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Was Dr. Bunn Insensitive Or Just Efficient? FDA Imbroglio Points To Larger Problems

Patients with metastatic breast cancer who testified before an FDA advisory committee that reviewed the drug Taxotere last month were treated rudely, a breast cancer activist charged in a sharply worded letter last week.

Amy Langer, executive director of the National Alliance of Breast Cancer Organizations, said Paul Bunn, chairman of the Oncologic Drugs Advisory Committee, failed to extend a courteous greeting to the cancer patients who testified Oct. 17. Subsequently, Bunn asked the patients to shorten their testimony, and scolded them for taking too much time, Langer wrote.

"You were caustic, irritable, chastising," Langer wrote in a Nov. 2 letter to Bunn, director of the Univ. of Colorado Cancer Center. "Your fellow committee members and FDA officials present [did] nothing to stop you as you raised your cranky objections and repeatedly checked your watch while these women told their tragic stories."

Contacted by **The Cancer Letter**, Bunn said he was trying to keep the meeting on time, and was protecting the time allotted to scientific discussion. "I feel terrible that someone thinks I was caustic or irritable,"

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In Brief

ASTRO Officers Named; AACR Fellowships Available; NRC Won't Revoke NIH License

AMERICAN SOCIETY for Therapeutic Radiology and Oncology named new officers for 1995-1996, at the society's annual meeting in Miami Beach, FL. They are: board chairman, **Jay Harris**, Harvard Medical School; president, **Steven Leibel**, Memorial Sloan-Kettering Cancer Center; president-elect, **Richard Hoppe**, Stanford Univ.; secretary, **Karen Fu**, Univ. of California, San Francisco; and treasurer, **John Earle**. . . . **RESEARCH FELLOWSHIPS** for young scientists are available from the American Association for Cancer Research. The Research Fellowship in Clinical/Translational Research and the Research Fellowship in Basic Research will be awarded to scientists who have been postdoctoral or clinical fellows for at least two years. Application deadline Feb. 15. Contact AACR, tel: 215/440-9300. . . . **US NUCLEAR** Regulatory Commission declined a request for an immediate revocation of the NIH license to use radioactive materials. The action was requested by the attorneys for the NCI researcher Maryann Wenli Ma, who sustained internal contamination with phosphorus-32. Ma was pregnant at the time of the contamination.

FDA Procedure On Patient Involvement Likely To Change

(Continued from page 1)

Bunn said. "That's not the case. I don't usually view myself as caustic and irritable. Amy wants a good forum for consumers and patients, and that is what the committee wants, that is what FDA wants, and at the last meeting, it didn't work. Who is to blame? Obviously, I'm the chairman, I share the blame, and it is part of my responsibility to make it work better."

FDA officials said that for the first time since ODAC was formed the public comment session exceeded the alotted time.

Ever since patient advocates started to exert their political will in oncology, they have found themselves in occasional clashes with scientists. An examination of the Langer-Bunn imbroglio brings into focus the problems that stem from the immensely complicated relationships between patients and scientists, patients and FDA, as well as patients and pharmaceutical companies.

Fran Visco, president of the National Breast Cancer Coalition, summarized the lesson to be learned from the controversy: the public comment session is no longer a sufficient forum for consumer involvement in the drug approval process.

"FDA still hasn't found a way to incorporate a true non-scientist consumer perspective into decision-making," said Visco, co-chair of the National Action Plan on Breast Cancer, and a member of the President's Cancer Panel.

"There should be a full, voting member of ODAC who is a non-scientist consumer, to bring a genuine consumer perspective to the table, and FDA should incorporate that perspective at every level," Visco said to **The Cancer Letter**.

"Just giving people an open mike is not enough," Visco said.

Ruth Merkatz, director of the FDA Office of Women's Health, said the agency is treating Langer's criticism seriously. "We certainly are not happy with the situation," Merkatz said to **The Cancer Letter**. "We want to get to the bottom of it, understand it better, and put in a new process so it won't happen again."

