THE



PO Box 9905 Washington DC 20016 Telephone 202-362-1809

# ODAC Under Attack From FDA Official And Patients Seeking Fast Drug Approvals

In recent months, the FDA Oncologic Drugs Advisory Committee has been under attack from patient groups fighting to expand access to investigational drugs, from the editorial writers of The Wall Street Journal exhorting FDA to approve new drugs faster, and now, from within the agency itself.

Patty Delaney, an FDA official involved in handling expanded-access programs and patient testimony, lambasted ODAC members for (Continued to page 2)

## In Brief:

## Congress Approves \$27.2 Billion For NIH, \$4.62 Billion For NCI, In FY 2003 Budget

NIH received \$27.2 billion for fiscal year 2003, \$3.8 billion more than last year, under a consolidated budget bill passed by Congress Feb. 13. The 16 percent increase was the largest for any single program in the bill, according to the conference report, and represents the final installment in the plan to double the NIH budget over five years. Included in the NIH appropriation is \$4.622 billion for NCI, an increase of \$456 million over the Institute's FY 2002 operating budget of \$4.166 billion.... FDA received \$1.39 billion for FY 2003 in the spending bill passed last week, a \$22 million increase over last year and \$13 million more than the President's budget proposal. . . . CENTERS FOR DISEASE CONTROL AND PREVENTION received \$4.3 billion for FY 2003, \$107 million less than its FY 2002 budget, but \$288 million more than the President's budget request. . . . MARIN COUNTY breast cancer study received \$500,000 in the omnibus spending bill, according to Rep. Lynn Woolsey (D-CA). The funds will expand research, data analysis, and health systems improvements by the Marin County Department of Health and Human Services.... LASALLE LEFFALL JR. was re-designated as chairman of the President's Cancer Panel for a one-year term, the White House said Feb. 6. Leffall is the Charles R. Drew Professor of Surgery at the Howard University College of Medicine and Howard University Hospital. ... CANCER ETIOLOGY BRANCH has been formed in the NCI Division of Cancer Biology by combining the Biological Carcinogenesis Branch and the Chemical and Physical Carcinogenesis Branch, division director Dinah Singer said. The branch will provide a focus for cancer etiology research within the division, she said. Jack Gruber, chief of the (Continued to page 8)

Vol. 29 No. 8 Feb. 21, 2003

© Copyright 2003 The Cancer Letter Inc. All rights reserved. Price \$305 Per Year

FDA Approval Process: **Anecdotal Accounts** No Substitute For Data, Says Former ODAC Chairman Schilsky ... Page 3

**ASCO President Bunn:** Give ODAC Chairman Role In Planning Meeting ... Page 4

Fourteen Advocates Spoke For Iressa At ODAC Meeting ... Page 5

National Academies: Council Suggests NCI, **CDC** Reanalyze I-131 Exposures

... Page 7

Funding Opportunities: Nominations Sought For Paul Marks Prizes ... Page 7



## FDA Official Ups Pressure On ODAC To Listen To Patients

(Continued from page 1)

"infantilizing" patients who testify at the open-mike sessions of the committee's meetings.

"I'd like to ask those members if they have any idea what it feels like to have cancer and to stand in front of a very august and intimidating group of people-not to mention the audio and video recording equipment-and talk about a highly personal and devastating experience," Delaney, a cancer survivor and an official of the Cancer Liaison Program of the Office of Special Health Issues, said in an interview published in the Jan. 25 Oncology Times.

"They ignore them, they read during the open public hearing, they look bored," Delaney said. "The committee tends to infantilize the patients who come to speak, and it really makes me mad. This is a government process, and during the time they are serving on ODAC, the members are representatives of government and are therefore obligated to treat these people respectfully."

