

Former VA researcher sentenced in drug trial scandal

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By MICHAEL VIRTANEN, Associated Press Writer, The Associated Press
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A former cancer researcher at an upstate Veterans Affairs hospital was sentenced Monday to nearly six years in prison for criminally negligent homicide in the death of an Air Force veteran enrolled in a drug experiment.

Paul Kornak, who admitted forging medical records at the Stratton Veterans Affairs Medical Center in 1999-2003 to make dozens of patients eligible to participate in drug studies, also pleaded guilty last year to mail fraud and making a false statement.

In handing down the 71-month sentence Monday, U.S. District Court Judge Frederick J. Scullin Jr. called Kornak "callous and insensitive."

Kornak, 54, said Monday he was "a broken man" and apologized, but added that everything he did was ordered by the VA hospital's cancer program director.

The criminally negligent homicide charge stemmed from the death of 71-year-old James DiGeorgio in May 2001, who died a few weeks after participating in a drug-research program for stomach cancer.

Scullin said at least 27 other VA cancer patients were likewise vulnerable. While it was not clear the experimental chemotherapy treatments caused or hastened the deaths of the patients, he said it was clear they did not qualify for the experimental program and that Kornak doctored their records.

A 48-count indictment handed up in 2003 charged Kornak with manslaughter, criminally negligent homicide, fraud and other counts. His arrest sparked a nationwide review of practices at VA hospitals.

In 2003, a General Accounting Office report discovered gaps in human clinical trials conducted at VA research centers across the country, including inadequate policies and training to protect volunteers from abuse.

In court papers, Kornak's lawyer, E. Stewart Jones, had said DiGeorgio suffered from pre-existing medical conditions and dismissed claims that his death was linked to his participation in the study.

DiGeorgio was hospitalized with advanced-stage stomach cancer on May 14, 2001. His death certificate said he died of respiratory arrest due to cancer.

A month before DiGeorgio died, Kornak forged the test results of a blood sample provided by DiGeorgio so that he could qualify for the study even though he suffered from impaired liver and kidney function, said Assistant U.S. Attorney Grant Jaquith.

Kornak was hired by Stratton in 1999 to coordinate and conduct clinical trials, although he had previously served three years' probation on a mail fraud conviction in Pennsylvania for falsifying information on a medical license application. He acknowledged posing as a doctor though he never completed his training at a school on the Caribbean island of Grenada.

The 2003 indictment said Stratton earned thousands of dollars for each patient enrolled in drug trials in which drug companies test novel drugs on cancer patients, a necessary step in trying to get government approval of drugs.

Stratton officials say the institution has strengthened its hiring methods, research practices and oversight activities since Kornak's arrest.

Kornak was fired in January 2003 along with his boss, Dr. James Holland, a cancer specialist. Holland has not been charged. Jaquith declined comment Monday whether any charges will be filed.

Jeffrey Fudin, a hospital pharmacist, said Monday the experimental chemotherapy testing at Stratton has been stopped. He said he'd tried to call attention to problems since 1993, but that he was punished for doing that. He added that several medical professionals involved over that span have since moved on to other posts within the VA.

A call to hospital director Mary Ellen Piche was not immediately returned Monday.

A civil suit filed in late 2003 seeks more than \$1 million from Kornak and Holland on behalf of Jayne Steubing, widow of one of the cancer patients, and about 100 others who participated in the drug trials. A trial in that suit is tentatively set for January 2007.

A second suit has been filed against the VA itself. Steubing was in court Monday and said she was happy Kornak received the maximum sentence.

"I also see this as the beginning of responsibility," she said.