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Judge Rules Privacy Act Not Applicable In Bernard Fisher's Suit Against HHS

A federal judge last week ruled in favor of the government in a suit brought by cancer researcher Bernard Fisher under the Privacy Act.

In a ruling delivered unexpectedly to attorneys who had gathered for a pre-trial "status conference" June 25, Judge Ricardo Urbina of the US District Court for the District of Columbia ruled that the Privacy Act did not apply in the Fisher case.

(Continued to page 2)

In Brief

Brady Wins ACRO Gold Medal; Society Elects New Fellows, Officers; Calabresi Honored

LUTHER BRADY JR. received the American College of Radiation Oncology Gold Medal for outstanding achievements and service, at the group's annual meeting. Brady is the Hylda Cohn Professor of Clinical Oncology and chairman of the Department of Radiation Oncology and Nuclear Medicine, Medical College of Pennsylvania and Hahnemann University and Hospitals. ACRO elected as fellows of the college **David Krause**, senior radiation oncologist, E.W. Sparrow Hospital, Lansing, MI, and **Arthur Porter**, professor and chairman of the Department of Radiation Oncology, Wayne State University. Officers of the college for 1996-97 are **William Bloomer**, chairman of the Board of Chancellors; **Omar Salazar**, president; **James Marks**, vice-president; and **Douglas Olson**, secretary-treasurer. . . . **PAUL CALABRESI**, professor of medicine and chairman emeritus, Division of Biology and Medicine, Brown University, and director, Division of Clinical Pharmacology, Rhode Island Hospital, received an honorary Doctor of Medicine degree, Laurea Honoris Causa, from the University of Genova last month. Calabresi is a member of the President's Cancer Panel. . . . **JOB OPENING:** Thomas Jefferson University, Kimmel Cancer Center has an opening for coordinator of a cancer network, which includes over 12 community hospitals and cancer centers. The coordinator will work closely with **Robert Comis**, clinical director of the cancer center and chairman of the Eastern Cooperative Oncology Group. Send resume and letter to Leslie Davis, administrator for clinical programs, Thomas Jefferson University Hospital, 111 South 11th St., Suite 5480-Gibbon Bldg., Philadelphia, PA 19107, tel: 215/955-7660, fax: 215/923-9713. . . . **WILLIAM NEGENDANK**, 55, a physician researcher at Fox Chase Cancer Center who was involved in clinical use of magnetic resonance imaging, died June 16 of a heart attack.

(Continued to page 6)

Judge Rules Privacy Act Doesn't Apply In Fisher Case

(Continued from page 1)

Attorneys for Fisher said they would appeal Urbina's decision as soon as they receive it in writing.

"The judge has issued a very narrow, legal ruling, which says, the Privacy Act does not protect you, Bernie Fisher, from Government officials talking about what's in your confidential files," said Stuart Newberger, an attorney with the Washington firm of Crowell and Moring.

"Our appeal will claim that this very narrow interpretation of the Privacy Act is wrong as a matter of law," Newberger said to **The Cancer Letter**.

"System of Records"

The Privacy Act mandates the government to maintain accurate "systems of records," thereby protecting the individuals from improper disclosures of information.

Fisher claimed that during the scandal surrounding the National Surgical Adjuvant Breast and Bowel Project, HHS officials violated his rights under the Privacy Act of 1974 by disclosing confidential information contained in his files at the HHS Office of Research Integrity.

Fisher claims his rights were further violated when HHS officials annotated his articles contained in the Medline and CancerLit databases with flags that included the words "scientific misconduct" (**The Cancer Letter**, Feb. 24, 1995; Oct. 20, 1995; Jan. 19, 1996).

The trial in the case was scheduled to begin Aug. 5. The purpose of the trial would have been to determine the extent of damages incurred by Fisher. Before the trial, both sides had filed "motions for a summary judgment," requesting Urbina to rule on the case, thereby making the trial unnecessary.

Decision Made Unexpectedly

Urbina's unexpected ruling granted the government's motion. However, on request from Fisher's attorneys, the judge kept in force a restraining order that precludes the government from flagging Fisher's articles in the NIH databases.

According to the official transcript of the conference, Urbina said he had reached his decision after reviewing the Privacy Act, the case law and the filings in the case during the previous night and early morning.

After laying out his decision, Urbina apologized to the attorneys for both sides, who had prepared for a trial that would now not take place.

"I would not have put you through the trouble I put you all through if I had reached a firm decision that coincides with the decision I announced today," Urbina said. "I don't like to see people put out more effort than is necessary in order to achieve something."