Delaney's comments come at a time when pharmaceutical companies are using patients as political constituencies for approval of their drugs and relying on patient testimonials to sway public opinion and FDA. At recent ODAC meetings, testimony by patients giving anecdotal accounts of their disease and requesting that the drugs in question be approved



Newsletter and Electronic Publishers Association World Wide Web: http:// www.cancerletter.com

Editor & Publisher: Kirsten Boyd Goldberg Editor: Paul Goldberg Editorial Assistant: Shelley Whitmore Wolfe

Editorial: 202-362-1809 Fax: 202-318-4030 PO Box 9905, Washington DC 20016 E-mail: news@cancerletter.com

Customer Service: 800-513-7042 PO Box 40724, Nashville TN 37204-0724 E-mail: info@cancerletter.com

Subscription \$305 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Other than "fair use" as specified by U.S. copyright law, none of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, photocopying, or facsimile) without prior written permission of the publisher. Violators risk criminal penalties and damages. Founded Dec. 21, 1973, by Jerry D. Boyd

took almost as much time as the sponsors' presentations of the data.

The testimony was backed by editorial writers of The Wall Street Journal in what appears to be a campaign to equate scientific skepticism with mindless bureaucratic delay. At a recent ODAC meeting, the unofficial first order of business was the reading of an editorial titled: "FDA to Patients: Drop Dead."

FDA spokesman Lawrence Bachorik expressed support for Delaney, describing the agency employee as a "patient advocate."

"I can't speak for Ms. Delaney on this issue, but I'd wager that her observations came in part from her personal experience as a cancer survivor and in part from her role as a cancer patient advocate deeply invested in an open and productive advisory committee process for cancer drugs," Bachorik said to **The Cancer Letter**. "Delaney has brought an essential perspective to the FDA's outreach and its programs designed to expand access to unproven therapies for patients suffering from serious and life-threatening diseases."

Delaney did not return a call from **The Cancer** Letter.

## Solid Data Vs. Quick Approval?

Ellen Stovall, a cancer survivor and president of the National Coalition for Cancer Survivorship, said allegations of slights by ODAC members threaten to obscure the committee's primary role.

"We rely on ODAC members as our best safeguard against bad drugs and bad data," Stovall said. "ODAC constitutes a crucial link in the process of analyzing evidence that will assure safe and effective new therapies reach the marketplace for all who could benefit from them."

"Expanded access protocols is not a new controversy," Stovall said. "Responsible advocates have been at the forefront of helping design clinical trials, supporting industry's drug development plans, developing approval criteria, and ensuring access to cancer therapies through a variety of mechanisms when all options to participation in a clinical trial have been foreclosed."

While advocates of rapid approval and expanded access to cancer drugs have been vocal in recent months, Stovall and other proponents of rigorous criteria have kept a lower profile. One of these groups, the National Breast Cancer Coalition, recently formulated a policy statement on early access to breast cancer therapies.

The Cancer Letter Page 2 ■ Feb. 21, 2003



"NBCC believes that public policy should discourage access to investigational interventions outside of clinical trials," the coalition said in a policy statement adopted last summer. "But there are a few circumstances in which it would be fair and appropriate to implement an expanded access protocol.

"A breast cancer patient with no treatment options left should have access to a new intervention through an expanded access protocol if 1) the therapy has shown some effectiveness and a low risk of serious harm in a phase II trial and 2) she is not eligible for any open clinical trial investigating the therapy in question."

## Who Is To Blame? Sponsors? FDA?

Collegiality at ODAC meetings is eroding at a time when FDA is starting to review the first of the targeted drugs that have different safety and efficacy profiles than hormonal agents and chemotherapy. Hype based on presentations of early data, opinions of Wall Street analysts, and coverage in the press can create demand for drugs long before the submission of the New Drug Application, let alone the FDA approval.

Patients demand that firms set up expandedaccess programs for new, unapproved agents, and while some companies are reluctant to do so, others are capitalizing on the opportunity to create highly motivated, vocal political constituencies for approval of their agents. Patients who receive drugs at no charge under such programs instantly become beholden to the companies who give them scarce, sought-after drugs at no cost. And as companies give their drugs to thousands of patients, they increase their chances of running into atypical disease—and therefore anecdotes to present at ODAC.

