

FBI closes inquiry at VA

Bureau probed cancer drug studies by discredited researcher; inspector general continues effort

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The FBI abandoned an investigation of the troubled cancer research program at Stratton VA Medical Center early last year, concluding that corruption allegations raised by two pharmacists were unfounded, according to internal agency records.

The FBI's quick exit from the probe, however, came before interviews were conducted with some witnesses, and despite hospital accounting documents -- recently obtained by the Times Union -- that appear to support some of the allegations.

The records indicate that in the 1990s, physicians in the cancer program may have augmented their government salaries with hundreds of thousands of dollars in research money. Thousands more in research funds were moved into non-research accounts and used for other hospital projects, including paving parking areas at the facility, the documents show.

Dr. Min-Fu Tsan, who was associate chief of staff for research and development at Stratton in the mid-1990s, did not respond to a request for comment. Tsan is now regional director of the Mid-Atlantic Office of Research Oversight at the Department of Veterans Affairs.

Records were provided to the newspaper by the widow of a deceased former hospital official. The widow, who asked not to be identified, said her husband brought the records home for safe keeping years ago because he believed they were evidence of criminal conduct.

When questioned last week about the content of the records, an official for the Department of Veterans Affairs Office of Inspector General asked the newspaper for copies so their investigators could examine them. The materials were provided. The official said their office is continuing to investigate Stratton.

A spokesman for the FBI, and prosecutors with the U.S. Attorney's office who are overseeing the investigation, declined comment.

Meanwhile, a former special agent with the VA's inspector general office said he believes the sprawling investigation could extend beyond a cancer research specialist who pleaded guilty to homicide charges in January. The investigator said money and prestige might have been a motive

for why researchers at Stratton allegedly pushed dozens of unqualified veterans into drug studies that were funded by pharmaceutical companies.

"That's why the investigation isn't closed," said Bruce T. Sackman, who retired last month as special-agent-in-charge of the Northeast field office. "A lot of stuff that went on years ago is going to be a little more difficult to corroborate. ... My agents, they were running down every possible lead no matter where it was, no matter how far it went back."

It was an IG investigation that led to the homicide conviction of Paul H. Kornak, 54, of Clifton Park, who was already a convicted felon when he began working at Stratton in 1999. Kornak quickly moved into a position where he helped oversee research programs, while masquerading as a doctor and being involved in the treatment of dozens of patients.

Hospital insiders, and Kornak's attorney, have insisted he was a pawn, following orders to keep the research studies thriving. Kornak admitted forging medical records of veterans to enroll them in the experimental studies, which are used by drug companies to bolster their applications for Food and Drug Administration approval.

Kornak had altered the records of veterans whose medical conditions should have disqualified them from certain studies.

As a result, several veterans died or suffered unduly when they were given infusions of experimental cancer drugs, authorities have said.

A Times Union investigation found that Stratton's cancer research program was the target of internal complaints dating back to the mid-1990s, several years before Kornak was hired.

Hospital staffers said they were subjected to retaliation after warning hospital administrators as early as 1994 that cancer patients were placed at risk by being enrolled in drug studies without proper consent.

In April 2000, several months after the two pharmacists from Stratton brought their concerns to the FBI, the agency backed away from investigating the allegations because they were told by the VA's Office of Inspector General that one of the pharmacists was under investigation.

The pharmacist, Jeffrey Fudin, was later cleared of accusations that he had prescribed drugs without authorization.

The other pharmacist, Anthony Mariano, who said he lost his job at Stratton as a result of fallout from the disclosures, was assigned to a desk on a vacant psychiatric ward during the height of the scandal.

In 2002, the problems at Stratton became public when a Texas drug company, Ilex Oncology, which was funding cancer studies, uncovered "irregular documents" in the research program and alerted the hospital. Hospital officials failed to act on the company's information for several months, records show, until the Office of Inspector General opened the investigation that led to Kornak's indictment.

Fudin, who still works at Stratton, and Mariano, who works at a private pharmacy, said last week they were stunned to learn the FBI had walked away from the investigation. They first went to the FBI in 1999 to report allegations of misuse of research funds, patient abuse, patient deaths and falsification of patient records.

Years earlier, after reporting the allegations to hospital officials, they themselves became targets of IG investigations, they said.

The pharmacists' claims about retaliation were supported two years ago when Dr. Thomas Ferro, a former cardiologist at Stratton VA, confirmed that hospital administrators had plotted to discredit the two pharmacists. Ferro said top administrators manipulated an internal investigation he headed in 1995 to examine Fudin's warnings about the cancer program.

"It was obvious that Dr. Fudin and I knew too much, and that this latest evidence of wrongdoing that emerges from the research department now establishes the early motives for the six-year retaliation that targeted Fudin and myself," Mariano said. "They fired Dr. Fudin and myself so we wouldn't interfere with the research program and millions of dollars in lost income to the facility."

Fudin said he is concerned that the investigation has become an effort to discredit them rather than get to the truth.

"I'm not concerned about they won-I won," he said. "The bottom line is this is about patients' lives."

Jeff Hughes, who took over the IG's northeast regional office when Sackman retired last month, said there is no coverup and federal agents are continuing to aggressively investigate the case.

"We truly are independent. We don't answer to any of these hospitals," Hughes said. "The FBI's out, but we're not stopping. We want to really put this thing to bed and uncover whatever's going to come out. ... We're prepared to go after anybody."

Kornak pleaded guilty to three felony charges, including criminally negligent homicide, and faces a maximum term of up to 20 years in prison. His sentencing has been adjourned several times and is scheduled to take place in August.

Kornak's case triggered congressional action, including new rules governing background checks on VA workers. Kornak carried the title "doctor" at Stratton -- including on his VA-issued business card -- even though he never finished medical school. He was convicted of fraud in 1991 for forging his credentials to try to obtain a medical license in Pennsylvania.

Several widows of veterans have filed lawsuits against Kornak and his former boss, Dr. James A. Holland, as well as the Department of Veterans Affairs. Last year, Holland was identified by federal authorities as a target in the criminal investigation. He was fired from Stratton three years ago and now works for a Georgia hospital.

Sackman, who worked for the IG's office for 25 years and handled hundreds of criminal investigations at VA hospitals, said Holland could still face charges in the case.

"It's just my unofficial personal feeling," Sackman said, without elaborating. "Dr. Holland was over-extended (professionally), as many researchers are, and there's a lot of money in research."

Sackman said he doesn't believe VA officials will ever convince Fudin or Mariano the investigation has not been mishandled.

"If we verify 50 percent of what they said, they'll say we covered up 50 percent," he said. "We're in the business of getting to the truth and finding out exactly (what took place). If it turns out half the VA is guilty, we'll round them up." Lyons can be reached at 454-5547 or by e-mail at blyons@timesunion.com.