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Ex-workers at Stratton VA sued by widow

Albany-- Claim is first involving cancer program at Stratton medical center

By <u>BRENDAN LYONS</u>, Staff writer First published: Wednesday, March 19, 2003

The wife of a former patient who died last year at Stratton VA Medical Center filed a federal lawsuit Tuesday against two research specialists who are allegedly targeted in an ongoing criminal investigation that centers on the hospital's troubled cancer program.

The lawsuit may be the first of many that will be filed against the researchers and the U.S. Veterans Affairs Department as the hospital's cancer research program faces intensive scrutiny from federal authorities. Investigators are currently trying to determine whether the medical backgrounds of some patients were forged to enroll them in drug studies, including some patients who may have died or suffered as a result of taking certain chemotherapy regimens.

"You can't treat a patient like a human guinea pig and abuse the privilege of the informed consent document," said Alan Milstein, a Philadelphia attorney who is handling the case along with lawyer Donald Kinsella of Albany, a former federal prosecutor.

The complaint filed Tuesday was brought by Jayne Steubing, whose husband, Carl, formerly of Scotia, died a year ago at Stratton VA two weeks after allegedly being given a breast cancer drug to treat esophageal cancer. The lawsuit names Paul Kornak of Clifton Park, a former clinical specialist at the VA, and Dr. James Holland of Voorheesville, the VA's former oncology chief.

Both men stopped working at Stratton VA several months ago as federal investigators moved in and began sifting through patient records to determine whether any crimes were committed. Kornak had no medical license, even though he carried the title "doctor" around the hospital, and Veterans Affairs officials have called for a separate investigation of VA hiring practices as a result.

Kornak's medical license was revoked, and 10 years ago he pleaded guilty to a federal mail fraud charge in Pennsylvania for allegedly forging a medical license application.

In a recent interview, Steubing said she met Kornak before her husband was enrolled in a cancer research program in January 2001. Six months later, his cancer appeared to be in remission and his treatment ended. But early last year, Steubing went back to the VA after learning his cancer had come back, and Holland allegedly put him on a new drug regimen.

"He died two weeks after one dose of the chemotherapy, which I questioned the combination that was given," Steubing said. "He was given a chemotherapy drug that is primarily used for breast cancer."

Carl Steubing was a World War II veteran who enlisted in the Army in 1942 and served for three years, fighting in the pivotal Battle of the Bulge. He was awarded the Bronze Star for bravery after leading his platoon to safety when their commanding officer was shot and a Purple Heart for injuries sustained in combat.

Milstein contends veterans like Steubing should never have been used as guinea pigs.

"Even somebody who is in his last days ... they deserve to die with dignity and not be used as an object, a thing to be studied and abused," Milstein said.

As a result of what allegedly took place at Stratton VA, human research studies at dozens of Veterans Affairs hospitals are undergoing a review. Federal authorities said the review was triggered in part by allegations that patients at Stratton VA received questionable chemotherapy and radiation treatments for almost a year after a drug company warned Holland in December 2001 about troubling data discrepancies in the program, according to an official familiar with the case.

Veterans Affairs officials said it took too long for hospital officials at Stratton VA to learn about the alleged discrepancies discovered by Ilex Oncology, a Texas drug company, and even longer for them to do anything about it. Last fall, Food and Drug Administration investigators were called in and uncovered serious problems in the Stratton VA cancer research program.

The FDA report found numerous violations in cancer studies, including evidence of altered medical histories of numerous patients who qualified for drug research programs as a result of the alleged forgeries, records show. There were also follow-up assessments of patients that were not completed and some received improper doses of drugs because their heights, weights and other information were incorrectly recorded, according to the FDA study.

Federal authorities have 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.

Kinsella said Steubing and her family are not seeking wealth from her husband's death as a result of the lawsuit filed in U.S. District Court in Albany.

"The goal of the family is to see to it that these things don't happen to other people in the future when they trust their loved ones to the VA," he said.

Kornak has declined comment, and Holland could not be reached for comment.

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