

THE

# CANCER LETTER INTERACTIVE

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## ODAC Backs Full Approval Of Bexxar For NHL, Despite Small Study Size

The FDA Oncologic Drugs Advisory Committee voted 10-3 to recommend full approval of Corixa's radiolabelled monoclonal antibody for chemotherapy-refractory non-Hodgkin's lymphoma patients who had not had Rituxan.

The committee also voted unanimously for accelerated approval of the agent for chemotherapy-refractory, low grade, and follicular NHL with or without transformation.

By voting to recommend approval for Bexxar at the Dec. 17 meeting, ODAC demonstrated its willingness to disregard the small size of the  
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### In Brief:

## Zoon, Critic Of FDA Consolidation, Named Deputy, NCI Center For Cancer Research

**KATHRYN ZOON**, director of the FDA Center for Biologics Evaluation and Research since 1992, resigned to become principal deputy director for research in the NCI Center for Cancer Research. Zoon had been critical of the reorganization plan to move most of CBER's therapeutics review responsibility to the Center for Drug Evaluation and Research. She joined FDA in 1980. FDA Commissioner **Mark McClellan** appointed CBER Deputy Director **Jesse Goodman** to replace Zoon. "As head of FDA's biologics center, Kathy Zoon has skillfully presided over a decade of dramatic change in the world of biotech, cellular, and gene therapies," said McClellan. "She has helped forge CBER into the world's premier biologic regulatory agency, the global leader in the development of vaccine, blood, and novel therapeutics. NCI Director **Andrew von Eschenbach** and I are convinced that the close FDA ties Dr. Zoon brings to her new post at NIH will enhance FDA's efforts to collaborate closely with NIH to bring safe and effective products to the market—one of my top priorities as FDA Commissioner." Goodman, a virologist who is board certified in internal medicine, oncology, and infectious diseases, joined FDA's Office of the Commissioner in 1998, where he directed the Interagency Task Force on Antimicrobial Resistance. . . . **MEMORIAL SLOAN-KETTERING** Cancer Center has begun the Developmental Biology Program within the Sloan-Kettering Institute to study pathways that cause cells to become cancerous. **Kathryn Anderson**, head of the Developmental Genetics Laboratory, has been  
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## ODAC Majority Overlooks Small Study Size For Bexxar

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studies and the fact that the studies were phase II, whenever there is evidence of benefit for some patients. Bexxar therapy is co-developed in the U.S. by Seattle-based Corixa and Philadelphia-based GlaxoSmithKline.

In many ways, ODAC's deliberations were reminiscent of the committee's decision on the AstraZeneca agent Iressa.

Like Iressa, Bexxar claims dramatic responses that would have been unexpected with other existing therapies (**The Cancer Letter**, Sept. 27). However, as with Iressa, the Bexxar data were anything but overwhelming. The full approval recommendation was based primarily on the results of a single-arm trial of 40 patients, and the accelerated approval was based on the analysis of data pooled from five single-arm studies conducted over 12 years and enrolling 250 patients.

And, as was the case with Iressa, the scientific presentation was preceded by nearly an hour of testimony by patients and advocacy groups. Some of those who testified appeared to have made a determination that the agent in question was safe and efficacious.

"Bexxar is yet another example of an effective drug that needed to be more widely available to

patients than has been allowed," said Frank Burroughs, president of Abigail Alliance for Better Access to Developmental Drugs. "Many other drugs, such as Iressa, are also examples of life-saving drugs and therapies that need to get to patients sooner... If Bexxar had been at least conditionally approved for patients that had run out of options, how many lives might have been saved or extended?"

When clinicians on the committee discern some glimmer of patient benefit from the drug, such testimony by patients and advocacy groups appears to work in favor of the sponsor. In interviews regarding the Iressa recommendation, ODAC members acknowledge taking patient testimony into account as they form their judgment on the drug applications (**The Cancer Letter**, Nov. 8).

The Bexxar trial Corixa described as "pivotal" enrolled 60 patients with chemotherapy-refractory low grade or transformed low grade NHL. Patients acted as their own controls, and the comparison was made between Bexxar and the last qualifying chemotherapy.

In that trial, overall response rate to Bexxar was 47 percent, compared to 12 percent for last chemo. Complete responses were 20 percent, compared to 2 percent for last chemo.

