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Mendelsohn Defends ImClone's Actions And His Role In Development Of C225

In Congressional testimony last week, John Mendelsohn joined other officers of ImClone Systems Inc. in defending the company's controversial development of C225, a monoclonal antibody he co-invented.

At the Oct. 10 hearing of the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, Mendelsohn faced the lawmakers' questions about the ImClone scandal,

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In Brief:

Waksal Pleads Guilty To Securities Fraud; UPCI Dedicates Hillman Cancer Center

SAMUEL WAKSAL, former president and CEO of ImClone Systems Inc., pleaded guilty to six charges, including securities fraud, bank fraud, conspiracy to obstruct justice, and perjury. In his Oct. 15 plea, Waksal did not admit having tipped off members of his family that FDA planned to refuse to file ImClone's application for Erbitux. Waksal, 55, is expected to be sentenced early next year. . . . **HILLMAN CANCER CENTER** at University of Pittsburgh Medical Center Shadyside Hospital in Pittsburgh held its dedication ceremony Oct. 10. The Hillman Cancer Center, a 350,000-square-foot building, serves as the new home to the University of Pittsburgh Cancer Institute and as the central hub of UPMC Cancer Centers' clinical services. "In its relatively short history, UPCI has become one of the country's important contributors to basic, translational and clinical cancer research," NCI Director **Andrew von Eschenbach** said at the ceremony. "This new facility brings together patient care and research and offers new opportunities for Pittsburgh researchers to translate laboratory findings into effective therapies for cancer patients." The $130 million center houses research and clinical pavilions. The research pavilion can accommodate more than 450 laboratory personnel. "There is a vast sea of sadness and despair called cancer, but in that sea are islands of hope," said **Henry Hillman**, Pittsburgh philanthropist and primary donor for the new building. "One of those greatest islands will be this center." **Ronald Herberman** is director of UPCI. . . . **UNIVERSITY OF CALIFORNIA San Francisco** Brain Tumor Research Center in the Department of Neurosurgery has been awarded a Specialized Program of Research Excellence grant by NCI. The SPORE includes basic researchers, physicians, and population scientists, concentrating in the areas of epidemiology, cancer genetics,

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Mendelsohn Praises Waksal As Visionary Businessman

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which has resulted in a guilty plea from the company's ousted president and CEO Samuel Waksal.

Mendelsohn, president of M.D. Anderson Cancer Center, has connections to two of the business scandals investigated by the subcommittee. In addition to his role at ImClone, he served on the audit committee of the board of directors of Enron Corp., where he took part in overseeing the work of Arthur Andersen LLP.

"You serve or served on both the ImClone board and the Enron board, obviously two firms where shareholders have taken a great deal of financial adverse effect, while very well-compensated management has been charged with crimes involving their fiduciary duty," asked Rep. Peter Deutsch (D-FL). "Would you tell us whether you feel that you did your job successfully? What happened?"

Facing the subcommittee that has elicited many a dramatic mea culpa, Mendelsohn had none to offer.

"We are here, I believe, to talk about ImClone," he said. "And I believe that I have fulfilled my duties, and that management has fulfilled its duties. Management has admitted in front of this subcommittee that there were aspects of the way that the registration clinical trial was carried out, which could have been done better, and we are hoping to have this reviewed by FDA, after we hear from them on the final details. But the answer to your question is, 'Yes, I believe have fulfilled all my duties.'"

Since last December, when FDA refused to file the Biologics License Application for C225, and the ImClone scandal began, many observers wandered how a scientist as respected as Mendelsohn became associated with two rogue companies.

Though he has not been accused of wrongdoing, Mendelsohn figures prominently in the ImClone scandal.

Besides having co-invented C225 (trade name Erbitux), he owns ImClone shares that at their peak were valued at about $30 million. He is a member of both the company's board of directors and the scientific advisory board. Until recent changes in company policies, he was a paid consultant to the company, a role that experts in corporate ethics describe as potentially conflicting with a board member's fiduciary responsibility to protect the interests of shareholders. As president of M.D. Anderson, he oversees an institution where his agent is being tested in clinical trials. On top of that, he is a member of a board of oncologists who advise Bristol-Myers Squibb, the company that last year invested $2 billion in Erbitux and ImClone.