As a result of Langer's letter, FDA is examining the process of consumer interaction with advisory committees, Merkatz said. The agency earlier this year began appointing ad hoc consumer representatives to advisory committees.

"There must be much more attention to how the public session is handled," Merkatz said. "Consumer advocacy should be viewed as an integral part of the whole process of review."

NABCO, based in New York, is a non-profit group of 370 breast cancer organizations that provides information, assistance and referral to people with questions about breast cancer. The organization had a budget of $1.5 million in 1994. The organization is a member of NBCC, and Langer is a member of the coalition's board.

At the meeting, ODAC recommended that FDA grant marketing approval for Taxotere, a drug sponsored by Rhone-Poulenc Rorer of Collegeville, PA, and Paris.

Getting Patients On The Agenda

It was Langer who assembled the nine metastatic breast cancer patients and two patient advocates who spoke at the public comment session Oct. 17. The speakers' travel expenses were reimbursed by NABCO.

"We have been concerned that FDA needs to hear more from people with cancer, particularly breast cancer," Langer said to **The Cancer Letter**. "There is a general misperception that women with breast cancer cannot decide for themselves about whether they can withstand the side effects of treatments being considered."

At a meeting last December, ODAC recommended against approving Taxotere, citing its side effects. Patient concerns were not well represented at that meeting, Langer said.

"At a certain point in the meeting, side effects were being discussed in a way that seemed to me not relevant to people with a life-threatening disease, so

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I sent a note to the ODAC chairman at that time, Dr. [Charles] Schiffer, asking to be recognized from the floor, and he did not recognize me," Langer said.

Langer said she wanted the October meeting to be different.

Following the procedure in the Federal Register notice, Langer called Adele Seifried, the ODAC executive secretary, to register her group to speak on the second day of the meeting, when Taxotere would be discussed.

Told that only 30 minutes would be devoted to public comment on each day of the meeting, Langer agreed to move her own testimony to the first day. Further, she agreed that on the second day, when the committee was scheduled to consider Taxotere, patients would limit their comments to three minutes each.

Langer said she realized that something was amiss when she and other speakers walked into the meeting at the Quality Hotel in Silver Spring.

"We were greeted with a mix of irritation and impatience by the executive secretary and by the chair," Langer said. "As soon as we came into the room, the first greeting we got [from FDA staff] was: What were we going to do about this problem we were creating for FDA, and wasn't there something we could do to limit our remarks.

"It is a rather astonishing undertaking for a woman with breast cancer to travel to a meeting," Langer said. "They were not welcomed. They were treated extremely rudely."

FDA's Seifried disagreed with Langer's account of that morning's events.

"I do not recall any rude behavior from Dr. Bunn," Seifried said to **The Cancer Letter**. "I re-read the verbatim transcript and saw no rudeness. I did see him take the time to thank the speakers.

"The speakers did run considerably over their allotted time and it is Dr. Bunn's job to keep the meeting on track to protect time for the scientific review of the clinical trials and for the committee discussion and votes," Seifried said. "However, Dr. Bunn was very patient and asked the cooperation of the speakers only once in speeding up the process. He did not cut off anyone and allowed everyone to finish."

RPR: NABCO Acted On Its Own

A spokesman for RPR said the company did not ask NABCO to advocate the approval of Taxotere.

"We are aware that as matter of policy NABCO does not accept pharmaceutical company support for its advocacy activities," RPR spokesman Jim Weiss said to **The Cancer Letter.** "Like other pharmaceutical companies, RPR has granted money to NABCO, but has no control over how the money is used."

RPR also provides funding to the Susan G. Komen Foundation, Y-Me National Breast Cancer Organization, and the National Breast Cancer Coalition, Weiss said.

In her testimony, Langer noted that NABCO received a grant from RPR. Altogether, 10 companies have given funds to the patient group. Other grantmakers include Avon Products Inc., Bristol-Myers Squibb Oncology Division, Glaxo Wellcome Inc., the Herman Goldman Foundation, and Immunex Corp.

