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## **Drug Topics® Archive**

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**HEALTH-SYSTEM EDITION  
PROFESSIONAL PRACTICE**

### **VA pharmacists who blew whistle faced retaliation**

The two pharmacists who lost their jobs in the clinical trials scandal that is rocking the Department of Veterans Affairs are confident that they did the right thing when they spoke up about possible violations of medical protocol at their hospital.

Jeffrey Fudin, clinical pharmacy specialist in primary care, and Anthony Mariano, former pharmacy director, lost their positions within the VA's Stratton Medical Center in Albany after Fudin told administration that he believed patient care within the institution was being compromised.

"Fudin, who was a clinical pharmacy specialist for oncology services at that time, provided oversight on all patient care treatment plans to patients under investigative protocol," Mariano related. "It was during a routine review of orders that he discovered what appeared to be an unusual treatment plan. He did what was expected of him. He questioned the treatment and reported it."

Fudin claimed that patients were often enrolled in clinical trials without their informed consent. More specifically, according to documents that were filed with the Inspector General, he charged that:

- Colon cancer patients were being placed on 5-fluorouracil (5-FU) combined with leucovorin in a single ambulatory infusion device. Data were being collected on these patients even though there was no Institutional Review Board (IRB)-approved protocol. The doses of intravenous leucovorin were so high that there was a physical incompatibility between the two drugs. Several patients' central line catheters clotted because of the incompatibility. Many of the patients had to go back to surgery for central line replacements.
- Three esophageal cancer patients were placed on a regimen of continuous infusion of Taxol (paclitaxel, Bristol-Myers Squibb) plus cisplatin, 5-FU, and leucovorin. At the time, paclitaxel was approved by the Food & Drug Administration only as a single agent to be infused over two to three hours for ovarian cancer in patients who failed first-line or

subsequent chemotherapy. The prescriber was not only using the drug for a nonapproved indication not cleared by the IRB, but continuous IV administration of paclitaxel makes it more toxic.

- At least one patient in a study for small cell lung cancer, which compared the use of cisplatin with etoposide and erythropoietin on the one hand and of cisplatin plus etoposide on the other, did not meet the criteria for the study.

Records indicate that at least one person may have died as a result of the paclitaxel study. But after Fudin brought these matters to the attention of the administration, he faced retaliation, he said. "Within days, I was brought up on charges of patient abuse and failure to dispense medications." Although he was exonerated of the charges by a peer review board, he claimed he faced further harassment. He was eventually charged with ordering blood work outside his scope of practice, a claim he says is false. He was terminated in December 2001. The Merit Systems Protection Board, which hears whistleblower suits for federal employees, found in his favor and reinstated him at the VA. Although he is back at work, the decision is under appeal by the VA.

Mariano, Fudin's supervisor, also suffered consequences. For supporting Fudin, Mariano claims his desk was moved to an empty psychiatric ward where he had no computer or phone. He was eventually terminated for allegedly allowing R.Ph.s to perform outside their scope of practice. He is employed elsewhere, but he is still embroiled in litigation to have his position reinstated.

Fudin's initial allegations centered on one oncology physician who is no longer employed by the VA. The current criminal investigation into practices at the VA focus on two physicians who could face manslaughter charges if it can be proven they altered the medical records of cancer patients in clinical trials. A spokeswoman for the VA Stratton Medical Center said, "I regret that the VA can't comment on personnel issues involving employees."

"I'm not happy about the way I was treated, but I feel good about myself," Fudin said. And others feel good about Mariano and Fudin's actions as well. In an endorsement of their efforts, the two pharmacists were asked to serve as grand marshals of the recent Albany Memorial Day parade.

Besides the VA in Albany, patient deaths at VA hospitals in Fargo, N.D., and Detroit are also under investigation. The VA press office in Washington, D.C., was contacted for a response but did not return our calls.

**Kathi Gannon**

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