

placing propoxyphene products in Schedule IV. In the petition which he 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 increase since the drug was placed in Schedule IV. His petition characterized the DAWN figures for 1977 as representing a "crescendo of abuse." But, in his testimony to this Subcommittee, Dr. Wolfe did not repeat this allegation—and for good reason, because the increase to which his petition referred has not, in fact, occurred.

Mr. Durrin, the DEA witness who appeared on Wednesday, 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, and a partial update of Dr. Finkle's 1975, 18-site study, carried out over the past two months, indicates that the number of propoxyphene-related deaths has been decreasing.

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 recent decline in propoxyphene-related deaths in Oregon was due to educational efforts.

Lilly has examined the results of Dr. Finkle's study and the data from DAWN in an effort to determine the reasons for propoxyphene abuse. This examination indicates, contrary to the assertions that have been made in these hearings, that propoxyphene-related deaths seldom result from accidents, abuse for psychic effects, "experimentation," or similar misuse. Instead, they are the consequences, in the great majority of cases, of deliberate, suicidal motivations. There is widespread agreement that suicides are under-reported. The DAWN medical examiner reports officially classify about 42 percent of propoxyphene-related deaths as suicides. Several factors indicate that these reports substantially understate the actual incidence of suicides. For example, on a city-by-city basis, the incidence of *all* propoxyphene-related deaths (whether officially attributed to suicide, accident, or other causes) is significantly correlated with *overall* suicide rates in those cities.

An evaluation of laboratory data from DAWN reports shows that, in a large proportion of cases not officially described as suicides, blood or tissues concentrations of propoxyphene were detected that represent a quantity of drugs that could not reasonably have been ingested by accident. Dr. Finkle's study shows that the great majority of propoxyphene-related deaths involve persons with a history of alcoholism, emotional problems, psychiatric treatment, or a record of self-destructive behavior. Dr. Hudson's conclusion, reported to the Subcommittee on Wednesday, is consistent with this information. He believes that as many as 80 percent of the propoxyphene-related deaths in North Carolina are suicides. In short, the facts do not support the contention that a significant number of propoxyphene-related deaths are accidents.

Nor do the facts support the contention that the deaths result from the accumulation of the metabolic product norpropoxyphene in patients who take normal doses of propoxyphene over a period of time. Lilly has conducted extensive studies of the manner in which the body metabolizes propoxyphene and the effects that the drug's metabolic by-products can have. Those studies are summarized in detail in a memorandum we have submitted to the Chairman of this Committee.

The nor-propoxyphene metabolite has little of the central nervous system depressant action of propoxyphene, one twentieth to one fortieth, depending on the assay method used, and there is no reason to believe that nor-propoxyphene significantly increases any additive central nervous system depressant effects of alcohol or other drugs.