

## **Jurisprudence Section – 2006**

## E14 The VA Research Murders – The Dr. Paul Kornak Story

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The goal of this presentation is to assist the attendee in learning how patients in a hospital were selected for pharmaceutical research studies in spite of failing to meet strict medical inclusion/exclusion criteria. These patients were incorrectly administered investigational drugs, and expired as a result of that action. Determining cause of death and the steps involved in the successful investigation and prosecution will be shown.

This presentation will detail the first homicide conviction directly resulting from pharmaceutical research. It will open the eyes of the forensic community to criminal acts associated with pharmaceutical research, how patients can be victimized by unscrupulous physicians, what are the red flags that indicate patients can be in danger, and how to suc- cessfully investigate and prosecute allegations of this nature.

This presentation will focus on a step-by-step review of the medical research process beginning with the sources of funding, common con-tractual requirements, government oversight, informed patient consent, and the importance of adhering to medical inclusion/exclusion criteria.

A detailed discussion will then concentrate on how and why the VA hired a medical researcher in spite of his federal conviction for mail fraud, and having lost his license to practice medicine. This researcher had practiced medicine throughout the United States based on forged and fraudulent medical school transcripts. The role of the pharmaceutical companies in marketing and promoting medical research will be explored. What are the pharmaceutical research requirements, how are they audited, and what happens when researchers fail to meet them will be explained. The speaker will discuss which patient documents were altered, why they were selected for alteration, and what impact these alterations had on the case. A dis-cussion of the criminal charges filed including criminally negligent homicide; the role of the forensic medical examiner in determining cause of death in this case; and finally the details of the conviction and sentenced imposed will be addressed. This may be the first research fraud resulting in a homicide conviction in the United States.

Medical Research, Criminally Negligent Homicide, Informed Consent