In 1994, NABCO reported to the Internal Revenue Service that 15 contributors gave group $5,000 or more. Of these contributors, seven are pharmaceutical or medical companies. Others are foundations and non-medical corporations, Langer said to **The Cancer Letter**. Amounts donated by individuals are not required to be released.

Langer said NABCO does not endorse specific products. "My purpose in advocacy is not to support a specific product, but to speak to issues concerning access to needed drugs and devices for women with breast cancer," she said.

Langer said that in preparation for the last month's ODAC meeting, NABCO conducted a survey on side effects of chemotherapy. The survey was underwritten by RPR and co-sponsored by NABCO, the Komen Foundation and Y-Me, Langer said.

"Over three-quarters of the survivors surveyed said that their priority was response to treatment, and were willing to tolerate physical effects and financial and emotional risks to reach this goal," Langer testified at the ODAC hearing.

In addition, Langer said, "93% felt that the FDA was too slow in approving new treatment options for breast cancer."

Patient Advocacy And Product Advocacy

Cancer and AIDS patient groups appear to have varying policies on endorsement of products.

NBCC, for instance, takes no positions on approval of specific products. Instead, the umbrella group of breast cancer organizations addresses policy issues, such as the responsiveness of the drug approval process to the needs of the patients.

National Coalition for Cancer Survivorship similarly takes no positions on specific products. "Our policy-making is never related to a product or company, but is aimed at the need for products or information," said Ellen Stovall, NCCS executive director.

"Sometimes groups find themselves taking positions that are quasi-medical, but there is a whole sector out there that can do this," Stovall said to **The Cancer Letter**.

"Everyone knows patient groups take money from the corporate sector. We couldn't exist without it, and it helps us do the wonderful educational things we can do. But when we get up there and act like quasi-medical people, it is counterproductive to our goals," Stovall said.

Grace Powers Monaco, a founder of the Candlelighters Childhood Cancer Foundation, said her organization rarely speaks in favor of specific products.

"If there was a drug that was particularly important in pediatric oncology and we were interested in it, we would send information out to a panel of five experts and get their opinions on whether the drug was ready, and whether they had any questions about it," Monaco said.

The Treatment Action Group, a New York-based AIDS activist group, earlier this week issued a statement calling on FDA to approve three AIDS drugs. In a press release, the group made specific recommendations to FDA about the indications, labeling and future studies of the drugs.

At the ODAC Meeting

According to the agenda, the public comment at the Oct. 17 meeting was scheduled to last 30 minutes. Altogether, 15 people were signed up to speak.

"We have requests to speak at the open public hearing and, since there are so many, I hope the people will try very much to stay on time," Bunn said, according to the official transcript of the meeting.

Speakers from four other groups addressed the committee before NABCO.

Langer introduced her group and noted that the patients and one oncology nurse would receive reimbursement for their travel from NABCO. "It is NABCO's policy not to accept financial support from any pharmaceutical or device manufacturer in connection with FDA patient advocacy activities," Langer said.

First to speak was Gayle Black, a nine-year breast cancer survivor from New York. Black said she had to travel abroad for treatment, which included beta and gamma interferon injected into the tumor.

"In our country, nobody is doing anything," she said. "Nobody is giving us any options.... We take too long, much too long in testing the drug. When it's a stage 4 cancer, you don't have much time."

Black spoke for seven minutes.

"Amy, we're going to have to try to speed this up, or we're not going to be able to address the drug this morning," Bunn said to Langer.

The remaining 10 women spoke for about 30 minutes.

"It is worthwhile to have a few comments," Bunn said when the testimony ended. "We are a society of laws. We obviously on the committee all are sympathetic to what's been said. I think our goals are pretty much the same. The rules—and we are a society of rules—are that there's an hour of public hearing for each session, which we've exceeded by more than 50%, and we do have important drugs, and we need to have time to consider them....

"Some people haven't been here before. We appreciate people coming from a long distance.... We serve on this committee because we're interested in seeing new drugs get to the marketplace. Certainly, yesterday two were approved for breast cancer."

