Dr. Bryan Finkle, of the University of Utah. Dr. Finkle reviewed medical examiner reports and files in 18 geographic areas in the United States and Canada which represented a total population of over 50 million persons. He concluded that most of the deaths associated with propoxyphene involved use of the drug at doses far in excess of therapeutic amounts and in combination with alcohol and other drugs, especially tranquilizers and other central nervous system depressants. A majority of the persons had a history of suicidal tendencies, emotional instability, or drug or alcohol abuse.

In April 1976, Lilly published the results of Dr. Finkle's study in a letter to the editor of the Journal of the American Medical Association. In cooperation with the Food and Drug Administration, the company revised the labeling for its Darvon products to reflect the new findings. A brochure containing the new labeling and Lilly's letter to the editor of JAMA was personally delivered to 114,000 physicians by Lilly pharmaceutical representatives, and copies were mailed to other physicians.

In February 1977, acting on the recommendation of the Department of Health, Education, and Welfare, the Drug Enforcement Administration issued an order placing propoxyphene products in schedule IV. In the petition submitted to the Attorney General, Dr. Wolfe asserted that the Drug Enforcement Administration's action had no effect and that the number of propoxyphene-related deaths had actually increased since the drug was placed in schedule IV. His petition characterized the DAWN figures for 1977 as representing a "crescendo of abuse." However, in his testimony to this subcommittee last week, Dr. Wolfe did not repeat this allegation—and for good reason—because the increase to which his petition referred did not, in fact, occur.

Mr. Durrin, the DEA witness who also appeared last week, testified that the deaths in 1977 appeared to be at a constant level and that the reports from emergency rooms participating in the DAWN system showed a statistically significant decrease in propoxyphene abuse. Lilly's own analysis of reports from medical examiners in the DAWN system indicates that the number of propoxyphene-related deaths has been decreasing since the first quarter of 1977.

Lilly recognizes that the DAWN system has limitations—some of which have been pointed out by other witnesses in these hearings. But the decrease in propoxyphene abuse which the DAWN reports show is consistent with information from other sources. Drs. Hudson and McBay, for example, have reported that propoxyphene-related fatalities have decreased in North Carolina. A partial update of Dr. Finkle's 1975 18-site study, carried out over the past 2 months, also indicates that the number of propoxyphene-related deaths has been diminished.

Now, the reason for this downward trend in medical examiner and emergency room reports that mention propoxyphene is not yet clear. One may reason, however, that the DEA's action placing propoxyphene products in schedule IV, and the attendant publicity, played a role. Increased physician awareness of the information from medical examiners' offices—including that which was based on the Lilly-sponsored study—probably also contributed to the decline. In his testimony on Wednesday, Dr. Lewman stated his belief that the re-