

Drug research at VA at heart of 2 inquiries

Albany -- Criminal probe of cancer program linked to whistle-blowers' cases

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For four months, nurses on the top floor of the Stratton Veterans Affairs Medical Center Hospital watched the man with a hospital ID walk to an empty psychiatric ward and sit alone at a desk.

He had no phone or visitors. But he carried a briefcase and wore a tie, so they figured he must do something.

"They'd say: 'Who the hell is the guy coming down to 10-D every morning?' " said Roxene Corrigan, a retired psychiatric nurse who worked at Stratton VA for 20 years.

Anthony Mariano, the hospital's former pharmacy director, would later claim his exile to the abandoned psych ward in 1999 was punishment for supporting a fellow pharmacist, Jeffrey Fudin, who questioned whether hospital cancer researchers were putting patients at risk by allegedly prescribing drugs outside medical protocol.

Both men were later fired by the hospital following years of alleged retaliation for their whistle-blowing. Mariano eventually accepted an out-of-court settlement and no longer works for the hospital. Fudin's job was reinstated by a federal whistle-blower court, but the VA is fighting the decision.

Their cases are now woven into the backdrop of an ongoing federal criminal investigation that centers on the cancer program at the Stratton VA. Federal authorities are examining whether a hospital oncologist, Dr. James A. Holland, and his clinical research assistant, Paul H. Kornak, whose medical license had been revoked before he was hired, allegedly altered the medical backgrounds of patients in order to enroll them in drug study programs.

While hospital officials have insisted the new investigation has nothing to do with the allegations made seven years ago by Fudin, other VA insiders said both cases involve alleged violations of medical protocols in the cancer program.

Stratton VA officials and a spokesman for the Department of Veterans Affairs in Washington, D.C., have declined comment on the criminal investigation and the pending whistle-blower cases.

The whistle-blower cases also raise questions about how seriously the VA's Office of Inspector General investigated Fudin's allegations and whether the FBI's Albany field division erred three years ago when special agents declined to conduct an independent inquiry of the case, records show.

Hospital insiders insist Fudin's allegations were covered up, and as a result, patients in the hospital's cancer research continued to be used as "guinea pigs," in which many veterans may have suffered unduly or died prematurely after being recruited into questionable drug programs.

The oncology department finally faced an intensive investigation last year after a Texas company, Ilex Oncology, reported to federal authorities that one of its cancer drugs was being used improperly in the hospital's research program.

In November, FDA investigators reported serious record-keeping flaws following a 50-day review of Stratton 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.

Now, as a criminal investigation unfolds and federal authorities said it's possible manslaughter charges could be brought against those responsible, some hospital insiders blame a federal system they contend failed to protect Fudin and Mariano or insure their allegations were properly investigated.

The cases also underscore what some critics and former VA workers characterize as a vindictive cycle of retaliation by certain Veterans Affairs hospitals to keep employees quiet. Lawsuits brought by Fudin and Mariano, who have declined comment, are still pending before a federal whistle-blower court in Washington, D.C., but some employees said the federal protections are not enough to reassure workers.

"Many of us were afraid to go to anybody to report anything because we knew we'd be out of a job," Corrigan said. "You had to keep your mouth shut."

The four-month exile of Mariano to the empty psych ward, which was ended in November 1999 by a top-ranking staffer with a Congressional Veterans Affairs subcommittee, apparently was not an anomaly.

At a VA hospital in Columbia, Mo., in the early 1990s, where an investigation into suspicious patient deaths was unfolding, the office of a high-ranking hospital official was moved into an empty trailer alongside the facility, according to VA officials.

In the Albany case, though, it appears the whistle-blowing activities of Fudin and Mariano, who also questioned the hospital's decision to switch cardiac patients to cheaper drugs several years ago, may have collided with the VA's desire to maintain lucrative and prestigious cancer study programs.

At Stratton VA, the alleged effort to discredit Fudin and Mariano began in 1996 when a "site team" was brought in from Washington, D.C., to investigate the VA pharmacy where they both worked. Officials who worked in that department at the time, but spoke on condition of anonymity, claim the site team members told some people they were there to get rid of Mariano and Fudin.