In an apparent response to Black's testimony, Bunn said that cancer patients in the US have access to investigational therapies through NCI protocols, the Group C and Treatment IND processes.

"As far as I know, even though some comments were made about other countries, as far as the ODAC is concerned, we've been meeting for two days four or five times a year, and I'm not sure that there is evidence that there are drugs for cancer that are getting approved more rapidly in other countries.

"Of course, there are exceptions, but many drugs are approved here first. And we do have standards," Bunn said. "And I think standards are very important."

The Aftermath

In her letter to Bunn, Langer wrote:

"Perhaps you did not truly understand the nature of this group. The nine women who appeared through NABCO's arrangements ... are terminally ill. It is likely that their appearance before ODAC will be the last time that they are able to speak out as advocates in such a powerful public forum.... The public hearing section of the meeting, established by

statute for public input on cancer-related issues, was the proper and appropriate forum for their remarks.

"As chair of a committee of leading cancer experts, representing the FDA to the public, you did not welcome these patients, or thank them for coming, or commend them for making a contribution in the face of difficult emotional and physical challenges. Rather, you chose to admonish them, and me as their advocate...for running over the allotted time of the public hearing by a final total of 28 minutes....

"ODAC business is always pressing, and I understand the need to have sufficient time for presentation about the agent seeking approval. However, although most stories have two sides, this is an exception. This is a pure example of a wrong *that must be righted.* You were wrong, and owe these women, and the public, an apology....

"Perhaps the positive aspect of this embarrassment is that it may move the FDA further along in what has been too slow a process: offering appropriate recognition and involvement to people with cancer. Until then, what are your plans to make amends to your public?"

Copies of Langer's letter to Bunn were sent to FDA Commissioner David Kessler, other FDA officials, ODAC committee members and the women who testified.

The Patient Perspective

NABCO provided **The Cancer Letter** with phone numbers of two patients who agreed to comment on the meeting.

Sharyn McConkey, a flight attendant who lives in Miami, said her doctor told her about the ODAC hearing and asked if she would testify. McConkey agreed, and soon thereafter, received a call from NABCO, she said.

"All the women were very excited about being able to tell their story to FDA," McConkey said to **The Cancer Letter**. "We were hurt that they took it so lightly and were rude about the time factor. Some of us had longer stories to tell. I thought it was heartless.

"I don't think FDA really cares about women," McConkey continued. "I've always felt the doctors and the companies are in a conspiracy to make money. They don't really care about why we got sick. I wish somebody would just care a little bit more."

McConkey said that at the meeting, FDA staff instructed the women to keep their remarks to two minutes. "It made us seem unimportant," she said. "They just wanted to get to the corporate stuff and get the drug approved.

"It would have been nice if they had taken more time to meet us personally, not just as someone up there for two minutes," McConkey said. "There wasn't much compassion there."

Beverly Matusow, of Boca Raton, FL, also said her doctor called her and asked her to testify.

"We took the trip hoping to change some things," Matusow said to **The Cancer Letter**. "I'm surprised someone can be so cold-hearted. We felt like we were rushed and they didn't want to give us the time."

Matusow said she had read Langer's letter to Bunn. "I agree completely with Amy," she said. "I think they should set aside the time and listen. Its a courteous thing to do.

"Maybe they should talk a little less and listen to the women more."

McConkey and Matusow, who have the same oncologist, said NABCO paid their travel expenses. The two women's oncologist, Charles Vogel, said NABCO asked him if he had patients who would be interested in speaking to ODAC.

"There was a feeling on the part of NABCO that perhaps patient testimonials could be helpful in influencing ODAC in the direction of speeding up approval of compounds that probably need to be approved," Vogel, head of the Comprehensive Cancer Research Group Inc., a nonprofit research corporation that provides clinical trials to oncologists in South Florida, said to **The Cancer Letter**.

"I have always attempted to be helpful to patient advocacy organizations," Vogel said.

Vogel said his research group received a grant from RPR to conduct one trial of Taxotere.