Jane Reese-Coulbourne, a breast cancer survivor and a consultant who helps companies design expanded-access programs, said the rising tempers at ODAC are a symptom of breakdown in the systems of drug development and drug approval.

"Is it any wonder the volume has gone up?" Reese-Coulbourne said. "Good people in all parts of the system are frustrated as they try to make solid, scientific, life-and-death decisions with little data, work with out-of-date systems and rules, and desperately try to get access to what they think may be their last chance. Let's face it, no one group or person is to blame—the drug approval system no longer works well in today's realities, and we need to work together to fix it."

Does the fault lie with the FDA drug approval system or does it lie with the drug development system? Are the pharmaceutical companies trying to tug on the heartstrings to distract attention from weaknesses in the data? Are patients being exploited in the process? It's no easy task to answer these questions—especially in the middle of a brawl.

## The Role of ODAC

Even the most disciplined reviewers have a hard time blocking out the anecdotes when considering recommending a new agent for approval, said NCCS President Stovall

"We are all pained by and affected emotionally with the terrible dilemma and desperation faced by patients who have exhausted all treatment options and who often attend ODAC meetings to encourage broader access to unapproved agents," Stovall said.

Stovall and others have long advocated for a systematic way of assuring that all reviewers of cancer therapeutics at the FDA receive adequate training on how the drugs will actually be used by oncology professionals.

"Is it the function of an advocate to get unapproved drugs to desperate patients or to promote better clinical trial designs to allow more people to participate in the only process that can be used to approve new therapies and provide us with evidence about what actually works?" Stovall said.

"Is it useful to publicly chastise ODAC members for being dismissive and inattentive, or would it be more helpful for FDA officials to assure that ODAC members, and all who testify before them, are prepared to address safety and efficacy questions that must be answered before recommending approval?"

Former ODAC chairman Richard Schilsky is also concerned about anecdotal accounts influencing the committee's recommendations on approval.

"Anecdotes are not a substitute for solid data in evaluating the safety and effectiveness of a new treatment, and ODAC would do the American public a disservice if they did not focus their attention primarily on the objective evidence," said Schilsky, associate dean for clinical research at the University of Chicago Biological Sciences Division.

"I would certainly agree that patients who testify should be treated respectfully, as—whatever their reason for being there—they are doing something that is difficult to do, i.e., speaking publicly about a



deeply personal experience," Schilsky said. "But what is ODAC to make of these presentations? One could argue that they almost always represent the bestcase scenarios in that they are both surviving and feeling well enough to travel to Washington to present at a federal panel.

"How did they come to be there? What are their motivations? Do they really represent the views and experiences of the average patient who might receive the therapy under consideration? How should their experiences and opinions be weighed against the objective clinical trial data that is before the committee?"

Paul Bunn, president of the American Society of Clinical Oncology and former ODAC chairman, said the system would be improved if committee chairmen were involved in planning all aspects of the meetings, including the open-mike session.

"I personally believe that the structure of the current system is a good one for the following reasons: 1) the entire process is open and public; 2) all groups are represented and have the opportunity to present their views, including patients, patient advocates, industry, consumers, the FDA, and the ODAC; 3) the times alloted for each group are reasonable, i.e., one hour of the public hearing, one hour for the industry presentation, and one hour for the FDA and questions and answers for ODAC in between," Bunn, director of the University of Colorado Cancer Center, said to **The Cancer Letter**.

"I do believe, however, that issues have arisen that indicate the existence of problems that need to be addressed," Bunn said. "First, the ODAC chair and committee have no input into the public meeting and the speakers at that meeting. Often, the public meeting has problems, because there are too many speakers, many speakers address the same issues, there are competing advocacy groups trying to get time, and industry tries to influence the public presentations.