Urbina said the filings for the pretrial helped him reach the decision. "That was part of what I gathered in last night and early this morning as I was digesting what I finally needed to digest in order to reach this decision," Urbina said.

In his decision Urbina said the ORI files do not constitute a "system of records" under the Privacy Act.

Promising to supply his reasoning in a memorandum, Urbina said the language of the act does not define a "system of records."

However, case law indicates that to be covered by the Privacy Act, information in government records must (1) contain the individual's name or another identifying particular, and (2) be about the individual, Urbina said. Moreover, case law indicates that the courts should consider the purpose for which information is gathered as well as retrieval practices and policies, Urbina said.

"For reasons that I will elaborate upon more fully

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in written form in my memorandum order, I conclude that the ORI files are not qualified as a system of records," Urbina said.

Fisher claimed that during the NSABP controversy three years ago, then NCI director Samuel Broder and HHS Assistant Secretary for Health Philip Lee improperly disclosed confidential information on Fisher.

Urbina said Fisher's voluminous case that relied heavily on depositions with various players in the NSABP drama left him unconvinced

"There has been a failure to demonstrate the necessary nexus that is required in order to demonstrate the conduct from which liability can be recognized," Urbina said.

"Moreover, the plaintiff has failed to demonstrate that during the relevant time the records were retrieved by Dr. Fisher's name," Urbina said. "Therefore, that having failed, the court concludes that the files are not a system of records for the purpose of the Privacy Act."

Databases Not Covered

In another blow to the case, Urbina said the Privacy Act did not apply to the "scientific misconduct" annotations that HHS officials placed on Fisher's articles in the Medline and CancerLit databases.

Urbina ruled that the databases do not constitute a "system of records" since they are maintained and consulted for their scientific content rather than information about the authors.

"What's involved here is retrieval of information that gives the retriever insight about the subject area, and that its main thrust is not to convey something materially substantive or otherwise primary about the authors," Urbina said.

After Urbina announced his decision, Fisher's attorney Newberger asked the judge to keep in force a restraining order that prevented the government from annotating Fisher's publications in the NCI databases.

Newberger requested that the injunction remain in force while the case is being decided in the Court of Appeals.

"Since my client has been harmed, I'd hate to have that harm continue unnecessarily while the lawyers are arguing legal briefs up in the Court of Appeals," Newberger said.

After attorneys for the government said they had no objection to keeping the injunction in force, Urbina ruled that the injunction would be incorporated in the court's decision.

Newberger: "An Inconsistency"

Following the ruling, Newberger said he saw an inconsistency between Urbina's ruling and his decision to keep the injunction in force.

"Even though he threw the case out as a matter of law, the judge is allowing us to keep the preliminary injunction while we are going to the Court of Appeals," Newberger said to **The Cancer Letter**.

"You might say, isn't there some kind of an inconsistency there? He is essentially saying that on one hand, the Privacy Act doesn't apply to these annotations, but on the other hand, we are going to continue a very broad and important injunction," Newberger said.

"Basically , the judge said, if I am wrong on the law, and the Privacy Act applies, if I lift this injunction, Dr. Fisher could be harmed even more," he said.

If the Court of Appeals reverses Urbina's decision, the case would be expected to be returned for trial to his courtroom.

Another Fisher Suit in US Court

The legal aftermath of the NSABP crisis has not been confined to DC courts.

A suit originally brought by Fisher against the University of Pittsburgh officials and their Washington lawyer during their inquiry into allegations of scientific misconduct has been amended for the third time and is now in discovery.

The current version of the suit names the University of Pittsburgh officials and Washington attorney Martin Michaelson who represented the university early in the NSABP controversy. The latest version of the complaint also names the top officials at HHS, NIH, NCI and ORI.

Fisher claims violations of his rights of association and free speech, as well as age discrimination and violations of due process.

His demands include compensation for damages from officials at the University of Pittsburgh, a declaration that the government acted arbitrarily and capriciously by removing him from his posts at NSABP as well as an injunction requiring his reinstatement as Principal Investigator and chairman of the cooperative group.

Kassebaum Bill Authorizes $3 Billion For NCI In FY97

A bill introduced in the Senate would authorize $3 billion in funding for NCI in fiscal year 1997 and "such sums as necessary" for FY98 and FY99.

The amount, included in the NIH Revitalization Act of 1996, is $300,000 million higher than the Institute's own assessment of its research needs. The NCI Bypass Budget released earlier this year requested $2.7 billion.