"We get a grant, just as we get grants from the National Surgical Adjuvant Breast and Bowel Project and the Southwest Oncology Group, to pay data management costs," he said.

Responding to a reporter's question, Vogel said RPR never approached him about bringing patients to the meeting.

Late Faxes, No Phone Numbers

Kathy Troutner and Maria Edelstein came to the meeting from Greenbrae, CA. Troutner is nurse manager for Marin Oncology Associates, where Edelstein is being treated.

Troutner's boss, Peter Eisenberg, medical director of Marin Cancer Institute, said his practice is a member of NABCO. Marin Oncology paid the travel

expenses for Troutner and Edelstein, and expects to be reimbursed by NABCO, he said. Eisenberg is principal investigator of the California Health Care System Cancer Research Group, which enrolled 24 breast and lung cancer patients on a Taxotere study funded by RPR.

"That's the way everybody does clinical trials," Eisenberg said to **The Cancer Letter**. "Either you are doing a cooperative group trial or a company-funded study.

"Do we have a relationship with RPR? Of course. And we have 25 other pharmaceutical studies up and running," Eisenberg said.

Troutner said that several days before the meeting, FDA official Seifried called her and said she had missed the deadline to register to speak and there would be no time left.

"I said that I was told this was an open forum and that my patient and I had made plans to come and I was sure we were included on the [NABCO] list," Troutner said to **The Cancer Letter**.

"Who invited you to this?" Seifried asked, according to Troutner.

Told that NABCO had invited Troutner and Edelstein, Seifried said NABCO "already has too many people," Troutner said.

In an interview with **The Cancer Letter**, Seifried said she learned about several NABCO speakers when she received their faxes the Friday and Saturday before the meeting, past the deadline printed in the Federal Register.

The public hearing is not an open mike, she said. "People are supposed to contact me individually and let me know how long they want to speak and what they want to speak about," Seifried said. "One of my goals is to try to accommodate as many different perspectives as possible.

"Most of the NABCO people did not contact me directly, and most of their faxes did not have phone numbers, and most did not say that they came from NABCO," Seifried said.

John Treacy, director of the FDA Advisors and Consultants Staff, which oversees the work of 17 advisory groups, said that on Oct. 17, for the first time in ODAC's history, the public hearing exceeded one hour. Altogether, ODAC has held 47 meetings.

"I want to express my regrets and apologies to anyone who felt offended by what took place," Treacy said to **The Cancer Letter**. "We encourage public participation at our meetings."

Treacy said the agency tries to accommodate anyone who misses the deadline to register to speak. "In this case we did make the extra effort to allow them to speak," he said.

Treacy commended Bunn for allowing all the speakers to finish.

"It is his job to make sure the meeting runs on schedule," Treacy said of Bunn. "I thought he made the right decision to allow people to speak beyond the time allowed. Asking people to stay within the time limit was appropriate."

"They Practiced Their Speeches"

Nurse Troutner said she wanted to attend the ODAC meeting because she admires the strength of the patients she treats.

"I want to be an advocate for them, and I had a once-in-a-lifetime chance," Troutner said.

ODAC members seemed distracted as they listened to the patients, Troutner said. "These women practiced their speeches in their hotel rooms," she said.

"Dr. Bunn was rude, there's no other way to put it," Troutner said. "He admonished them for running over, instead of thanking them for having the courage to come. Not only were most of the patients in tears, they were ready to walk out."

Following the RPR presentation, ODAC members questioned the company repeatedly about the data on fatigue in patients taking Taxotere. Troutner said some of the patients hoped the panel would turn to them for answers.

"They have the most expert people, the patients, right there to talk about fatigue," Troutner said. "Taxotere is not unlike any other chemotherapy we have for cancer. Adriamycin and cisplatin also have these side effects. These women have very few choices."

Troutner said she went up to two ODAC members during the coffee break and asked them to talk with the patients. "These doctors were very sincere, and they said they did not want this to be the message the patients went away with," she said.

