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## Court papers detail dark chapter at VA

By BRENDAN J. LYONS, Senior writer

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Albany -- The veterans and their spouses called it the drip room.

It was a grim place, located on the first floor at Stratton Veterans Affairs Medical Center just past the cashier's office and the pharmacy. Hard plastic seats spilled into the hallway, with relatives who waited hours for their loved ones to get the cancer drugs that offered them hope.

The spacious room, with its IV-friendly lounge chairs and a row of beds for the patients who got nauseous, began filling to capacity about nine years ago.

The crowds were in large part caused by experiments on dozens of desperate cancer patients who were given powerful mixtures of drugs that were being tested for their marketability.

In September 2001, as the number of cancer drug studies at Stratton tripled to more than 20, two nurses warned a VA oversight board that conditions were unsafe and patients were at risk. No one took action.

Yet that bustling business was only a symptom of a systemic breakdown in which veterans were being pushed into poorly run drug studies for which they didn't medically qualify. They also were the victims of fraud and deception, and top hospital officials privately suspected that as many as five veterans, and possibly more, died prematurely from the fallout.

New information surfaced last month in hundreds of pages of depositions and internal reports filed in a lawsuit by several widows of veterans who died after enrolling in Stratton's drug studies, providing a spotlight on a government research program that had spiraled out of control.

Attorneys in the case declined comment.

The federal court documents, which include confidential investigative reports never made public, indicate that about 70 percent of Stratton's former cancer research patients were victimized in the scandal, which triggered nationwide hiring reforms in VA research programs. In early 2002, at the time it began unfolding, 91 veterans were involved.

Allegations include:

Cancer patients were pres into joining experimental studies in which they and their families did not want to be enrolled.

A nurse who still works for a VA hospital received only a reprimand for issuing pre-signed prescriptions for controlled substances without doctor approval.

Three research coordinators were ordered to enroll as many people as possible in drug studies by a physician who said their salaries and job security were at stake.

Paul H. Kornak, a convicted felon who never completed medical school, was hired as a research coordinator and fraudulently posed as a doctor when supervisors knew of his background.

Research coordinators were allowed to illegally use a physician's electronic signature and computer access codes to perform functions for which they were not qualified.

Kornak and the former cancer research director, Dr. James A. Holland, continued working for months after their scientific misconduct was discovered.

Stratton's Institutional Review Board, which monitors research studies, "did not adequately protect the rights and welfare of human subjects."

Glenn McGee, a bioethics expert at Albany Medical College enlisted as an expert witness by the attorneys for the widows, characterized the situation as a "systematic deception by clinicians in plain violation of medical and research ethics across 3,000 years of the development of such principals."

"The clinical trials conducted at the VA involving the plaintiffs and their loved ones in this case violated the standards and regulations governing the conduct of clinical trials in this country and throughout the world," McGee wrote in a report filed in the case.

The case is pending in U.S. District Court in Albany. The hospital is being defended by Justice Department attorneys from Massachusetts because federal prosecutors in Albany oversaw the prosecutions of Kornak and Holland, both of whom were convicted of federal crimes related to research fraud.

At a hearing scheduled for Monday, the government's attorneys are expected to argue for a dismissal of the class action lawsuit on the grounds there is no proof the experimental drugs caused more than one death. They have also argued that since the participants were terminally ill cancer patients their deaths were already likely, and their pain and suffering from the experimental drugs cannot be quantified.

The widows' attorneys have filed hundreds of documents alleging negligence by the Department of Veterans Affairs, and comparing the scandal to Nazi experiments on humans during World War II.

The fraud at Stratton was discovered in December 2001 by a monitor for a Texas drug company who visited Stratton and began scrutinizing the records of a cancer patient. The monitor, whose job was to check the integrity of drug studies, found a forged radiological report and confronted Kornak, the study coordinator.

Kornak, 56, who had been working at Stratton for two years, got into a shouting match with the monitor and they had to be physically separated, according to sworn depositions of witnesses.

It wasn't the first time Kornak had argued with a drug company monitor, witnesses said. This time, Kornak's behavior and the discovery of the forged medical record further raised the suspicions of co-workers who were already unsettled by the fact he was allowed to wear a name tag with "M.D." on it. He also was introduced to patients and their families as a doctor and carried VA-issued business cards that listed him as a medical doctor.