Last week's ImClone hearing was the subcommittee's second. So far, Congressional investigators have examined the structure of the Erbitux clinical trials, FDA standards for approval of cancer drugs, issues related to insider trading, responsibilities of corporate boards, and the interaction between FDA and the Securities and Exchange Commission. The committee has also examined the details of the deal between Bristol and ImClone (**The Cancer Letter**, June 21).

The investigation has led to the FDA decision to standardize its procedures for review of drugs and biologics and broadened the Department of Justice investigation of Samuel Waksal's friend, the home decorating entrepreneur Martha Stewart, who sold all of her ImClone stock one day before the biotechnology company received a refusal to file letter from FDA. The committee alleged that Stewart made false statements to its investigators, an action that can constitute a felony (**The Cancer Letter**, Sept. 13).

Mendelsohn Defends Waksal, ImClone

The recent hearing could have given Mendelsohn an opportunity to distance himself publicly from

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ImClone and the people who run it.

At the time of the hearing, Waksal was facing federal charges stemming from machinations involving ImClone. (On Oct. 15, he pleaded guilty to securities fraud, bank fraud, conspiracy to obstruct justice, and perjury.) He is also being sued by his former company, which claims that he destroyed documents sought by federal prosecutors.

ImClone is being sued by shareholders, and has received a Wells notice from SEC, an indication that the agency staff intends to prosecute. Old misdeeds of ImClone executives are being trotted out of the past. In June, Vanity Fair published an account of Waksal's less than stellar academic career. The Wall Street Journal, on Sept. 27, reported that Waksal was forced out of Stanford and Tufts universities, NCI, and Mount Sinai Medical Center for "misleading and, in one case, falsified scientific work."

Waksal's brother Harlan, the company's current CEO, who sat to the right of Mendelsohn at the witness table, has not escaped scrutiny. In 1981, as a medical student at Tufts, Harlan was arrested with a kilogram of cocaine in his underwear, bag, and coat. Harlan was convicted for possession of cocaine with intent to distribute, but the conviction was overturned on appeal. In 1993, Barron's published an account of this misadventure.

Instead of making distance from the Waksals and ImClone, Mendelsohn praised company founder Samuel Waksal for his vision, and vigorously defended ImClone's clinical development of Erbitux that resulted in a refusal to file letter from FDA last December (**The Cancer Letter**, Jan. 4, Jan. 11).

ImClone's phase II registration trial of Erbitux as a treatment for advanced colorectal cancer achieved its goal of demonstrating activity, Mendelsohn said.

"As someone who has devoted his life to cancer research, I can't stress enough just how critical ImClone has been to the development of this revolutionary cancer drug," Mendelsohn said. "Until ImClone licensed C225 in 1993, no other company had taken a serious interest in developing this treatment."

Mendelsohn praised Samuel Waksal as a businessman and as a scientist.

"Sam Waksal was one of the few scientists who not only understood the molecular basis of treatment with C225, but developed and executed a plan to transform it from a molecule in the lab into a powerful and innovative cancer treatment," Mendelsohn said. "Under Sam Waksal's leadership, ImClone raised money for the drug's research and development, guided the drug through completion of phase II studies of its efficacy, and made it the centerpiece of a major collaboration with one of world's leading pharmaceutical companies."

Mendelsohn said Samuel Waksal's checkered history in academia first came to his attention in June, when he read the Vanity Fair story about ImClone. Mendelsohn said he did not check out Waksal's reputation before joining the firm's scientific advisory board. (In his testimony, ImClone president Harlan Waksal said that he, too, was unaware of his brother's track record in academia.)

"I was delighted that there was somebody who seemed to have the energy and the vision to try to bring this forward," Mendelsohn said, describing Samuel Waksal's efforts in 1993 to license the C225 patent from the University of California.

"I talked with a number of pharmaceutical companies, who were not interested in moving this idea forward, and, frankly, I was delighted when I met Dr. Sam Waksal that he quickly saw this wasn't just an immunotherapy with an antibody, but that we were acting on the EGF receptor, which is relevant in a large number of human cancers," Mendelsohn said.

In his testimony, Mendelsohn said that Waksal's problems should not be allowed to impede Erbitux.

"Sam Waksal's personal failings should not detract from what is really important—that Erbitux shows great promise," Mendelsohn said. "Although questions rightfully abound about why the FDA did not accept the Erbitux BLA for filing, each study that has been conducted strongly suggests that Erbitux is an active anti-cancer agent in end-stage colon cancer."

