

Researcher Hired Despite Revoked License; Feds Launch Probe of VA Hiring Practices

Doctors at Stratton Veterans Affairs Medical Center in Albany, N.Y., hired Paul H. Kornak in 1999 to work on drug studies despite knowing that his medical license had been revoked, according to oncologist Dr. William J.M. Hrushesky.

Kornak and former Stratton oncology chief Dr. James A. Holland are now under federal criminal investigation for at least five deaths at the VA center in drug studies involving almost 100 patients. The pair could face involuntary manslaughter charges if federal investigators conclude they were responsible.

The Food and Drug Administration uncovered serious problems in an exhaustive, 51-day review of seven of Holland and Kornak's studies, according to the FDA inspection report, obtained by BNA. Participants received drugs they should not have been given, necessary medical tests were not performed, and serious diagnoses-including a possible heart attack-were ignored.

Kornak, who was Holland's assistant, recruited patients for the studies and collected data after they were enrolled. Holland oversaw the projects, a VA source explained.

Concerns about Kornak's hiring have prompted a nationwide probe into how VA medical centers hire health care workers. Arthur K. Wu, staff director of the House Veterans Affairs Oversight and Investigations Subcommittee, confirmed the investigation, which will be conducted by the federal General Accounting Office, the investigative arm of Congress.

VA administrators are worried the VA does not do enough to keep unscrupulous researchers and health care workers out of its medical centers, and that, as a result, patients may be at risk, the source said.

A Second Chance.

Kornak responded to a Stratton research assistant ad in 1999. During his interview, he told Hrushesky he had lost his medical license because he could not document his first year of medical school in Poland. Two references from Temple University, where Kornak had worked, confirmed the story for Hrushesky and said that Kornak had been a good employee.

Hrushesky, who was employed by Stratton at the time, relayed the information to two Albany researchers who, like himself, needed an assistant. The three physicians recommended Kornak to the Stratton VA research foundation, which took their advice and hired him.

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

But Albany had only part of the story on its new research assistant. With more digging, administrators might have discovered that Kornak's medical license had been revoked in Iowa in 1991 and in Pennsylvania in 1992 because he had lied about his medical education, according to state medical board records.

A Hiring Mistake.

New Jersey, the first state to discover a problem with Kornak's background, denied him a medical license in 1990 because he lacked adequate medical training. According to the board, Kornak altered his

undergraduate transcripts and created bogus records from the Academy of Medicine in Poland to get into medical school. Kornak also falsified many of the documents he filed with the New Jersey board. Iowa and Pennsylvania soon heard about the fraud.

The information comes from Public Citizen, a consumer watchdog group founded by Ralph Nader. Public Citizen has tracked Kornak for years and publishes his disciplinary record annually in its widely available book, *Questionable Doctors*. Medical board records also are available directly to the public, often on the Web.

Had Kornak's full medical background been known, Albany probably would not have hired him, VA employees told BNA. Federal investigators currently are unraveling the details of how Kornak came to work with severely ill patients in sensitive medical studies.

Hrushesky and his peers were unaware of the full extent of Kornak's problems when he was hired.

Public Citizen has no record of disciplinary action against Holland, who has a valid medical license in New York state. However, in response to the Veterans Affairs criminal probe, the Albany Medical Center is looking into Holland's credentials and has asked for an explanation of the VA deaths, spokesman Greg McGarry said.

Holland has admitting privileges at AMC, but has not treated any patients there. AMC gave him a month to respond to its requests.

Stratton fired Holland and Kornak in January, almost a year after concerns about their studies emerged. Neither was available for comment.

Holland replaced Hrushesky, who left the Albany VA in 2000 to assume his current post as director of research at the Dorn VA Medical Center in Columbia, S.C.

Heart Attack, Kidney Disease Ignored.

The seven studies FDA examined looked at new ways to treat prostate, bladder, stomach, and colon cancer. Genentech Inc., Aventis Pharmaceuticals Inc., Pharmacia Corp., and Ilex Oncology Inc. funded the trials. Aventis's Taxotere and Pharmacia's Bextra were among the drugs studied. Fifty-five patients participated.