"These issues in the open public hearing should be addressed," Bunn said. "I agree with the need to adequately train new ODAC members. I also think that the authorities and responsibilities of the ODAC chair need to be readdressed.

"The chair must be able to be involved in the planning and oversight of all portions of the hearings, so that it is run properly. This includes involvement of the chair in the public hearing schedule and in the design of the questions asked of the ODAC members," Bunn said.

#### **Interpreting Anecdotes**

ODAC member Stephen George said he pays attention to patient testimony, as do his colleagues on the committee.

"Public testimonials at the ODAC meetings serve as an important reminder to the committee that our recommendations ultimately concern fellow human beings with serious diseases," said George, a Duke University biostatistician. "I believe that most ODAC members recognize this and give proper attention and respect to the speakers. Indeed, in my private discussions with other committee members, I have never heard any disrespectful comments of any kind."

Interpreting anecdotes is a challenge, George said.

"It is important to recognize that, almost by definition, the testimonials are from or about patients with unusually favorable outcomes," George said. "Just how unusual they are is difficult to assess without proper evidence from controlled trials.

"Because of this, as powerful and moving as many of these testimonials are, and as heartfelt the belief that the agent in question is the cause of the favorable outcome, such testimonials are in reality near the bottom on any scale of strength of evidence relevant to the issues before the committee," George said. "To recognize this in no way demeans the presenters or shows any disrespect for their testimony."

Ultimately, ODAC has to make its decisions based on data, George said. "ODAC has an important obligation to the public as well as to the FDA to insist on reliable and persuasive evidence on safety and efficacy, in particular from 'adequate and wellcontrolled clinical trials', before recommending approval for any therapy," he said. "This may appear to some to be dismissive or unfeeling toward those with few options, but hard experience demonstrates that to do otherwise can lead to disastrous consequences."

George's experience with cancer is not limited to statistics. "I believe that I am one committee member that does indeed have an idea of what it feels like to have cancer," he said. "Not only am I a cancer survivor myself (prostate cancer), but all of my immediate family members, without exception, have also been diagnosed with cancer: Mother (breast cancer diagnosed at age 39; died at age 47); Father (renal cell carcinoma); and only child, a daughter (melanoma diagnosed at age 26)."



#### Fourteen Speakers For Iressa

In at least one case, that of the AstraZeneca agent Iressa, the patients' testimony appears to have influenced the committee's recommendation to approve the small-molecule drug.

When the committee met to review the Iressa application on Sept. 24, 2002, the level of unpleasantness was unusual even by the standards of FDA-bashing. The tone was set by The Wall Street Journal:

"Iressa is a new cancer drug that is helping desperately ill people in clinical trials, and is already approved in Japan," the Journal said in an editorial. "But it looks like that won't be enough to pass through the bureaucratic maze known as the Food and Drug Administration, which once again seems ready to put process above patients."

The first public hearing speaker that morning was Carl Dixon, then president and CEO of the Kidney Cancer Association.

Dixon chastised a former ODAC chairman for describing the public hearing as a "federally mandated nuisance" in an interview with Oncology Times. Attacking this individual, who was not quoted by name, Dixon extended his remarks to the committee members.

"Well, perhaps what we have to say is not, indeed, scientifically relevant," he said. "The committee does have a choice about how they handle advocacy comments. The ODAC members can choose to understand that the deck is stacked against the public and pay close attention to the speakers and, perhaps, ask them questions which would inform the committee about an insight or experience of a 'non-physician,' otherwise known as 'of the public' or a patient advocate.

"It is dangerous when Americans' comments on the activities of their government are viewed as a 'federally mandated nuisance.' It might make the average American wonder if the rulers aren't just a little bit too far removed from the ruled."

Dixon was followed by 13 other public speakers, nearly all of whom were Iressa patients.

In interviews, several members of the committee said their decision to vote on the agent was influenced by the presence of patients whose performance was atypical for patients with advanced lung cancer (**The Cancer Letter**, Sept. 27, Nov. 8, 2002).