The smallest of the company's studies, conducted in patients with relapsed or refractory low-grade, transformed low-grade or follicular large cell NHL whose disease failed to respond or progressed after Rituxan therapy, enrolled 40 patients. The largest trial, a phase II randomized comparison of Bexxar and tositumomab in patients who relapsed or were refractory to chemotherapy for low-grade or transformed NHL, enrolled 78 patients.

Much of the company's presentation, and the claim that resulted in accelerated approval, was based on the "integrated efficacy population," a composite of five studies. In this unusual analysis, overall response was 56% (95% confidence interval of 50% to 63%), with the median duration of response of 13 months. Complete response was 30% (95% CI 24%-36%), and median duration of CR was 58.4 months.

In a retrospective analysis, the company identified a subset of 76 patients whose responses lasted a year or longer.

FDA elaborated on this analysis, breaking up the long-term responders into two subsets: 68 patients who had a response of a year or longer following a single dose of Bexxar, and eight patients who achieved long-term response after multiple doses. The



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sponsor and FDA provided no criteria, based on medical literature for identifying these subsets.

ODAC found no meaning in this exercise, voting unanimously that identification of long-term responders does nothing to demonstrate that Bexxar provides “meaningful therapeutic benefit to patients over existing treatments.” Only a randomized trial comparing the new agent with existing treatments can yield such data, the committee said.

Though Bexxar has not been compared head-to-head with Zevalin, an agent approved for similar indications, the company presented slides with safety and efficacy data from the two agents. This cross-study comparison was presented to demonstrate that the agents have similar safety and efficacy profiles, the company said.

Many of the Bexxar and Zevalin trials were conducted concurrently. Zevalin is sponsored by San Diego-based IDEC Pharmaceuticals Corp.

Corixa’s data failed to convince three members of the committee: Duke University biostatistician Stephen George, University of Kansas oncologist Sarah Taylor, and Emory University oncologist Otis Brawley. The three maintained that the trials were not designed with sufficient rigor to demonstrate “substantial evidence of clinical benefit,” the basis for full approval.

“I don’t want to be a wet blanket, but I am still concerned with the ‘substantial evidence of clinical benefit,’” said George. “I have difficulty separating my approach to this on this committee as an advisor to FDA, as opposed to what I would say if I were reading this in the literature.

“I would say, ‘That’s very interesting. I would like to see a lot more additional study of this,’” George said. “We have to remember, we are talking about 30 or 40 patients here, and we would be approving something that will be used in a much wider population.”

The study’s size notwithstanding, the data indicates that Bexxar is better than other therapies oncologists use for such patients, said James Krook, principal investigator of the Duluth, MN, CCOP, a voting consultant to the committee.

“I have to agree, it is a relatively small study, but it took a long time to get this together, and it’s probably never going to be done again,” Krook said. “I look at the duration, and I look at the patients who are treated, and I am impressed by the duration and what’s occurred. Usually, we wind up with arm No.

5 or No. 6 of some chemotherapy, and to me this looks better what I can do in arm 4 or 5.”

The agent’s long, tortuous development produced murky data, while earning support of prominent lymphoma specialists, many of whom sat with Corixa officials at the ODAC meeting.

“I do believe that the company has demonstrated that this is an active agent, but I am very much concerned about the quality of the data that they have presented,” said Brawley. “Behind me here is the Dream Team of lymphoma, and I would hope that whatever happens today, Corixa works with that Dream Team to better develop this drug and to better answer the questions that we have here. I am sure that five or six years ago, when many of these trials were being run, the Dream Team was not consulted.”

FDA officials said there would be no need to compare Bexxar to Zevalin for the purposes of approval.

“The legal standard for approval in that setting do not at all involve comparative efficacy or safety over already approved regimens,” said Jay Siegel, director of the Office of Therapeutics Research and Review at the FDA Center for Biologics Evaluation and Research, who recently announced plans to leave the agency. “For hypertension, for diabetes, there are lots of approved therapies. When a new one comes along, it has to be safe and effective. It doesn’t have to be as good or better.

“For this indication, the standard is ‘safe and effective.’ Although the legal standard isn’t written that way, certainly in areas of treatment of acute myocardial infarction, cancer, or other settings where we know we have a drug with an impact on mortality, there largely has been a de facto standard that you better be as good, if not better,” Siegel said.

“Although the law is not written like this, once there is a drug with mortality effect or serious reversal in morbidity, the general advice of the advisory committees, and the general approach has largely been one to one to raise the bar, being as good, but not necessarily addressed by head-to-head studies.”