Mendelsohn's reference to questions about the Erbitux development program can be construed as a reference to either (a) criticism of the company, or (b) criticism of FDA. In fact, throughout the ImClone controversy, The Wall Street Journal editorial writers have repeatedly blamed the Erbitux fiasco on what they describe as the agency's intransigence.

Mendelsohn said his involvement with ImClone continues.

"I am disappointed that Erbitux will not be available for patients who need it as soon as we had originally hoped," he said. "I joined and continue to work with ImClone, because I believe its scientists have the vision, the desire, and the capability to get

this new treatment to patients.

"My personal goal remains to do everything in my power to bring Erbitux through the approval process and to patients with cancer," he said.

Mendelsohn Defends ImClone Studies

Mendelsohn and Harlan Waksal asserted that the clinical trial of C225 was appropriately designed.

"The company and the investigators who were working on that protocol did not feel—and I do not believe they feel today—that that protocol was flawed," said Harlan Waksal. "It is not a fair characterization to state that the company was out promoting a flawed protocol. What we were doing was working to move the drug forward through clinical studies.

"We are a very small company that used clinical research organizations, individuals with great knowledge in this area, to oversee these studies and protocols," Waksal said. "We had great expertise from the oncology community, from individuals with great expertise from all of these centers, 25-plus centers, who were working with us to make sure that our protocols were well-defined and moving forward appropriately."

Mendelsohn said ImClone consulted premier experts in oncology as it designed the trial.

"The protocol was developed with the advice of medical oncologists from some of the world's greatest institutions, 27 of which participated in carrying it out," Mendelsohn said.

"There were numerous meetings," Mendelsohn said. "I went to those meetings to give background. I often attended meetings to give background and the scientific rationale for what we were doing, and many of these various experts from many institutions around the country would get together and work with the company. The company also brought in expert consultations from individuals who worked closely with it and developed the protocol."

The problems with the trial were catalogued at length last December, when FDA said ImClone's data were uninterpretable and sent a refusal to file letter to the company.

To begin with, the trial lacked a proper definition of eligibility, and was not structured to separate the contribution of C225 from the contribution of irinotecan, a chemotherapy agent used in the two-drug combination tested in the trial, the agency said.

The agency also noted a lack of justification for the dose of C225, problems with assessment of response, and numerous protocol violations (**The Cancer Letter**, Jan. 4, Jan. 11).

Subsequently, **The Cancer Letter** obtained a copy of the protocol and asked three experts to review the document. In their critiques, the experts—Otis Brawley of Emory University, Mace Rothenberg of Vanderbilt University, and Howard Ozer of the Oklahoma University Cancer Center—agreed with the FDA conclusion that the trial was fundamentally flawed (**The Cancer Letter**, Feb. 15).

As the Oversight and Investigations Subcommittee launched its probe of ImClone, it hired Raymond Weiss, an expert in designing and auditing clinical trials, to review the protocol and the data from the trial.

Concurring with the analysis by Brawley, Rothenberg and Ozer, Weiss presented the results of his audit of the data, which showed that 26.6 percent of the patients in ImClone's clinical trials were ineligible for enrollment. Generally, in trials conducted by cancer cooperative groups, about 3 percent of patients are found ineligible (**The Cancer Letter**, June 21).

In his testimony last week, Mendelsohn said that much of the criticism of the study was irrelevant.

"We believe that many of the issues that have been raised in the press are not relevant to that trial," he said.

"Excellent investigators at many institutions stand by these data," Mendelsohn said. "We want to have it reviewed in a way the FDA wants it, so it's recorded and documented properly. ImClone is planning, with its partner, Bristol, a large number of additional trials that are answering all the questions that are being raised."

From the start of the controversy last December, ImClone officials acknowledged only that FDA threw out the ImClone application because the company failed to produce proper documentation of patient's eligibility for the trial.

"Clearly, one of the problems we had with that clinical study was that we had faulty documentation," Harlan Waksal said in testimony last week. "That was something that I talked about at the last hearing, something that I regret took place, and something that we are still working to make sure is in place and correcting."

Mendelsohn and Waksal said the company's scientific advisory board had not met formally since 1997.

"Up until around 1996 and 1997, we met as a

group regularly," Mendelsohn said. "After 1997, the company's emphasis shifted more towards two or three products that they were bringing into clinical trials, and the scientific advisory board was consulted with individually or in groups of two or three, as needed."