Since the Iressa meeting, FDA officials said they would delay the decision on final approval, most likely

in order to review data on elevated incidence of deaths related to interstitial lung disease in Japan, where the drug is on the market.

This delay, in the Journal's opinion, was inappropriate. Citing a Hong Kong physician's characterization of Iressa as a "miracle," the Journal called for the drug's immediate approval. "Cancer patients are dying as Iressa remains bottled up," the Journal wrote on Jan. 16. "New FDA Commissioner Mark McClellan has a lot to do, but the doctors who treat dying patients will tell him that approving Iressa deserves priority."

In the case of Iressa, the patients were not paid to testify, but some received "travel grants" from the National Organization of Rare Disorders, the advocacy group that received funds from AstraZeneca to administer the expanded-access program.

"I remember hearing many such testimonials for laetrile after tens of thousands US patients had traveled to Mexico to receive that agent in the late 1970s, until scientific trials were conducted that established that laetrile provided no benefit," said Thomas Fleming, chairman of the Department of Biostatistics at the University of Washington, who, as a consultant to ODAC, cast a vote against approval of Iressa (**The Cancer Letter**, Nov. 8, 2002).

## "What If It Was Your Daughter?"

On Dec. 17, 2002, Frank Burroughs, one of the new voices of the movement for fast approval and expanded access, stepped up to the open mike at the ODAC meeting on Bexxar, an agent that went though a long clinical development process.

The company's data, which received a recommendation for approval, were pooled from a series of small clinical trials (**The Cancer Letter**, Jan. 3).

"I'm here for two reasons," said Burroughs, president of the Abigail Alliance for Better Access to Developmental Drugs, an organization named after his daughter, who died of squamous cell carcinoma two years ago.

"One is to urge the rapid approval of Bexxar and to make a very important point about Bexxar and other drugs. They need to be approved sooner, at least conditionally approved sooner for people who have run out of options. And it's not being done. Where's Iressa? People can't get Iressa except in a very limited expanded access program. The slow access to new drugs is nothing short of a tragedy—a tragedy.



What if it was your daughter?

"Bexxar is another example of a drug that's been around for a long time that needed to get to people sooner. Bexxar's been available since 1990—yes, 1990. A few people were able to get it in an expandedaccess program for a few years, but a lot of people who could have benefited from it couldn't get it. They ran out of options, they couldn't get it. Their last option was the loss of their lives.

"Bexxar should have been at least conditionally approved years ago. It showed efficacy and safety. There was maybe—certainly, there was—more things to learn about the drug, but imagine if you had run out of options.

"If there is a bad car wreck down the road, guess what happens? Right, they send out ambulances, they send out the paramedics, and they try to save the lives of those who are in the car wreck. But we're not making an emergency response to cancer patients. Come on...

"What's going on is wrong and it's tragic. There are cancer patients out there that we're leaving by the side of the road to die... Let's get Bexxar approved. It should have been approved conditionally years ago. We have lost lives with Bexxar, Iressa, oxaliplatin, and other drugs that waited and waited to be approved. We need changes now.

"We are talking about people's lives.

"That's Abigail one month before she died," said Burroughs, showing the picture of his daughter on the screen above the committee's table.

"She was 21. Iressa had a significant chance of saving her life. We could not get it. Let's conditionally approve... drugs like Bexxar and Iressa for people like Abigail."

Burroughs has high expectations from expanded access to new cancer drugs. In a recent email commenting on the decision by Bristol-Meyers Squibb and ImClone Systems Inc. to set up an expandedaccess program for Erbitux, Burroughs said such programs would increase survival.

"It is important to note that there is much more that can and will be done to provide better access to developmental drugs to patients that have run out of options in there battle to live," Burroughs wrote. "The Abigail Alliance continues to work vigorously and creatively to make changes that will save tens of thousands of lives."

## Was Bexxar Called For?

ODAC member Otis Brawley regularly points

out to speakers that they are attending a scientific meeting, which requires competence and decorum.