Sen. Nancy Kassebaum (R-KS) introduced the bill, S.1897, on June 28. The bill was referred to the Committee on Labor and Human Relations.

The amount Congress authorizes for an agency usually is higher than the actual appropriation. However, advocates for the cancer program said the $3 billion figure represented a milestone in the history of the Institute.

"If appropriated, these funds will go a long way to support some of the greatest research opportunities which have existed since the enactment of the National Cancer Act in 1971," Albert Owens, president of the National Coalition for Cancer Research, wrote in a letter to Kassebaum.

"Further, your strong support of the peer review system as demonstrated by the deletion of cancer-specific earmarks is a strong signal to the research community that Congress believes funding should be based upon promising research opportunity and not an arbitrary mathematical formula," Owens wrote in the July 1 letter.

The bill removes specific dollar earmarks for NCI spending on breast, ovarian and prostate cancer, instead calling for "such sums as necessary" for fiscal years 1997-99.

The NIH reauthorization bill currently in effect mandated that NCI spend $225 million on breast cancer research, as well as $100,000 for other programs in breast cancer, including prevention and control programs, information and education programs, and research and demonstration programs. The bill also earmarked $75 million for ovarian cancer research and $72 million for prostate cancer research.

Elevates Genome Center To Institute

The new bill would elevate the National Center for Human Genome Research to institute status, creating the National Human Genome Research Institute. The bill authorizes "such sums as necessary" for the institute for the next three years.

The purpose of the institute would be to "characterize the structure and function of the human genome, including the mapping and sequencing of individual genes," according to the bill.

The bill mandates that the institute spend at least five percent of its extramural research budget for research on ethical, legal and social issues.

Changes To Advisory Committees

The new bill includes several provisions that Kassebaum said would streamline administration. The bill would:

—Allow NIH to convene advisory committees on an "as-needed basis," rather than three or four times a year currently required by law.

—Eliminate the requirement that the President's Cancer Panel meet "not less than four times a year."

—Repeal three advisory boards in the National Institute of Diabetes, Digestive and Kidney Diseases.

—Increase from $50,000 to $100,000 the amount that an institute can grant on the basis of technical and peer review alone.

Also under the bill, the provisions of the Federal Advisory Committee Act would not apply to a "scientific or technical peer review group" established by NIH.

Strengthening Clinical Research

The reauthorization bill includes several provisions from a bill introduced by Sen. Mark Hatfield (R-OR), S.1534, designed to increase support for clinical research. These provisions would authorize the General Clinical Research Centers. The 75 centers have never been authorized, though they have been supported by appropriations since 1965.

The bill also establishes two new award programs: the Clinical Research Career Enhancement Awards and the Innovative Medical Science Awards, to provide bridge funding for both young and established investigators.

In addition, the bill raises the maximum level of loan repayments from $20,000 to $35,000 for each year of service for qualified health professionals employed by NIH. The bill establishes an additional loan repayment program for research fellowships, to be developed by the NIH director.

The bill increases the number of National Research Service Awards from 50 to 100 and expands this awards program to include clinical research

training positions at General Clinical Research Centers and other extramural sites.

National Health Research Fund

The Kassebaum bill also includes a provision from S.1251, a bill introduced by Hatfield and Sen. Tom Harkin (D-IA), to establish a National Fund for Health Research in the Department of the Treasury. The fund would supplement annual appropriations to NIH by contributing public and private donations.

"While the language in this bill does not specify a funding source, I am hopeful that when the bill comes to the floor we will have several options to consider to secure its financial future," Hatfield said on the Senate floor last week. "I have proposed a 25-cent increase in the tobacco tax, as well as a voluntary Federal income tax checkoff in the past, and would be willing to look at other options in the future such as some sort of managed care set-aside."

Cosponsors of the bill include Sens. Edward Kennedy (D-MA), Jim Jeffords (R-VT), Claiborne Pell (D-RI), and Hatfield.

The excerpted text of Kassebaum's comments on the bill follow:

We all can take great pride in the exceptional contributions that the NIH has made to the improvement of the health of our citizens. NIH grants constitute the bulk of support for biomedical research throughout this country—almost $10 billion every year, distributed in nearly 25,000 separate grants. This unique investment of talent and dollars has one simple, overriding goal—the advancement of the health of Americans.

This agency is, indeed, an extraordinary success story. To cite just one illustration: An NIH grant made possible the discovery of the BRCA1 gene, a genetic marker for an important form of breast cancer. Such a discovery offers great promise for new strategies for diagnosis and
treatment of breast cancer and other serious illnesses.