Kornak was not a doctor. He was a convicted felon who never finished medical school and had tried more than once to use forged transcripts to obtain a medical license, according to federal court records. Fifteen years ago in Pennsylvania, Kornak pleaded guilty to federal mail fraud charges and was sentenced to probation after admitting he lied on a medical license application, the records show.

After the drug company's monitor confronted Kornak, he told Holland what had happened. Holland responded by writing a memorandum to his research staff affirming their ethical obligations. On May 28, 2003, some five months after it was first discovered, Kornak and Holland reported the incident to Dr. Donald Pasquale, the chief of research and head of the hospital's Institutional Review Board for research.

Pasquale initiated an internal probe, but the investigation began slowly and Kornak continued working.

At that time, hospital officials were apparently unaware of the scope of the scandal or that nearly three-fourths of their cancer research patients had been subjected to fraud.

Despite the fact that Kornak had admitted "scientific misconduct," and also that top hospital officials had begun questioning his credentials, he was allowed to continue working for almost 10 months, and he continued to commit more fraud.

Hospital officials defend their actions, noting that Kornak was removed from caring for "sensitive patients" and his computer access was limited.

"I strongly feel that our (system) functioned adequately," a high-ranking Stratton physician said during an interview at the newspaper last week. The physician declined to be identified on the grounds he or she is not authorized to talk about the case.

Kornak was finally barred from Stratton's premises in October 2002 after a clerk in the cancer unit reported he'd tried to get her computer access code to hack into the system, according to court records.

On Nov. 2, 2002, Pasquale and Dr. Eina Fishman, who was chief of staff at Stratton, met for two hours in Fishman's office with Holland. The meeting, which is characterized in the court documents as a "conversation," was tape recorded.

According to a transcript of the meeting, Holland admitted he was overwhelmed with work and had relied on his three research coordinators, none of them physicians, to carry out many of his duties. Most notably, he said, the researchers took the lead in getting cancer patients to sign consent forms that would enroll them in drug studies.

Still, Holland blamed Kornak.

"This is so black and devious," he said in the meeting. "There's got to be a lot more to this and he's put all of our jobs at risk. And he put my

medical license at risk. ... If I was (not) a calmer person, I would've strangled him."

The infusion suite, where the drugs were administered, became so busy nurses were "pounding me ... this is not safe," Holland said. He recounted a case in which a patient could have died because of a prescription mishap that wasn't caught until the nurse who was supposed to administer the drugs noticed a problem.

"That was cutting it really close; it should have never have gotten that far," Holland said.

As for the high number of patients, Holland said he often felt "rushed" to treat them and under pressure from the drug companies to get more veterans in studies. Yet, he also said Kornak was pushing people into studies who didn't qualify, claiming Kornak's motive was to earn overtime pay from the added work.

Looking back, Holland said at the time, he was concerned that at least four deaths may have been linked to Kornak's fraud and forgeries. Holland specifically cited the case of James J. DiGeorgio, an Air Force veteran from Rensselaer County who died during a drug study. Kornak would later be convicted of negligent homicide for DiGeorgio's death.

Four deaths involving veterans on drug studies, including DiGeorgio, bothered Holland as he reflected on the circumstances of their cases, he said in the interview.

Another veteran, George Hunt, died after being infused with experimental drugs that required subjects have no history of heart disease in order to qualify for them. In Hunt's case, his EKGs (electrocardiograms) used as criteria for admission to study had been handled by Kornak.

"I was told that Paul had altered some EKGs, and I was hoping I saw the right EKG at that particular point," Holland said of his decision to order a drug infusion. "I'm afraid, hoping he wasn't the one that the EKG had been altered beforehand. ... Next thing I know, I come back in the morning and the guy had coded in the middle of the night."

Hunt died later that day.

In a deposition on Jan. 16 at the federal prison in Ohio at which he is serving a 71-month prison sentence, Kornak invoked his Fifth Amendment right against self-incrimination four times as he was pressed by an attorney for the widows about the extent of his crimes.

Kornak cast blame on Holland, saying the former researcher knew Kornak lacked a medical license and that Holland encouraged staffers to push patients into the drug studies.

"There was a blackboard or a marker board in the office areas that listed all the studies and he would urge that more patients be placed on the study that was less than fulfilled," Kornak said. "He told me there was no reason why a patient shouldn't be placed on a study ... that is the mantra that he lived by at the VA."

Between 1998 and 2002, the number of studies at Albany's VA hospital jumped from five to nearly 30, Kornak said.