"I tend to ignore people who speak to me in disrespectful terms," said Brawley, a medical oncologist at Emory University. "I am sorry, but this is something the nuns taught me in elementary school."

Informed advocates are important players in cancer research and the drug approval process, Brawley said.

"Unfortunately, many of the people we have heard over the past year at ODAC default on their responsibility to stay informed," Brawley said. "For example, at the most recent meeting, a representative for a major prostate cancer advocacy group interpreted two-year data as an indication that the drug he was advocating was associated with two years of progression-free survival. Even the sponsors were laughing at this."

At the open-mike session for Bexxar, Brawley started to wonder whether one of the indolent lymphoma patients needed treatment at the time she received it.

The patient said she wanted to see the agent approved, so she could receive it again if her disease recurred. This hope was unrealistic, since Bexxar is based on a mouse antibody, and therefore can be used only once during the course of a patient's disease.

"There are diseases where therapy, although causing a partial or a complete remission, doesn't make a patient live longer," Brawley said at the ODAC meeting. "Indeed, several of the stories that I heard suggest that those individuals didn't necessarily need Bexxar, even though they went to complete remission and are doing well.

"There can be an advantage to treating someone who has symptoms from the disease in improving their quality of life, even though you don't live longer," Brawley said.

In some cases, a patient can do as well or better without treatment than with treatment. "They only get the inconvenience of that treatment and sometimes they even get harmed or even get killed from getting that treatment," Brawley said. "And, unfortunately, there are some folks out there who are dishonest and just want to take advantage of sick people to make a buck.

"We have to rely upon the scientific method," Brawley said. "Sometimes that involves randomized trials to actually see if people benefit, and to see if the drug really is as good as it appears to be."



#### **Criteria For Expanded Access**

The controversies that have recently become so visible at ODAC emerged years ago, at a time when the National Breast Cancer Coalition was guiding Genentech in the development of the monoclonal antibody Herceptin.

At the time, the NBCC emphasis was to help the company complete the trial and get the agent approved and on the market as soon as possible. Since early access to the agent was not among the coalition's priorities, NBCC and Genentech became targets of protests by several breast cancer activists.

Last summer, NBCC adopted a position on expanded access to cancer drugs. The position statement is available at <u>www.natlbcc.org</u> under "Position Papers."

## <u>National Academies:</u> I-131 Reanalysis Needed

A report by NCI and the Centers for Disease Control and Prevention on the increased risk of cancer for Americans who were exposed to fallout from nuclear-weapons tests did a good job estimating the amount of radiation exposure and the potential health risks associated with it, according to the National Academies' National Research Council.

However, the authors should reanalyze the public's exposure to iodine-131 in light of new information from the Chernobyl incident, the council said Feb. 11. A substantially expanded study of all the radionuclides found in the fallout is unnecessary, the council said.

The council report, "Exposure of the American Population to Radioactive Fallout from Nuclear Weapons Tests," is available at <u>www.nap.edu</u>.

## *Funding Opportunities:* MSKCC Seeks Nominations For Paul Marks Prizes

Nominations Receipt Date: April 30.

Nominations are being sought for the Paul Marks Prizes for Cancer Research, established by Memorial Sloan-Kettering Cancer Center and named for Paul Marks, president emeritus of the center.

The prizes, awarded to up to three investigators every other year, recognize young investigators in basic or clinical research.

Nominees are required to be age 45 or younger at the time of the submission deadline. The winners will present their work at MSKCC, be honored at a dinner, and share a cash award of \$125,000. Nomination packets must include a letter from the nominator outlining the significance of the accomplishments for which the candidate should be recognized. This should be accompanied by a one-page scientific biography of the candidate; a list of up to eight of the candidate's significant published papers with a brief (fewer than 100 words) explanation of the importance of each one; and the candidate's curriculum vitae. Up to three supporting letters may also be submitted.

