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Adverse Data From Cancer Prevention Trial Makes Merck Withdraw Vioxx From Market

By Paul Goldberg

Merck & Co. Inc. spent five years building Vioxx (rofecoxib) into a $2.55 billion drug.

Vioxx, a non-steroidal anti-inflammatory drug (NSAID) which inhibits cyclooxygenase–2, received FDA approvals for the reduction of pain and inflammation from osteoarthritis, rheumatoid arthritis, acute pain, and menstrual pain.

Trials required for approval in these indications were relatively short, about six months. Then, the company asked a research question that required

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In Brief:

Zvi Fuks Heads MSKCC Radiation Oncolgy, Pfister Named Chief, Head & Neck Service

MEMORIAL Sloan-Kettering announced the following appointments and awards: **Zvi Fuks** was named chairman of the Department of Radiation Oncology. Fuks, an incumbent of the Alfred P. Sloan Chair, received the Gold Medal Award from the American Society for Therapeutic Radiology and Oncology, and the MSKCC Willet F. Whitmore Award for Clinical Excellence. He has served before as chairman of radiation oncology from 1984 to 1998, and in 1998 he was appointed deputy physician-in-chief for planning, Office of Clinical Research at MSKCC. **David Pfister** was named chief of the new Head and Neck Medical Oncology Service in the Division of Solid Tumor Oncology, Department of Medicine. Pfister joined the MSKCC Genitourinary Oncology Service in 1989. **Joseph Huryn** was named chief of the dental service, Department of Surgery. Huryn, an expert in prosthetic restoration of facial features and rehabilitation, joined the MSKCC staff in 1987. **Kathleen Foley**, attending neurologist and former chief of the Pain and Palliative Care Service, was named a 2004 McCann Scholar for mentoring healthcare professionals in symptom management in seriously ill patients. **David Abramson**, chief of the Ophthalmic Oncology Service, received the Mildred Weisenfeld Award for Excellence on Ophthalmology from the Association for Research in Vision and Ophthalmology. **Lauren Abrey**, neurologist, received the 2004 Preuss Award in Clinical Neuro-Oncology from the American Academy of Neurology. **Jakob Dupont**, of the Developmental Chemotherapy Service, is the recipient of a Damon Runyon-Lilly Clinical Investigator Award for his work with **Richard O'Reilly**, chairman of pediatrics, on analysis of tumor-specific T cells for adoptive immunotherapy

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Data Raises Questions About Class Versus Molecule Effect

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longer followup: Can Voixx prevent recurrence of colon polyps?

To obtain the answer, the company enrolled 2,600 patients in a trial called Adenomatous Polyp Prevention on Vioxx, or APPROVe, and started rigorous, long-term follow-up.

Late last month, about 18 months into the trial, the data and safety monitoring board recommended that the study should be stopped after thromboembolic events on the Vioxx arm reached 3.5 percent, almost twice the rate observed on the placebo arm. On Sept. 28, the company told FDA that it would voluntarily pull Vioxx off the market.

Is it possible that Merck asked one question too many?

"The moral of this story is that these agents are much more carefully scrutinized in cancer prevention studies," said Fadlo Khuri, the Blomeyer Professor of Hematology and Oncology at Emory University Winship Cancer Institute and an expert in chemoprevention, who isn't involved in COX-2 studies. "If this drives pharmaceutical companies away from testing promising agents in the cancer prevention setting, that would be truly a tragic outcome."

The demise of Vioxx illustrates the need for rigorous monitoring in cancer prevention trials and raises questions about safety of the entire class of drugs, scientists say. At least one other commercially available drug, Celebrex (celecoxib), is being tested for prevention of recurrence of polyps, a possible surrogate endpoint for reduction of risk of colon cancer. Celebrex is sponsored by Pfizer Inc.

"Obviously, the most important question is whether this is a class effect or not," said Raymond DuBois, the Hortense B. Ingram Professor of Molecular Oncology at the Vanderbilt-Ingram Cancer Center, who is also an investigator on an NCI-sponsored trial of Celebrex and an advisor to the Pfizer-sponsored U.S. and European study of the agent. "Some people are saying it's related more to Vioxx and not to selective COX-2 inhibitors in general, but because of these important safety issues, it needs to be evaluated carefully."