Rep. Ernie Fletcher (R-KY) asked Mendelsohn whether the group was consulted about the Erbitux clinical program.

"It seems rather odd to me that you have a scientific advisory board that is made up of some very distinguished members, and I assume their responsibilities was to oversee the scientific side of these protocols, and yet they were so flawed," said Fletcher, a physician. "And at the whole time when the scientific advisory board was not meeting, not overseeing protocols, you have the company and the board still promoting this product as being very promising in the future."

"The scientific advisory board members were nearly all Ph.D.s, and were much more focused on the pre-clinical work than the clinical work," Mendelsohn responded. "The protocol was not reviewed by that board for flaws at all. It was not the business of that scientific advisory board to review that protocol."

After FDA refused to file the ImClone application, P. Frederick Sparling, a member of the ImClone scientific advisory board and the J. Herbert Bate Professor and emeritus chairman of medicine, microbiology, and immunology at the University of North Carolina School of Medicine, suggested that the advisory board guide ImClone out of its predicament.

"Since many outsiders apparently are suffering from a lapse in confidence in the company as a result of the various public statements and disclosures, I suggest that your scientific advisory board could help if you were to bring us together to review the situation in some detail," Sparling wrote in a letter dated Jan. 15 and addressed to Samuel and Harlan Waksal. "I realize that I am not a cancer investigator, but I think the board could be very useful at this particular time, and I suggest that you bring us together again for this purpose."

More than a month later, on Feb. 21, Sparling had not heard from the Waksals, and resigned from the board.

"I think it's advisable for me to resign from the SAB effective immediately," he wrote. "I just do not believe that I can be useful to the SAB, and the long-term inactivity of the SAB suggests that the SAB is not useful to the company."

The Question of Disclosure At M.D. Anderson

Mendelsohn said he was aware of potential problems of running an institution involved in clinical trials of his agent.

"From the point of view of conflict of interest, I have never treated a patient with C225," he said. "From the point of view of potential conflict of interest, whenever I have given scientific talks or written papers, I have always stated my holdings in the company and my membership in its scientific advisory committee."

Shortly after coming to M.D. Anderson in 1996, Mendelsohn instituted a rule prohibiting any physician with an interest in a drug from treating patients with that drug or serving as the principal investigator on trials involving that drug.

In 1998, when he joined ImClone board of directors, Mendelsohn agreed to take no part in studies conducted by ImClone at M.D. Anderson.

Last November, shortly after Mendelsohn sold about $6 million in ImClone stock, he amended the M.D. Anderson informed consent forms for Erbitux trials to disclose that he had a financial stake in the company.

On June 30, The Washington Post reported that 195 patients at M.D. Anderson were treated with Erbitux prior to that disclosure's appearance on the consent forms. The Post story was not an exposé, but an exploration of ethical issues that emerge when the president of a major cancer center benefits financially from development of a therapy that is being tested in his institution.

"Before any of this happened, because of the concern I had about even a perception of conflict, I instructed M.D. Anderson that on all patient consent forms, my name be placed as a member of the board and holder of stock options in the company," Mendelsohn said at the hearing.

"I was concerned enough about the potential perception of conflict of interest that I added that [disclosure]," Mendelsohn said. "I regret that I didn't do that at the very beginning, when all of this started. But I added that to our procedures at M.D. Anderson without prompting, and of my own volition."

M.D. Anderson was not involved in ImClone's registration trial of C225 in colorectal cancer.

Having a stake in ImClone did not cause Mendelsohn to restrict other companies' access to

M.D. Anderson, he said.

"I have bent over backwards to support research with any product that blocks the EGF receptor," he said. "I was contacted by AstraZeneca at M.D. Anderson and asked, 'Would you be willing to study Iressa?' I put them in contact with the same doctors that were studying Erbitux. And, as point of fact, there have been more studies of patients on Iressa at M.D. Anderson than on Erbitux.

"My goal is to give the patients the opportunity to have access to any drug that a particular patient and his or her physician feel is the best chance they have," Mendelsohn said.

The issue of disclosure of financial interest by research institutions and their key officials is largely unsettled.

"I wish it were easy, but this is one of the most difficult issues we've had to deal with in my seven years in this institution," Leonard Zwelling, vice president for research administration at M.D. Anderson, said to **The Cancer Letter**. "We constantly reexamine the manner in which we handle potential conflicts, and I envision that this is going to evolve constantly. Every institution that we talk to is struggling with this. We don't want to dampen the investigators' enthusiasm, but we want to preserve the trust that exists between an institution like ours and the public."

