# THE CANCER LETTER

P.O. Box 15189 WASHINGTON, D.C. 20003 TELEPHONE 202-543-7665

Vol. 21 No. 42 Nov. 3, 1995

© Copyright 1995 The Cancer Letter Inc. Price \$255 Per Year US \$280 Per Year Elsewhere

## P-32 Ingestion At NCI Attracts Attention; Similar Cases Seen At Labs In The Past

Following months of press coverage, the story that began when a postdoctoral researcher at NCI received an internal dose of phosphorus-32 is continuing to attract national attention.

In the latest development, the CBS news show 60 Minutes is preparing a report on the circumstances surrounding the contamination of Maryann Wenli Ma, the researcher, who was pregnant at the time she had ingested the isotope.

Setting the stage for a public hashing out of this immensely complicated story, Ma's lab chief John Weinstein, who is portrayed as a villain in Ma's complaint to nuclear regulatory authorities, is also expected to appear on the program.

In a complaint to the Nuclear Regulatory Commission, Ma and husband Bill Wenling Zheng allege that Weinstein, chief of the Laboratory of Molecular Pharmacology at the NCI Division of Cancer Treatment, (Continued to page 2)

In Brief

### James Institute Receives \$9 Million Gift; NCI's Fraumeni Wins Public Health Award

ARTHUR G. JAMES Cancer Hospital and Research Institute at Ohio State Univ. received a gift of more than \$9 million from the founders of a real estate development company. Dorothy Klotz and Marion Rowley, founders of Klotz-Rowley Income Investment Co., made the gift to support cancer genetics research. Klotz is a breast cancer survivor. The funds will endow the Kathleen Klotz Chair in Cancer Research, named for Klotz' late sister who died of breast cancer, and will benefit the Cancer Genetics Scholars Program to recruit molecular cancer genetics researchers to the center. The center is an NCI-designate comprehensive cancer center. . . . JOSEPH FRAUMENI, acting director of the NCI Div. of Cancer Epidemiology and Genetics, this week received the John Snow Award from the American Public Health Association. The award recognizes distinguished contributions to public health through epidemiology. Fraumeni joined NCI in 1962. . . . US BIOSCIENCE INC. of West Conshohocken, PA, has received the Technology Transfer of the Year award, an Enterprise Award sponsored by the Eastern Technology Council and Business Philadelphia magazine. The award recognized the company for acquiring rights to products for cancer and allied diseases, and for taking its first three products through the development and regulatory process.

NCI's Weinstein Said He Never Pressured Researcher . . . Page 4

Weak Structure,
Deficiencies, Cited
In Dana-Farber Reviews

... Page 5

Groups Urge Congress To Enact NIH Budget Increase; Encourage Individual Letters

... Page 7

US Files Motion To Dismiss Fisher Suit Over Database Flags

... Page 7

UT-Houston Wins NIH Center Grant For Alternative Cancer Medicine Studies

... Page 8

RFA Available

... Page 8

# Six Life Science Labs Report Deliberate Contaminations

(Continued from page 1)

had been relentlessly pressuring the Chinese scientist to terminate the pregnancy. The complaint also alleges that Weinstein had interfered with the assessment of Ma's exposure and her treatment.

"Frankly, the whole discussion is quite ridiculous," Weinstein said to **The Cancer Letter**. "Given my record as a supervisor, the notion that I would be involved in such a thing to save some time on the maternity leave just doesn't make sense.

"Anybody who has worked in my group will know that I take a mentor's interest in the welfare, not just in research, of those involved," Weinstein said in his first interview since the case became public

#### A Series of Incidents

The incident at NIH appears to be a part of a seried of similar incidents involving contamination and poisoning in US life science laboratories. Ingestion of radioactive materials and poisons has occurred in at least five other lab since 1982.

"These events occur when you take an individual who is psychologically unstable and expose him to the stress ingrained in the laboratory environment," a victim in one of the cases said to **The Cancer Letter**. "The real reason for these events is that the environment of research will always be stressful, and that means these events are going to occur again."

The radioisotope P-32 was used in four of the six cases.

So far, only one case has resulted in an arrest and two cases are under investigation. No deaths were reported in any of the incidents.