The APPROVe trial "has shifted the burden of proof," Garret FitzGerald, of the Institute for Translational Medicine and Therapeutics at the University of Pennsylvania, wrote in the New England Journal of Medicine. The article, which will be published in the Oct. 21 issue, is posted at www.NEJM.com.

Another observer, Eric Topol, chief of cardiology at the Cleveland Clinic, wrote that FDA and Merck had known for at least two years that Vioxx was associated with a "clear-cut excess number of myocardial infarctions." Celebrex, too, was associated with a numerical, albeit not statistically significant excess of cardiovascular events, Topol wrote.

In 2001, the FDA Arthritis Advisory Committee recommended that the agency ask for a trial specifically to assess cardiovascular risks and benefits of these agents, wrote Topol, who was a member of the committee.

The trial of the two agents in patients with established coronary artery disease was never conducted, Topol wrote.

APPROVe stopped short of asking the cardiotoxicity question. In fact, the Merck trial excluded patients who had cardiovascular disease.

"Only by happenstance, in a trial involving 2,600 patients with colon polyps who could not have been enrolled if they had any cardiovascular disease, was it discovered that 3.5 percent of patients assigned to rofecoxib had myocardial infarction or stroke, as compared with 1.9 percent of the patients assigned to placebo ($P<0.001$), necessitating premature cessation of the trial and the decision to discontinue treatment with rofecoxib," Topol wrote.

Unlike APPROVe, the two trials of Celebrex for polyp recurrence included patients with cardiovascular disease. The NCI trial enrolled 2,100 patients, who

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were randomized to two treatment arms or placebo. The company trial enrolled about 1,600 patients. Both trials were begun before APPROVe and remain blinded.

"If there is something with Celebrex, it should be apparent by examining the adverse cardiovascular events in different groups," DuBois said. "I've been told that there is no difference, but I haven't seen the data. If it's a time-dependent effect, it should have shown up by now."

On the molecular level, Vioxx and Celebrex differ substantially, scientists say. Though the mechanisms of action of the agents haven't been conclusively determined, it appears that they work through different cellular pathways, and Vioxx appears to be a more specific COX-2 inhibitor than Celebrex.

Literature suggests that at least in part, tumor-suppressive activity of NSAIDs could be unrelated to COX-2. One such paper was published last August in the Proceedings of the National Academy of Sciences: www.pnas.org/cgi/doi/10.1073/pnas.1631086100.

"COX-2 inhibitors differ in their degree of COX-2 specificity and inhibitory activity and probably more importantly in their interactions with non- COX-2 targets," said Bernard Levin, vice president for cancer prevention and population sciences at M.D. Anderson Cancer Center and co-principal investigator of the Pfizer-sponsored study of Celebrex.

Nonetheless, an agent used over many years by patients who are asymptomatic and may not have a serious disease has to meet high safety standards, Levin said. "The best way to determine if any adverse effects occur is from long-term, randomized, blinded, placebo-controlled trials monitored by independent Data Safety and Monitoring Boards with appropriate expertise," he said.

Richard Goldberg, principal investigator on a National Surgical Adjuvant Breast & Bowel Project trial of Celebrex in patients with resected stage I colon cancer, said the Vioxx story demonstrates the importance of rigorous monitoring of toxicity in prevention trials.

"The system of toxicity monitoring and DSMBs is effective in picking up differential toxicity in studies like this," said Goldberg, associate director for clinical research at the University of North Carolina Lineberger Comprehensive Cancer Center. "Even though it's a disappointment that the drug that many people had come to depend on for treatment ended up being withdrawn from the market, it's reassuring that we can find these things."

In 1999, Celebrex received FDA approval for reducing the number and size of polyps in patients with familial adenomatous polyposis, a hereditary condition that inevitably leads to colorectal cancer. Following that accelerated approval, NCI and the drug's sponsor Pharmacia initiated studies to test the agent's ability to reduce recurrence of polyps in a broader population. Pharmacia subsequently merged with Pfizer.

