

# Records reveal earlier VA alert

Albany-- Pharmacy specialist claimed he was retaliated against after questioning cancer patient care in 1996

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First published: Sunday, March 2, 2003

Federal authorities were warned seven years ago that cancer patients at Stratton VA Medical Center were unduly suffering and at risk of dying prematurely because they were being given drugs in violation of medical protocol.

At least one patient may have died as a result of the alleged practices, which included giving certain drugs to patients whose medical backgrounds did not fit the criteria for use of both experimental and FDA-approved drugs, according to hospital records.

The allegations were made by Jeffrey Fudin, a clinical pharmacy specialist at the medical center who forwarded his complaints to hospital officials and investigators for the U.S. Department of Veterans Affairs, according to documents obtained by the Times Union, interviews with hospital staff and court records.

The new information raises questions about how thoroughly federal officials investigated the troubled cancer program at the Albany VA hospital, and whether Fudin, who is a doctor of pharmacy specializing in pain management for cancer patients, and a pharmacist who supported him at the time were retaliated against for making the claims.

Hospital officials contend Fudin's allegations, which centered on former VA oncologist Dr. William Hrushesky, are not related to a federal criminal investigation that began last year and centers on the VA's cancer research program. But some hospital workers dispute that, contending veterans in the cancer program unwittingly may have been used as guinea pigs for years.

Hrushesky did not return telephone calls seeking comment. He left the Albany VA approximately three years ago and is now director of research at Dorn VA Medical Center in Columbia, S.C.

The federal criminal investigation that began last year focuses on two researchers whom authorities said may face possible manslaughter charges if it can be shown they altered medical records of cancer patients, including those of as many as five who may have died after being given experimental drugs.

The researchers, Dr. James Holland and Paul H. Kornak, no longer work at the VA and have declined comment. Authorities also are investigating whether Kornak should have been hired as a clinical researcher at the VA in 1999. At the time, his medical license had been revoked, and in 1993 he pleaded guilty to federal mail fraud charges in connection with the alleged forgery of a medical license application, records show.

Linda Blumenstock, a spokeswoman for the Albany VA, declined comment on Fudin's allegations and the current investigation. A spokesman for the Department of Veterans Affairs in Washington, D.C., declined comment Friday.

Cancer research programs are lucrative for hospitals, which generally are reimbursed for patient care and the programs' other expenses by drug companies. On a national level, medical research programs at VA hospitals top \$1 billion annually.

Federal investigators are exploring whether researchers at the Albany VA may have benefitted financially or professionally from enlisting patients in cancer drug programs there, law enforcement officials said.

But it's not clear how far back the investigation reaches. VA officials who spoke on condition of anonymity said the alleged problems in the hospital's cancer program predate Holland and Kornak, who was hired in 1999 on Hrushesky's recommendation.

FUDIN In a memorandum to the VA's inspector general in August 1996, Fudin claimed that there "may be a financial incentive" behind the alleged violations of medical protocol in the hospital's cancer treatment program. He noted that in some cases veterans were being drawn into experimental drug studies "without informed consent," which resulted in "needless premature patient suffering and/or death."

But while many of the patients at that time were being given FDA-approved drugs, rather than drugs still being tested in research studies, Fudin said the way they were being dispensed was arguably experimental, records show. He claimed some patients were being given drugs in unapproved mixtures or for types of cancers that were not meant to be treated by a certain drug.

Fudin, who lives in Delmar, declined repeated requests for comment. But some of his claims are outlined in a federal whistleblower lawsuit that he filed against the VA three years ago. He alleges that VA officials retaliated against him at work, including cutting certain medical privileges, after he voiced his concerns about the cancer-drug program.

Fudin's attorney, Ronald Dunn, said he could not comment on Fudin's claims or discuss the details of the alleged retaliation against his client. Fudin was fired from his job several years ago. A federal administrative judge for the Merit Systems Protection Board, which hears whistleblower suits for federal employees, reinstated Fudin's job and awarded him back pay. Fudin has returned to work, but the VA is appealing the judge's decision.

Dunn also is the attorney for Anthony Mariano, Fudin's former supervisor in the hospital pharmacy.

Mariano, who lives in Albany, declined comment. But records contained in Mariano's own lawsuits against the VA allege that he also faced years of retaliation by top VA officials -- including having his desk moved to an empty psychiatric wing, where

employees were told not to speak with him and where he had no computer or phone, according to his lawsuit.

"These cases are good examples of the kind of subtle retaliation that goes on in a lot of workplaces," Dunn said, declining further comment.

But aside from the alleged retaliation against Fudin and Mariano, their cases raise questions about whether top VA officials, including federal lawmakers, knew about potential problems in the VA's cancer programs or did anything to stop them.

For instance, records show that in October 1996, several months after Fudin and Mariano voiced their concerns, a pharmacy "site team" from Washington, D.C., arrived at the Albany VA and began an investigation of the pharmacy program.

Fudin and Mariano claimed they were subjected to intense scrutiny and accused of mismanaging the pharmacy and of violating standard medical procedures. Hospital insiders said the site teams are commonly referred to among VA workers nationwide as "hit teams."

"They would send in these guys from Washington to basically make life miserable for any whistleblower. Their mission would be to force the person out or find something minor they may have done wrong and turn it into a reason for firing them," said a VA physician, speaking on condition of anonymity. "There is a lot at stake. If drug companies learn that a hospital's research program has problems, they pull their funding."

In 1999, Kenneth W. Kizer, the VA's undersecretary for health, implemented systemwide review procedures in the VA system's medical research program. The reviews were in response to congressional outcries about the alleged use of VA patients as guinea pigs at a Los Angeles hospital.

Despite the overhaul, which included procedures in the Albany VA's research program, problems apparently persisted.

Last year, a Texas company, Ilex Oncology, told Albany VA officials that it believed one of its cancer drugs was being used improperly in the hospital's research program. Hospital officials said they requested an investigation by the Food and Drug Administration.

In November, FDA investigators reported serious record-keeping flaws following a 50-day review of the Albany VA's cancer research program. The FDA report said medical records appeared to have been altered to conceal serious ailments of patients used in drug studies.

Also, cancer bone scans, heart scans, prostate cancer checks and other tests were not done on patients even though study records showed they had been. In other cases, some patients' drug doses were incorrect, supervision was lax and patients with hearing

problems received medications that may have worsened the condition, the FDA report said.

As a result, a federal prosecutor in Albany and an investigator with VA's Inspector General Office are conducting a criminal investigation. Their work includes sifting through hospital records and interviewing staff and the families of former patients, according to law enforcement officials familiar with the investigation.

But physicians familiar with the Albany VA program said the allegations uncovered last year are similar to what Fudin alleged was taking place seven years ago.

"It's the same thing," said a VA doctor who spoke on condition of anonymity. "It was done a different way, but they put patients in studies who did not have the proper bloodwork (and) would've otherwise been excluded from the study."

The current federal probe is examining the relationship between researchers and four drug companies that funded cancer studies at Stratton. Investigators seek to determine if anyone could have benefited financially or professionally by having more patients included in programs, a law enforcement official said.

The House Veterans Affairs Subcommittee on Oversight and Investigations asked the General Accounting Office to conduct an independent inquiry of the VA's cancer research program.