### THE CANCER LETTER

Editors: Kirsten Boyd Goldberg
Paul Goldberg

Founder & Contributing Editor: Jerry D. Boyd P.O. Box 15189, Washington, D.C. 20003 Tel. (202) 543-7665 Fax: (202) 543-6879

E-Mail: 73322.2044@compuserve.com
Subscription \$255 per year US, \$280 elsewhere. ISSN 0096-3917.
Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, mechanical, photocopying, facsimile, or otherwise) without prior written permission of the publisher. Violators risk criminal penalties and \$100,000 damages.

A summary of the cases follows:

•At NIH, the source of Ma's intake of as much as 1,000 microcuries of P-32 remains uncertain.

The researcher alleges that the contamination occurred on June 28, after she ate three-day-old leftovers from a meal at a Chinese restaurant. The leftovers were kept in the office refrigerator, Ma states in her complaint to NRC.

On July 14, NIH officials reported that radioactivity was detected in a water cooler near Ma's lab. Altogether, 26 people were exposed to small doses of P-32, NIH officials said.

•On Aug. 14, a little over six weeks after Ma's exposure, a postdoctoral researcher at MIT ingested about 579 microcuries of P-32 (The Cancer Letter, Oct. 27).

Though the intake was relatively small, NRC gave the case a high priority because of its apparent similarity with the NCI case.

In a press conference that concluded the on-site investigation last week, NRC officials said the exposure was not accidental, and it appeared that someone had placed P-32 in the researcher's food or drink.

•On June 6, 1994, at Rockefeller Univ., 15 people were poisoned with coffee tainted with sodium fluoride. Following the poisoning, gas jets were turned on in two laboratories, and two days later, a fire was started in a closet, police and Rockefeller officials reported at the time.

According to press reports, the New York Police Department investigation centered on a male scientist. Rockefeller, too, conducted an investigation, and, ultimately beefed up security in the laboratories. However, no arrest was made in the case.

"Neither investigation yielded enough evidence to prompt the police to make an arrest," Rockefeller spokesman Marion Glick said to **The Cancer Letter**.

•On April 20, 1988, at Duke University, a laboratory scientist ingested an estimated 3 to 9 millicuries of P-32, said Richard Fry, deputy director of the North Carolina Division of Radiation Protection.

The circumstances of the exposure or the source of the isotope were never determined, Fry said. The researcher's exposure was measured at 31 rem.

Investigators were unable to locate the source of contamination, and the case, which received no news coverage, remains unsolved.

•In 1983, a scientist at Quidel Pharmaceuticals, a La Jolla, CA, biotechnology firm, pleaded guilty to

having used a laboratory chemical to lace the office coffee pot.

Acrylamide, a substance used to separate proteins, lowers blood potassium levels. According to press reports, four people were hospitalized in the incidents that occurred in 1982 and 1983.

The scientist was sentenced to serve a year in an honor camp, a five-year probation and a \$1,000 fine, the Los Angeles Times reported at the time.

•On Feb. 8, 1982, at Brown University, a postdoctoral researcher triggered an alarm on an area monitor after returning from a lunch break, NRC documents state.

An investigation revealed radioactivity readings on the researcher and the uneaten portion of her sandwich. University officials estimated that the researcher ingested about 350 microcuries of P-32.

#### "I Carry NoDoz"

No federal agency keeps track of ingestions of poisons or radioactive materials, **The Cancer Letter** has learned

The NRC keeps records of the cases it had investigated, thereby leaving out the cases handled by state radiation safety agencies. Moreover, under NRC regulations, institutions are not required to report ingestions of under 600 microcuries.

Thus, the recent case at MIT was not reported to the authorities for two months until the journal Nature informed the institute that it was planning to publish a story on the incident.

Laboratory poisonings that do not involve radioactive materials are even more difficult to trace since they are generally investigated by local and state authorities.

The few researchers who are familiar with the lab poisonings expressed surprise that such events do not occur more frequently, especially at the time when the scarcity of research grants is putting additional pressure on scientists.

A victim in one of the cases said to The Cancer Letter that attempts to strengthen security at laboratories would be unlikely to stop these acts.

"The people who do this are more intelligent than average, and no matter what you do to thwart them, they will find a way to get around it," the victim said. "The bottom line is that people have to protect themselves. I never drink coffee brewed in a public area.

"I carry NoDoz," he said.

The existence of other cases of deliberate

poisoning and radiation exposure in laboratories may cast a different light on the NCI case.