A decrease in the number and size of polyps in this population is a surrogate endpoint which may or may not be found convincing by FDA. An alternative strategy—colonoscopy and surgical removal of polyps—is generally safe, but inconvenient and expensive.

Announcing the decision to pull Vioxx of the market, Merck officials stressed that their move was voluntary.

"Although we believe it would have been possible to continue to market Vioxx with labeling that would incorporate these new data, given the availability of alternative therapies, and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course of action," William Keane, Merck vice president for U.S. medical and scientific affairs, said in a "Dear Doctor" letter.

The company said it withdrew the drug because APPROVe demonstrated an increased relative risk for confirmed cardiovascular events after 18 months of Vioxx treatment. "The results for the first 18 months of the APPROVe study did not show an increased risk of confirmed cardiovascular events on Vioxx and, in this respect, are similar to the results of two placebo-controlled studies described in the U.S. labeling for Vioxx," the company said in a statement.

Merck said it would present the APPROVe data Oct. 18 at the American College of Rheumatology meeting in San Antonio.

The special session will include a scientific presentation by Robert Bresalier, chairman of gastrointestinal medicine and nutrition at M.D. Anderson and a member of the trial's steering committee. The presentation will include comments from FDA.

Withdrawal of Vioxx caused Merck's stock to drop by a third, from about $45 per share before the announcement to the current level of $30 per share. Also following the announcement, personal injury lawyers across America started to advertise their services to the hundreds of thousands of patients who took Vioxx. Several suits have been filed.

Michael Friedman, president and CEO of City of Hope National Medical Center, who is also a former FDA acting commissioner and a former Pharmacia executive, said Merck made the right decision.

"This is unfortunate for the company, but it

reaffirms the need to keep studying things even though they have what appears to be a good safety profile," said Friedman. "I think Merck did exactly the right thing by pulling the drug entirely off the market. You always do the studies, because if you don't, there are patients who are being harmed, and you didn't know about it."

Friedman said drug companies have a moral obligation to study their products after obtaining FDA approval. "A pharmaceutical company, just like a physician, can't hide its eyes and pretend not to see something," Friedman said. "They can't say, 'Don't ask me that question, because I don't want to hear the answer.' You ask the questions, and you get the answers, and you know that there is no product that's totally safe."

In his New England Journal of Medicine commentary, Topol called for a Congressional investigation of the Vioxx matter, arguing that the agency and the company had ignored alarming data. "The senior executives at Merck and the leadership at the FDA share responsibility for not having taken appropriate action and not recognizing that they are accountable for the public health," he wrote.

According to a spokesman, FDA plans to review data from long-term trials of all NSAIDs, and then decide whether to request additional studies. No new trials have been requested.

Congressional criticism of FDA began immediately after Merck announced its decision on Vioxx. Sen. Chuck Grassley (R-Iowa), Chairman of the Senate Committee on Finance, immediately started an investigation.

So far, the investigation has turned up a complaint by an FDA official, who claimed that the agency attempted to suppress his paper about safety of Vioxx. The official, David Graham, a medical officer at the Center for Drug Evaluation and Research, said the FDA clearance process prevented him from publishing his paper on Vioxx. Grassley's statement is posted at http://finance.senate.gov/press/Gpress/2004/prg100704.pdf.

FDA officials disputed Graham's and Grassley's version of events.

"As a scientific agency, FDA values open discussion and frank exchange about scientific and medical issues," an agency spokesman said. "Dr. Graham discussed with his supervisor the abstract of a poster about Vioxx he presented last August in France. Such a discussion is part of the standard FDA review process for this type of abstract. After that discussion, it was Dr. Graham's decision to revise the abstract. He did so voluntarily, and presented the abstract during a scientific meeting. He transmitted his completed report to his agency supervisors on Sept. 30. The standard agency review process for this type of report is a more rigorous scientific peer review."

Last year, NCI officials, the American Association for Cancer Research and C-CHANGE proposed plans for giving drug companies additional incentives to pursue cancer prevention indications.

One such plan, floated by NCI officials, called for reliance on surrogate endpoints for prevention studies and suggested that the government use the FDA adverse events reporting mechanisms and the NCI Surveillance Epidemiology and End Results program to monitor toxicity in such trials. The NCI plan also called for reform of product liability laws to make it more difficult for patients to make personal injury claims against drug companies (**The Cancer Letter**, May 30, 2003).