As long term commitment to further support of research into the mysteries of the human genetic code, this bill authorizes the creation of the National Human Genome Research Institute.

The elevation of the National Center for Genome Research to institute status, while budget neutral, will ensure a continued focus of NIH resources for this important work.

Another critical area that this bill addresses is the education and training of the next generation of clinical researchers, the biomedical scientists who perform research that directly involves patients. This bill provides for greater support for expert training of young biomedical scientists who have elected the difficult, and increasingly competitive, careers in scientific inquiry. In addition, it provides important resources for the 75 general clinical research centers that exist in academic medical centers throughout the country.

The role of NIH in clinical research is critical, since academic health centers in the 21st century will be posed with an unprecedented challenge: how to maintain their research mission in the face of a fundamentally changed health care system. These changes are the consequence of dramatic market shifts that are taking place in health care in this country. They have a potentially deleterious effect on the irreplaceable work of this country's academic health centers. Cost competition has made it particularly difficult for the continuation of many of these established institutions that frequently care for the sickest, as well as the poorest, citizens of our communities.

This bill also makes substantial efforts to reduce administrative excess and duplicative infrastructure at NIH. It reduces redundant committees and reports. Every dollar saved from unnecessary administrative burdens is another dollar freed up for support of biomedical research.

By its very nature, ever-expanding scientific knowledge places pressure on the limited resources for biomedical research support. Accordingly, this bill provides for a Biomedical Research Trust Fund within the Treasury. This trust fund is a first small step toward affording additional funds for the indispensable research mission in this era of shrinking Federal resources.

ONS Forms New Council

The Oncology Nursing Society has formed the ONS Steering Council following the society's recent reorganization.

The council, comprised of volunteers and ONS staff, is responsible for implementing the society's strategic plan and coordinating the work of the society.

Following are appointments to the council:

Susan Weiss Behrend, Fox Chase Cancer Center; Rose Mary Carroll-Johnson, Oncology Nursing

Forum; Susan Ezzone, Ohio State University; Betty Ferrell, City of Hope National Medical Center; Wende Levy, Social and Scientific Systems Inc.; Kevin Sowers, Duke University Health System; DeLois Pittman Weekes, Boston College School of Nursing; Marie Bagay, ONS; Bridget Culhane, ONS; Mel Haberman, ONS; Leonard Mafrica, Oncology Nursing Press; Lynne Suhayda, ONS; and Linda Worrall, ONS.

ICC Endorses NCI Decision To Create New Office

The Intercultural Cancer Council said it endorsed the decision by NCI to create a new Office of Special Populations, to be headed by Otis Brawley (**The Cancer Letter**, June 21).

"This critically needed new office will help NCI increase its focus on research around those cancers that have a disproportionately high incidence and mortality among many minority and medically underserved communities," said Lovell Jones, co-ICC chairman and director of experimental gynecology/ endocrinology at M.D. Anderson Cancer Center.

The council includes representatives from 19 cancer patient advocacy groups and professional societies. Since its formation last year, the council met with NCI Director Richard Klausner to propose the establishment of the office.

"Dr. Brawley can bring judgment to this new office so NCI can sift out the politics from the real research needs surrounding cancer and minorities," said Armin Weinberg, co-chairman of the council and director, Division of Cancer Prevention and Control, Baylor College of Medicine.

"While poverty and access to care affect cancer rates, they are too often used as reasons--or excuses--to not do research on important scientific factors such as genetics, cultural matters, behavior, diet, geographic and environmental issues," Weinberg said.

The ICC said leading research needs include prostate cancer in African-American men, cervical cancer in Hispanic women, and lung cancer in Native Americans.

"These population groups are America's leading cancer victims," said Jones. "Enhanced research is critical if we hope to save lives. But just as important, research into cancer where it is most common may better explose its complexities so we can find the cures to help all Americans, regardless of their ethnic or racial status."

In Brief:

Negendank, 55, MRI Specialist

(Continued from page 1)

Negendank was a member of the Department of Nuclear Magnetic Resonance and Medical Spectroscopy, and head of the clinical program for the study of tumors using MRI and whole-body magnetic resonance spectroscopy. Negendank joined Fox Chase in 1991. Prior to that, he was a member of the medical physics graduate faculty at Wayne State University School of Medicine and director of clinical research at the Meyer L. Prentis Comprehensive Cancer Center Biomedical MR Program. Donations may be made to the Hawk Mountain Sanctuary, designating the William Negendank Memorial to support a student internship in wildlife conservation and sent to Joe Murphy-Boesch, NMR and Medical Spectroscopy Dept., Fox Chase Cancer Center, 7701 Burholme Ave., Philadelphia, PA 19111.

