

# VA had hospital warning

*A 1998 report on facility's cancer program describes low morale, infighting, "hostility" and predates research scandal and investigation*

By **BRENDAN LYONS**, Staff writer

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ALBANY -- Top officials at Stratton Veterans Affairs Medical Center Hospital were warned of poor patient care and conflicting data in their cancer program several years before a corrupt researcher began forging the backgrounds of veterans to enroll them in drug studies.

Hospital records recently obtained by the Times Union show that VA cancer experts told Stratton officials their cancer program was in disarray, morale was low, there was widespread infighting among staffers and doctors were spending more time on research than with patients.

Years later, the cancer program became the subject of a federal grand jury investigation that has led, so far, to one criminal conviction -- for negligent homicide and fraud. Records of dozens of veterans were forged to qualify them for studies of new cancer drugs.

An attorney representing widows of veterans who died or suffered as a result of the fraud said documents obtained by the newspaper support their assertion that the U.S. Department of Veterans Affairs bears much responsibility for what occurred.

"If true, it would clearly establish that the VA was responsible," said Donald T. Kinsella, an attorney for relatives and widows of several deceased cancer patients. "It shows how criminality was allowed to occur."

Many problems, including allegations doctors were more invested in research than patient care, were outlined in a 1998 report delivered to top Stratton officials.

That August, a review team of cancer physicians from other VA hospitals were called in to evaluate Stratton's hematology and cancer programs. It's not clear who called for the outside review, but a copy of the report indicates they uncovered a mess.

The evaluation took place three years after a VA researcher, Dr. Rostislav Vyzula, had filed a formal complaint against Stratton's former oncology chief, Dr. William Hrushesky, alleging that he had altered the results of research studies in an effort to get them published. That same year, Jeffrey Fudin, a Stratton pharmacist, reported that Hrushesky was prescribing drugs outside accepted protocols, possibly as a form of research and without patients' consent.

Rather than acting on Fudin's warnings, Stratton's bosses made Fudin the target of an internal investigation -- alleging patient abuse. Two years ago, a cardiologist, Dr. Thomas Ferro, who headed the probe of Fudin, admitted to the Times Union that hospital officials encouraged him to discredit Fudin in order to protect Hrushesky and his valuable research program.

Retaliation against Fudin and his former boss, Anthony Mariano, became well documented.

The fallout from that scandal was still unfolding when the independent review team arrived at Stratton in 1998. The team's report was never made public -- until now.

"Shortly after our arrival it became apparent that this review would indeed be a challenge," Dr. Harold S. Ballard, one of the examiners and head of the cancer program at New York Veterans Affairs Medical Center in New York City, said in a cover letter to his report. "Conflicting data, conflicting statements, conflicting perspectives and an atmosphere of tension prevailed."

Ballard's report was sent to the VA's Office of Inspector General and to Dr. Lawrence H. Flesh, Stratton's former medical director and chief of staff, and now deputy director for this region's VA hospital network. Flesh declined comment through a spokeswoman.

It's not clear whether the Inspector General's office took any action. A former hospital official familiar with the allegations against Hrushesky said Stratton officials chose to keep the information quiet, in part to protect their research programs.

"(Hrushesky) was bigger than life during the time he was there," the former official said. "The chief of staff chose not to deal with a lot of these issues."

Ballard wrote in his report that Hrushesky and his wife, Dr. Patricia Wood, who worked alongside her husband at Stratton, complained they were not given enough time to devote to research "based on the amount of grant money they bring in."

Meanwhile, Wood and Hrushesky were not well liked or respected by their own staff, according to the independent reviewers.

"In fact, (there was) general outright hostility between them and Drs. Hrushesky and Wood, which is severely interfering with patient care and the day-to-day functioning of Hematology/Oncology Service," the report said. "The relationship between the various disciplines has broken down. This can only impact negatively on the quality of care for patients with cancer."

