

THE

# CANCER LETTER INTERACTIVE

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## Bristol-Myers Claims Settlements Are Close In Lawsuits Over Generic Taxol, BuSpar

Bristol-Myers Squibb said that it is close to settling the lawsuits stemming from the company's efforts to block generic competitors from the market for the cancer drugs Taxol and the anxiety drug BuSpar.

A series of separate deals announced by Bristol would require the troubled pharmaceutical company to pay \$670 million to settle claims by state attorneys-general and private litigants.

Completion of the deals, if they are approved by the courts, would bring Bristol a step closer to recovery from its slump, or would give the company better leverage in potential acquisition talks.

In a statement dated Jan. 7, Bristol described the deal as a business  
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### In Brief:

## FDA Forms Office of Combination Products To Process Complex Agents, Devices

FDA established the Office of Combination Products to streamline the processing of drug-device, drug-biologic, and device-biologic combination products. OCP will be part of the Office of the Commissioner. OCP will assign the review and regulation of specific combination products to one of the three product centers—the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, or the Center for Devices and Radiological Health. "This is a significant step to increase the efficiency and timeliness of the procedures that make these important products available to patients," said FDA Commissioner **Mark McClellan**. "I also believe that the activities of this new office will help provide insights into how the Commissioner's office can better support a range of issues that cut across the three product centers, and thus bring greater uniformity and coherence to our processes." The establishment of OCP is part of the FDA's implementation of the Medical Device User Fee and Modernization Act of 2002. The statutorily mandated functions of OCP are to: promptly assign a center with primary jurisdiction for a combination product; ensure the timely and effective premarket review of combination products, by overseeing the timeliness of and coordinating reviews involving more than one center; ensure the consistency and appropriateness of postmarket regulation of combination products; resolve disputes regarding the timeliness of premarket review of combination products; review and modify, revise, (or eliminate if appropriate),  
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## Attorneys General Say Terms Remain To Be Finalized

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move that did not reflect on propriety of the actions in question.

"In this litigation, antitrust violations had been alleged against the company based on actions the company took to protect patents and other intellectual property for the drugs, both of which Bristol-Myers Squibb had pioneered," the company said. "And while the company said that it stood behind its actions and believed they were entirely lawful, it decided that it would be prudent to enter into settlements to put the uncertainty and risk of this litigation behind the company."

### State Attorneys-General Surprised

The news release was a surprise to state attorneys-general, who filed two separate suits claiming that Bristol had violated federal and state antitrust laws as it protected BuSpar and Taxol from generic competitors (**The Cancer Letter**, June 7, 2002).

The attorneys-general confirmed that the financial terms of the settlement with Bristol had been settled, but the terms of an injunction barring the company from anticompetitive practices in the future remained to be worked out.

"We don't have an agreement in principle," said

Meredith Smith Andrus, an assistant attorney general in Maryland, a state that led the Taxol and BuSpar cases. "We have reached agreement on the monetary component of the future settlement, and that's true for both the BuSpar and the Taxol case.

"We are in the process of negotiating appropriate injunctive relief, and for government prosecutors that's of paramount importance," Andrus said to **The Cancer Letter**.

The states are expected to receive about \$155 million of the \$670 million Bristol would pay to settle the litigation, Maryland officials said.

Another plaintiff, Mylan Laboratories Inc., a Pittsburgh-based maker of generic drugs, said it would receive \$35 million from the settlement involving buspirone, the generic version of BuSpar.

Mylan said it would also receive a non-exclusive, royalty-free, irrevocable licenses from Bristol to manufacture, market, and sell buspirone and paclitaxel, a generic version of Taxol.

The settlement also includes class action suits filed on behalf of "direct purchasers," entities who bought Taxol and BuSpar directly from Bristol, and "indirect purchasers," who purchased the drugs through intermediaries.

### Bill Would Close Apparent Loophole

The BuSpar and Taxol cases have one thing in common: in both cases, Bristol had exhausted the seven-year market exclusivity period to which it was clearly entitled under the Hatch-Waxman Act, as well as one 30-month extension automatically available to companies to settle patent disputes.