Siegel said the agency is trying to decide on a standard to apply to accelerated approval, which is granted only for indications where no other therapy exists. If approved, Bexxar’s accelerated approval indications would overlap with the accelerated approval indications for Zevalin.

“An accelerated approval requires a demonstration of meaningful therapeutic benefit beyond existing therapy,” Siegel said. “However,



where drugs are developed sequentially, it become very difficult to address that. All I can say in that regard is that there are substantial discussions within the agency about how best to interpret our regulations and laws regarding what is an appropriate way to meet the legal requirements.

“The interpretation in oncology to this point in time has been the same that we told Corixa in our communication of March of this year, which is that they needed to demonstrate how they met the standard of meaningful therapeutic benefit beyond existing therapy in order to be eligible for accelerated approval,” Siegel said.

“We hadn’t seen that in their application, and we indicated that we would expect additional clinical trials to be necessary,” he said. “The company has come back to us with data about prolonged and durable complete responses.”

Apparently, Corixa’s evidence supporting the accelerated approval claim convinced even the skeptics on ODAC. The committee unanimously recommended approval for the chemotherapy-refractory, low grade and follicular NHL with or without transformation.

Bexxar is a radiolabeled monoclonal antibody that attaches to the target molecule CD20 found on NHL cells, mediating an immune response and delivering a dose of Iodine-131 radiation to tumor cells, the company said. The agent is dosed based on individual drug clearance rates, resulting from such factors as tumor size.

The agent’s toxicities include neutropenia, observed in 42% of the 620 patients who received the agent in clinical trials and through the expanded access program, thrombocytopenia (36%), and anemia (11%). Human Anti-Mouse Antibody was observed in 10% of patients who received the agent, and annualized incidence of myelodysplasia and acute leukemia was 1.7%.

**In another action**, on Dec. 18, ODAC recommended against approval of a supplemental New Drug Application for Codex. The sponsor, AstraZeneca sought two indications: “(1) adjuvant therapy to radical prostatectomy and radiotherapy of curative intent in patients with locally advanced non-metastatic prostate cancer at high risk of recurrence, or (2) immediate treatment of localized non-metastatic prostate cancer in patients for whom therapy of curative intent is not indicated.”

The company sought approval for a 150 mg dose of the agent that is now available in 50 mg tablets in

the U.S, and is indicated for use in combination therapy with a luteinizing hormone-releasing hormone analogue for the treatment of Stage D2 metastatic disease. The sNDA was based on what the company described as the largest prostate cancer treatment trial program ever conducted. The trials enrolled 8,000 patients in 23 countries.

In a 13-3 vote, the committee said the data presented by the Anglo-Swedish company required longer follow-up.

Company data had the median follow-up of 2.6 years. According to the company, 15.6% of patients had objective progression of prostate cancer or died from any cause in the absence of disease progression. However, the agency’s preferred endpoints lowered that estimate 9.3%. The company presented no quality of life data.

While the data suggested that some patients in the U.S. might benefit from the therapy, it was impossible to identify those patients prospectively. Several committee members said they were not convinced by the data on Casodex in the adjuvant setting, but said that the drug may be appropriate for high-risk patients following surgery.

Committee members said the long natural history of prostate cancer requires long follow-up. This could mean that survival data would not become available for about 15 years.

ODAC was split 8-8 in answering the question of relevance of non-U.S. data to the U.S, where patterns of care for prostate cancer include more aggressive screening and early intervention, committee members said.

### Regulatory Policy: **Bush To Seek Legislation For Pediatric Drug Testing**

The Bush Administration said it will seek legislation giving FDA authority to require pharmaceutical companies to test their drugs in children.

The Administration decided not to appeal an Oct. 17 decision by Judge Henry Kennedy of the U.S. District Court for the District of Columbia, which held that FDA lacked the legal authority to enforce requirements for pediatric testing.

That decision prevented FDA from enforcing regulations published in 1998, known as the “pediatric rule” (**The Cancer Letter**, Vol. 28 No. 39, Oct. 25, 2002).





The rule was challenged by three conservative groups, the Association of American Physicians and Surgeons, the Competitive Enterprise Institute and Consumer Alert. Now, instead of continuing the court battle to keep the rule in force, the Administration decided to ask Congress to give the agency authority to require pediatric trials.