NCI Programs:

NCI Tobacco Clinic Closed; Budget, Slow Accrual Blamed

By Kirsten Boyd Goldberg

NCI has closed its Tobacco Intervention Research Clinic and concluded the clinic's single study due to a flat budget and slow accrual, Institute officials said.

The Institute had envisioned the clinic, opened in the fall of 2003 in Rockville, Md., as a "state-of-the-science" center that would conduct genetic, epidemiological, basic science, and behavioral research studies, and provide "research-based tobacco cessation services to patients from the NIH community," according to the NCI fiscal 2004 budget proposal.

Despite these plans, the clinic accrued "less than six subjects over a six-month period" for its first study, said Glen Morgan, the clinic's co-director and a clinical psychologist and program director in the NCI Division of Cancer Control and Population Sciences.

"Because this occurred within the backdrop of many competing priorities at NIH during a period of a flattened budget, the Tobacco Control Research Branch decided to close the clinic in order to sustain funding for other tobacco control initiatives, including the reissuance of the Transdisciplinary Tobacco Use Research Centers RFA, a new contract RFP to fund projects concerning new tobacco products, and a new Tobacco Health Disparities Research Network," Morgan said to **The Cancer Letter**.

The clinic's budget for FY 2004 was $723,000, but not all of the funds were spent, Morgan said. Besides Morgan and another co-director employed by NCI, the clinic's staff included eight contract employees, four

full-time and four part-time.

Last week, NCI announced that seven new Transdisciplinary Tobacco Use Research Centers were funded for a total of $12 million (**The Cancer Letter**, Oct. 8). NCI provided $7 million, while two other NIH institutes, the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism, supported the remaining cost.

NCI spent about $151 million on tobacco-related research in FY 2004, about 3.2 percent of the Institute's $4.7 billion budget. NCI's fiscal 2005 "bypass" budget proposal submitted to the President and Congress asked for an increase of $75 million for tobacco research, over the Bush Administration's request.

The clinic's first and only study, "Contingency Management to Enhance Smoking Cessation for Cancer Survivors: A Proof of Concept Trial," sought to accrue 100 cancer survivors. Participants would receive the FDA-approved medication Zyban (bupropion) as well as one-on-one counseling.

"The study was highly significant, because a large percentage of cancer survivors (17-45 percent) continue to smoke after their diagnosis, and because there are no empirically validated treatments to help this subgroup of smokers," Morgan said to **The Cancer Letter**. "Contingency management is a powerful technique that has had excellent results in treating persons addicted to substances of abuse and, thus, held promise for this hard-to-treat group."

Contingency management is a way to reinforce a behavior. "In this study, contingency management referred to immediate, monetary incentive provided [to subjects] for delivering biological samples indicative of smoking abstinence," Morgan said.

Other researchers have had trouble accruing cancer survivors to smoking cessation studies. "We believe that the biggest reason for slow accrual was that the population selected, cancer survivors who continue to smoke, may be inherently difficult to recruit," Morgan said.

"There may be many reasons why cancer survivors might not want to participate in a study on quitting smoking, including: quitting smoking may not be their highest priority given other demands they are facing; they may be discouraged from previous unsuccessful quit attempts and fear that they cannot quit; they may not fully recognize the health benefits of quitting smoking during cancer survival; and they may not have wanted to take any more drugs than were already required to treat their cancer," he said. "Of course, we don't know the definitive answer to this question."

Extramural researchers said they were surprised to hear the clinic had closed.

"If the NCI had provided a smoking cessation clinic as a model program for risk reduction, it would have been an important service to the community," said Ellen Gritz, chairman of the Department of Behavioral Science at M.D. Anderson Cancer Center. "It's a shame they were unable to overcome the barriers that seemed to be present."

David Abrams, director of behavioral and preventive medicine at Brown Medical School, said the decision to close the clinic seemed reasonable. "It was a flat budget and people have to make some tough choices," said Abrams, who was a PI on one of the original TTURC awards.

