



Case Summary: Kornak, Paul H.

- [Findings of Research Misconduct and Administrative Actions](#)

2008 and Older

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Debarment

ACTION: Notice.

SUMMARY: Notice is hereby given that the Deputy Assistant Secretary for the Office of Acquisition Management and Policy of the Department of Health and Human Services (HHS) has taken final agency action in the following case:

Paul H. Kornak, Stratton VA Medical Center, Albany, New York: Upon recommendations from the Office of Research Integrity (ORI), Acting Assistant Secretary for Health for the Department of Health and Human Services (HHS), the Office of Research Oversight (ORO), and the Under Secretary for Health, Department of Veterans Affairs (VA), that were based on the criminal convictions of making and using a materially false statement, in violation of 18 U.S.C. 1001(a)(3); mail fraud, in violation of 18 U.S.C. 1341 and 1346; and criminally negligent homicide, in violation of 18 U.S.C. 13 and New York Penal Law Sec. 125.10, the HHS debarment official has permanently debarred Mr. Paul Kornak, former research coordinator at the Stratton VA Medical Center. This action is taken pursuant to the HHS government-wide nonprocurement debarment and suspension regulation at 45 CFR part 76. As such, Mr. Kornak is excluded for life from participating in any and all Federal agency transactions, both procurement and nonprocurement, as set forth in part 76.

Of the 48 criminal charges contained in his Indictment, Paul Kornak pled guilty to the three criminal charges listed above. See United States of America v. Paul H. Kornak, Criminal Action No. 03-CR-436 (FJS), U.S. District Court (N.D.N.Y.) (January 18, 2005). In addition to the 71-month term of imprisonment imposed, Mr. Kornak was directed to pay restitution to two pharmaceutical companies and the VA in the amount of approximately \$639,000.

As part of his guilty plea, Mr. Kornak admitted to the following facts:

In August 2000, Mr. Kornak applied for employment to the VA, submitting a false "Declaration for Federal Employment" form. Mr. Kornak denied that he had been convicted or on probation in the preceding 10 years, whereas in fact, he had been convicted of mail fraud in 1992 and placed on probation for 3 years.

By October of 2000, Mr. Kornak was responsible for organizing, coordinating, implementing, and directing all research elements in the Stratton VA Medical Center oncology research program. Specifically, Mr. Kornak was the site coordinator at the Stratton VA Medical Center for the "Iron (Fe) and Atherosclerosis Study" (FeAST), cancer studies known as Tax 325 and Tax 327, and a bladder cancer study. The FeAST study was a clinical trial that tested a novel procedure for controlling atherosclerosis, also known as hardening of the arteries, by reducing the iron in the body through blood drawing. The Tax 325 cancer treatment study involved the administration of pharmaceutical products to patients with metastatic or locally recurrent gastric cancer previously untreated with chemotherapy for advanced disease. The Tax 327 study involved the administration of pharmaceutical products to patients with metastatic hormone refractory prostate cancer. The purpose of the bladder cancer study, which was co-sponsored by the National Cancer Institute, National Institutes of Health, was to compare the use of difluoromethylornithine (DFMO) to the use of a placebo in patients with low grade superficial bladder cancer according to time to first recurrence of the tumor and toxicities.

From May 14, 1999, to July 10, 2002, in connection with the above protocols, Mr. Kornak participated in a scheme to defraud the sponsors of the clinical studies in that "he would and repeatedly did submit false documentation regarding patients and study subjects and enroll and cause to be enrolled persons as study subjects who did not qualify under the particular study protocol."

Mr. Kornak caused the death of a study subject when he "failed to perceive a substantial and unjustifiable risk that death would occur when he knowingly and willfully made and used documents falsely stating and representing the results of [the study subject's] blood chemistry analysis, which false documents purported that [the study subject] met the inclusion and exclusion criteria for participation in Tax 325 when the actual results did not meet the inclusion and exclusion criteria and showed impaired kidney and liver function, and [the study subject] thus was administered the chemotherapeutic drugs docetaxel, cisplatin, and 5-FU in connection with Tax 325 on or about May 31, 2001, and died as a result thereof on or about June 11, 2001."

Based on the criminal conviction and the facts admitted to above, HHS and VA believe that a debarment period longer than the standard length of debarment is warranted in this case. Mr. Kornak admitted to a dishonest handling of the research records and demonstrated a complete disregard for the well-being of vulnerable human subjects under his care. In pleading guilty to criminally negligent homicide, Mr. Kornak admitted that a reasonable person would have perceived a substantial and unjustifiable risk of death if an ineligible subject were enrolled in the cancer study in question and that his failure to perceive such a risk in enrolling the ineligible subject constituted a gross deviation from the standard of care.

Moreover, a longer debarment period is warranted in this case because of an established pattern of misconduct and criminal behavior on the part of Mr. Kornak. As stated above, Mr. Kornak has a prior conviction of mail fraud. In addition, the Office of Personnel Management excluded Mr. Kornak from all Federal nonprocurement transactions for an indefinite period, effective July 22, 1993. Nonetheless, beginning in 1999, Mr. Kornak actively participated in federally sponsored research protocols in violation of the imposed exclusion.

A lifetime debarment of Mr. Kornak is necessary to protect the public interest overall. Given the scope of his criminal conviction, his longstanding pattern of criminal behavior, and his total disregard for the safety and well-being of human subjects, Mr. Kornak's responsibility to engage in transactions with the Federal Government cannot be assured at any time in the future.