"It is disturbing that Dr. Ma, Dr. Zheng and their lawyers have rushed to judgment in this matter instead of taking a good hard look at the facts," said Weinstein's attorney Fred Joseph. "There are many explanations for what has taken place [at NCI], and certainly there is evidence that there have been similar situations at other labs."

Ma's attorney Lynne Bernabei said the existence of analogous cases can be construed as evidence of dysfunction in the environment of research laboratories.

"It's a response to unproductive competition, where members of the same lab, instead of working cooperatively, are out for themselves to reap the benefits of any discovery," Bernabei said.

#### The Mystery of Symptoms

The reports by Ma and the MIT researcher Yuqing Li that they experienced pain and discomfort following ingestion of P-32 would run counter to clinical experience with the radioactive material, several clinicians said to **The Cancer Letter**.

In her complaint, Ma said she experienced "sharp pains on the right side of her liver area" the night after eating the leftovers, which, according to the complaint, included fish and shrimp. MIT researcher Li reported nausea and pain in the joints, a woman who identified herself as Li's wife confirmed to The Cancer Letter.

"I am not familiar with any side effects associated with oral P-32, even in millicuries doses," said Emil J Freireich, professor of hematology and oncology at M.D. Anderson Cancer Center.

"There are no symptoms at the 1,000 microcuries level," agreed Louis Wasserman, a hematologist at the Mt. Sinai School of Medicine and former chairman of the Polycythemia Vera Study Group. P-32 is one of the treatments for polycythremia vera, a blood disorder.

Kenneth Miller, editor of the Health Physics Journal, said that even at 15-millicuries doses of P-32, patients report no pain or nausea.

"The patient experiences none of the classic symptoms you would associate with radiation overexposure," said Miller, professor of radiology and director of the Division of Health Physics at the Hershey Medical Center at Pennsylvania State University.

If the complaint is accurate, psychosomatic pains

in Ma's case would have to be ruled out because, according to the document, the researcher experienced pains in the liver area the day before her contamination was discovered.

"I think they cannot tell you that patients who receive radiotherapy experience no pain," Ma's attorney Bernabei said. "I would be surprised. That would run counter to all scientific evidence that has led to setting occupational exposure limits.

"Even in external exposures, P-32 has been reported to produce very serious side effects," Bernabei said.

Ma was not available for comment. The scientist's agreement with 60 Minutes precludes her from speaking to other news organizations, Bernabei said.

#### Revoke the NIH Licence?

One possible explanation for the symptoms was suggested by Anthony Fainberg, an expert in safety of nuclear materials.

"It does not take a rocket scientist to see that anyone who eats three-day-old shrimp may be susceptible to gastric distress, particularly in the second trimester of pregnancy," Fainberg said to **The** Cancer Letter.

Ma was in the 17th week of pregnancy at the time of her contamination, the complaint states.

In the complaint, Ma's attorneys argue that NIH has systematically failed to control and secure radioactive materials.

To support the claim, the complaint presents an overview of problems NRC has found during inspections on the NIH campus.

These included a contamination of a sink with Iodine-125, external contaminations of researchers with P-32, as well as citations for the lack of "constant surveillance of radioactive materials in the nuclear pharmacy" and "failure to refrain from drinking and eating in a restricted area."

"At the very least, I see a materials handling problem at NIH," said Fainberg, a physicist who until recently was a science policy analyst at the congressional Office of Technology Assessment. "At worst, I see a security problem, which could be particularly serious, especially if there is a lunatic running loose."

Fainberg, who reviewed the Ma complaint at the request of **The Cancer Letter**, said the majority of violations cited in the complaint were minor.

"When NRC goes to a facility and looks, they always find violations," said Fainberg. "That's why

they do it.

"It would be outrageous to use any of the problems and violations cited in the complaint as a pretext to shut down DNA research at one of the world's premier AIDS and cancer research facilities," Fainberg said.

#### Weinstein's Version

In his first detailed response to the allegations in Ma's complaint, Weinstein said he had never pressured Ma to terminate her pregnancy.

"The subject of the termination of pregnancy did come up, but it's interesting to note that it was Dr. Zheng who brought up that subject," Weinstein said to **The Cancer Letter**.

Weinstein said that after learning about Ma's pregnancy he encouraged her to fill out the forms required by the NIH Radiation Safety Branch, he said.

