

Concerns over VA hospital unheeded

Albany -- Insiders wonder why something wasn't done sooner after complaints about research programs at medical center in Albany

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In August 1999, two pharmacists from Stratton VA Medical Center drove to FBI headquarters in downtown Albany to deliver a three-hour presentation on problems they described as having turned the hospital's research programs into a house of horrors.

Their allegations included corruption in the cancer research program, including patients being given experimental drugs outside medical protocol, and they said the violations had been happening for at least four years.

This week, a federal grand jury in Albany handed up a 48-count indictment against a former Stratton VA researcher. At least one patient died and dozens of others were endangered, according to the charges. Though the charges cap a yearlong investigation, some VA insiders said they are left wondering why something wasn't done sooner.

"We could've prevented this type of thing from happening," said Anthony Mariano, Stratton's former pharmacy director.

Mariano said he and Jeffrey Fudin, another pharmacist, went to the FBI four years ago out of desperation after their pleas for help were unanswered by U.S. Rep. Michael J. McNulty, D-Green Island, and by Department of Veterans Affairs investigators.

As early as 1995, they had warned that patients with cancer and other illnesses had been placed at risk -- or had died -- because of the way experimental drugs were being used. Patients also were enrolled in drug studies without signing consent forms indicating they had been informed about the risk, they said. Instead of investigating the allegations, hospital administrators allegedly retaliated against the men and ended the pharmacy's role in monitoring research drugs, according to allegations contained in court records.

McNulty on Saturday defended his office's handling of the matter, saying he brought many of the claims made by Fudin and Mariano to VA administrators in Washington, D.C., and to the VA's Office of Inspector General.

Still, Mariano criticized McNulty, contending the inspector general's office worked at the direction of the VA and may not have examined the allegations objectively. "It seems they were enlisted to discredit us rather than to get to the truth," Mariano said.

McNulty said it now may be necessary to have an independent review of the entire case.

"I'm not an investigator," he said. "My role is to support whistleblowers, to support openness and that's exactly what our office has done. ... If Mr. Mariano has suggestions for structural changes we'll look at that, too."

The alleged corruption at Stratton came to light about two years ago when a Texas drug company that was funding cancer studies there questioned whether some patients were qualified to be enrolled in the experiments. A subsequent Food and Drug Administration investigation uncovering widespread fraud and forgery that may have led to as many as five patients deaths, according to the FDA's report.

At that time the VA's inspector general opened the investigation that led to the charges being filed this week against former cancer researcher Paul H. Kornak of Clifton Park. The charges include making false statements, falsifying documents, mail fraud, wire fraud, involuntary manslaughter and criminally negligent homicide.

At least one patient died as a result of Kornak's falsification of medical records, and many more were endangered, according to the indictment.

But questions about the program's troubled history and the breadth of the federal probe remain unanswered. Authorities have refused to say if others are under investigation, or to say exactly what motivated Kornak's actions.

A House Veterans Affairs subcommittee staffer, who asked not to be identified, this week said the federal investigation should include an audit of the hundreds of thousands of dollars that flowed into Stratton for drug studies funded by drug companies.

"It is a cash cow," the Congressional staffer said, referring to the estimated \$400 million budget for (all) Veterans Affairs research programs. "We do this to make money. Where did the money go?"

VA officials and prosecutors declined at a news conference this week to say whether they will analyze how the money was spent.

The indictment also details Kornak's checkered past -- including a history of fraud

-- and raises questions about how he was given the key job of recruiting veterans for drug studies.

Kornak called himself "doctor," but he apparently never finished medical school -- he was dismissed from St. George's University School of Medicine in Grenada in 1984 for falsifying transcripts. He's accused of lying on a federal employment application about his undergraduate performance at the College of Saint Rose in Albany. He also stated he had never been convicted of a crime, even though in 1992 he had been convicted of federal mail fraud in Pennsylvania for falsifying information on a medical license application, according to the indictment.

"He was hired as a research assistant, therefore the checks that were conducted at that particular time were not the same as if he had been hired today," said Bruce T. Sackman, special agent in charge of the VA's regional Office of Inspector General.

While much of the focus of the investigation centers on Kornak, VA insiders said the probe falls short of exposing years of alleged abuse in the cancer program. "The FBI wanted to investigate but the Inspector General persuaded them not to because they were already investigating," Mariano said. "Well, the Inspector General works for the VA. They never wanted to investigate it because they were covering it up."

Mary-Ellen Piche, the hospital's director, U.S. Attorney Glenn T. Suddaby and officials for the VA's Office of Inspector General this week declined comment on the pharmacist's claims. They also declined to say whether the investigation will stretch beyond Kornak and his former supervisor, Dr. James A. Holland.

The pharmacists' claims about retaliation were supported in May when Dr. Thomas Ferro, a former cardiologist at Stratton VA, told the Times Union that hospital administrators tried to discredit the pair. Ferro claimed administrators manipulated an internal investigation he undertook in 1995 to examine Fudin's warnings about the cancer program. Ferro said he was encouraged to "thwart the truth."

Ferro now works for a VA hospital in Richmond, Va. He said he has not been contacted by investigators about his admissions.

Kornak's attorney, E. Stewart Jones of Troy, this week said that Kornak should not have been charged because he was part of a "team" and followed orders. Donald T. Kinsella, a lawyer representing several widows of former cancer patients who have filed lawsuits against the VA, said Jones' comments "confirm the theory of our lawsuit."

"The Veterans Administration allowed this to occur and failed to supervise these rogue employees properly," Kinsella said.

Meanwhile, Holland has been not charged and is currently working for a cancer program at a hospital in southern Georgia. He was hired as chief oncologist at Stratton VA in 1999, but he and Kornak were fired 10 months ago as the criminal investigation intensified.

Suddaby on Thursday declined to say whether Holland is a target in the investigation.

But in June, as authorities considered whether to represent the researchers in a civil lawsuit filed by the widow of a former cancer patient, federal prosecutors wrote a letter confirming their investigations of Holland and Kornak.

"The United States attorney for the Northern District of New York may have to recuse itself from this matter due to the pending criminal proceedings that may be brought against the defendants," Assistant U.S. Attorney James C. Woods wrote in a letter to U.S. Magistrate Judge Randolph F. Treece.

Dr. William Hrushesky, an oncologist who ran Stratton's cancer program before Holland, is currently working for a VA hospital in Dorn, S.C., and has not responded to requests for comment. Hrushesky allegedly recommended hiring Kornak, who started at Stratton in February 1999.

In all, Kornak is accused of undermining at least four major research studies involving dozens of veterans and hundreds of thousands of dollars. The indictment alleges the hospital earned thousands of dollars for each patient enrolled in the programs, many of them trial studies in which drug companies were testing new drugs on cancer patients in order to obtain approval for them from the Food and Drug Administration.

Prosecutors have not said what Kornak's motive was in carrying out his alleged scheme.

Piche said the money pays for research programs, including the drugs, the procedures and staff salaries.

"There's no personal gain for an individual," she said. "It didn't mean more money for him (Kornak)."

On Thursday morning, Piche issued a statement to all staffers at Stratton, warning them to expect intensive media coverage but not to speak to reporters.

"To those special individuals who have come forward with information that led to this indictment, I admire your courage. I can only imagine that this was one of the most difficult things that you have ever had to do," Piche's memorandum said. "We must prepare for some difficult days ahead."