"He opened up every study he could and decided to fill them to their capacity," Kornak said. "It seemed to me that he wanted me to take over more of his duties."

Lori Megherian, another research coordinator, backed Kornak's version.

In a seven-page affidavit given to investigators with the Food and Drug Administration, Megherian recounted Holland's drive to get patients enrolled.

Holland would say "we need to get patients on the studies and our salaries are based on enrollment, on how much money we were bringing in," Megherian said.

In January 2003, 13 months after the fraud was discovered, hospital officials began drafting letters to the families of research patients to notify them there was a problem.

Fishman said she chose to personally attempt to contact the families of five veterans, including DiGeorgio and Carl M. Steubing, both of whose widows are plaintiffs in the lawsuit.

"I had a concern that the deaths may have been related to the documentation issues," said Fishman, who no longer works at Stratton.

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\* Independent audit of Stratton research program: "Subjects were consented, enrolled, and examined by an individual posing as a medical doctor.... The Internal Review Board did not adequately protect the rights and welfare of human subjects."

\* Karen Sutton, whose father, Charles G. Merritt, a World War II Army veteran, died Aug. 10, 1999: "I remember my father saying he understood the importance of experimental chemo but he didn't want to do it. He was overmedicated and things got kind of out of control there for him. He was hallucinating. They falsified his records and Dr. Holland coerced him into signing the paper."

\* Interview of Dr. James Holland by VA officials, Nov. 8, 2002: "I was told that Paul had altered some EKGs and I was hoping I saw the right EKG -- I'm afraid, hoping he wasn't the one that the EKG had been altered beforehand -- I come back in the morning and the guy had coded in the middle of the night."

#### Scandal in the making

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1992: Kornak, who never completed medical school and forged his college transcripts, is convicted of federal mail fraud in Pennsylvania for lying on a medical license application. He is sentenced to probation and fined \$2,500.

1995: Stratton Veterans Affairs Medical Center pharmacist Jeffrey Fudin warns hospital officials of corruption in Stratton's cancer program that he said is resulting in "needless premature patient suffering and/or death."

1998: A review of Stratton's cancer program by other VA oncologists determines it is in disarray and patient care is poor. Dr. James A. Holland is hired by Stratton VA.

1999: Kornak is hired as a laboratory technician at Stratton through nonprofit Albany Research Institute.

2000: Holland appointed head of Stratton's cancer program, including research. Despite lying on his application, Kornak gets a government job at Stratton as a human research coordinator.

2001: Two nurses complain to Stratton's research oversight board that patients are at risk because of an overtaxed research department. One of the nurses is later reprimanded for issuing presigned prescriptions for controlled substances to patients. The cancer program's research studies have swelled from five in 1998 to more than 20. A monitor for Ilex Oncology, a Texas company funding a drug study at Stratton, discovers fraud in a patient's file at Stratton.

2002: FDA investigators report serious record-keeping flaws in Stratton's cancer research program, including alteration of patient medical tests. A federal criminal investigation is launched. Kornak and Holland are suspended and later terminated.

2003: Legislation is introduced in Congress creating an independent oversight office to keep tabs on medical research programs at Veterans Affairs hospitals nationwide.

Dr. Thomas Ferro, a former pulmonary physician at Stratton who was appointed to lead the 1995 internal investigation of Fudin's allegations, tells the Times Union that he took part in a cover-up designed to "thwart the truth."

Quintiles Consulting, an independent clinical site auditor hired by Stratton, discovers fraud in 70 percent of Stratton's cancer research patients' files. The confidential report concludes the hospital's human experiments "lack adequate oversight" and that an Institutional Review Board, which monitors research protocols, "did not adequately protect the rights and welfare of human subjects."

A federal grand jury hands up a 48-count indictment against Kornak, including charges of negligent homicide.

The first of seven widows of veterans, all of whom died after being enrolled in experimental drug studies at Stratton, files what is now a class-action lawsuit against the U.S. Department of Veterans Affairs, Kornak and Holland.

2005: Under a plea and cooperation agreement, Kornak pleads guilty to three felony counts and is sentenced to 71 months in federal prison.

2007: Holland pleads guilty in federal court to a misdemeanor count of failing to keep accurate records on research patients. He continues to practice medicine. His sentencing is pending.

