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## **Class Action Lawsuit Filed Against Albany VA Researchers**

Class Action Lawsuit Filed Against Albany VA Researchers; Subsequent Tort Claim Notice Sent To Federal Government

The problems at the Stratton VA Medical Center in Albany, NY, have been brewing for several years, but earlier this month they erupted into a potentially precedent-setting lawsuit. Alan Milstein, JD, of Sherman, Silverstein, Kohl, Rose & Podolsky, in Pennsauken, NJ, and Donald Kinsella, a former federal prosecutor from Albany, filed a class action complaint on behalf of about 100 subjects who were enrolled in trials conducted by investigators James Holland, MD, and Paul Kornak, at the Stratton Veterans Affairs Medical Center, from 1999-2003.

In addition to the class action suit, the attorneys also have filed a tort claims notice of intent to use the U.S. Government/Department of Veterans Affairs. The government must respond to this notice separately, according to Milstein. Given the scope of the allegations and the number of possible victims, an award in favor of the plaintiffs could potentially be enormous, Milstein tells CTA.

The lawsuit specifically asks for damages "in excess of \$1 million" for each individual in the case; this does not include any potential punitive damages.

Justice Department officials investigating the Stratton VA research program say manslaughter charges could be filed against the investigators if they determine their actions lead to patient deaths.

The problems uncovered at Stratton have triggered a complete review and potential overhaul of the VA oversight system, and have led to suggestions by a congressional panel for a massive restructuring of the VA's two offices.

In addition, the offices of Research Compliance and Assurance (ORCA) and Research and Development (ORD) are embroiled in the controversy. The House Veterans Affairs Subcommittee on Oversight and Investigations has asked the General Accounting Office to conduct an independent inquiry into VA hiring practices, sources tell CTA. A bill restructuring ORCA and ORD likely will be introduced in the House in the near future, sources tell CTA.

In the meantime, ORD officials announced a "stand down" of all human subject research at VA Medical Centers across the country. That term, used in the military, implies a shutting down after an incident, with a goal of focusing on the identification and correction of the problem, as well as education and training.

In a memo to VA researchers in early March, however, ORD's Chief Officer Nelda Wray, MD, MPH stopped short of shutting down all clinical research. She said that the review would last until June 6, and would examine hiring practices and credentialing, GCP training and adverse event reporting. "If university affiliates provide the VA IRB function, the affiliate will be encouraged to participate in these educational activities," said Wray. Case against Stratton Researchers Milstein says these latest cases filed against clinical research professionals and institutions are complex because they involve not only charges of negligence but also personal injury and death "as a direct and proximate result of defendants' actions." Another charge: VA officials knew of possible violations of federal regulations governing human subject protection, but did nothing about them: "Federal authorities were warned seven years ago that veterans with cancer at Stratton were unduly suffering and were at risk of dying prematurely because they were being given drugs in violation of medical protocols; some former staff members complained that these veterans were treated as guinea pigs, a circumstance that unfortunately has been all too common in the history of medical care offered to American's veterans."

The plaintiff in the case, Jayne Steubing, is the widow of a subject who died while enrolled in a VA clinical trial for colon cancer last year. She represents the class of other study subjects, but the lawsuit also states that other plaintiffs may independently or derivatively sue the defendants.

Class action allegations include:

- violation of Fifth Amendment right to bodily integrity;
- violation of Fifth Amendment right to dignity;
- violation of federal regulations barring enrollment of ineligible subjects; and
- failure to obtain informed consent noting the "substantial risk of serious health effects ... or death.

Attorneys also charge that the defendants conduct included making "false promises to ill and terminally ill patients in order to lure them into the study." This conduct "shocks the conscience," they allege.

Steubing's husband had a previous history of colon cancer when he was diagnosed with gastro-esophageal cancer in January 2001. He was recruited into a Phase III trial by study coordinator Paul Kornak. The study was an open label, randomized, multi-center phase III/IV study of two experimental drug therapies. Prior to enrollment, Kornak and Holland took Steubing's blood chemistry and hematology and also did a medical history that showed his prior cancer, a factor that should have made him ineligible for the study.

"Defendants purposefully and intentionally altered the dates of the lab reports in order to meet the assessment time-frame criteria," says the lawsuit. His creatinine clearance level was 49.5 ml/mn, and exclusion criteria was anything less than 60 ml/mn, according to the court documents.

Steubing received his first study-drug treatment in February 2001, experienced a serious adverse event, but stayed in the trial. He died March 15, 2002, after an infusion of two study drugs. The lawsuit claims that after his death, "the Chief of Staff of Stratton informed Mrs. Steubing that her husband's condition may have been compromised by defendants' wrongful conduct and that he may not have been qualified for the study."

#### The Defendants

The hiring and credentialing of Paul Kornak is a central point in this lawsuit and in the federal tort claim. Kornak was denied a medical license by two states, falsified documents relating to his application, and was convicted of mail fraud by one state after forging credentials to obtain a medical license. Despite his background, he was hired by Stratton as a research assistant in 1999. The lawsuit states: "Stratton hired Kornak with the knowledge that Kornak's medical license had been revoked; Kornak was not scientifically qualified to conduct human subject research."

From 1999 to 2003, Holland, Stratton's Chief of Oncology, conducted seven clinical trials enrolling subjects with prostate, bladder, gastric and colorectal cancer. Plaintiffs are alleging that there were falsified and incomplete case reports, protocol violations and mismanagement of study drugs for all of these trials.

Two pharmacists at Stratton initially reported protocol violations by VA researchers to FDA seven years ago. It is unclear what government officials did in response to the alleged violations then, but FDA compliance officers visited Stratton late in 2002 and uncovered numerous violations in the program, including falsified case report forms and failures to comply with the protocol.

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