The report also noted that officials at neighboring Albany Medical Center, which had a long history of teaming with Stratton, had broken off relations with the VA's cancer program, in part because of Hrushesky's "autocratic style as moderator."

But there were more than just personality conflicts.

Ballard's report indicated Stratton's head chemotherapy nurse was concerned that neither Hrushesky nor Wood were spending even half their time with patients.

Six months after the report was issued, Hrushesky hired Paul H. Kornak, a convicted felon who washed out of medical school, and put him in charge of research duties that included recruiting veterans for drug studies. At the time he was hired, the Department of Veterans Affairs did not require background checks for jobs such as Kornak's.

Hrushesky has declined repeated requests for comment. In 2003, Hrushesky told BNA, Inc., a health care publication, that he and two other physicians agreed to give Kornak a job.

Hrushesky said he conducted the job interview. He told BNA that Kornak "presented himself as someone with significant medical experience and with a wife and two kids and no obvious way of making a living. He gave us a resume with an 'M.D.' on it and a lot of gaps. We decided to give him a chance."

Hrushesky admitted he knew Kornak didn't have a medical license. Kornak allegedly told Hrushesky he had been unable to get a license because he couldn't document having

attended his first year of medical school in Poland. That claim turned out to be false. Federal authorities said there's no proof Kornak ever attended medical school in Poland.

"Mr. Kornak was not hired as a physician and he had no clinical privileges," said Linda Blumenstock, a Stratton spokeswoman, declining further comment.

However, even with a criminal record and no medical credentials, Kornak began taking on patient-care duties, including the recruitment of research patients, while Stratton's cancer physicians immersed themselves in the hospital's lucrative research studies, according to court records and hospital reports.

Five years ago, Hrushesky left Stratton to take a job as director of research at a VA hospital in Dorn, S.C.

Kornak remained at Stratton and began reporting to a new oncology chief, Dr. James A. Holland, who was later terminated with Kornak when the research scandal erupted. Several widows of veterans have said Kornak was introduced to them as "Dr. Kornak," and that he handed out VA business cards denoting he had a medical degree.

Holland, who has declined comment, was identified by the U.S. Attorney's office last year as a target in the investigation.

But Hrushesky's name has not surfaced in the criminal probe. It's also not clear whether Hrushesky was ever disciplined or exonerated following the allegations filed against him.

One of the most serious surfaced in 1995 when a research colleague accused him of "scientific misconduct" for allegedly altering the results of cancer research studies on mice. An internal committee determined the allegations warranted "further investigation," according to a 1995 memorandum, but there is no indication a follow-up investigation was done.

Kornak's sentencing for negligent homicide and fraud is scheduled to take place Sept. 21.

E. Stewart Jones, Kornak's attorney, said he suspects federal authorities have been reluctant to dig deeply into the case beyond Kornak, who pleaded guilty in U.S. District Court in January.

"What they're looking for is a layup, in other words, a very easy case," Jones said.

Kornak contends he was a pawn following orders and that other hospital officials took part in altering patient records to enroll veterans in lucrative drug studies, which thrived with more patients. In Kornak's case, authorities showed medical backgrounds were forged to qualify veterans for the cancer drug studies.

"This is not something that could have possibly have happened on Kornak's watch alone," Jones said. "There was absolutely no reason for Kornak to do this, he didn't gain anything from it. On the other hand, (researchers) did."

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# Years of investigation, disarray at VA hospital

**1992:** Paul H. Kornak is convicted of mail fraud in a federal court in Pennsylvania for lying on a medical license application.

**1995:** Stratton Veterans Affairs Medical Center Hospital pharmacist Jeffrey Fudin warns hospital officials of alleged corruption in Stratton's cancer



▲ Jeffrey Fudin

program that he contends resulted in "needless premature patient suffering and/or death."

**1995:** Allegations of "scientific misconduct" are lodged by a physician against Dr. William Hrushesky, chief of Stratton's cancer program. A three-man committee determines the allegations warrant further investigation.