However, in both cases, just before exclusivity was to end, Bristol claimed additional patent disputes and sought another extension. It is unclear whether such extensions are allowed under Hatch-Waxman. However, earlier this week Sens. Charles Schumer (D-NY) and John McCain (R-Ariz.), reintroduced a bill that would close this apparent loophole in the law.

The dispute over Taxol began when American Bioscience Inc. of Santa Monica, Calif., claimed that Bristol had violated its newly issued patent involving packaging of paclitaxel (**The Cancer Letter**, Oct. 20, 2000). Bristol at first objected to filing certification in the FDA Orange Book, but ultimately made the filing.

While Bristol's generic competitors and attorneys-general claimed collusion between Bristol and ABI, the two companies maintain that their dispute was genuine. ABI was not named in the



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attorneys-general suit.

The settlement of the BuSpar case follows two rulings by Judge John Koeltl of the U.S. District Court for the Southern District of New York, holding the Bristol had acted unreasonably in listing a buspar metabolite patent in the FDA Orange Book, and then suing Mylan and another company over that patent.

The terms of the settlement were scheduled to be reviewed by Koeltl in a hearing Jan. 10.

Bristol's announcement of the settlement had no discernible impact on its share price, which declined slightly from \$25.27 as trading closed on Jan. 7 to \$25.10 the following day. On Jan. 8, Bristol suffered another setback: withdrawal of its antidepressant Dutonin from the European market. The agent, which is suspected of causing liver failure, is marketed in the U.S. under the name Serzone. In the U.S., Serzone's label includes a "black box" warning about the risk of liver failure. As trading ended Jan. 8, the price of Bristol stock fell by about \$1, just under 4%, to \$24.15.

### Obituary:

## **Ellen Tobin, Consultant, Championed Patients' Needs**

Ellen Tobin, an oncology consultant who championed the needs of cancer patients, died Dec. 18 of non-Hodgkin's lymphoma at her home in Chevy Chase, MD. She was 63.

Tobin was president of Cancer Care Strategies, a consulting firm that specialized in conducting focus groups with cancer patients. Her clients included more than 200 academic and community healthcare organizations, cancer centers, NCI, the Southwest Oncology Group, professional and advocacy associations, managed care organizations, and pharmaceutical firms.

"Ellen Tobin was a true champion of patient-centered care in oncology," said Ellen Stovall, president and CEO of the National Coalition for Cancer Survivorship. "On almost a singular level, she ran focus groups for cancer centers, NCI, and others to find out what patients really think and what their own needs were."

Tobin was a developmental psychologist and an administrator at a community health center affiliated with the Johns Hopkins Medical Institutions before founding her first company, Health Surveys and Marketing Inc., in 1981.

She became interested in oncology when her mother was diagnosed with mesothelioma and died of the disease. Tobin began Cancer Care Strategies as a subsidiary of HSM in 1989.

"Because of her qualitative research background, she started out doing focus groups with patients, and studying oncology referral patterns," said Kathie Bowing, a consultant with Oncology Associates, a firm that Tobin worked with regularly. Sometimes it was a struggle to convince administrators of the value of cancer patients' perspectives, Bowing said.

But more often, administrators trusted her advice. Marsha Fountain, a consultant with The Stichler Group and Oncology Associates, met Tobin in 1990 when Fountain was a cancer center administrator at Harris Methodist Fort Worth Hospital in Fort Worth, Texas. "Her work laid the foundation for the design of a new cancer center," Fountain said. "Patients and doctors talked to her about what they liked and didn't like. Based on her work, we developed a breast center, and this was before the days when every hospital had a breast center."

### **Set The Standard For Oncology Focus Groups**

Tobin was considered the best focus-group researcher in oncology. "If you wanted to do an oncology focus group, you had to get Ellen," Fountain said. "She was the gold standard. She was very good at getting people to talk."

After conducting several focus groups with prostate cancer patients, "she used to say that this little Jewish grandmother could even get men to talk about their sexual problems," Fountain said.

Tobin didn't simply elicit information and dump it on an administrator's desk, Fountain said. She had a talent for translating what patients told her into point-by-point recommendations that administrators could put into action.