"I was the one who got the declaration of pregnancy form [and] I explained it to them," Weinstein said.

Moreover, Weinstein said that, contrary to allegations, he had never insisted that Ma continue her work with radioactive isotopes. "I leave it to an individual investigator to decide on the kind of work they are doing," he said.

In the interview Weinstein offered his version of a crucial event in the controversy: a meeting with Ma and Zheng, followed by dinner at a Chinese restaurant. It was the leftover food from that dinner that may have been contaminated with P-32, the complaint states.

Contrary to the complaint, which characterized the meeting as "unpleasant," Weinstein said the meeting was amicable and productive.

"Their experiments had been failing [and] they were frustrated," Weinstein said. "I thought we had made good progress in [pinpointing] possible reasons for why their experiments were failing and what to do about it."

After the meeting, Weinstein reluctantly accepted the invitation to have a late lunch with Ma and Zheng, he said.

"I was scheduled to go out at 6:30 that evening, so it wouldn't have been my choice to go out to lunch starting at 2:30, but I felt that this was a gesture on their part, and so I had to take it up," he said.

Weinstein also disputed the allegations that after learning of Ma's contamination, he had objected to informing the NIH Radiation Safety Branch, delayed Ma's transportation to a hospital and, later, advised a hospital physician to "discontinue his efforts to collect [Ma's] urine over a 24-hour period."

"My reaction throughout was one of concern for Dr. Ma, concern for Dr. Zheng, and an attempt to help provide the best possible care, reassurance and information for diagnosing the amount of contamination," Weinstein said.

Weinstein said that after ascertaining that contamination had in fact taken place he called Radiation Safety Branch. Weinstein said he had never advised hospital physicians to stop collecting Ma's urine. "That's ridiculous," he said.

The complaint quotes Weinstein telling Ma that "the baby should be worried," an apparent reference to possible health effects of the exposure on the fetus.

In an interview, Weinstein said he could never have made that statement.

"I don't know what those words mean," he said. "It's certainly not the way I would speak."

### Weak Structure, Deficiencies Cited In Dana-Farber Reviews

Dana-Farber Cancer Institute said this week that two committees found weaknesses in the center's organizational structure and deficiencies in quality assurance, clinical care and training programs.

An internal peer review committee and an external peer review committee concluded that the clinical leadership of the institute needed to be strengthened. Neither committee found evidence of an attempt to cover up the incidents.

The institute appointed the committees to investigate its clinical care after one patient died and another patient had severe heart damage following overdoses of chemotherapy. The patient who died was Boston Globe health columnist Betsy Lehman.

To improve patient safety, the institute said it has made 42 changes in procedures and personnel, including the replacement of its top leadership. In recent months, David Nathan replaced Christopher Walsh as the institute's president, and Stephan Sallan replaced David Livingston as chief of staff.

"We have made, and are continuing to make, whatever changes are necessary to insure that Dana-Farber Cancer Institute always provides the safest, most compassionate, state-of-the-art cancer care available anywhere," Nathan said in a statement. "This has been a painful period for us all, but the lesson has been learned."

The external committee was chaired by Vincent

DeVita, director of the Yale Cancer Center.

The institute released a summary of the findings of both committees because Massachusetts law protects the privacy of peer reviews.

#### Phase I Protocol

According to the summary, both patients who received overdoses were enrolled in a phase I trial of a new high-dose chemotherapy regimen for metastatic breast cancer: Dana-Farber protocol 94-060, "Modulation of high dose CTCB with PBPC support for metastatic breast cancer."

The protocol was designed as part of the institute's Solid Tumor Autologous Marrow Program (STAMP). The treatment plan consisted of three chemotherapy cycles increasing in potency: four days of high-dose cyclophosphamide; high-dose cyclophosphamide plus cimetidine; finally, cyclophosphamide plus cimetidine, thiotepa, and carboplatin. At the end of the third cycle the patients were to be given infusions of their own stem cells.

The protocol called for the infusion in each phase of the treatment plan, a cyclophosphamide dose of 1,000 mg/m<sup>2</sup> for each of the four days of each cycle. The patients were to receive a total dose over four days of 4,000 mg/m<sup>2</sup>.