Inquiries: Send nominating packages to: MaryAlice Yates, senior executive assistant, Office of the President, Memorial Sloan-Kettering Cancer Center, 1275 York Ave., New York, NY, 10021.

## **New NIH Resubmission Policy**

NIH is changing its practice regarding resubmissions of three categories of grant applications. Those categories include: A. Applications that were originally submitted in response to an RFA and then resubmitted as an investigator-initiated application. B. Applications that were originally submitted as investigator-initiated applications and subsequently resubmitted in response to an RFA. C. Applications that were originally submitted using one grant mechanism and subsequently resubmitted using a different grant mechanism (for example, an application that was originally an R01 and then is resubmitted as an R21).

The NIH policy changes are as follows:

1. When an application that was submitted in response to an RFA is not funded and the investigator wishes to resubmit the application, it is to be submitted as a NEW application, unless provisions for submission of a revised application are clearly delineated in the RFA. In addition, if a subsequent RFA specifically solicits revisions of unfunded applications from a previous RFA, the instructions in the second RFA should be followed. In all other cases, applications submitted in response to an RFA and then resubmitted as an investigator-initiated application must be submitted as a NEW application.

2. When a previously unfunded application, originally submitted as an investigator-initiated application is to be submitted in response to an RFA, it is to be prepared as a NEW application.

3. When an unfunded application that was reviewed for a particular research grant mechanism (for example, R01) is to be submitted for a different grant mechanism (for example, R03), it is to be prepared as a NEW application.

The change in policy is effective for applications submitted on or after May 10, 2003.

Inquiries: GrantsInfo, Office of Extramural Research, phone 301-435-0714; fax 301-480-0525; e-mail <u>grantsinfo@nih.gov</u>. OR Division of Receipt and Referral, Center for Scientific Review, phone 301-435-0715; fax 301-480-1987; 6701 Rockledge Dr., Rm 2030, MSC 7720, Bethesda, MD 20892-7720 (20817 for courier delivery).



## <u>In Brief:</u> Researchers At VA Center In Albany Subject Of Inquiry

(Continued from page 1)

BCB, was appointed to lead the new branch. David Longfellow, chief of the CPCB, will serve as senior coordinator for carcinogenesis, Singer said. . . . **INSPECTOR GENERAL** for the Department of Veterans Affairs has begun a criminal inquiry into deaths of patients enrolled in clinical trials at the VA Medical Center in Albany, NY. James Holland, former chief of oncology, and research assistant Paul Kornak, could face charges of involuntary manslaughter if federal investigators determine they were at fault in the deaths of patients, according to reports in the Albany Times Union. Both no longer work at the hospital. They allegedly fabricated data and improperly enrolled patients in a trial of eflornithine, under development by Ilex Oncology, of San Antonio, Tex., for treatment of bladder cancer. Ilex alerted authorities of irregularities with the center's data and is cooperating with the investigation, the company said. Holland is not related to internationally-known cancer researcher James F. Holland, chief of the Division of Neoplastic Diseases at Mount Sinai School of Medicine and 1972 recipient of the Lasker Award. ... EVE SLATER is stepping down as HHS Assistant Secretary for Health to pursue other opportunities. Slater was nominated by President Bush in 2001. Surgeon General Richard Carmona will serve as acting assistant secretary for health.... CITY OF HOPE appointments: Shiuan Chen, an authority on the hormone action and biochemistry in breast and prostate cancer, has been named director of surgical research at City of Hope Cancer Center. He joined City of Hope's Beckman Research Institute in 1985. Michael Benedict was named vice president for research administration. He spent 12 years at the H. Lee Moffitt Cancer Center and Research Institute, and the past two years as executive director for research at the San Diego Children's Hospital and Health Center. ... LELAND CHUNG, Emory University scientist whose prostate cancer experiment was on board the space shuttle Columbia (The Cancer Letter, Jan. 17), said about half of the project can be salvaged with data the astronauts sent daily before the shuttle broke apart on Feb. 1. Chung said he hoped to publish the data in a paper dedicated to the lost crew.