“The fastest and most decisive route for establishing clear authority in this area is to work with Congress for new legislation,” HHS Secretary Tommy Thompson said in a statement Dec. 16. “Children are a special population that need to have access to drugs that can benefit them, and these drugs need to be properly tested for pediatric use, not prescribed and sold without testing. Congress alone can speak clearly on the authority that FDA needs and the provisions that may be appropriate for drug manufacturers when they are required to carry out these tests.”

The decision to seek authority for the Pediatric Rule is the first major action on the watch of the new FDA Commissioner Mark McClellan. “We have strongly defended the Pediatric Rule in court, because public health will be best served by enabling FDA to require testing of drugs for pediatric use,” McClellan said in a statement. “But continued litigation is likely to take years, and its outcome is uncertain. The better course now is to work with the committees in Congress and enact new, specific legislation rapidly.”

Supporters of the rule include the American Academy of Pediatrics, Children’s Oncology Group, and the Alliance for Childhood Cancer.

It is unclear whether the legislation the Administration wants would differ from the bills introduced in Congress last year. The bills are S2394, co-sponsored by Sens. Hillary Clinton (D-NY), Michael DeWine (R-OH), and Christopher Dodd (D-CT). In the House, two bills attempted to accomplish the same goal: HR4730, sponsored by Henry Waxman (D-CA), and HR5594, sponsored by Deborah Pryce (R-OH) and Connie Morella (R-MD).

Thompson said the Administration would work closely with Senate Health, Education, Labor and Pensions Committee Chairman Judd Gregg (R-NH) and ranking member Edward Kennedy (D-MA) as well as House Energy and Commerce Committee Chairman Billy Tauzin (R-LA) and ranking member John Dingell (D-MI) toward achieving legislation in the first session of the new Congress.

Thompson outlined principles for the new legislation, saying it should include clear FDA

authority for:

—Consultation between manufacturers and the FDA early in the drug development process regarding pediatric plans.

—Pediatric data to be provided by manufacturer at the time of new drug approval application, or timeline for pediatric data submission, if deferral deemed appropriate.

—Pediatric studies of already marketed products.

—Creation of a new FDA Pediatric Advisory Committee.

Thompson also announced further steps in the implementation of the Best Pharmaceuticals for Children Act, which President George W. Bush signed into law in early 2002, including announcement of the first products to be named for testing under this Act.

This new law reauthorized an economic incentive (extended protection from market competition) for pharmaceutical companies that conduct pediatric studies requested by FDA. However, this economic incentive only applies to drugs with existing patents or exclusivity. For these drugs, this incentive has resulted in a significant increase in the number of pediatric studies performed. Many medicines used in children, but never specifically studied for use by children, are not eligible for this kind of incentive because they no longer have patent protection or exclusivity.

Therefore, BPCA provides a new mechanism to help study these products, providing for a listing of candidate drugs and federally-funded testing.

Working with FDA, the American Academy of Pediatrics, and other experts, the National Institute of Child Health and Human Development is developing the list, Thompson said. The first two drugs for which requests to perform clinical trials under the BPCA will be issued in early 2003 are nitroprusside, for controlled reduction of blood pressure; and lorazepam, for treatment of status epilepticus and for sedation in the pediatric intensive care unit. NICHD also will request proposals to establish a BPCA Coordinating Center, which will help those conducting pediatric clinical trials funded under BPCA.

“Working with our partners, we are making good progress toward development of the full list of off-patent products that need review under the BCPA,” said NICHD Director Duane Alexander. “This kind of look-back at older drugs is an important complement to the clear legislative authority FDA will seek for pediatric testing.”



## *NCI Programs:*

### **NCI Materials Inform Public On Cancer Risk From Fallout**

NCI is sending new publications to health care providers and advocacy groups on the potential thyroid cancer risk from Iodine-131 radioactive fallout due to nuclear testing in the 1950s and early 1960s.

The materials were developed as a result of the Institute's 1997 report estimating thyroid doses of I-131 received by Americans as a result of atmospheric nuclear bomb tests conducted at the Nevada Test Site. The study was conducted in response to legislation enacted by the 97<sup>th</sup> Congress.

Results of the study show that, depending on their age at the time of the tests, where they lived, and what foods they consumed, particularly milk, Americans were exposed to varying levels of I-131 for about two months following each of the 90 tests.

Based on NCI data published in 1997, it is estimated that between 11,300 and 212,000 thyroid cancers could be expected to occur among the U.S. population from exposure to I-131 from above-ground testing in Nevada, the Institute said.