"It would be nice to continue it, but given that it was a small program, and just getting up and running, it's not like a big resource that is a huge loss," he said. "A lot of clinical work is being done at centers across the country."

Part of the reason for establishing the clinic was to attract researchers outside of NIH, Abrams said. "The loss might be that certain innovations that would be higher risk and not attractive to companies might not be done," he said.

Earlier this year, NCI Director Andrew von Eschenbach ordered all NCI divisions to take a 5 percent cut in their operating budgets, in order to free up funds for "strategic priorities."

In 1998, a working group appointed by NCI to identify opportunities for tobacco research found that the Institute spent $76.2 million, less than 3 percent of its FY 1997 budget, on tobacco-related research projects.

"The disproportionate funding of tobacco research relative to the NCI's total research budget is remarkable given the contribution of tobacco to the total cancer burden (approximately 30 percent of all cancer deaths)," the group wrote in its report, "Tobacco Research Implementation Plan: Priorities for Tobacco Research Beyond the Year 2000."

The report called for "an unequivocal commitment of the NCI to a comprehensive but focused program of research on tobacco use" to help reverse the epidemic of tobacco-related cancer.

Abrams, who served on that working group, said NCI should increase its support for tobacco research. "Though the budget for tobacco research has gone up more than it was years ago, it's too small, if you look at it from a public health cost-benefit point of view," he said. "If tobacco is causing 30 percent of the cancer, it should get more than 3 to 5 percent of the budget. You

can't match dollars to percent, but you can make an argument that it should be more proportional."

Tobacco Buyout Passed, No FDA Provision

Earlier this week, tobacco control advocates saw their hope sink for legislation that would subject tobacco products to FDA regulation.

The Senate voted to pass a bill containing $137 billion in corporate tax breaks, including a $10 billion buyout program for tobacco farmers. A bipartisan group of lawmakers had earlier convinced the Senate to link the buyout with a provision that would give FDA authority to regulate tobacco products. But in a conference bill approved last week, House Republicans rejected the FDA provision.

The tobacco buyout doesn't cut tobacco farming, and continues to pay farmers, but ends the quota system that has supported tobacco farming since the 1930s. The funds are supposed to come from manufacturers. In another blow to health advocates, manufacturers will not be required to pay the states "Phase II" of the tobacco settlement.

"Until Congress grants the FDA authority over tobacco, the tobacco companies will be free to continue selling candy-flavored cigarettes and engage in other marketing that appeals to children," the American Cancer Society said in a statement. "They will continue to mislead consumers and discourage smokers from quitting by making unproven claims that some tobacco products are safer than others. They will continue to hide the truth about the dangers of their products and fail to take even the most minimal steps to reduce the number of Americans who die from tobacco use.

"Granting the FDA authority over tobacco is one of the most important steps Congress could ever take to protect the health of our children and significantly reduce the fearsome diseases caused by smoking, including cancer, heart disease, emphysema and many others. We are heartened that Congress this year came closer than ever before to enacting FDA authority into law, but we are profoundly disappointed that this historic opportunity to protect the nation's children and the nation's health was squandered."

ACS said it was "grateful to the members of Congress who have courageously pursued enactment of this legislation," particularly the sponsors, Sens. Mike DeWine (R-Ohio) and Edward Kennedy (D-Mass.) and Reps. Henry Waxman (D-Calif.) and Tom Davis (R-Va). Also, Sens. Tom Harkin (D-Iowa), Richard Durbin (D-Ill.), and John McCain (R-Ariz.) "have been vociferous and effective advocates for this legislation as well."

Medicare:

Groups Urge CMS To Allow Open Formulary For Cancer

By Kirsten Boyd Goldberg

An umbrella group of cancer patient organizations urged the federal government not to limit the choice of antineoplastic drugs that Medicare patients and their physicians can select from for treatment.

Under proposed rules for the new Medicare prescription drug benefit slated to go into effect next year, the Centers for Medicare & Medicaid Services would limit choice to only two drugs per therapeutic class or category. However, the government asked for public comment on whether certain "vulnerable populations" should have access to an open formulary.