In January 2001, about 10 months before Mendelsohn amended the consent forms to disclose his interest in ImClone, HHS published a draft interim guidance on management of conflicts of interest.

The document states: "If a financial conflict of interest on the part of the institution and/or clinical investigator has not been or cannot be eliminated, what the financial arrangement is and how that conflict is being managed should be disclosed in the consent document. The document should explain what additional protections have been put in place. An IRB should consider taking special measures to modify the consent process when a potential financial conflicts exists."

The HHS document is posted at http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/finguid.htm.

Earlier this month, the Association of American Medical Colleges proposed a set of guidelines for oversight of the institutions' financial interests in human subjects research. The AAMC guidelines are posted at www.aamc.org/members/coitf/start.htm.

The guidelines recommend that in situations similar to that faced by M.D. Anderson, institutions "should conduct a specific, fact-driven inquiry into whether the particular financial relationship may affect or reasonably appear to affect human subjects research conducted at or under the auspices of the institutions."

Such inquiries should be conducted whenever officials with direct responsibility for human subjects research "hold a significant financial interest in the commercial research sponsor or the investigational product," the guidelines state. AAMC defines "significant financial interest" as ownership of stocks, potential for royalties, board membership, and receiving of over $10,000 a year from the company in question.

Until a recent change in corporate policies, ImClone paid Mendelsohn $12,000 a year in consulting fees, company filings show. Now, as a member of the board, Mendelsohn earns $30,000 a year. Another member of the ImClone board, Vincent DeVita, director of Yale Cancer Center, received $100,000 in consulting fees, company filings show (**The Cancer Letter**, July 5).

Closer Interaction Between FDA and SEC

FDA Deputy Commissioner Lester Crawford said his agency is transferring the application review functions from Center for Biologics Evaluation and Research to Center for Drug Evaluation and Research.

All new cancer agents will be reviewed by the expanded Division of Oncology Drug Products, headed by its current director Richard Pazdur, Crawford said.

Erbitux was reviewed by CBER.

At this point, CDER and CBER are putting together a guidance document for the industry on "Good Review Management Principles" for the first review cycle of new drug or biologics licensing applications, Crawford said.

As a result of the ImClone controversy, the agency has been working more closely with Securities and Exchange Commission, Crawford said. "FDA has undertaken a systematic review of its interactions with the SEC, and we intend to systemize our interactions further based on discussions with those officials," he said.

A recording of the ImClone hearing is available on the committee's Web site at http://energycommerce.house.gov/107/hearings/10102002Hearing746/hearing.htm.

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RFA-CA-04-002: Mouse Models of Human Cancers Consortium

Letter of Intent Receipt Date: Feb. 19, 2003

Application Receipt Date: March 19, 2003

NCI invites new and competing renewal cooperative agreement U01 and NIH intramural applications from groups of investigators to propose risky approaches that incorporate broad knowledge of human cancer research into design, analysis, and applications of mouse cancer models, and to incorporate biocomputational, mathematical modeling, and systems biology strategies to inform design of genetic models and their cross-comparisons to human cancer. The newly implemented trans-disciplinary nature of the MMHCC will sustain discoveries that should stimulate mechanistic hypotheses for future research and generate additional tools in support of translational and clinical cancer science.

NCI encourages applications from groups with broad expertise that may include, but is not limited to: mouse-related research, such as genetics, genetic engineering, biology, physiology, and phenotyping; application of cancer models to human basic, translational, clinical, and population science; application of computational, statistical sciences, mathematical modeling, and bioinformatics to integrate human and mouse cancer research; use of chemistry, genomics, proteomics, imaging, and image analysis to inform model design, characterization, and application; development of innovative technologies to support derivation, phenotyping, and translational applications of new or existing mouse cancer models. The RFA is available at http://grants1.nih.gov/grants/guide/rfa-files/RFA-CA-04-002.html.

Inquiries: Cheryl Marks, NCI, Division of Cancer Biology, Executive Plaza North, Room 5000, Bethesda, MD 20892-7380, phone 301-594-8778; fax 301-496-8656; e-mail marksc@mail.nih.gov.