"When I began working on the design of facilities, I often used Ellen's work to assist architects in design of patient-friendly facilities," Fountain said. "Her touch is seen at many facilities. Ellen taught us to go beyond the science and look at the patients and what their needs were, to seek their advice, and to move toward meeting their physical, emotional, social, and environmental needs."

Tobin conducted more than 2,000 focus groups in her career, and more than half of those were with breast cancer patients, said Claudia Lee, president of C Z Lee & Associates, a consultant to breast



centers. "She developed a special interest in breast cancer, and she and I often worked in tandem as breast centers across the nation were struggling to get started," Lee said.

Tobin presented the results of her research on the evaluation of patient satisfaction and quality-of-life at meetings of the Association of Community Cancer Centers, the Association of Cancer Executives, and the European Society for Psychosocial Oncology. Several of her articles were published in peer-reviewed publications.

"She challenged all of us to listen more closely to what patients have to say," said Catherine Harvey, of Oncology Associates. "Her studies ultimately helped cancer centers improve the quality of care they offered."

### **Developed Palliative Care Expertise**

In recent years, Tobin developed an interest in palliative care and end-of-life issues. She held contracts with NCI and Sibley Hospital in Washington, DC, for palliative care program assessment.

"She was interested in making sure patients could have choices throughout the course of their disease," Fountain said. "Palliative care is more than care of the dying; it's goal is to meet the symptoms of the disease. She gave a number of talks on that."

Tobin had a warm and welcoming manner, a sparkling sense of humor, and was always smiling, even in her last weeks of life, said Brian McCagh, executive director of the Washington Cancer Institute at the Washington Hospital Center, where Tobin received most of her treatment.

McCagh met Tobin 10 years ago and considered her a mentor. "Ellen was a role model for many of us," he said. "Professionally, Ellen was a risk-taker who always maintained her cool, her high values and personal ethics."

Tobin trained in her youth to become a concert pianist and received a Bachelor of Music from Boston University in 1960. She often entertained colleagues after ACCC or ACE conferences, taking over the hotel ballroom piano to play old standards. Several times she played "dueling pianos" with Charles Nash, medical director of the Northeast Georgia Medical Center Cancer Program, in Gainesville, Ga.

"One time we sat around for two hours while Ellen and Charlie would try to out-play each other," Fountain said. "It could be hilarious, because Charlie is an aggressive, loud pianist, while Ellen was little."

Frequently, she played the piano in the lobby of

the Washington Cancer Institute when she came in for treatment or consultations for the center's palliative care and end-of-life initiatives, McCagh said. Sometimes the staff asked her to play during special events.

Lee said Tobin's sense of humor was delightful and infectious. "Whenever we talked on the phone, or roomed together at a conference, we were continuously laughing, and I mean real belly laughs," Lee said. "She was a natural humorist, no matter what the occasion or topic."

Characteristically, Tobin rigorously interviewed oncologists at major cancer centers to determine her course of treatment, which took place at the Washington Hospital Center and NCI. Between recurrences, she continued to work and attend conferences.

"She never quit observing what was going on around her and never hesitated to give advice on how to improve it, even when she was hospitalized at the NCI," Lee said. "Can you imagine this tiny lady, in a great deal of pain, would nicely suggest improvements to the NCI staff?"

"The great thing is that they really listened. She was highly respected in all circles."

In her last weeks, Tobin made her own funeral arrangements, asking friends to speak at her memorial service. Her friends gathered their talks into a memorial book that was given to her about 10 days before her death, "so she could read what she really meant to us," McCagh said. "She was very much at peace with herself."

Tobin was a member of Adas Israel Congregation in Washington, DC, where she began a program to provide home services to congregation members undergoing cancer treatment. When her lymphoma progressed, Tobin found it ironic that she needed to use the program that she had started.

In addition to her music degree, Tobin received a Master of Education from Western Maryland College in 1975. She was a fellow of the Program in Organizational and Community Behavior at Johns Hopkins University.

Tobin is survived by a daughter, Diane Kuchuk, of Annapolis, Md.; a son, Maury Tobin, of Port Tobacco, Md.; sister Faith Hamlin, of New York City; brother Michael Zager, of Monticello, NY; and grandson, Matthew Gregory Cox, of Annapolis, Md.

