

# *Pharmacy Practice News*

## *December 2003*

# Whistle-Blowers Sound the Alarm on Faulty Clinical Trials

Atlanta—The words still ring in his ears: "Don't ever do anything like this again, because starting today I will bury you." The menacing threat leveled nine years ago at Jeffrey Fudin, PharmD, was no empty warning. It signaled the start of a campaign to intimidate and harass him, and eventually drum him out of his job as a Clinical Pharmacy Specialist at the Stratton Veterans Affairs Medical Center Hospital in Albany, N.Y. But it also marked the first link in a tortuous chain of events that led to congressional and criminal investigations of Stratton personnel and procedures, and a systemwide examination of the VA's clinical trials program.

Dr. Fudin's harrowing experience, which he touched on as an audience member of a "Meet the Experts" session on whistle-blowing at the 2003 annual meeting of the American College of Clinical Pharmacy, and then described in more detail during follow-up interviews, illustrates just how taxing it can be to come forward about alleged misdeeds in today's high-pressure healthcare environment. For pharmacists in similar situations, the lessons that Dr. Fudin learned along the way can be invaluable.

(Scott D. Harrington, PharmD, the chair of the ACCP session on whistle-blowing, offers his views on page 34).

Dr. Fudin's ordeal began in November 1994, when he noticed that patients enrolled in investigative cancer protocols were receiving intravenous 5-fluorouracil combined with excessively high doses of leucovorin in a single ambulatory infusion device. The physical incompatibility between the two drugs resulted in the clotting of central line catheters. He discovered also that the Institutional Review Board had never approved the protocol.

When he reported the irregularity, the physician in charge of the research refused to change the order, instead hurling the ominous remark warning Dr. Fudin to back off. The next month, the Chief of Medicine ordered an investigation of Dr. Fudin for over-recommending opiate narcotics. During his previous 12 years at the VA, Dr. Fudin said he had accrued an exemplary work record and had never been subject to disciplinary measures. He was exonerated of the charges.

In January 1996, Dr. Fudin approached the same researcher about questionable uses of paclitaxel for patients with esophageal cancer. But the order stood and Dr. Fudin and Anthony Mariano, RPh, his supervisor at the time, are convinced that at least one patient died as a result. Two days later, Dr. Fudin was accused by the hospital's Chief of Staff of patient abuse for refusing to dispense a medication as ordered by an oncologist, though Dr. Fudin had simply reported a problem but took no action. He was cleared of any wrongdoing. Almost immediately, he received a memo from the Chief of Staff, accusing him of practicing outside of his approved scope of practice because he had asked a medical resident to order blood work for cancer patients who did not meet study criteria. But according to Dr. Fudin, his request was well within his job description. Again, he was absolved.

When the Stratton VA did examine Dr. Fudin's charges, the circumstances surrounding the inquiries were suspect. "It was the investigation from hell," said Thomas Ferro, MD, a former pulmonary physician at Stratton who was appointed to head the internal investigation of Dr. Fudin's charges of impropriety. "I stopped a few months after the fact and I thought: 'What was the purpose of this whole thing?' The purpose of this whole thing was to thwart the truth," he told the Albany newspaper Times Union. Dr. Ferro also admitted witnessing retaliatory measures against Dr. Fudin and Mr. Mariano.

The pattern continued unabated. Each time Dr. Fudin reported questionable practices, hospital administrators undermined him. According to a Times Union series, hospital insiders corroborated Dr. Fudin's contention that his allegations were covered up. Mr. Mariano stood behind Dr. Fudin and ultimately became a whistle-blower himself when he protested a 1997 drug substitution policy that called for all patients who were taking the calcium channel blocker amlodipine (Norvasc, Pfizer) to be switched to felodipine (Plendil, AstraZeneca). "If the substitution had been just for patients with simple hypertension, that would not have been a problem," Mr. Mariano said. "But many of our patients had uncontrolled angina, and our staff cardiologist claimed they fared better with amlodipine." He added that the substitution also posed a potential hazard to patients with congestive heart failure, since only amlodipine's safety for CHF patients had been established in clinical trials. "It soon became apparent that some veterans who had been automatically switched began to suffer from acute myocardial infarctions," Mr. Mariano said. The policy was amended, he added, only after the VA officials feared that some patients had died as a result of the automatic substitution policy.