National Comprehensive Cancer Network

# It's Not Too Late – Register Today!

Clinical Practice Guidelines & Outcomes Data in Oncology

# Annual Conference

## March 12–16, 2003

The Westin Diplomat Resort & Spa Hollywood, Florida

Conference attendees will be the first to receive the new 2003 version of the CD-ROM: *The Complete Library* of NCCN Clinical Practice Guidelines in Oncology.

# Experts present updates of the following NCCN Clinical Practice Guidelines:

- Acute Myeloid Leukemia
- Breast Cancer
- Colorectal Cancer
- Gastric and Esophageal Cancer
- Gastric and Esophageal C
- Prostate Cancer
- Thyroid Carcinoma
- Cervical Cancer Screening
- Cancer-Related Fatigue

#### Faculty Include:

- Joseph S. Bailes, MD US Oncology
- Barrie Cassileth, PhD
  Memorial Sloan-Kettering Cancel
- Larry Norton, MD Memorial Sloan-Kettering Cancer Center
- Richard Pazdur, MD
  U.S. Food and Drug Administration
- Leonard B. Saltz, MD Memorial Sloan-Kettering Cancer Center
- Peter T. Scardino, MD, FACS Memorial Sloan-Kettering Cancer Center
- Martin S. Tallman, MD Robert H. Lurie Comprehensive Cancer Center of Northwestern University

## Register online at www.nccn.org.

For more information, call NCCN at 866-788-NCCN (6226). Indicate priority code "CAN" when registering.

#### Other Talks Include:

- Dose Density in Adjuvant Chemotherapy
- NCCN Oncology Outcomes Database
- Roundtable: FDA Approval Process Meeting the Need for Promising Therapeutics for Patients with Serious and Life-Threatening Disease
- Novel Treatments for Pancreatic Cancer
- Implementation and Application of
- Anemia Clinical Practice Guidelines
- Risk Assessment in Prostate Cancer
- Management of Gastric Cancer: A Japanese Perspective
- Applications of Oral Fluoropyrimidines in Colon Cancer: Their Role and New Directions
- Memorial Sloan-Kettering Cancer Center Larry Norton, MD - Collaboration in the Delivery of Breast Cancer Care Across Institutional Settings
  - Management of Opioid-Induced Bowel Dysfunction
  - Quality Assurance in Cancer Care: A Managed Care Perspective
  - Oncology Business Update
  - Reimbursement for Oral Chemotherapy
  - HIPAA and Issues in Clinical Research
  - Interactions between Alternative and Complementary Therapies and Conventional Therapies

The Cancer Letter Page 8 ■ Feb. 21, 2003



## Copying Policy for The Cancer Letter Interactive

The software that comes with your issue allows you to make a printout, intended for your own personal use. Because we cannot control what you do with the printout, we would like to remind you that routine cover-to-cover photocopying of The Cancer Letter Interactive is theft of intellectual property and is a crime under U.S. and international law.

Here are guidelines we advise our subscribers to follow regarding photocopying or distribution of the copyrighted material in The Cancer Letter Inc. publications in compliance with the U.S. Copyright Act:

What you can do:

--Route the printout of the newsletter to anyone in your office.

--Copy, on an occasional basis, a single story or article and send it to colleagues.

--Consider purchasing multiple subscriptions. Contact us for information on multiple subscription discounts.

What you can't do without prior permission:

--Make copies of an entire issue of the newsletter. The law forbids cover-to-cover photocopying.

--Routinely copy and distribute portions of the newsletter.

--Republish or repackage the contents of the newsletter.

We can provide reprints for nominal fees. If you have any questions or comments regarding photocopying, please contact Publisher Kirsten Boyd Goldberg, phone: 202-362-1809, email: kirsten@cancerletter.com

We welcome the opportunity to speak to you regarding your information needs.