Memorial contributions may be made to the National Coalition for Cancer Survivorship, 1010 Wayne Ave., Suite 770, Silver Spring, MD, 20910.



*National Toxicology Program:*  
**Feds Lists Estrogen, UV Light,  
Wood Dust As Carcinogenic**

The National Toxicology Program of NIH published its biennial Report on Carcinogens, adding steroidal estrogens to its official list of “known” human carcinogens.

This and 15 other new listings bring the total of substances in the report, “known” or “reasonably anticipated” to pose a cancer risk, to 228.

The reports are mandated by Congress and published every two years.

A number of the individual steroidal estrogens were already listed as “reasonably anticipated carcinogens” in past editions, but this is the first report to so list all these hormones as a group. The report does not address or attempt to balance potential benefits of use of these products.

Also newly listed as “known” causes of cancer in humans are broad spectrum ultraviolet radiation, whether generated by the sun or by artificial sources; wood dust created in cutting and shaping wood; nickel compounds and beryllium and its compounds commonly used in industry. Beryllium and beryllium compounds are not new to the list but was previously listed as “reasonably anticipated to be a human carcinogen.”

Copies are available at [www.ehponline.org](http://www.ehponline.org).

*Regulatory Policy:*  
**Patent Policies Complicate  
Commercialization, Study Finds**

The process of commercializing university research discoveries is beset with complex problems: excessive secrecy, inadequate government policy and inappropriate patent law that affect academe, government funding agencies and industry, according to a study published in the December 2002 issue of the *Milbank Quarterly* ([www.milbank.org/quarterly.html](http://www.milbank.org/quarterly.html)).

The case study analyzes the patent infringement battle between Johns Hopkins University and CellPro, a biotech startup. The findings argue for significant changes to the Bayh-Dole Act of 1980, legislation that sought to spur the interaction between private and public research through the transfer of university research results to the market.

According to the authors, that case—in which Johns Hopkins claimed that CellPro had infringed upon

its patents on a cancer treatment technology—exemplifies the problems arising from academic secrecy, broadly defined patents, and the lack of government oversight of commercialization of university discoveries made using federal funds. CellPro’s loss of the patent infringement case ultimately caused its demise.

“The secrecy that currently surrounds licensing transactions at academic research centers seems likely to come under fire, as well it should,” wrote the paper’s authors, Avital Bar-Shalom and Robert Cook-Deegan. “In our view, terms should be public when the research underlying intellectual property involves public funds.”

Bar-Shalom is a science and engineering fellow at the American Association for the Advancement of Science, and Cook-Deegan is director of the Duke University Center for Genome Ethics, Law, and Policy. They began this research as staff for the National Cancer Policy Board of the Institute of Medicine and National Academy of Sciences. Cook-Deegan was also supported by a grant from the Investigator Awards in Health Policy Research program, funded by the Robert Wood Johnson Foundation.

Cook-Deegan said he and Bar-Shalom examined the conflict between Hopkins and CellPro as part of the policy board’s efforts to streamline the process of developing cancer diagnostics and therapeutics.

“CellPro is a cautionary tale that there is also a dark side of patenting that needs to be assessed, and current data simply do not speak to it,” Cook-Deegan said.

The case revolved around a dispute over patent rights to a technology for isolating stem cells from bone marrow. Since stem cells have the capability of maturing into a range of immune cells to reconstitute a destroyed immune system, the separation technology can be used as the basis for cancer treatments in which stem cells are used to restore a patient’s immune system destroyed by radiation or chemotherapy.

In 1981, a Hopkins scientist developed antibodies that could recognize such stem cells, enabling the cells to be isolated. Hopkins received a broad patent that the university believed covered any use of antibodies for such isolation. The antibody-based technology was licensed to Baxter Healthcare, which began to develop cell-separation instrumentation based on the technique.

Hopkins did not make public its licensing



agreements, a common practice and entirely permissible under the Bayh-Dole Act. This secrecy, the authors said, reduced the university's credibility and complicated efforts to judge the merits of the technology and of Hopkins' position.