NCI Clarifies Policy on Small, Short-Term Research Grants

From the June 28 "NIH Guide to Grants and Contracts":

NCI advises potential grant applicants that acceptance by the NCI of small research project grants (R03) will be considered only in response to an NCI announcement specifically inviting such applications.

Unsolicited grant applications in areas not covered by the announcements proposing preliminary short-term research projects limited in time and amount of support will not be accepted.

Currently, three specific program announcements inviting small grant (R03) applications are ongoing annually but as of this date will have newly assigned receipt dates of September 15, January 15, and May 15 annually.

—PAR-95-091, Cancer Prevention and Control Research Small Grant Program, NIH Guide, Vol. 24, No. 33, Sept 22, 1995.

—PAR-95-077, Small Grants Program for Cancer Epidemiology, NIH Guide, Vol. 24, No. 26, July 21, 1995.

—PAR-95-023, Small Grants for Therapeutic Clinical Trials of Malignancies, NIH Guide, Vol. 24,

No. 3, January 27, 1995.

Inquiries: Vincent T. Oliverio, NCI Division of Extramural Activities, 6130 Executive Blvd Rm 600, Bethesda, MD 20892, tel: 301/496-9138, e-mail: oliveriv@dea.nci.nih.gov

NCI RFAs Available

RFAs may be obtained electronically through the NIH Grant Line (data line 301/402-2221), the NIH GOPHER (gopher.nih.gov), and the NIH Website (http://www.nih.gov), and by mail and email from the program contacts listed below.

RFA CA-96-011

Title: **Cooperative Family Registry for Epidemiologic Studies of Colon Cancer**

Letter of Intent Receipt Date: Aug. 6

Application Receipt Date: Sept. 20

The NCI Division of Cancer Epidemiology and Genetics and the NCI Division of Cancer Prevention and Control invite cooperative agreement (U01) applications from investigators to participate, with the assistance of the NCI, in a network of organizations constituting a Cooperative Family Registry for Colorectal Cancer Studies (CFRCCS).

Approximately $3 million in total costs per year for four years will be committed to fund between two and five applications submitted in response to this RFA. The purpose of the proposed awards is to stimulate a cooperative effort to: (1) collect pedigree information, epidemiological data and related biological specimens from patients with a family history of colon cancer in order to provide a registry resource for interdisciplinary studies on the etiology of colon cancer, and to encourage translational research in this area; and (2) identify a population at high risk for colon cancer that could benefit from new preventive and therapeutic strategies.

Inquiries: Daniela Seminara, NCI Division of Cancer Epidemiology and Genetics, Executive Plaza North, Suite 535 - MSC 7395, Bethesda, MD 20892-7395, tel: 301/496-9600, e-mail: seminard@epndce.nci.nih.gov

RFA CA-96-016

Title: **Minority-Based Community Clinical Oncology Program**

Letter of Intent Receipt Date: Aug. 7

Application Receipt Date: Sept. 25

The NCI Division of Cancer Prevention and Control invites applications from domestic institutions for cooperative agreements to the Minority-Based Community Clinical Oncology Program. New community and research base applicants and currently funded programs are invited to respond to this RFA.

This issuance of the Minority-Based CCOP RFA seeks to build on the strength and demonstrated success of the program over the past six years by continuing the program to support community participation in cancer treatment and cancer prevention and control clinical trials through research bases (clinical cooperative groups and cancer centers supported by NCI) and utilizing the Minority-Based CCOP network for conducting NCI-assisted cancer prevention and control research.

It is anticipated that up to ten Minority-Based CCOP awards will be made. Up to $2.7 million in total costs per year for three years will be set aside to fund applications submitted in response to this RFA.

Inquiries: Otis Brawley, NCI Division of Cancer Prevention and Control, Executive Plaza North Rm 300-D, 6130 Executive Boulevard, MSC-7340, Bethesda, MD 20892-7340, tel: 301/496-8541, fax: 301/496-8667, e-mail: ob6g@nih.gov

RFA CA-96-017

Title: **Investigator Grants for Clinical Cancer Therapy Research**

Letter of Intent Receipt Date: Aug. 30

Application Receipt Date: Nov. 8

The NCI Division of Cancer Treatment, Diagnosis, and Centers invites research project grant (R01) applications to conduct therapeutic clinical trials research employing new agents, concepts, or strategies for the treatment of cancer. This initiative is aimed at encouraging new clinical investigators who have not previously had independent grant funding to submit research applications in this area of research.