After the coffee break, Bunn again thanked the patients for coming, but Troutner said his remarks did not help. "He tried to apologize, but he should have stopped, because he went on to talk about the time constraints," she said.

In an Oct. 23 letter to the committee, Troutner wrote, "I believe the committee members made the classic 'medical' mistake—talking about patients without acknowledging their presence."

The View From The Committee

ODAC member Robert Ozols, senior vice president, medical science, Fox Chase Cancer Center, said committee members care deeply about patients.

"Most of us are oncologists, and we treat patients, and we are well aware of what they are dealing with," Ozols said to **The Cancer Letter**. "It is important for us to hear about what advocates say, but it is a balancing act in terms of timing, to be fair to the company, the agency, and our own deliberations."

Ozols described the committee's work as intense, even on days when the public comment session does not exceed the allotted time.

"It's a short agenda for a complicated issue," *Ozols said. "If we didn't have those time limits, we* wouldn't get the job done. RPR was turned down last time, and the pressure was to be very fair, and it was clear this was going to take a lot of time."

Ozols said he did not sense any hostility on the part of the committee toward the patients. "They all had a turn to speak, and they were eloquent, and we all appreciated that," he said.

"Paul Bunn has been an advocate for cancer patients all his life," Ozols said. "I've known Paul a long time, and the last thing I think he would want to do is admonish a patient. He's a compassionate doctor. I'm sorry the patients feel the way they do.

"I think Paul's goal is to get those drugs out that that are safe and effective, and he takes the responsibility seriously," Ozols said. "That's why it is sad that there is a feeling that we are working against them."

ODAC Conflict Of Interest Rules

Prior to every ODAC meeting, committee members must provide information on their financial ties and the ties of their institutions to the sponsors of drugs that would be reviewed. Panel members can be barred from taking part in the deliberations if a potential conflict of interest, or the appearance of conflict, is found.

For instance, a conflict can occur when a panel member's institution is conducting a study of the drug under review or a competing product.

At the October meeting, FDA disclosed that Bunn's employer "has financial interests in Bristol-Myers Squibb which did not constitute a financial interest in the particular matters within the meeting...but which could create the appearance of a conflict. However, the agency has determined that, notwithstanding these interests, it is in the best interest of the government that Dr. Bunn be permitted to participate fully in matters relating to Taxotere."

The statement, with a different company mentioned each time, is almost always read at the beginning of ODAC meetings due to the volume of studies Bunn's institution conducts, involving many different pharmaceutical companies, Bunn said.

FDA precluded Ozols from voting on Taxotere, citing "his and his employer's interest in Bristol-Myers Squibb," which manufactures a competing product, Taxol.

ODAC members Sandra Swain and Judith Ochs were excluded from participating in the discussions and the vote.

"NABCO Put Up Too Many People"

ODAC member James Krook said anyone attending the committee's meeting for the first time can feel out of place.

"When I went the first time I thought, this is a circus," he said. "You've got the company on one side and FDA on the other, but everybody's goal is the same. The goal is to come up with reasonably good drugs with limited side effects.

"Maybe we can learn from this, to allow more time [for patient testimony]," Krook said. "I congratulate the ladies for being there. I think they did a nice job, and I can only apologize as a member of the committee if they felt rushed."

Krook noted that rarely does a speaker at the ODAC public hearing urge the committee not to approve a drug. "I think NABCO put up too many people," he said. Some of the speakers could have presented the previous day, he said.

"We bumped into this terrible time constraint," Krook said. "The drug was voted down last December because the company could not answer the toxicity question. The goal of the committee is to look at the scientific merit of the studies and particularly the toxicity of the drug in question.

"I don't think Dr. Bunn was particularly inappropriate," Krook said. "I think he was trying to stay on schedule, knowing that it was not going to be a straightforward discussion."

Bunn: Regrets About The Meeting

Bunn said he had several regrets about the events at the meeting. "I regret that people have an impression which is not the impression you want them to have," Bunn said to **The Cancer Letter**. "You want

them to have the impression that they are welcome and we listen to their comments, and it is an important part of the hearing."