RFA-CA-03-017: NCI Institutional Pre-Doctoral Research Training Partnership Award

Letter of Intent Receipt Date: Feb. 27, 2003

Application Receipt Date: March 27, 2003

The NCI Cancer Training Branch invites applications to support the development of new pre-doctoral training programs that are partnerships between extramural institutions and areas of research within the components of the NCI Intramural Program to enhance training opportunities at these institutions for pre-doctoral students in high priority areas of cancer research. Participation in the initiative is anticipated to expand opportunities for students and faculty at the institutions for training and the conduct of research, provide greater access of trainees and researchers to unique aspects and resources—for example, databases and study cohorts—of the NCI Intramural Program; and stimulate important new scientific collaborations between extramural and NCI scientists and students. The RFA is available at http://grants1.nih.gov/grants/guide/rfa-files/RFA-CA-03-017.html.

Inquiries: Lester Gorelic, Cancer Training Branch, Office of Centers, Training and Resources, NCI, 6116 Executive Blvd Suite 7025, Bethesda, MD 20892, phone 301-496-8580; fax 301-402-4472; email lg2h@nih.gov

In Brief:

UCSF Wins SPORE Grant For Brain Tumor Research

(Continued from page 1)

cancer biology, and molecular therapeutics. Researchers are supported by administration and tissue core resources, a steering committee, and an external advisory board. The SPORE focuses on the development of new therapeutic approaches to brain tumor treatment and prevention. The principal investigator is **Mitchel Berger**, professor and chairman, neurological surgery and director, Brain Tumor Research Center, UCSF. The clinical co-principal investigator is **Michael Prados**, Charles B. Wilson Endowed Chair in Neurological Surgery and chief, Neuro-Oncology Service, UCSF. . . . **NEW YORK UNIVERSITY Division of Nursing** was awarded a $2 million grant from NCI to conduct a clinical trial of education and counseling approaches for breast cancer patients and their partners. The trial will compare four groups receiving four different approaches or combination of approaches including standard disease management intervention, educational tapes and telephone counseling. "We know that education counseling combined with medical treatment are important components for recovery," said **Carol Hoskins**, principal investigator and professor in the Steinhardt School of Education, NYU Division of Nursing. . . . **FRAN VISCO**, president of the National Breast Cancer Coalition, has received the 2002 Frances Williams Preston

Award for Breast Cancer Awareness from the Vanderbilt-Ingram Cancer Center for her advocacy. The award is named for Nashville native **Frances Williams Preston**, president and CEO of BMI, a performing rights organization. Preston is president of the T.J. Martell Foundation for Leukemia, Cancer and AIDS Research, which supports research laboratories that bear her name at Vanderbilt-Ingram, and she serves on Vanderbilt-Ingram's Board of Overseers. Visco, a breast cancer survivor, is a former appointee to the President's Cancer Panel and chairman of the Integration Panel of the Department of Defense Peer-Reviewed Breast Cancer Research Program. . . . **FDA PROPOSES ACRYLAMIDE STUDY**: Earlier this year, Swedish researchers reported finding the chemical acrylamide in a variety of fried and baked foods. Acrylamide is known to cause cancer in laboratory animals, but research to date has been inconclusive about the chemical's cancer-causing potential in humans. FDA has put forth an action plan to learn more about the chemical. The draft of the action plan is available at: www.cfsan.fda.gov/~dms/acryplan.html. . . . **DONNA DEAN**, formerly the acting director of the National Institute of Biomedical Imaging and Bioengineering, has been named as its first deputy director. In the formation and development of NIBIB, Dean served as senior advisor to then NIH acting director, **Ruth Kirschstein**. **Roderic Pettigrew** is the NIBIB director. . . . **TEXAS** is the most recent state to take advantage of the federal Breast and Cervical Cancer Prevention and Treatment Act of 2000, which allows states to expand Medicaid coverage to women who were screened through the National Breast and Cervical Cancer Early Detection Program run by the Centers for Disease Control and Prevention and found to need treatment for breast or cervical cancer. To date, HHS has approved the expanded Medicaid eligibility in 46 states. . . . **ALFRED KNUDSON Jr.**, Fox Chase Distinguished Scientist and advisor to the president, has received the FCCC14th Wick Williams Memorial Award and Lectureship. In 1995, Knudson became special advisor to former NCI Director Richard Klausner. He worked with Joseph Fraumeni, director of the NCI Division of Cancer Epidemiology and Genetics and served as acting director of the NCI human genetics program until 1998, when he returned to FCCC full-time. Knudson is known for his two-hit theory of cancer causation.

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