For both Lehman and the second patient, the trial continued as designed. The accidental overdoses occurred in the third cycle. In both cases, a medical oncology fellow wrote orders for the patients to be given 4,000 mg/m<sup>2</sup> of cyclophosphamide and Mesna for each of four days.

"While there were some pharmacists and nurses who were initially concerned that the prescribed chemotherapy doses seemed higher than usual, these individuals did not express their reservations because it is the reality of modern cancer treatment that, particularly in clinical trials, patients are being given ever-increasing doses of toxic agents in an attempt to cure more patients," the institute's summary said.

Lehman began cycle three on Nov. 14, 1994. On Nov. 16, the second patient began cycle three. On Nov. 25, the second patient had a toxic cardiac reaction to the drugs and was transferred to intensive care at Beth Israel Hospital. The STAMP team did not suspect an overdose because cyclophosphamide can cause heart damage at much lower doses than that called for in the protocol, the institute said.

Lehman completed all three treatment cycles. "Although she had considerably more difficulty with cycle three than she did with the first two treatment

courses, the side effects and toxic reactions she experienced had been observed in a number of other STAMP patients who successfully completed treatment," the summary said.

"By Dec. 3, she had recovered from treatment to the point where she was able to walk around the unit unaided, and was scheduled to be discharged the following day," the summary continued. Lehman told the nurses she was going to take a nap. A nurse who checked on her found her unconscious and not breathing. Lehman could not be revived after 40 minutes of cardiopulmonary resuscitation and was pronounced dead.

The principal investigator ordered that no additional patients begin the treatment, and the death was reported to the institute's protocol administration office on Dec. 5. Six days later, the PI sent the office a report on all three patients who had received the third cycle. By Dec. 12, the Scientific Review Committee had reviewed and re-approved a revised version of the protocol. By Jan. 5, the Institutional Review Board had reviewed and approved a toxicity report filed by the PI. The protocol, modified by lowering the cyclophosphamide doses, was reopened five days later.

On Feb. 8, as part of normal data review, a data manager discovered the overdoses. A review found that the same fellow wrote both overdose orders, which were filled by the same pharmacist, and one additional pharmacist reviewed each order. Seven nurses were involved in providing the chemotherapy.

#### **Recommendations And Corrective Actions**

Following are the summarized recommendations of the review committees and Dana-Farber's response:

- 1. The performance of the fellow who wrote the orders should be formally reviewed by a professional review group. Dana-Farber said the fellow was relieved of patient care responsibilities and is the subject of a disciplinary procedure at the institute.
- 2. The performance of the PI should be formally reviewed by an appropriate professional body. "The committee concluded that this individual bore partial responsibility for the ambiguous nature of the protocol schema. This ambiguity contributed to the accident. Further, the manner in which this physician investigated the incidents contributed to the delay in detecting the overdoses."

Dana-Farber said the PI was relieved of patient care duties and a peer review committee found that the physician was not responsible for the overdoses themselves, but should be reprimanded because of "inadequacies in the PI's initial review of the incident." The PI was reprimanded, was temporarily assigned to administrative duties, and now is being "reintegrated into the clinical programs of the Institute."

- 3. The institute should examine and improve its protocol administration and review process. Dana-Farber said all protocol reviews now include a review of the proposed schema. Protocol documents now are written to make it impossible to determine chemotherapy dosage without referring to the treatment section.
- 4. The structure of, responsibility and accountability within the Dept. of Medicine needs to be defined more clearly and integrated more fully with other clinical services of DFCI. Both committees said the institute "had not sufficiently valued clinical experience when it last selected its most senior leadership."

Dana-Farber said that in addition to a new president and chief of staff, the institute created a clinical executive committee. The group will be responsible for maintaining standards of clinical care. In addition, the medical oncology and pediatric oncology department chiefs will report directly to chief of staff Sallan.

