Federal Health Matters

Former VA Employee Convicted in Research Abuse Trial

Last month at the federal courthouse in Albany, Paul H. Kornick, former research coordinator for the Samuel S. Stratton VA Medical Center in Albany, NY, pleaded guilty to fraud, making false statements, and criminally negligent homicide in the death of Air Force veteran James DiGeorgio. These charges were related to abuses within the cancer research program at the Stratton VA that were uncovered between 2001 and 2003, prompting a nationwide investigation of VA human research activities and accelerating implementation of an external research accreditation process involving the National Committee for Quality Assurance (NCQA).

According to an article published in the February 6 issue of the *New York Times*, Kornak had a criminal history prior to being hired by the VA. In 1993, he was charged with and convicted of felony fraud by the U.S. District Court in Harrisburg, PA after he forged credentials to obtain a medical license. Although the Stratton VA hired him for a nonphysician position in 1999 (a time when VA policy did not require extensive credential checking for such positions), he performed physical exams and even had "MD" appear on his VA business cards.

Kornak admitted to falsifying medical records in order to enroll ineligible patients in at least five studies of experimental drugs. These actions were believed to have caused at least one patient death, but they may have contributed to others. Carl M. Steubing, a 78-year-old man with gastroesophageal cancer, was not qualified for a chemotherapy trial due to his history of previous cancer and poor kidney function. Nevertheless, he was enrolled in 2001 and died after six cycles of the aggressive treatment.

Kornak has agreed to cooperate in an ongoing investigation of the Stratton VA's research program. The facility first came under scrutiny in 2001, when the pharmaceutical company sponsoring a bladder cancer study discovered discrepancies in the paperwork for this study. This led to an audit, an internal review of the cancer research program, and, eventually, an FDA investigation. The FDA team reviewed the files of over 50 research subjects and found problems in almost all of them. At this point, Kornak and his physician supervisor, Dr. James A. Holland, were dismissed.

The VA's research problems, however, may have been larger than a few "bad apples." Jeffrey Fudin, a clinical pharmacist at the Stratton VA, told the *Times* that "research violations were a way of life" at this facility, and that "officials turned a blind eye to unethical cancer research practices and punished those who spoke out against them." Factors some suggest may have contributed to the breakdown of effective research oversight at Stratton and elsewhere are the recent rise in the number of drug trials being conducted (which may have overwhelmed institutional review boards and research directors) and the pressure to obtain large amounts of industry funding that research studies bring in.

But the VA's policy changes, training efforts, and investigations over the past few years seem to be making a difference. "There's been a lot of education and culture change in the VA," NCQA Spokesperson Brian Shilling told the *Times*. At this point, approximately one third of the VA's 118 research centers have been accredited under the new process.

NIH Reforms Ethics Policy

On February 3, the National Institutes of Health (NIH) implemented a set of new ethics rules, which focus on regulating employees' outside activities, financial holdings, and awards. This reform is the result of a year of evaluations, reviews, and Congressional hearings, spurred by allegations that several NIH employees had conflicts of interest, such as involvement in consulting relationships with

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pharmaceutical and biotechnology companies.

The new rules, developed by the HHS and approved by the Office of Government Ethics, prohibit all NIH employees from engaging in outside employment with: organizations that are "substantially affected" by the NIH (including pharmaceutical and biotechnology companies); supported research institutions (such as NIH grant recipients); heath care providers and insurers; and related trade, professional, or similar associations. In addition, NIH employees who are required to file public and confidential financial disclosure reports cannot invest in "substantially affected" organizations. For all other employees, such investments are subject to restrictions. Scientists can continue practicing medicine and pursuing such academic endeavors as teaching courses at universities, writing textbooks, performing scientific journal reviews, and participating in scientific meetings and lectures—as long as the activities are otherwise in accordance with the new regulations.

Over the next year, the HHS will evaluate certain provisions in the rule, consider public comments (which will be accepted until April 4), complete a review of employees' current outside activities, and develop and test more effective oversight systems. "I am confident that these new rules will preserve the historic role of NIH as the primary source of unbiased scientific health information for the country," asserts NIH Director Elias A. Zerhouni, MD. ●