

16916 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

examiner files of deaths involving propoxyphene alone and propoxyphene in combination with other substances were reviewed at eighteen selected sites representing both urban and rural areas. Examiners were selected because of their high level of technical competence and the quality of their record systems.

Analyses of 1,022 medical examiner cases involving propoxyphene alone and in combination with other drugs were shared with FDA and DEA. In cooperation with the FDA, Lilly revised the labeling of its Darvon products in 1976. Lilly notified the medical profession through distribution of revised labeling, a special brochure presented to approximately 114,000 physicians, and publication of the results of Dr. Finkle's study in the Journal of the American Medical Association.

Complete information on Dr. Finkle's study was provided the FDA Controlled Substances Advisory Committee in April of 1976. After a full and careful evaluation of information relevant to the incidence of deaths, dependence liability, and abuse potential of propoxyphene, the Controlled Substances Advisory Committee concurred in the recommendation of DEA to place propoxyphene in Schedule IV.