The Cancer Leadership Council, a group of 27 patient and professional organizations, urged CMS to consider cancer patients "a vulnerable population that requires an open formulary to allow immediate access to a wide variety of antineoplastic drugs," according to the letter delivered to CMS on Oct. 4.

"Because cancer care is based on protocols that reference specific anticancer drugs, rather than a category or class of drugs, we believe that cancer patients must have access to all antineoplastic drugs without restriction if they are to receive care according to current protocols," the letter said.

Forcing physicians to substitute drugs not specified by the protocol would be "inconsistent with the practice of oncology in the 21st century," the letter said.

"A restrictive formulary will be particularly problematic for those patients who might be best treated with a targeted therapy, which may be effective in a narrowly defined population of cancer patients," the letter said. "A formulary that includes only two drugs per class will likely exclude some of the most important new targeted therapies."

Also, the CLC recommended that Medicare:

--Add antineoplastic drugs to its formularies immediately upon FDA approval.

--Clarify that off-label uses of anticancer drugs will be allowed.

The letter was signed by: American Cancer Society, American Society of Clinical Oncology, Cancer Care Inc., Cancer Research and Prevention Foundation, The Children's Cause for Cancer Advocacy, Fertile Hope, International Myeloma Foundation, Kidney Cancer Association, The Leukemia & Lymphoma Society, Lymphoma Research Foundation, Multiple Myeloma Research Foundation, National Coalition for

Cancer Survivorship, North American Brain Tumor Coalition, Pancreatic Cancer Action Network, Sarcoma Foundation of America, The Susan G. Komen Breast Cancer Foundation, Us Too International Prostate Cancer Education and Support Network, The Wellness Community, and Y-ME National Breast Cancer Organization.

Funding Opportunities:

RFA Available

RFA-AG-05-005: Planning Project for Testosterone Trials in Aging Men

Letters of Intent Receipt Date: Dec. 10

Application Receipt Dates: Jan. 11

The National Institute on Aging invites applications for planning and protocol development of a coordinated set of clinical trials of efficacy and safety of testosterone treatment in older men for specific symptomatic conditions that may be related to low testosterone levels, and of effects of testosterone treatment in middle-aged men on outcomes and risk factors possibly related to low testosterone levels.

The NIA intends to commit up to $700,000 in total costs in FY 2005 to fund one award in response to this RFA. The award will support planning activities, biostatistical and other data analyses needed for trials design, and protocol development. This RFA will use the NIH cooperative agreement (U01) award mechanism.

Inquiries: Sergei Romashkan, Clinical Trials Branch, Geriatrics and Clinical Gerontology Program, National Institute on Aging, phone 301-435-3047, email: romashks@nia.nih.gov.

RFP Available

RFP N02-CP-41016-50: Interdisciplinary Studies of Genetic and Environmental Causes of Cancer

Response Date: Dec. 6

The NCI Genetic Epidemiology Branch is re-competing a contract for support for interdisciplinary studies, NO2-CP-91026, currently held by Westat Inc. The contract will establish a mechanism to provide all the services required to conduct a wide variety of domestic and international family studies and field (case-control and cohort) studies. The maintenance of s secure record room which allows GEB investigators access to the medical records within 15 minutes is a mandatory requirement. There is also a mandatory requirement of the capability of nearly daily face to face meetings with the GEB staff. It is anticipated that one incrementally funded, cost-reimbursement, term type contact will be awarded for a period of five years, with a required total level of effort of 160,000 direct labor hours. The RFP is available at http://rcb.cancer.gov/rcb-internet/.

Inquiries: Karen McFarlane, phone 301-435-3782, email km63k@nih.gov, or Sharon Miller, phone 301-435-3783, email sm103r@nih.gov.

