that was inconclusive, and is conducting another a double-blind trial.

—Mylotarg (gemtuzumab ozogamicin) for CD33 positive acute myeloid leukemia patients in first relapse who are 60 years of age or older and who are not considered candidates for cytotoxic chemotherapy. The agent was approved in 2000. The sponsor, Wyeth-Ayerst Laboratories Inc., has had safety problems with venoocclusive disease and had difficulty accruing patients for the trial.

—Depocyt (cytarabine) for intrathecal treatment of lymphomatous meningitis. The agent was approved in 1999. Skyepharma Inc. has had manufacturing problems and difficulty coming up with a trial design. The company recently began accrual

to a two-arm study.

—Celebrex (celecoxib) for reduction in number of adenomatous colorectal polyps in familial adenomatous polyposis patients. The drug was approved in 1999. Pharmacia has had difficulty with trial design and patient recruitment.

—Temodar (temozolomide) for refractory anaplastic astrocytoma. Since approval in 1999, Schering-Plough Corp. has had to go back to phase I studies to determine a proper chemotherapy dose in combination with radiation. A three-arm study is getting started, the company said.

The text of Pazdur's remarks to ODAC follows:

I would like to discuss three areas of oncology accelerated approvals.

First, the Division's premise that these confirmatory trials are an integral part of a comprehensive drug development plan.

Accelerated approval does not end with the approval of the drug. Hence, the confirmatory trial should be discussed with the Division early in the development process and be an inherent part of the drug development strategy.

The second issue I would like to discuss is the patient population examined in the confirmatory trials. Frequently, the Division has allowed clinical benefit to be demonstrated in less refractory, earlier stage of the disease than that studied during accelerated approval.

Lastly, I would like to comment on the merits of different trial designs—specifically, single arm versus randomized trials to obtain the accelerated approval.

The preamble to the accelerated approval regulations comment that post-marketing studies would usually be underway at the time of the accelerated approval. Although we have not insisted that the post-marketing confirmatory trials be underway, which may potentially delay drugs to patients with life-threatening diseases, the Division believes that these studies need to be carefully planned and discussed with the Division early in the development plan, preferably at or before the end of phase II meeting.

There needs to be a continuous dialog during the conduct of the trial and strategies in place for alternatives.

The Division envisions that a sponsor is committed to a comprehensive drug development program which does not end with the receipt of the accelerated approval letter. We believe that these confirmatory trials should be an inherent part of the accelerated approval process. These confirmatory trials are equally important as the initial trials for accelerated approval. Confirmatory trials should be fully integrated into the development program.

There are reasons that the confirmatory trials should be considered as an integral part of the total drug development plan. Pragmatically, the accelerated approval provides commercial drug to patients and may interfere with patient accrual in the confirmatory trial. Hence, consideration must be given to measures that would ensure timely completion of the confirmatory trial once accelerated approval is awarded. These may include the addition of study sites or expansion of the trial to geographic areas where the drug may not yet be approved.

Integration of the confirmatory trial early in the development plan allows further questions to be formulated and answered. These may include studying different doses or population pharmacokinetic investigations in the confirmatory trial.

As stated, the Division would like a thorough discussion of the confirmatory trials early in the drug's development. We envision discussions of the clinical trial milestones at the initiation and during the clinical trials. These discussions should focus on timely accrual, problems with the study's conduct, and potential alternative trial designs and timely execution of new trials if accrual or the expected outcome is not likely to be attained.

The Division encourages that these confirmatory trials be submitted to the FDA as special protocol assessments, a provision that is a binding agreement between the FDA and sponsor on an agreed upon protocol.

Both the FDA and sponsor should have a clear understanding of the term "due diligence" [in relation to study completion] with periodic review of timelines.

The Division has allowed accelerated approvals examining patient populations in refractory settings using a single arm study. One reason for this approach is that even small response rates in a highly refractory population may identify a drug with a unique mechanism of action and bring novel agents to the clinic early. We have allowed the confirmatory trials to be conducted in an earlier stage or less heavily treated population than the initial accelerated approval. Oncology drug development is expedited by the earlier introduction of promising agents to the first-line and adjuvant settings.

Accelerated approval may limit patient accrual into trials in the approved indication; allowing patients to be entered in a less refractory setting may obviate this accrual problem. Nevertheless, allowing the demonstration of clinical benefit in a different population may leave the question of clinical benefit in the accelerated approval indication unanswered.

Studying drugs initially in a refractory setting presents problems. Response rates may be progressively smaller in progressively more heavily treated patients. Hence, a promising agent may be missed.

Encouraging sponsors to study refractory patients can channel drug development to progressively more heavily treated patients. This may lead to developing drugs in highly select groups of patients with natural histories and responses that may not be easily extrapolated. In addition, studying patients with extensive prior therapies may pose problems in adequately characterizing toxicities because of chronic residual toxic effects of prior therapies or progressive disease symptoms

Accelerated approvals have been granted with a trial design using single-arm trials in refractory patient populations. These trials allow more rapid trial completion and, hence, expedite drugs to patients with life-threatening diseases.

