

Drug trials at VA queried

Albany -- Treatments continued at Stratton nearly a year after warning, official says

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Cancer research patients at Stratton VA Medical Center Hospital received controversial chemotherapy and radiation treatments for almost a year following a drug company's warning to a hospital official about troubling data discrepancies in the program, according to an official familiar with the case.

Patients in the research program continued to receive the controversial treatments for at least 10 months before investigators with the Food and Drug Administration uncovered serious problems in the program last fall. Relatives of former cancer patients are now questioning whether family members may have died prematurely or suffered intense discomfort because hospital officials were slow to investigate the allegations.

In one case, a patient whose eyelid was burned off during a radiation treatment last year died two weeks after receiving elevated levels of drugs in what was scheduled to be his last chemotherapy session. In another, a veteran suffering from esophageal cancer died shortly after being given a drug designed to treat breast cancer, according to the patients' relatives.

Federal authorities have opened a criminal case in which they said manslaughter charges are possible if investigators find that patients died as a result of being wrongly enrolled in drug studies, especially if their medical backgrounds were forged. Meanwhile, officials with the U.S. Department of Veterans Affairs in Washington, D.C, are re-examining drug research protocols under the eye of a House veterans affairs subcommittee.

Ilex Oncology, a Texas company, raised questions about the VA's troubled cancer research program in December 2001. That same month, the company allegedly notified Dr. James Holland, the hospital's chief oncologist and research investigator, about the apparent problems they uncovered.

But several months passed before hospital officials learned about the warning, an official said. Even then, Holland's program was not investigated until last fall, and hospital officials are facing scrutiny for their handling of the case.

In December, Holland and his chief research assistant, Paul Kornak, both were suspended by the hospital.

Families of patients are now reaching out to hospital officials and federal authorities for answers.

Earlier this month, a Massachusetts woman wrote a letter to Albany VA hospital Director Mary Ellen Piche questioning Holland's decision early last year to allegedly change her husband's chemotherapy regimen. The woman said her husband, George McGuire, had suffered no severe side effects from his chemotherapy up to that point.

"I must tell you, however, that after his final chemotherapy treatment he became disoriented, unable to walk, and lost all muscle control," Marie McGuire wrote. "He ate nothing the last two weeks of his life. I also want to make you aware that his left eyelid was completely burned off by radiation in an attempt to shrink one of the hundreds of tumors that riddled his body."

In another case, an Albany woman said her husband died last March, two weeks after being given a breast cancer drug for his esophageal cancer. The woman, who asked not to be identified, said Piche called her a couple of months ago and told her that her husband's death is one of several being investigated by federal authorities.

"She (Piche) said we're investigating whether or not your husband's care was compromised by the fact he may never have qualified for the study to begin with," the woman said. "They said in January 2002 that his remission had stopped and the tumor had started to grow again and that he would need more chemotherapy. He died two weeks after one dose, in which I questioned the combination drug that was given."

But alleged problems in the hospital's cancer program may predate Holland and Kornak.

Records obtained by the Times Union show 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, hospital and court records show.

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. Fudin, who is a doctor of pharmacy specializing in pain management for cancer patients, and Anthony Mariano, a pharmacist who supported him, both alleged in federal lawsuits that they were retaliated against for making the claims.

Other problems have surfaced as a result of the federal investigation started late last year.

Kornak, who was in charge of recruiting cancer patients for Holland's study program, had his medical license revoked and pleaded guilty in 1993 to federal mail fraud charges in Pennsylvania for allegedly forging a medical license application. Despite his troubled background, hospital officials hired Kornak in 1999. Hospital workers and families of former patients said Kornak used the title "Dr. Kornak" even though he was not licensed.

The title also was carried in front of Kornak's name on the hospital's Web site.

As a result, the House Veterans Affairs Subcommittee on Oversight and Investigations has asked the General Accounting Office to conduct an independent inquiry of the VA's hiring practices.