In Brief:

Seither Promoted At Einstein; Spear, Noguchi Join Amgen

(Continued from page 1)

of epithelial ovarian cancer. . . . **ALBERT EINSTEIN CANCER CENTER** appointed **Richard Seither** as associate director for administration and scientific operations, said center director **I. David Goldman**. Seither, a Ph.D. in microbiology and MBA, has held senior administrative positions at Ruttenberg Cancer Center, Mount Sinai School of Medicine, and Massey Cancer Center, and has a background in biochemical pharmacology and computer modeling of anticancer drug actions. . . . **AMGEN Inc.** announced two additions to its staff. **Jonathan Spear** was named vice president for public policy, where he is working with **David Beier**, senior vice president for global government affairs at Amgen. Spear was vice president for government affairs and public policy at Baxter Healthcare Inc. **Philip Noguchi** was appointed director of regulatory affairs, where he is working with **Beth Seidenberg**, senior vice president of global development and chief medical officer at Amgen. Noguchi, a 30-year veteran of FDA, was medical officer in the Office of Orphan Product Development . . . . **STEPHEN RUBIN** was appointed chairman of the Department of Defense Ovarian Cancer Research Program Integration Panel. He is director of the Division of Gynecologic Oncology at the University of Pennsylvania Medical Center. . . . **SHEILA DEARYBURY WALCOFF** was named associate commissioner for external relations at FDA. She was a senior associate with Mayer, Brown, Rowe & Maw LLP of Washington, D.C. She will supervise the Office of Public Affairs, Office of the Ombudsman, Office of Special Health Issues, and the Advisory Committee Oversight and Management Staff, and will serve as a senior advisor to Acting Commissioner **Lester Crawford**. . . . **CARL KARDINAL** will receive the Annual Clinical Research Award from the Association of Community Cancer Centers for his research and promotion of community involvement in clinical research. Kardinal is director of clinical cancer research at the Ochsner Clinic Foundation of New Orleans. He is also clinical associate professor of medicine at Louisiana State University School of Medicine and clinical associate professor of medicine at Tulane University. In the early 1980s, Kardinal worked with NCI to develop the concept of community involvement in clinical research. In 1983, he became a Community Clinical Oncology Program principal investigator and

served on the CCOP advisory committee. He serves on the executive committee of the North Central Cancer Treatment Group and the board of directors of the National Surgical Adjuvant Breast and Bowel Project. The award will be presented at the ACCC National Oncology Economics Conference in Salt Lake City, Oct. 8. . . . **CAROLE EDWARDS**, retired from Bartlett Regional Hospital of Juneau, Alaska, is the first recipient of the Oncology Nursing Society Excellence in Oncology Nursing Health Policy and Advocacy Award. ONS established the award for oncology nurses who participate as state health policy liaisons and other members who are active in advocacy efforts, said **Pearl Moore**, CEO of ONS. . . . **ONCOLOGY NURSING** Certification Corp. board of directors said it has received renewal of its accreditation status from the American Board of Nursing Specialties. ABNS reaccredited the ONCC Oncology Certified Nurse, Advanced Oncology Certified Nurse, and Certified Pediatric Oncology Nurse certification programs for a period of five years through 2009. . . **NATIONAL CANCER** Fighters Awards Trust announced two awards. **Oliver Beahrs**, professor of surgery emeritus at Mayo Medical School is the recipient of the Lifetime Achievement Award. **Philip Saia** was named Cancer Fighter of the Year. He is professor of gynecologic oncology, associate dean for clinical affairs, and vice-chancellor of health sciences at the University of California, Irvine. . . . **ROGER CHOU** was appointed director of the American Pain Society Clinical Practice Guideline Program. He succeeds **Ada Jacox**. Chou is director of internal medicine at Beaverton Health Center, Oregon Health and Science University. . . . **ERIC RADANY** was appointed associate professor of radiation oncology at City of Hope Cancer Center's Division of Radiation Oncology, said division chairman **Jeffrey Wong**. He was an assistant professor of radiation oncology at University of California, Irvine, and a radiation oncologist at the Chao Family Comprehensive Cancer Center. . . . **COLUMBUS CHILDREN'S Hospital** of Ohio received a $100,000 two-year research award for Development of Palliative Care Education for Pediatric Oncologists, a training curriculum from Hope Street Kids. **Kathryn Klopfenstein,** medical director for Columbus Children's Hospice, will serve as the principal investigator. **Cynthia Gerhardt,** a specialist in bereavement and cancer, and **Tammy Young-Saleme**, pediatric psychologist who specializes in hematology/oncology, will be co-investigators. The award will be underwritten by National City Corp., a financial holding company of Cleveland.

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