The Bureau of Narcotics and Dangerous Drugs (now the Drug Enforcement Administration) proposed that propoxyphene products be placed in Schedule IV of the Controlled Substances Act in 1973. This proposal was thoroughly reviewed by the FDA Controlled Substances Advisory Committee in 1974, and the Committee did not concur in the Schedule IV recommendation of DEA at that time.

In 1975 Dr. McBay, North Carolina state toxicologist, reported an increasing incidence of deaths, primarily suicides, attributable to propoxyphene alone or in combination with other drugs (Tab A). Following Dr. McBay's report in the Journal of the American Medical Association, Dr. Ivan F. Bennett, of Lilly, met with Dr. McBay and Dr. Page Hudson, chief medical examiner of North Carolina. Dr. Bennett was provided complete access to the information on propoxyphene cases in the files of the state medical examiner's office. Dr. McBay's observations were unique in that they were based on a systematic analysis of specimens on all drug deaths from all the coroners' offices in the state.

Following Dr. McBay's report, and in consultation with the Food and Drug Administration, Lilly requested Dr. Bryan Finkle to undertake an evaluation of medical examiner case records at various sites throughout the country. Medical