

VA Officials Ignored Cancer Research Violations

Over the last several months, I have carefully scrutinized local media sources regarding cancer research at the Stratton VA Medical Center in Albany. Before proceeding with comments, I wish to express that the content herein is not indicative of the current cancer clinicians at the Stratton VA. To the best of my knowledge, the current cancer team includes highly qualified professionals who uphold every ethical standard, and have the highest regard for their veteran patients.

Local reports of research violations began in November 2002, and articulated that Mr. Paul Kornak and Dr. James Holland were being investigated by the FDA for falsifying patient medical records in order to qualify them to participate in clinical research trials. Although personal reasons for falsifying this data have not been elucidated, for each patient placed on such research protocols, there are generally substantial monetary benefits paid to researchers and/or institutions. Policy dictates that this money be used to foster further research.

It is particularly bothersome to me that Stratton VA officials continue to deny that Kornak's recent alleged involvement in unethical cancer research activity was unique and unrelated to similar activities in the past. It is well documented that I reported (in writing) similar activities to VA officials as early as 1995.

In a letter to the VA Inspector General dated 8/1/96, I outlined a number of alleged cancer research violations with supportive documentation, too numerous to list here. The letter alleges falsifying research data, placing patients on studies without consent, embezzling research funds, and more. Stratton VA officials, including one doctor who remains in a regional administrative position today, were made aware of my concerns.

During the mid-1990's, Anthony Mariano (previous Pharmacy Manager), was informed of my findings and supportive that proper steps be taken to correct deficiencies. His reward for supporting me was 4 months of seclusion on an abandoned psychiatric ward with no phone, computer, or work assignments. His employment at the VA eventually ended.

Official reports were filed with appropriate overseeing agencies, alleging Stratton VA administrators participated in calculated reprisal against me for exposing major ethical flaws, some of which allegedly led to patient harm and/or death. This information all remains public access and is on file with the FBI, FDA, VA Inspector General, Congressman Michael McNulty's office, Office of Special Council, Merit Systems Protection Board, and NYS Office of Professional Discipline.

Almost every administrator accused of alleged reprisal against me for disclosing research violations, has since received a major promotion.

A Regional Pharmacy Manager was hired, who accused my previous manager and myself of several improprieties, purportedly in an attempt to make our lives so miserable that we

would leave. One week after he sent me a memo of proposed termination, he announced that he was taking a promotion reporting directly to Washington VA officials.

The Hospital Director was eventually promoted to the Upstate Regional VA Manager for 5 VAs in northeastern NY.

The Chief of Staff helped to cover up an investigation led by former Stratton physician Thomas Ferro. New York Times' Medline Plus reported on 5/27/03 Dr. Ferro admitted that he was instructed to cover up and destroy information that otherwise would have validated the research violations I reported. Soon after this cover-up, the Chief of Staff was promoted to a regional position.

The Chief of Research eventually left Stratton for a substantial promotion where he is now involved with VA research at a national level.

The doctor who was originally accused of alleged research violations in 1995, left the Stratton VA in 1999 and took a promotion as Chief of Research at another VA facility. Prior to leaving Stratton, he hired Paul Kornak. According to Medical Research Law & Policy Report (Thu, 20 Feb 2003), the oncologist that hired Kornak admitted to knowing Kornak's history of fraud for falsifying documents in the past.

Four reports were filed with VA Inspector Generals, locally and nationally. The information was presented to the FBI in 1999. The VA Inspector General (IG) convinced the FBI that the matter would best be handled from within the facility. The FBI dropped the investigation.

The NYS Office of Professional Discipline referred the investigation back to the IG, since it was their opinion that federal agencies are to police themselves.

Congressman Michael McNulty's office was informed on several occasions.

Reports were sent to President Bill Clinton and Senatorial Candidate Hillary Clinton.

A letter was sent to then federal prosecutor Donald Kinsella, who never responded. Mr. Kinsella is now in private law practice and council for many families bringing suits against the VA specific to cancer research violations.

I have been the subject of harassment for disclosing information in an effort to protect our beloved veterans. I was eventually fired and subsequently reinstated by a federal law judge. Current Stratton officials were involved in my termination and filed an appeal to reverse the judge's decision that I return. Their appeal was denied.

Federal employees are hypothetically protected against harassment for disclosing major ethical and safety flaws. The very veterans we serve risked their lives to protect freedom of speech. Is this any way to repay them?

To say there is no connection between this administration, the alleged Kornak violations, and previous cancer research violations, is obviously absurd.

More accurately stated, cancer research violations were a way of life at Stratton for 10 years. Stratton officials turned a blind eye to unethical cancer research practices, and punished those who spoke out.

If VA officials acted responsibly when warned of dangerous research violations in 1995, Kornak would never have been hired, I would not have endured years of harassment, veterans would not have been exposed to questionable care, patients wouldn't be fearful of care at Stratton, and millions of dollars could have been saved in litigation brought on by families of affected veterans.

Dr. Jeffrey Fudin is employed as a Clinical Pharmacy Specialist at the Stratton VA Medical Center in Albany. His statements are not supported or disputed by VA officials and have NOT been made in his official capacity as a federal employee.

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