That March, two days after Fudin alerted VA officials that cancer patients may be at risk, hospital officials discussed his concerns. Dr. Min-Fu Tsan, who was then associate chief of staff for research at the VA, wrote an e-mail to Dr. Lawrence Flesh, the hospital's director, in which they discussed Fudin's allegations.

"I am concerned about the potential of a 'whistle-blower,' " Tsan said. "I believe that it would be wise for the Medical Center to take this seriously and a formal mechanism be taken to resolve this uneventfully," according to records obtained by the Times Union.

Fudin's allegations centered on former Stratton VA oncologist Dr. William Hrushesky, who left the Albany VA approximately three years ago and is now director of research at Dorn VA Medical Center in Columbia, S.C. Hrushesky did not return messages left at his office.

When he came to Albany in the late 1980s, Hrushesky was a highly regarded cancer research specialist recruited to help lead an oncology team treating patients at both Stratton VA and Albany Medical Center Hospital. But Hrushesky quickly gained a reputation among his fellow researchers for trying things outside of accepted standard medical practices.

"It was apparent to the rest of the practicing physicians that Dr. Hrushesky was not a team player and did not share similar clinical approaches to the rest of the group," said Dr. John Ruckdeschel, a former Albany Med cancer researcher who is now head of Karmanos Cancer Institute in Detroit.

Shortly after Albany Med officials questioned Hrushesky's methods, he was recruited to take control of the cancer research program at Stratton VA.

"The VA transfer was facilitated in part by Dr. Min-Fu Tsan ... who wanted Dr. Hrushesky's research dollars and support credited to the VA," Ruckdeschel said.

After Hrushesky moved to a full-time position across the street at Stratton VA, Ruckdeschel said he received a letter from a VA laboratory technician "suggesting that the data in some mice studies was less than reliable and that he was being harassed to leave as a result."

The laboratory technician who questioned the data in Hrushesky's mice studies was Dr. Rostislav Vyzula, who is now director of Masaryk Memorial Cancer Institute in the Czech Republic.

"I could not agree with some scientific results made on my study by somebody else," Vyzula said, referring to Hrushesky. "I came to U.S.A. in 1991 to improve my knowledge of conducting research, and I was leaving (in 1995) more frustrated than before my arrival."

Not long after Vyzula left the United States, Fudin, who is a clinical pharmacist focusing on pain management, wrote his memorandum to VA officials questioning Hrushesky's use of Taxol, an FDA-approved cancer drug.

Within months, Fudin was brought up on internal charges alleging he had abused patients.

In August 1996, Fudin wrote a letter to the Inspector General for Veterans Affairs outlining his situation and claiming he was the target of retaliation by hospital administrators.

"Hrushesky has been responsible in many cases for needless premature patient suffering and/or death," Fudin wrote in a memorandum obtained by the Times Union. "Hrushesky has an exorbitant amount of money in research funds at this institution. It just doesn't make sense to me that ... he continues to practice medicine at this institution."

Several months later, as Fudin faced an internal disciplinary hearing, Mariano wrote a letter to hospital officials supporting Fudin. A month later, the "site team" from Washington, D.C., arrived at Stratton VA to evaluate the VA pharmacy where Fudin worked and Mariano was the director, according to court records.

Fudin and Mariano would later claim that over the next several years 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" that are designed to get rid of whistle-blowers.

"The Inspector General has become part of the problem," said Ron Dunn, an attorney handling the pending whistle-blower cases for Fudin and Mariano. "How do you go about convincing employees to come forward who've watched Inspector General's (investigators) come in numerous times in the past, but not substantiate claims and then say they're not going forward with your claim of retaliation. How many times does that have to happen before the employees say, 'I'm not cooperating with them?' "

Mariano, who was fired by the VA in 1997, has since gone to work for a pharmaceutical company but is still suing to get his job back. Fudin also was fired and worked for a CVS store and a drug company before his job was reinstated last year by an administrative judge with the Merit Systems Protection Board, the court for federal whistle-blowers.