Compiled by Senior writer Brendan J. Lyons Sources: Interviews; U.S. Department of Veterans Affairs; federal court records; U.S. attorney's office

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DR. JAMES HOLLAND

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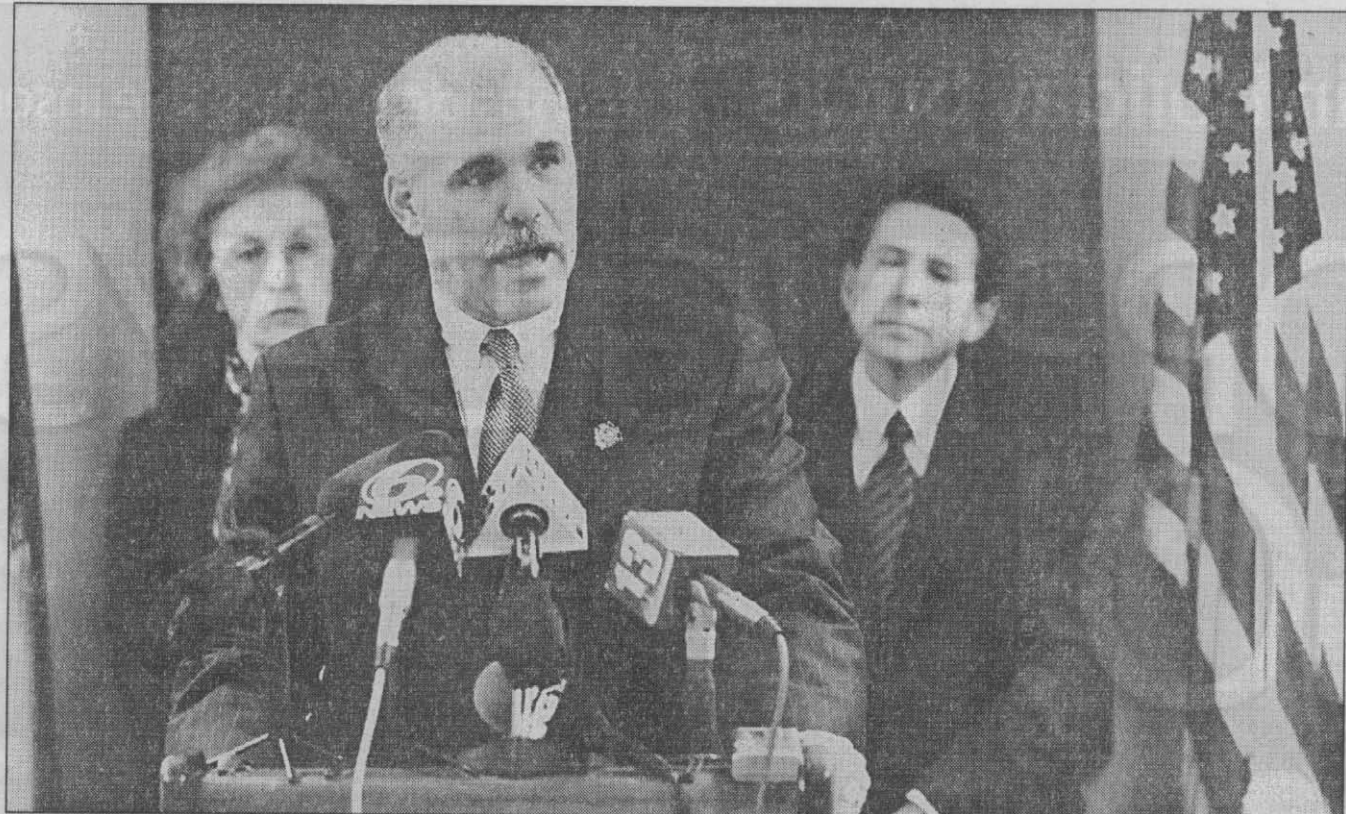
PAUL H. KORNAK



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**CHARGES  
AGAINST**  
Paul  
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were  
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at a news  
conference  
by Glenn  
Suddaby,  
U.S.  
attorney for  
the  
Northern  
District of  
New York,  
in October  
2003.





CINDY SCHULTZ/TIMES UNION ARCHIVE

**MARY SNAVLIN** holds a photo of her father, James DiGeorgio, an Air Force veteran from Rensselaer County. Paul Kornak was convicted of negligent homicide in DiGeorgio's death. Kornak, below left, leaves court in 2005 with attorney E. Stewart Jones.



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