Each year in the U.S., thyroid cancer is diagnosed in 14,900 women and 4,600 men. It is considered highly curable, with a 95 percent five-year survival rate.

The new publications include brochures, a thyroid screening decision aid, a flip chart, public service announcements, and a new Web site that incorporates a dose calculator for assessing individual exposure. NCI has sent the materials to community groups and health care providers, especially those in areas of high exposure to fallout.

The materials are designed for people who have increased risk of exposure to I-131 from nuclear testing in Nevada based on three key factors:

—**Age**—people who are now 40 years of age or older, particularly those born between 1936 and 1963.

—**Milk drinking**—childhood milk drinkers, particularly those who drank large quantities of milk or who drank unprocessed milk from farm or backyard cows or goats.

—**Childhood residence**—people who lived in the Mountain West, Midwest, East, and Northeast areas of the U.S. were generally more affected by I-131 fallout than those in other areas of the country.

The Web site is available at <http://i131.nci.nih.gov/>.

The site includes an I-131 dose calculator developed in 1998, but the Institute is user-testing a new risk estimator that will provide individuals with further context about their risk of thyroid cancer, said Margaret Farrell, a public affairs specialist at NCI. The new risk estimator will be posted online by the middle of January, she said.

The overall average thyroid dose to 160 million people in the U.S. during the 1950s is estimated to have been about 2 rad, former NCI Director Richard Klausner testified to Congress in 1997.

Routine medical use of x-rays during the 1940s and 1950s exposed children to anywhere from 5 to several hundred rad.

### **Two Hospitals Win Grants For Radiation Oncology**

NCI has awarded more than \$2.5 million in first-year funding to two institutions as part of a new grant program, the Cooperative Planning Grant for Cancer Disparities Research Partnerships.

The program, with a total budget of \$27 million over five years, provides support and resources for radiation oncology clinical research in institutions that traditionally have not been involved in NCI-sponsored research, but who care for a disproportionate number of medically underserved, low income, ethnic and minority populations.

Rapid City Regional Hospital, in South Dakota, and Mercy Health Center, in Laredo, Texas, are the first two recipients of grant awards from the CDRP. Rapid City Regional Hospital, which serves a predominantly Native American population, will receive \$1,404,486 and Mercy Health Center, which serves a predominantly Hispanic/Latino population, will receive \$1,120,013 for the first-year funding of the five-year projects.

NCI anticipates making four additional awards to other institutions in 2003.

“The CDRP gives radiation oncologists a unique opportunity to explore ways to reduce the significant negative consequences of cancer-related health disparities by targeting those populations who would not otherwise have access to radiation oncology research or be able to benefit from its progress,” said Frank Govern, deputy director of the Radiation Oncology Sciences Program at NCI.

“This program is attempting to bring new treatments for cancer closer to underserved



communities,” said Harold Freeman, director of the NCI Center to Reduce Cancer Health Disparities. “We’re hopeful that it will link underserved patients to appropriate cancer care.”

Cancer centers and hospitals that provide radiation oncology services to medically underserved populations often are not linked to other cancer research resources. A major component of the CDRP program is the development and maintenance of mentor partnerships between institutions who are new to radiation oncology clinical trials research and experienced institutions who are actively involved in NCI-sponsored cancer research.

The University of Wisconsin Comprehensive Cancer Center, in Madison, and the Mayo Clinic Comprehensive Cancer Center, in Rochester, Minn., will serve as mentor partners for the Rapid City Regional Hospital. The San Antonio Cancer Institute in San Antonio, and the University of Texas M. D. Anderson Cancer Center, in Houston, will serve as mentor partners for the Mercy Health Center.

The grants also support the establishment of telemedicine and teleconferencing systems between institutions and partners, including patient exam cameras and remote-controlled microscope capability to examine biopsy specimens, which allow sites to examine and discuss a case simultaneously.

“We are proud that Rapid City Regional Hospital has been selected as a recipient of this grant,” said Adil Ameer, president and CEO of the hospital. “This will allow us to further improve the care available to the many Native Americans we serve.”

According to Yadvindra Bains, director of radiation oncology at the A.R. Sanchez Cancer Center at Mercy Health Center and the only board-certified radiation oncologist in Laredo, “This grant has given us the opportunity to look forward, into our predominantly Hispanic community’s future, with hopes of alleviating negative outcomes of cancer patients. Not only does Mercy Health Center want to provide health care to those that are sick, but we want to find ways to recognize and prevent the incidence of cancer in our Hispanic community, as well.”