- 5. The STAMP team should be fully integrated into the medical care delivery system of DFCI. The institute said STAMP patients now are treated with all other BMT patients under the supervision of the BMT service, and the clinical work of the team has been more fully integrated into the medical oncology activities of the institute.
- 6. The structure, training and supervision in the medical oncology fellowship training program needs to be improved, and responsibility for the program clearly delineated. Dana-Farber said the program has been reorganized, and each fellow now is assigned a physician mentor. The director of the program, a Harvard professor of medicine, is responsible for the clinical practice of all fellows, and a staff physician, the associate director of the fellowship program, is directly responsible for the clinical practice of all first-year fellows. Each fellow is given a monthly evaluation.
- 7. Dana-Farber should examine its policies on cosigning of chemotherapy orders. The attending physician supervising the fellow who wrote the overdoses did not review or co-sign the orders since there was no policy to do so. The institute said its policy now requires that all chemotherapy orders written by fellows be cosigned by an attending physician.
- 8. The actions of the pharmacists who filled the prescriptions, and those who verified that they were correctly filled, should be reviewed by an appropriate professional body. A peer review committee reviewed the performance of the pharmacist who filled the orders and two pharmacists who verified the orders. The director of pharmacy resigned voluntarily last May, and three pharmacists were placed on probationary status. One left

the institute for a non-clinical position, and the other two have returned to their duties after in-service training.

- 9. Dana-Farber must evaluate its pharmacy policies, procedures, educational programs, and leadership. The institute said it had: named a new director of pharmacy; improved pharmacy computer software by including dosage limitations for all chemotherapy agents; all chemotherapy orders must be checked and compared to the protocol by two pharmacists acting separately; all pharmacists have attended inservice education sessions and instructed to compare orders to the treatment section of the protocol rather than the schema; and pharmacists must be educated by a member of the clinical team about each new protocol.
- 10. The Dana-Farber administration must evaluate and improve nursing policies, procedures, leadership structure and education programs. The institute said it now has a director of nursing who reports directly to the institute's president, and policies require that all chemotherapy orders must be checked by two nurses and compared with the treatment section of the protocol. Nurses are provided training about each new protocol, and nursing schedules were changed to provide greater continuity of nursing care for each patient.
- 11. There were substantial deficiencies in the institute's quality assurance program, resulting from unclear lines of responsibility and lack of emphasis upon formal quality assurance procedures by the institute's senior management.

Dana-Farber said the Board of Trustees has final authority for quality assurance, and a committee of trustees and senior clinical leaders has been charged with overseeing the process. The committee meets monthly to review the work of quality assurance and quality improvement groups. A quality improvement committee, consisting of clinical department leaders, meets at least monthly. The institute also has a new system of quality improvement teams. Patient complaints are now reviewed by the office of the patient representative, and serious complaints must be referred to this office within 24 hours.

# **Groups Urge Gingrich, Dole To Enact NIH Budget Increase**

Oncology societies and cancer centers have joined other medical organizations to sign a letter urging Congressional leaders to approve fiscal 1996 appropriations for NIH that had been recommended by the House and the Senate.

The House and Senate Appropriations Committees approved budget increases for NIH earlier this year, but the Senate has not acted on the Labor-HHS-Education appropriations bill. President Clinton has threatened to veto the bill out of opposition to amendments on abortion.

Under a continuing resolution in effect until Nov. 13, the NIH budget is 5% below last year's appropriation, a cut of about \$50 million. The organizations fear that the same level could be set in a year-long continuing resolution if Congress and the Administration do not reach an agreement on the appropriations bills.

"If this situation is allowed to continue for the duration of FY 1996, this nation's biomedical and behavioral research efforts will be seriously hampered," the letter, signed by the Ad Hoc Group for Medical Research Funding, said. "We strongly urge you to ensure that the National Institutes of Health are funded at the highest level possible in FY 1996, consistent with the recommendations of the House and Senate Appropriations Committees and the Administration."

The letter was sent to House Speaker Newt Gingrich (R-GA), Senate Majority Leader Bob Dole (R-KS) and President Clinton.

#### **Individual Letters Encouraged**

The National Coalition for Cancer Research and some of its organizational members, including the American Cancer Society, American Society for Clinical Oncology, American Society for Therapeutic Radiology and Oncology, and several cancer centers signed the letter.

In addition, medical societies and patient advocacy organizations are urging their members to write to their Congressional representatives.

"The NCCR is very concerned that the hard work that was done to ensure increases for NIH in the House and the Senate will be stymied by the political forces currently at work," Marguerite Donoghue, NCCR executive director, said to The Cancer Letter. "We are doing all that we can to communicate to Congress the importance of recognizing the increases recommended by the House and the Senate in whatever funding mechanism is finally achieved for NIH."