Medical records were altered to conceal kidney disease, cancer surgeries, and severe heart problems, including a possible heart attack, FDA found. Blood chemistries, cancer bone scans, echocardiograms, prostate cancer checks, and other necessary tests were not performed, though study records indicated they had been. Tests that were done had dates and results altered. Drugs were given in wrong doses and, in one case, patients already hard of hearing got a medication that could make hearing worse. Supervision of the projects was in all cases inadequate, FDA concluded.

The altered records made patients appear sicker or healthier than they actually were so they could be enrolled in drug studies for which they would not otherwise have qualified. Consequently, subjects were given drugs they should not have gotten in ways their makers had not intended them to be administered, according to FDA inspectors.

Federal investigators for the VA and U.S. attorney's office concluded that it is "highly likely" the actions caused one death and "possible" that they caused at least four more. Kornak worked with several doctors at the Stratton center, but FDA looked only at studies on which he collaborated with Holland.

Federal investigators are pressuring Kornak to implicate Holland in the research fraud, sources intimately connected to the criminal investigation said, but he has so far refused to do so.

The case has raised questions about staffing at the Albany center. Stratton has about 600 cancer patients a year, a VA physician said. The center's few oncologists can hardly keep up with the patient load, let alone monitor studies, and supervise employees, "regardless if they have a crazy person in the mix or not," the physician explained.

Meanwhile, attorney Alan Milstein, well-known in the research community after winning multimillion dollar settlements for patients hurt in medical studies, has told BNA he is looking into the Stratton case.

Local Hiring Standards.

Kornak's hiring probably did not break any VA rules, according to BNA's sources. The VA does not require thorough background checks of research assistants.

Doctors, nurses, and others hired by VA medical centers to care directly for patients go through the centers' human resources departments, which screen credentials and work history. Research staff, despite their sometimes intimate interactions with subjects, are not considered direct care givers and are not screened as thoroughly, sources explained.

Staff hired by research foundations, like Kornak, are often not screened by a VA HR department at all. The foundations are considered separate entities and do their own hiring. Foundations decide locally how to screen potential employees, said Barbara F. West, executive director of the National Association of Veterans' Research and Education Foundations in Bethesda, Md.

The foundations exist because the VA cannot take money directly from drug firms and other companies to study medical products, but, as separate entities, the foundations can. They hold, manage, and distribute money for VA research projects, West explained.

With the General Accounting Office probe into VA hiring practices, the system soon could change. Members of the House Committee on Veterans Affairs requested the GAO investigation. The office will review how VA centers and foundations hire medical staff and likely recommend stricter hiring requirements, a VA source said. The VA also might consider a credentialing program for research assistants, who do not currently need specialized training to work at the VA.

There was some confusion about Kornak's exact credentials even after the criminal probe began, one source said. The VA had referred to him as a doctor, but stopped doing so after his background became clearer. Still, one VA Web site continues to list Kornak as an M.D.

Hrushesky said the Stratton VA research foundation should have done further checking on Kornak before hiring him, explaining that "it's the responsibility of the research foundation to check employee credentials" despite staff recommendations.

Stratton's research foundation executive director Christine Palermo refused to talk to BNA for this story.

The Albany situation is not the only one driving the GAO probe. In 2002, Richard Williams, a former nurse at the Truman Memorial Veterans Hospital in Columbia, Mo., was charged with 10 counts of first-degree murder in patient deaths at Truman. Williams may not have been adequately screened before he was hired, a highly placed source suggested.

Gun to the Head.

Like many people interviewed by BNA, Hrushesky said he will be at a loss to explain the motives of Holland and Kornak if they ultimately are linked to the kinds of problems uncovered by FDA.

"I simply don't understand what happened, why Kornak [allegedly] did what he did," Hrushesky said.

Falsifying data would be akin to "putting a gun to your head" for a medical researcher like Holland, he added.

Even if Kornak acted independently, Hrushesky said "it is understood" in the medical community that Holland, as principal study investigator, was ultimately responsible for making sure his projects were done honestly.

No one interviewed by BNA could say whether Kornak or Holland had a financial stake in the drugs they studied or the companies that made them. In other research fraud cases, financial interests have prompted researchers to cheat on studies to get drugs approved by FDA more quickly.

VA research foundations typically keep about 15 cents out of every drug company dollar they receive, Hrushesky noted, but doctors, foundation executives, and other research employees are on fixed salaries and cannot touch the revues.

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