Mr. Chairman and Members of the Committee:

I appreciate the opportunity to discuss the activities of the Food and Drug Administration (FDA) with respect to propoxyphene.

Although previous actions by both FDA and the Drug Enforcement Administration (DEA) have had an important impact on the labeling and use of these drugs, the abuse and misuse of propoxyphene is nonetheless a genuine problem.

USE PATTERNS OF PROPOXYPHENE

Darvon (propoxyphene hydrochloride) and combinations with aspirin, phenacetin, and caffeine (Darvon Compound, Darvon Compound-65) were first marketed in 1957 by the Eli Lilly Company after approval on the basis of safety alone. After passage of the Drug Amendments of 1962, a panel of experts established by the National Academy of Sciences-National Research Council (NAS-NRC) reviewed propoxyphene products and concluded they were effective for the relief of pain. This group of drugs was then approved for effectiveness by FDA in 1969. New propoxyphene products containing the napsylate salt of propoxyphene rather than the hydrochloride, either alone (Darvon-N) or in combination with acetaminophen (Darvocet-N) or aspirin (Darvon-N with ASA), were approved and marketed in 1972.

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