# **US Files Motion To Dismiss Fisher's Privacy Act Suit**

The US Attorney filed a motion this week to dismiss a suit claiming that the government violated the law when NIH databases marked breast cancer researcher Bernard Fisher's articles with statements that included the words "scientific misconduct."

The government attorney, representing defendants

NIH, NCI and the Office of Research Integrity, filed the motion in the US District Court for the District of Columbia seeking dismissal or summary judgment in the government's favor.

Fisher brought the suit under the Privacy Act, seeking permanent removal of the statements, a public apology, and creation of a "system of records" for the databases (**The Cancer Letter**, Oct. 20).

The government's motion, filed Oct. 23, argues that the databases, Cancerlit, Medline and PDQ, are not "systems of records" as the term is defined by the Privacy Act.

If the database entries are not records as the term is used in the Privacy Act, then the databases are not "systems of records," the government argues. The statements "scientific misconduct—data to be reanalyzed" were placed on the database entries because of ORI's misconduct finding against Montreal surgeon Roger Poisson, a former contributor to the National Surgical Adjuvant Breast and Bowel Project, the motion said.

"As developed during the extensive discovery in this case, the annotations were placed on articles pertaining to the scientific research project, in which a contributing researcher (not plaintiff) had in fact committed scientific misconduct," the government's motion stated. "The record demonstrates clearly that those annotations were never intended to communicate that plaintiff himself had committed scientific misconduct; it would be very unlikely that anyone reading the database entry would interpret them as assertions that plaintiff himself had committed scientific misconduct; and there is no evidence that anyone in fact interpreted them this way."

# Alternative Cancer Medicine Grant Awarded To UT-Houston

The Univ. of Texas Houston Health Science Center has been selected as one of eight NIH-funded research centers that will study alternative medicine.

UT-Houston is expected to receive \$733,350 over a three-year period from the NIH Office of Alternative Medicine. The university's Center for Health Promotion Research and Development and the School of Public Health will conduct the research, led by principal investigator Guy Parcel.

Houston is the only center funded by OAM that will specialize in alternative cancer medicines.

The primary aim of the research will be to evaluate the effectiveness of biopharmacologic and herbal therapies for cancer prevention and treatment, Parcel said. A multidisciplinary team of clinicians and researchers will evaluate research opportunities. The team will include Eva Singletary of M.D. Anderson Cancer Center.

Other centers funded by OAM will study HIV, addictions, asthma and immunologic disorders, women's health, general medical conditions, geriatrics, stroke, pain, and neurological conditions.

"These centers are designed to efficiently evaluate promising alternative medical practices by establishing mechanisms for investigators to have their research ideas reviewed, developed and executed in a scientifically rigorous manner," said Wayne Jonas, director of the OAM since last July.

Other funded centers, the principal investigator, specialty area were: Univ. of Virginia School of Nursing, Ann Gill Taylor, pain; Kessler Institute for Rehabilitation and the Univ. of Medicine & Dentistry, Samuel Shiflet, stroke and neurological conditions; Columbia Univ. College of Physicians and Surgeons, Fredi Kronenberg, women's health; Beth Israel Hospital, Harvard Medical School, David Eisenberg, general medical conditions; Minneapolis Medical Research Center, Thomas Kiresuk, addictions; Bastyr Univ., Leanna Standish, HIV/AIDS; Univ. of Maryland School of Medicine, Brian Berman, pain; Univ. of California, Davis, M. Eric Gershwin and Judith Stern, asthma, allergy and immunology; Stanford Univ., William Haskell, aging.

### **RFA Available**

RFA ES-96-003

Title: Endocrine Disrupting Chemicals And Women's Health Outcomes

Letter of Intent Receipt Date: Dec. 1 Application Receipt Date: Jan. 18

Research on the health effects of chemicals and other exposures that are suspected to disrupt the normal activity of the endocrine system is a high priority of the National Institute of Environmental Health Sciences and the Office of Research on Women's Health. The goal of this RFA is to encourage toxicologic, basic science, and epidemiologic research on the human health effects of exposure to chemicals that mimic, antagonize, or indirectly alter the activity of hormones. Of particular interest are the health effects on women, since these affect both the woman herself and may affect future offspring.

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: Gwen Collman, Div. of Extramural Research and Training, NIEHS, PO Box 12233, Research Triangle Park, NC 27709, tel: 919/541-4500, fax: 919/541 2843, e-mail: collman@niehs.nih.gov