The CDRP was created by Govern and C. Norman Coleman, director of the Radiation Oncology Sciences Program at NCI, based on their experience in community outreach in Massachusetts. The program is designed to empower the communities to develop solutions and to bring the grantees and NCI together to share in one another’s experience.

Key requirements for applicants to the CDRP program are: necessary facilities to provide radiation oncology services; one or more board-certified radiation oncologists; one or more full-time Ph.D. or M.S. physicists; services provided to a target population at a rate greater than the state population average; and higher-than-average cancer rates among the identified population in the hospital’s service area.

Further information about CDRP is available at <http://grants1.nih.gov/grants/guide/rfa-files/RFA-CA-03-018.html> and <http://www3.cancer.gov/rrp/supguide.shtml>.

## ***Funding Opportunities:*** **CAM Research Centers**

National Center for Complementary and Alternative Medicine, NIH, will establish Centers for Research on Complementary and Alternative Medicine.

### **Centers of Excellence**

Letters of intent due date: March 29, 2003

Receipt date: April 29, 2003

The CE will support program project grants to elucidate the mechanisms of action of CAM modalities. The awards will provide opportunities for experienced molecular or cellular biologists, imaging scientists, immunologists, neurobiologists, pharmacologists, physiologists, and other scientists to investigate fundamental questions related to CAM.

### **Developmental Centers**

Letters of intent due date: March 14, 2003

Receipt date: April 15, 2003

The Des will support U19 cooperative agreements in which CAM and conventional institutions and investigators will partner to conduct exploratory and developmental research projects. The awards will provide opportunities for CAM institutions and investigators to strengthen their research expertise and infrastructure while enabling conventional researchers to gain clinical and cultural perspectives critical to the conduct of CAM research.

### **Planning Grants for International Centers**

Letters of intent due date: Feb. 28, 2003

Receipt date: March 28, 2003

The PGICs will support exploratory/developmental grants R21 to enable U.S. and international institutions to jointly plan exploratory and developmental studies of traditional/alternative healing approaches. The grants will lay the groundwork for developing applications for an International Center for Research on CAM that will be called for in 2004.

Inquiries: Requests for applications and program announcements are available on the NCCAM Web site: <http://nccam.nih.gov>.



*In Brief:*

## Anderson Heads New Program At Memorial Sloan-Kettering

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named chairman of the program. The program also will consist of four other researchers who also were in the SKI Molecular Biology Program: **Mary Baylies**, whose research focuses on the way molecules induce undifferentiated cells to become muscle cells in fruit flies; **Peter Besmer**, who studies the role of the molecule called Kit receptor tyrosine kinase in the early development of mice; **Elizabeth Lacy**, who studies complex cell movements in mouse embryos; and **Lee Niswander**, who works with chickens, mice, and bats to study limb development and neural tube formation. **Lorenz Studer**, of the Cellular Biochemistry and Biophysics Program, will also be involved in the program. . . . **WILLIAM CANCE** has been appointed professor and chairman of the University of Florida College of Medicine Department of Surgery. Cance, former chief of surgical oncology with the University of North Carolina at Chapel Hill, succeeds **Edward Copeland**, who served as chairman for 21 years and will remain

a full-time faculty member and the Edward R. Woodward Professor of Surgery. In his new position, Cance will oversee departments of surgery on both the Gainesville and the Jacksonville campus. Cance said he plans to give priority to building programs at the UF Shands Cancer Center, as well as attaining comprehensive cancer center designation from NCI. He has also been appointed associate director for clinical affairs with the cancer center. . . . **CHARIS ENG** has been designated the Doris Duke Distinguished Clinical Scientist for her work in the genetics involved in breast, ovarian, thyroid and other cancers. Eng is the holder of the Klotz Chair in Cancer Research and director of the Division of Human Genetics, Department of Internal Medicine, Ohio State University Comprehensive Cancer Center. The award is given annually by the Doris Duke Charitable Foundation and carries a grant of \$1.5 million over five years. . . . **DAVID GOLDBERG**, president of the Center for Molecular Medicine and Immunology and the Garden State Cancer Center, was honored by the Swedish Society of Medicine and the Swedish Society of Oncology at their annual meeting in Gothenburg in November. Goldberg was recognized for his work on radiolabeled antibodies.



National  
Comprehensive  
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### 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,  
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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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