An alternative trial design uses a randomized trial allowing accelerated approval on the basis of an interim analysis of surrogate endpoints (i.e. response rate, time to progression). These randomized trials allow the analysis of additional endpoints, such as time to progression. At the completion of the trial, the clinical benefit endpoint of survival can be evaluated. Randomized trials also allow a greater understanding of toxicity.

Randomized trials may optimize the evaluation of novel cytostatic agents by allowing an assessment of slowing or preventing tumor progression. This may not be possible with single-arm trials.

Randomized trials also allow "add-on" trial designs where the novel drug is added to standard therapy compared to standard therapy alone. Randomized trials are more expensive and take more time than single-arm trials. Survival results may be confounded by crossover and subsequent therapies

Although we have been discussing accelerated approval in oncology, the other life-threatening condition where this regulatory provision has been used is in the accelerated approval of anti-viral drugs in the treatment of AIDS. A different strategy has been employed. Usually two randomized trials (approaching 1,000 patients each) are required. The surrogate endpoint is viral load at 24 weeks, which provides evidence for accelerated approval. Full approval is obtained with the same study by demonstrating the effect of the same endpoint at 48 weeks. The same trial provides support for accelerated approval and subsequently provides evidence for full approval.

A similar approach has already been discussed for oncology trials. Accelerated approval can be granted by the improvement in response rate and time to progression in an interim analysis of a randomized trial. Full approval may be based on a survival advantage observed by continuing the study.

The goal of this meeting is to provide a constructive dialog with sponsors on confirmatory trials aimed at demonstrating clinical benefit after initial accelerated approval is granted.

The Division wants this meeting and subsequent discussions to be proactive in assessing study design issues, endpoints, accrual problems, and the timely completion of trials.

This is the first of what the Division plans to be recurring public meetings aimed at examining mandatory clinical benefit trials.

The confirmatory trials to demonstrate clinical benefit are equally important as the initial trial demonstrating an effect on a surrogate endpoint leading to approval. The subsequent confirmatory trial provides the demonstration of ultimate benefit to the patient.

Hence, confirmatory trials must be an inherent and integral part of a comprehensive drug development plan and strategy.

Georgetown, ASCO Plan Cancer Drug Workshops

Georgetown University's Center for Drug Development Science will sponsor a workshop, "Clinical Development of Oncologic Agents: Challenging the Tradition," on April 23-24.

The objective of the workshop is to advance the practice of oncology drug development toward more rapid, efficient, and informative clinical evaluation of cancer treatments.

The workshop will be co-chaired by Mark Ratain, an oncologist at the University of Chicago, and Carl Peck, director of the Georgetown Center for Drug Development Science.

Further information is available at http://cdds.georgetown.edu.

* * *

In a related development, the American Society of Clinical Oncology and FDA will convene a panel to discuss endpoints for development of lung cancer therapies. The panel will meet in the Washington area April 15. The meeting will be open to the public. Additional information will be posted on the society's Web site: www.asco.org

Letter to the Editor:

Drug Approval Process Must Respond To Patient Needs

To the Editor:

Chronic failure on most fronts of the "war on cancer" coupled with the recent introduction of a few dramatically successful new drugs has raised public awareness of, and frustration with, the process whereby experimental cancer drugs are developed and approved for marketing.

The highly publicized tribulations of ImClone Systems, the subsequent reorganization of CDER and CBER within the FDA, and the controversy over the incongruity between public testimony about individual clinical benefit and unimpressive efficacy statistics presented at the ODAC review of AstraZeneca's Iressa, are recent examples of why the underlying issues are important to consider.

The Feb. 21 issue of **The Cancer Letter** provides useful insight into this topic and raises at least two questions: What is the proper role of the public in the complex process of new drug approval, and how can promising new medicine best be made available to patients who need it as rapidly as possible?

The right of Americans to directly participate in their government is fundamental to the democratic process. In the case of drug development, patient advocates have a long history of fighting to have their voices added to the process. Their input has been beneficial—accelerating the pace of research, broadening drug availability, and speeding the timeframes for new drug approval. We believe that had advocates and activists waited to be invited into the process, these advances would have occurred much more slowly, or not at all.

Input from the public should be an important part of the work that occurs during ODAC deliberations. The fact that some FDA advisors do not perceive public input as central to their deliberations suggests that the process should be improved.

How? One simple improvement would be to make the FDA briefing documents available to the public earlier so that patients and advocates can more accurately comment on the data. Specialists and lay people working together can undoubtedly suggest other modifications that might improve the utility of advice provided by ODAC for use by the FDA in its decision-making process.

The Marti Nelson Cancer Foundation is an advocate of expanded access and compassionate use programs. Our organization's origins trace back to Marti's unsuccessful attempt to obtain compassionate access to Herceptin, for which there were promising phase II efficacy and safety data. Her first choice was to enroll in a clinical trial; unfortunately, she was ineligible for existing trials.