Mr. Mariano said he requested network-wide data to further explore the effects of the automatic substitution policy but was repeatedly denied access to the data. His "reward" for his efforts was a four-month banishment to work on a psychiatric ward—the furthest point in the hospital from the pharmacy—with no computer or phone.

Mr. Mariano contends that top Stratton VA officials were responsible for covering up all patient abuse violations that were reported. "The Office of Inspector General [of the Department of Veterans Affairs] not only ignored our calls for help, but also prevented other enforcement agencies such as the FBI and the Office of Special Counsel from investigating our claims," he said. "It's similar to finding an armed burglar in your home and discovering the phone line has been cut."

The cover-ups could only have occurred, Mr. Mariano insisted, with the blessing of officials at the highest level of the Department of Veterans Affairs in Washington, D.C. He was eventually removed from his position for allegedly allowing registered pharmacists to perform outside their scope of practice, but the charges were never substantiated.

Mr. Mariano now works as a retail pharmacist and said he is "continuing to fight for justice to be heard." He said he has gained the support of his local Congressman, U.S. Rep. Michael McNulty, who is requesting a face-to-face meeting with VA Secretary Anthony Principi.

#### More Whistle-Blower Fallout

Dr. Fudin's position at the Stratton VA also became threatened as a result of his whistle-blowing. He said the VA suspended him for one week without pay in October 2000. Subsequently, Dr. Fudin was fired on December 7, 2001, for failing to follow a direct order not to prescribe controlled substances. In the weeks immediately preceding his termination, he was charged with a laundry list of alleged subversive activities that included practicing outside his approved scope, practicing medicine without a license, giving lectures outside the VA (even though he contends he followed appropriate VA guidelines), having his own personal Web site and performing human research without informed consent.

Dr. Fudin won his job back when the Merit Systems Protection Board ruled in his favor; the VA's appeal was denied.

The case broke into public view in December 2002 when the biopharmaceutical company ILEX Oncology questioned patient documentation discrepancies in a Stratton study that involved one of the company's drugs. The ensuing FDA investigation revealed serious record-keeping flaws in Stratton's cancer research program. The Office of Inspector General opened a criminal investigation and found that records appeared altered to conceal serious ailments among patients

used in drug studies, according to Bruce T. Sackman, Special Agent in charge of the Northeast Department of Veterans Affairs Office of the Inspector General. A year later, the VA suspended two staff members, Chief Research Assistant Paul Kornak and his boss, oncologist James A. Holland, MD; both were later terminated. Mr. Kornak was hired in 1999 by the physician who first threatened Dr. Fudin. In October, a federal grand jury indicted Mr. Kornak on 48 felony counts, including involuntary manslaughter, criminally negligent homicide and fraud. Additional indictments are expected, and a congressional investigation by the House Veterans Affairs Subcommittee is in the offing, according to a spokesman for Rep. McNulty's office.

Asked to comment on the alleged misdeeds at the Stratton VA Medical Center, Linda Blumenstock, a spokeswoman for the facility, commented, "We are aware of certain allegations made by Mr. Mariano and Dr. Fudin. However, [because] these allegations are related to matters still under investigation by federal law enforcement officials, I am unable to comment further." Ms. Blumenstock added that "the Stratton VA Medical Center has fully cooperated with the VA Office of Inspector General and other proper authorities and continues to do so." But in Dr. Fudin's view, the entire process is rife with conflict of interest, since "the IG works for the VA," he noted.

As for Dr. Fudin's ongoing efforts to clear his name, in November, he requested federal whistle-blower protection in exchange for testifying before Congress. (Dr. Fudin said that an earlier request was denied review by the U.S. Office of Special Counsel, the federal agency in charge of reviewing whistle-blower cases.) "I want the public to know who is responsible and to know that their tax money is being used to retaliate against whistle-blowers where patients were harmed or killed. I want [the perpetrators] to be held accountable."

Though it appears that Dr. Fudin has finally won his prolonged struggle, he and his family have paid a heavy price. "It was absolutely horrible for me and my family. I lost 20 pounds that I've never been able to gain back. I couldn't eat, I couldn't sleep."

Looking back, Dr. Fudin said he had no choice but to report the unethical practices that he witnessed. "If you are serious about your profession and abide by the code of ethics, you're obligated to do the right thing. Unfortunately, the right thing is not always the easiest path to take."

–Steve Frandzel