Meanwhile, researchers at the Fred Hutchinson Cancer Center in Seattle had developed a different antibody-based separation technique, which was the basis for the 1989 founding of the startup company CellPro. The company decided not to license the Hopkins technology and began to develop its own bone marrow reconstitution technique for use following chemotherapy for breast cancer.

In 1994, Hopkins and the companies to which it licensed its technology filed a patent infringement suit against CellPro. CellPro ultimately lost the suit and as a result, was driven out of business. NIH decided not to exercise its right of "march-in" to compel Hopkins to license its technology to CellPro.

The case illustrates why federal agencies such as NIH should shoulder more responsibility for the commercialization of technology arising from federally sponsored research. "There is no option of government non-interference," the authors wrote. "NIH expressed a reluctance to act against one company on behalf of another, but it did so by not marching in just as much as it would have by marching in. CellPro's survival was in its hands, whether NIH wanted it or not. NIH can wash its hands, but cannot elude responsibility for the consequences."

The case study also shows that along with government reforms, universities must also commit to change. "The secrecy issue is not new for universities, if you look at the history of clinical research," said Cook-Deegan. "However, molecular biology and immunology did have an open science norm, but when universities began interacting with companies in those fields, the patent process imposed a cloak of secrecy, at least up to the point of filing a patent application. And such secrecy has intensified the tension in those areas of science where the norm use to be open sharing of information."

One final lesson to be learned from the CellPro case is that academic scientists and industry could benefit from greater education on the technology transfer process. "Scientists must understand that industry needs intellectual property protection if it is to invest in developing basic discoveries, and that complete, open sharing of information is not possible. On the other hand, the norms of secrecy that pervade business don't belong in academe."

### *Funding Opportunities:*

## **NIH Loan Repayment Programs**

Application Deadline: 5pm EST, Jan. 31, 2003.

NIH is accepting applications to its loan repayment programs. The programs can repay up to \$35,000 a year of qualified educational debt for health professionals pursuing careers in clinical, pediatric, clinical research for individuals from disadvantaged background, contraception and infertility, or health disparities research. The programs also provides coverage for Federal and state tax liabilities.

Participants must have achieved a doctorate-level degree, devote 50 percent or more of their time to research funded by either a non-profit organization or government entity (Federal, State, or Local) and have educational loan debt equal to or exceeding 20 percent of their institutional base salary. U.S. citizens and permanent residents can apply.

The NIH Loan Repayment Programs are the Clinical Research LRP, Clinical Research LRP for Individuals from Disadvantaged Background, Contraception and Infertility Research LRP, Health Disparities Research LRP, and Pediatric Research LRP.

Inquiries: Application information is available at the NIH Loan Repayment Programs Web site at: <http://www.lrp.nih.gov>; phone the Helpline at 866-849-4047.

## **RFA Available**

### **RFA DK-03-011: Hepatitis C: Natural History, Pathogenesis, Therapy and Prevention**

Letter of Intent Receipt Date: March 11, 2003

Application Receipt Date: April 15, 2003

National Institute of Diabetes and Digestive and Kidney Diseases, NCI, National Heart, Lung, and Blood Institute, National Institute on Alcohol Abuse and Alcoholism, National Institute of Allergy and Infectious Diseases, and National Institute on Drug Abuse, invite grant applications for both basic and clinical research in the areas of pathogenesis, natural history, therapy and prevention of hepatitis C.

The focus of the RFA is to elucidate the mechanism(s) responsible for the acute and chronic injury caused by hepatitis C, define the factors that determine the course and long-term outcome of chronic infection, including a search for markers of fibrosis progression, and establish the basis for resistance to the current therapeutic regimens followed by focused efforts to improve the response



rate with better and less toxic drugs. Since the most effective way to prevent the liver disease caused by hepatitis C is through the development of a preventive vaccine, the RFA also supports the submission of applications that aim at generating a vaccine for hepatitis C.

Research areas of focus include: The understanding of the pathogenic mechanisms and disease progression: Identification of biomarkers for disease progression, as well as non-invasive markers for fibrosis, cirrhosis and cancer and characterization of the molecular pathogenesis of cancer secondary to HCV infection. The RFA will use NIH R01 and R21 award mechanism(s). The RFA is available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-03-011.html>.

