While schedule II prescriptions are not refillable, an average propoxyphene prescription is roughly 40 dosage units, and the experts tell us it takes approximately 20 dosage units to cause death, probably less in combination with alcohol or with other drugs. So that even though we feel based upon our experience, there would definitely be a lessening in terms of the number of units of propoxyphene dispensed in the United States, toxicity would still continue to be a serious problem with this drug, even though it were on schedule II. The main impact and thrust of schedule II, is to prevent diversion of drugs that are in high demand by abusers, and with this particular product, the problem is the patients who obtain the drug legitimately and end up having problems with it, either intentionally or unintentionally.

If the Food and Drug Administration and HEW determine that removal from the market is not appropriate, it seems to us that there are additional options within FDA's purview over drug usage which directly address the toxicity problem.

These include:

A labeling change, perhaps a boxed warning, which would strengthen the warning to physicians of the toxicity problem and of the use of the drug in suicides.

A curtailment of the indications for use which would limit the drug's use to those conditions where it is clearly superior to other less toxic substances.

Discouragement of use, again through a labeling change, for the chronic, long term conditions which would necessitate that the patient continually have sizable quantities of the drug on hand.

Finally, a patient package insert which would warn the patient of the drug's dangers.

Only the Food and Drug Administration can pass upon the viability of these suggestions. Certainly, a review of propoxyphene's potency, efficacy, and risk-benefit ratio by FDA's medical experts is in order in light of the questions raised in the petition by Dr. Wolfe and the Public Citizen Health Research Group.

In support of this, the Drug Enforcement Administration will provide appropriate data to the FDA.

Mr. Chairman, whatever the mechanism, it is imperative that every effort be made to substantially reduce the number of propoxyphene-related deaths. The Drug Enforcement Administration will work to this end.

Senator NELSON. Any questions?

Senator LEVIN. You indicated you would support a move in Congress to consider the movement to schedule II?

Mr. DURRIN. Yes, sir.

Senator LEVIN. Have you recommended such a bill be introduced?

Mr. DURRIN. No; we have not, sir.

Senator LEVIN. Why is that?

Mr. DURRIN. Well, basically, it is an extraordinary procedure that would not normally be part of our process in terms of a drug.

The type of problem with this drug is not essentially a drug abuse problem in the usual sense.

It is a toxicology problem, and normally, that is addressed by HEW.

We have certainly monitored the deaths, and we of course furnished Dr. Wolfe information on deaths, in connection with his petitions, but that is not primarily a DEA area of responsibility.