**1995-2000:** Fudin and another pharmacist, Anthony Mariano, contend they have suffered retaliation for whistle-blowing. Both eventually lose their jobs. Fudin is reinstated by a federal court. Mariano loses his legal battle to be rehired.

**1998:** A review of Stratton's cancer program by other VA oncologists determines it is in disarray and its patient care is poor. Examiners make note of widespread staff-relations problems that center on Hrushesky.

**1999:** Kornak is hired by Hrushesky as a research assistant.

**1999:** Mariano's office is moved to an empty psychiatric ward on Stratton's top floor. He stays there for four months until a congressional staffer demands hospital officials return him to the pharmacy.

**2000:** Kornak gets a government job at Stratton as a program specialist and works as a coordinator of human research studies. Authorities say Kornak lied on his federal job application about his criminal history and credentials, including forging his college transcripts.

**2001:** Air Force veteran James J. DiGeorgio of Brunswick dies on June 11 at Stratton, weeks after enrolling in a human research drug program.



▲ James J. DiGeorgio

**2001:** Ilex Oncology, a Texas drug company, questions discrepancies in patient documentation at Stratton.

**2002:** FDA investigators report serious record-keeping flaws in Stratton's cancer research program, including alteration of patient medical tests.

**2002:** Kornak and Dr. James A. Holland are suspended and later terminated. The VA Office of Inspector General opens a criminal investigation.

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

**2003:** 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 coverup designed to "thwart the truth."

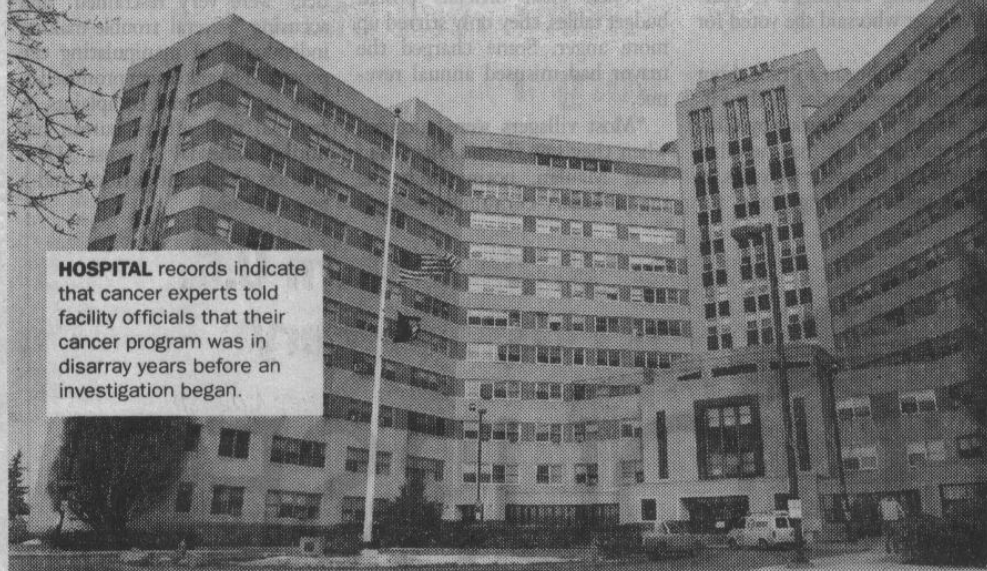
**2003:** Federal prosecutors file court documents indicating that Holland and Kornak may both face criminal charges. On Oct. 29, a grand jury hands up a 48-count indictment against Kornak.

**2005:** Kornak will be sentenced Sept. 21 in U.S. District Court for his guilty plea to negligent homicide and fraud charges. No one else is facing charges in the case.

Sources: U.S. Department of Veterans Affairs; federal court records; U.S. Attorney's office; Stratton hospital records.



▲ Paul H. Kornak



**HOSPITAL** records indicate that cancer experts told facility officials that their cancer program was in disarray years before an investigation began.