Inquiries: For NCI—John Cole, III, Division of Cancer Biology, NCI, 6130 Executive Blvd., Suite 5000 Bethesda, MD 20892-7398; phone 301-496-1718; fax 301-496-2025; e-mail [jc121b@nih.gov](mailto:jc121b@nih.gov).

## Program Announcements

### PA-03-052: Proteomics in Diabetes and Other Endocrine and Metabolic Diseases

The PA is part of a larger NIDDK and NCI proteome initiative to promote the use of proteomic technologies for diabetes and its complications, and other endocrine and metabolic diseases. The development and improvement of innovative proteomic technologies is also encouraged through their application to relevant biological questions related to diabetes, endocrinology and metabolic diseases. The PA will use the NIH R01 and R21 award mechanisms. For the R21 there is a limit of 2 years at \$100,000/year in requested support. The PA is available at <http://grants.nih.gov/grants/guide/pa-files/PA-03-052.html>.

Inquiries: For NCI—Mukesh Verma, Division of Cancer Prevention, NCI, 6130 Executive Blvd., Rm. EPN 3144, Rockville, MD 20852-7362, phone 301-496-3893; fax 301-402-8990; e-mail [mv66j@nih.gov](mailto:mv66j@nih.gov).

### PAR-03-045: Nanoscience and Nanotechnology in Biology and Medicine

Application Receipt Dates: Feb. 18, Aug. 18

The PA, issued as an initiative of the trans-NIH Bioengineering Consortium, is aimed at enhancing nanoscience and nanotechnology research approaches that could contribute to biology and medicine.

The purpose of the initiative is to stimulate cross-cutting, integrative research in the fields of science and technology. In particular, this initiative invites research on: i) the creation and use of structures, devices and systems that have novel properties and functions because of their small size, that may be used to achieve a understanding of biological processes and /or contribute to disease detection, therapy, or prevention; ii) conception and fabrication of devices, that will detect and analyze nanoscale entities of relevance to biomedicine; and iii) the study of biological systems at the nanoscale for the purpose of developing nanotechnologies and nanostructured materials for biology and medicine.

Research projects most responsive to the PA will require interdisciplinary collaborations among investigators with expertise in a range of disciplines, including but not limited to engineering, physics, chemistry, cellular and molecular biology, materials and computer science. Applications may propose hypothesis-driven, discovery-driven, developmental, or design-directed research. The PA will use the NIH R01 and R21 award mechanisms. The R01 is recommended for applications that propose basic and applied nanoscience and nanotechnology research and for which preliminary data exists. The R21 is appropriate for proposals that have little preliminary data and have potential for groundbreaking impact.

The PA is available at <http://grants.nih.gov/grants/guide/pa-files/PA-03-045.html>.

Inquiries: Jeff Schloss, National Human Genome Research Institute, 31Center Dr., Rm B2B07, Bethesda, MD, phone 301-435-5538; fax 301-480-2770; e-mail [schlossj@exchange.nih.gov](mailto:schlossj@exchange.nih.gov)

## NCI RFP Available

### RFP: N01-CM-37008-45: Early Clinical Trials of Imaging Agents

NCI Biomedical Imaging Program, Division of Cancer Diagnosis and Treatment, plans to develop contracts to support phase I (safety) and phase II (preliminary clinical efficacy) clinical trials of promising imaging agents. Full text of the RFP is available at [http://rcb.nci.nih.gov/appl/rfp/published\\_rfps.jsp](http://rcb.nci.nih.gov/appl/rfp/published_rfps.jsp).

Inquiries: Kathleen Giuliano, contract specialist, NCI, Treatment, Biology and Science Section, RCB, 6120 Executive Blvd., MSC 7193, Executive Plaza South, Suite 6000, Rm 6052, Bethesda, MD 20892, phone 301-435-3821; fax 301-402-6699; e-mail [giuliank@mail.nih.gov](mailto:giuliank@mail.nih.gov).