Approximately $2,000,000 in total costs per year for four years will be committed to fund applications submitted in response to this RFA. It is anticipated that ten new individual awards will be made.

Inquiries: Diane Bronzert, NCI Division of Cancer Treatment, Diagnosis, and Centers, Executive Plaza North, Room 734 - MSC 7432, Bethesda, MD 20892-7432, tel: 301/496-8866, fax: 301/480-4663, e-mail: bronzerd@dct.nci.nih.gov

NCI RFP Available

RFP NCI-CM-77017-28

Title: **Development of Dosage Forms And Delivery Systems For Antitumor and Anti-AIDS Agents**

Deadline: Approximately Aug. 26

The Pharmaceutical Resources Branch of the Developmental Therapeutics Program, NCI Division of Cancer Treatment, Diagnosis, and Centers, is seeking contractors to develop acceptable dosage forms for compounds to be subsequently evaluated in cancer and HIV patients and to carry out innovative studies leading to more effective approaches for the intravenous delivery of compounds that possess limited solubility and/or stability.

NCI will select and provide the compounds to be studied. In addition to solubility problems, the projects will require considerable analytical work, particularly the development of a stability-indicating assay to monitor the integrity of the parent compound during the formulation studies. These investigations will be directed toward a pharmaceutical dosage form that will meet certain solubility and stability targets determined by the Government. The Principal Investigator on this project should possess a Ph.D. in Pharmaceutics or Medicinal Chemistry and should also have at least three years experience in the development of injectable formulations.

It is anticipated that three cost-reimbursement terms type contracts will be awarded for a base period of three years, with two one year options for each contract.

The proposed contract project represents a recompetition of contracts N01-CM-27755 (University of Kansas), N01-CM-27756 (University of North Carolina), N01-CM-27757, (University of Arizona), and N01-CM-27720 (University of Utah).

Inquiries: Carolyn Barker, Research Contracts Branch, NCI, Executive Plaza South Rm 603, 6120 Executive Blvd-MSC 7220, Bethesda, MD 20892-7220, e-mail: barkerc@rcb.nci.nih.gov, fax: 301/402-6699.

SmokeLess States Program Expanding, $20 Mil. Available

The Robert Wood Johnson Foundation is expanding its program called SmokeLess States to support additional state-wide efforts to reduce tobacco use among Americans, particularly children and youth.

The program plans to make new grants to up to 21 state-wide coalitions working in partnership with community groups.

Grantees will develop and implement comprehensive tobacco control programs that include education, treatment, and policy initiatives.

The foundation said it will make available up to $20 million under the four-year competitive program, or an average of approximately $800,000 per grant.

In addition, grantees will be eligible to compete during 1997-99 for an additional $3 million in grant funds.

Public and private organizations are eligible to apply. Deadline for receipt of applications from new states is Sept. 30.

Inquiries: Thomas Houston, director, Department of Preventive Medicine and Environmental Health, or Kathleen Harty, deputy director, SmokeLess States, c/o American Medical Association, 515 North State St., Chicago, IL 60610, tel: 312/464-4903, fax: 312/464-4111.

Scientist Falsified Research In Grant Application, ORI Says

The HHS Office of Research Integrity has made final findings of scientific misconduct in the following case, according to a notice in the Federal Register:

Eric T. Fossel, Harvard Medical School: Based on ORI's analysis of the relevant evidence and conclusions submitted by the Harvard Medical School Committee on Faculty Conduct, ORI found that Eric T. Fossel, former Harvard Medical School associate professor of radiology at Beth Israel Hospital, committed scientific misconduct by reporting falsified research results in a Public Health Service grant application.

Specifically, Fossel altered nuclear magnetic resonance data in the Multicenter Breast Trial (MCBT) such that the NMR test, purporting to detect from a patient's blood sample a predisposition toward malignancy or a relapse, appeared to be more accurate, sensitive, and specific than was actually the case, according to ORI. Premised on these falsely reported results, Fossel proposed in a PHS grant application that the NCI provide funds to complete the MCBT.

Fossel has entered into an agreement with ORI in which he has voluntarily agreed, for the three-year period beginning May 9, to exclude himself from federal contracting, grants and cooperative agreements, and from serving in any advisory capacity to PHS. No scientific publications were required to be corrected as part of this agreement.