She faced a situation experienced by many cancer patients, and the logic behind her quest for compassionate use is equally valid now. We periodically work with companies willing to voluntarily establish expanded access protocols, and with individual patients seeking compassionate use of promising therapies. Properly designed expanded access programs, implemented during the late stages of the cancer drug development process, can be beneficial to individual cancer patients, to the overall drug development process, and to the individual drug sponsor. Despite the benefits, there are many critics of the concept.

The Feb. 21 issue of **The Cancer Letter** refers to a National Breast Cancer Coalition Position Statement, which begins with the following sentence: "Access to investigational interventions outside of clinical trials undermines the clinical trials system and the principle of evidence-based medicine." Actual experience over several years with a variety of cancer drugs suggests that this claim is incorrect on both counts.

Properly designed expanded access protocols do not undermine the clinical trials system and may actually contribute to both speeding clinical trial accrual and accumulating safety and efficacy data relevant to a broad population. The claim of incompatibility between clinical trials and compassionate use, or expanded access, can be permanently laid to rest by making sure that expanded access programs are designed to prevent such conflict. In fact, the FDA works with companies to assure compatibility between expanded access

protocols and efficacy-determining clinical trials.

Dr. Sackett's definition of evidence-based medicine, as quoted by NBCC, is "the conscientious, explicit and judicious use of current best evidence in making clinical decisions about the care of individual patients." [Sackett D et al. Evidence-Based Medicine: What it is and what it isn't. *British Medical Journal* 1996;312:71-2.]

Unfortunately, current reality is that most oncology drugs, even new drugs, do not provide clinical benefit to a majority of the individuals who receive them.

While many of the experimental agents currently in development may prove to be equally disappointing, we prefer to be optimistic about the future of cancer treatment. Even a drug demonstrating merely incremental benefit, as measured in large, randomized studies, may prove valuable to an individual patient with the right molecular profile and disease parameters.

Clinical trials are an important way for patients to access promising investigational agents (especially clinical trials designed with a cross-over provision). However, other valid ways to obtain innovative therapy include participation in expanded access protocols, individual compassionate use, off-label use of drugs approved for other indications and importation of drugs approved in other countries. Working out the best way to use this combination of routes is an important and legitimate topic for public debate, and one in which the voices of both specialists and non-specialist members of the public are equally likely to contribute to progress.

The government's role in drug development and approval must be responsive to the evolving needs of both drug sponsors and patients. To improve the current system, it makes sense to bring together a variety of people representing diverse views to consider what is possible. Do drug sponsors benefit from expanded access programs? Maybe. Do patients? Probably. While it is easy to focus on "conflicts of interest," it might be more productive to acknowledge "combinations of interest" and redouble our efforts to make meaningful progress in the "war on cancer" for everyone's benefit.

Robert Erwin
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Director, Marti Nelson Cancer Foundation

The Cancer Letter *accepts letters to the editor. Letters may be sent to news@cancerletter.com.*

In Brief:

Surgeons Honor Harry Pearce; NCCS Presents Annual Awards

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Stanford University; The Burnham Institute; and Dana-Farber Cancer Institute. . . . **HARRY PEARCE**, chairman of the General Motors Cancer Research Foundation, received the 2003 Layman Award from the Society of Surgical Oncology. The award, given annually to a non-physician who contributes to the care of cancer patients, was presented March 8 in Los Angeles. Pearce is board chairman of the Hughes Electronics Corp., a subsidiary of General Motors Corp. . . . **NATIONAL COALITION for Cancer Survivorship** will present its annual Ribbon of Hope Awards on April 1, in Washington, DC, to individuals who made a difference in the lives of people with cancer. **Carole Black**, president & CEO of Lifetime Entertainment Services, will receive the Lilly Tartikoff Hope Award. **Fran Drescher,** actress and author, will receive the Natalie Davis Spingarn Writer's Award for her book, "Cancer Schmancer." **Robert Bazell,** chief health and science correspondent at NBC News, will receive the Excellence in Media Award. **Cindy Melancon**, a grassroots organizer and founder and president of CONVERSATIONS! The International Ovarian Cancer Connection, will be presented the Catherine Logan Service to Survivorship Award by **Rep. Rosa DeLauro** (D-CT). . . . **VAN ANDEL INSTITUTE** in Grand Rapids was accepted as a member in the Michigan Cancer Consortium, a partnership of 75 organizations that work to reduce the impact of cancer in the state. The consortium has identified 10 cancer control priorities, including doubling the number and increasing the diversity of participants enrolled in cancer clinical trials by 2005, said **George Vande Woude**, VAI director of research. **Rick Hay**, VAI assistant to the director for clinical programs, will serve as liaison to the consortium. . . . **DANIEL SEDMAK** was appointed executive vice president for health sciences and executive dean of the Georgetown University School of Medicine, effective July 1. Sedmak is senior associate vice president for health sciences and executive vice dean of the College of Medicine and Public Health at The Ohio State University. He is professor and chairman of pathology at OSU, and director of the nephropathology and transplant pathology programs at The Ohio State University Hospitals.

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