*In Brief:*

## Mark Kramer To Direct FDA's Office of Combination Products

(Continued from page 1)

agreements, guidance documents or practices specific to the assignment of combination products; and submit annual reports to Congress on the activities and impact of the Office. OCP will assume and continue the functions of the Combination Products Program established earlier this year within the Office of the Ombudsman. These functions include working with the centers to develop guidance and regulations to clarify the agency's regulation of combination products. **Mark Kramer**, director of the Combination Products Program, will head the new office. . . . **ANN SCHWARTZ**, associate director of the Population Sciences Program at the Barbara Ann Karmanos Cancer Institute, has been named head of the program. In her new position, Schwartz is responsible for furthering cancer epidemiology and prevention research programs by building research groups in molecular and genetic epidemiology, early intervention and prevention, and behavioral oncology, and for promoting interactions with the basic sciences

and clinical research programs. Her research interests include the genetic epidemiology of lung cancer and identifying risks for adenocarcinomas of the lung in women. Schwartz is associate professor, Department of Internal Medicine, Wayne State University School of Medicine and principal investigator and director of the Wayne State University/Karmanos Cancer Institute NCI-sponsored Surveillance, Epidemiology and End Results Program, and co-director of the BAKCI community-based research management core. She was recently appointed to the scientific leadership council. . . . **SUZANNE ROBERTS** has been named national spokeswoman of the Grandparents Cancer Prevention Campaign by Fox Chase Cancer Center. The campaign supports the center's cancer prevention research and education. Roberts is the host of "Seeking Solutions with Suzanne," a public service television program for persons over age 50. . . . **DANIEL PETEREIT** is the principal investigator for the Rapid City (South Dakota) Regional Hospital's NCI-funded Cooperative Planning Grant for Cancer Disparities Research Partnerships. A story in the Jan. 3 issue of **The Cancer Letter** about the NCI program did not include his name.



National  
Comprehensive  
Cancer  
Network

### Clinical Practice Guidelines & Outcomes Data in Oncology

# Annual Conference

**March 12-16, 2003**

**Location:**

The Westin Diplomat Resort & Spa  
Hollywood, Florida

**Program Chairs:**

William T. McGivney, PhD,  
Chief Executive Officer, NCCN

Rodger J. Winn, MD,  
Guidelines Steering Committee Chair, NCCN

Conference attendees will receive the NEW 2003 version of the NCCN CD-ROM: "The Complete Library of Clinical Practice Guidelines in Oncology"

**Register online at [www.nccn.org](http://www.nccn.org).**

**For more information, call NCCN at 866-788-NCCN (6226).**

**Mention priority code "CAN" when registering.**

### Conference Agenda

**March 12, 6 p.m.—9 p.m.**

Conference Welcome Reception

**March 13, 8 a.m.—3 p.m.**

NCCN Guidelines Development Process

Update: Cervical Cancer Screening Guidelines

Update: Acute Myeloid Leukemia Guidelines

Roundtable: FDA Approval Process — Meeting the Need for Promising Therapeutics for Patients with Serious and Life-Threatening Disease

**March 14, 8 a.m.—3 p.m.**

NCCN Oncology Outcomes Database

Update: Colorectal Cancer Guidelines

Update: Cancer-Related Fatigue Guidelines

Update: Prostate Cancer Guidelines

Risk Assessment in Prostate Cancer

**March 15, 8 a.m.—3 p.m.**

Update: Gastric/Esophageal Cancer Guidelines

Management of Gastric Cancer: A Japanese Perspective

Applications of Oral Fluoropyrimidines in Colon Cancer: Their Role and New Directions

Reimbursement for Oral Chemotherapy

Update: Breast Cancer Guidelines

Management of Opioid-Induced Bowel Dysfunction

Quality Assurance in Cancer Care: A Managed Care Perspective

Collaboration in the Delivery of Breast Cancer Care Across Institutional Settings

Oncology Business Update

**March 16, 8 a.m.—12 p.m.**

Update: Thyroid Carcinoma Guidelines

Implementation and Application of Anemia Clinical Practice Guidelines

Interactions between Alternative and Complementary Therapies and Conventional Therapies





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