"I got the sense in the middle of the meeting that some of the patients were upset," Bunn said.

Bunn said he thanked the patients for coming to the meeting. "I regret that those comments came later, rather than in the beginning of the meeting," he said.

Bunn said he also regretted that in the afternoon session of the meeting, the committee did not complete its work and had to table discussion of CEA-Scan, a proposed product for colorectal cancer. "I felt we didn't get the job done," he said. "I don't want to give anyone the impression I'm blaming the afternoon's problems on [the patients]."

Most of the committee members had to catch flights later that evening, and the meeting adjourned at 6:05 p.m.

Bunn said he wrote a letter to FDA officials following the meeting. The letter was prompted by his realization that the patients were upset. Bunn said the letter included a suggestion that FDA's Office of AIDS and Special Populations handle the scheduling of the public hearings.

Bunn declined to release the letter to **The Cancer Letter**.

"The job of the chairman is to try to keep things on time," Bunn said. "FDA wants us to answer their questions. If we don't answer their questions, we haven't helped them very much. My instructions were that there were going to be all these people, that this is going to go over [the time allotted], and to try to keep it on time," he said.

The committee usually allows 45 minutes each for the company presentation and the FDA presentation, and time must be left for discussion.

Bunn said he plans to respond in writing to Langer's letter.

"Amy wrote me a very challenging letter that requires a private answer," he said.

Bunn said he felt the patients are mistaken if they think the committee does not want to approve drugs, particularly Taxotere. He noted that between last December's meeting and the October meeting, new information emerged about the toxicity of Taxotere to patients with liver abnormalities.

"Twenty percent of women with breast cancer have liver function abnormalities, and if you have liver abnormalities and you get 100 mg/m^2 of Taxotere, then you have a 20% chance of dying of drug toxicity," Bunn said. "Between the first and second hearings, hundreds of lives of women with breast cancer were saved."

FDA: "There Were Some Misunderstandings"

FDA's Merkatz said she did not attend the meeting, but two staff members were present to greet the patients and make sure they had seats.

"Perhaps there were some misunderstandings, and we thought we had worked it out as to time allotments," Merkatz said.

Merkatz said the ODAC chairman is responsible for ensuring that a full discussion of the drug takes place.

"The chairman's responsibility is to work the agenda and to ensure that there is a robust discussion of the issues that relate to the approval of the drug," Merkatz said. "It is just as important to be sensitive to the dynamics of the meeting.

"We are working on establishing a process so that we don't have something like this happen again," Merkatz said.

RFA Available

RFA AR-96-001

Title: **Skin Diseases Research Core Centers**

Letter of Intent Receipt Date: May 10

Application Receipt Date: June 19

The National Institute of Arthritis and Musculoskeletal and Skin Diseases invites applications for research core centers (P30s) in skin diseases. The Skin Diseases Research Centers (SDRCs) will provide the resources for a number of established, currently funded investigators, often from different disciplines, to adopt a multidisciplinary approach to common research problems in skin diseases and to ensure greater productivity than from each of the separate projects. The direct costs requested may not exceed $400,000 each year. The NIAMS intends to fund two SDRCs from this RFA in FY 1997, subject to the availability of resources and receipt of sufficiently meritorious applications. The estimated funds (total costs) available for the first year of support of these centers are $1.2 million.

Inquiries: The RFA may be obtained electronically through the NIH Grant Line (data line 301/402-2221) and the NIH GOPHER (gopher.nih.gov), and by mail and e-mail from Julia Freeman, Centers Program, EP, National Institute of Arthritis and Musculoskeletal and Skin Diseases, Natcher Building, Room 5AS.19F - MSC 6500, Bethesda, MD 20892-6500, Tel: 301/594-5052, fax: 301/480-4543, e-mail: freemanj@ep.niams.nih.gov

Copies of the SDRC guidelines may be obtained from the NIAMS Clearinghouse, 1 AMS Circle, Bethesda, MD 20892-3675, Tel: 301/495-4484, FAX: (301) 587-4352.