Mr. Miller. Could I elaborate on this?

We still have to wade through a great deal of difficulty in determining what constitutes a high potential for abuse, and what constitutes a severe dependence liability.

We know that Darvon is killing people, it is unsafe, insofar as

some users are concerned.

Whether that constitutes high potential for abuse, we still have to receive evidence on this.

We have our people on the streets trying to determine whether it really has a high abuse potential, or whether it is something lower, which would disqualify it from going into schedule II.

Senator Levin. Is that something defined by the law or in the

regulations?

Mr. Miller. We are held to this by the law.

We have the criteria in order to put it into schedule II, it must have a high potential for abuse.

Senator Levin. Is the definition of high potential for abuse in the

regulation?

Mr. MILLER. There is no definition. We work it on a case-by-case basis, depending on the drug.

We have never been able to come up with satisfactory regulations

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We rely to a great extent on the legislative history, but basically, it comes down to the evidence itself, the extent the drug is used, and the witnesses themselves that appear at the administrative hearings.

Mr. Durrin. I might add that for all of the drugs placed on schedule II, we have developed clear and convincing evidence of the high

potential for abuse, and the severe dependence liability.

Mr. Sturges. Mr. Durrin, on page 5, you gave the number of propoxyphene-related deaths, reported by the consistently reporting of medical examiner panel, as 429 for 1976 and 528 for 1977, and you say these numbers come from a DAWN system computer tape. Yet these numbers are lower than the most recent quarterly report numbers: The quarterly report for April-June 1978, which is hot off the press, shows 480 deaths for 1976 and 599 for 1977.

What is the difference between the tape and the quarterly report?

Mr. Durrin. Mr. Sturges, for the purpose of trending data, we go to our consistent panel of reports, which is 103, out of a total of 111 medical examiners in the systems from January 1975 through November 1978.

The reason for this is that we have had people drop in and out of the system, and, of course, this would skew the figures if we were to

use that data for the purpose of trending the deaths.

What we have used in 1975, 1976, and 1977 is the consistently reported data, which of course is less than the total number of DAWN deaths. The higher figures are correct and accurate figures in terms of total number of deaths reported, but they are not comparable from year to year, because they would skew the data.

Mr. Sturges. Well, I thought these were the total consistent DAWN system numbers, but you are saying the latest quarterly report includes

more than that?

Mr. Durrin. They include the consistently reporting medical examiners, but they include several other medical examiners as well.