In addition, HEW's recommendation is required as part of the scheduling process.

At this point in time, Mr. Chairman, I do not want to prejudice data yet to come in, but it is our preliminary conclusion, that it is questionable whether the data we are gathering will support the criteria required by law for the placement of propoxyphene in schedule II; that is, a high level of abuse as contrasted with other drugs, and a severe dependence liability. Even though propoxyphene is the leading cause of deaths among legitimate drugs, it does not, according to our preliminary information, reflect such a high level of abuse or a severe dependence of liability.

However, even though this is likely to be the case, the very significant toxicity problem cannot be ignored.

If Congress wishes to move Darvon to schedule II an amendment to the Controlled Substances Act, which of course would not require meeting the legal criteria, would probably be necessary.

If Congress decides to explore this, they will be supported by the DEA.

Now, schedule II would have an impact on the quantity of propoxyphene dispensed and hence there would be less available to cause the toxicity problems.

There would be no refills.

Senator NELSON. Your responsibility is not to make a judgment as to whether it is an effective drug for the purpose it is used, or whether it has any significant medical therapeutic effect on the function?

Mr. DURRIN. That is correct.

Senator NELSON. So the testimony of Dr. Moertel, and all of the others, in particular about the studies done to show it is less effective than ordinary over-the-counter drugs, over-the-counter drugs having fewer side effects, is not a factor that you take into consideration?

Mr. DURRIN. That is correct. We defer to the FDA, HEW for the medical and scientific judgment.

Incidentally, on that score, as I indicated in connection with our response to go to the petitions, we have been canvassing State officials for information on propoxyphene in their States, and I had a response from one State where the official indicated that the problem, one of the major problems in regard to propoxyphene was because medicare patients cannot receive a payment for aspirin, which would be the drug of choice in many instances, so they are getting prescriptions for propoxyphene, with whatever toxicity problems that may result because propoxyphene is reimbursable under medicaid in that State and aspirin is not. I think that is a sorry commentary.

Schedule II, as I said, would have an impact on the quantity of propoxyphene dispensed, and no refills would significantly cut down on the dispersing of propoxyphene. There is also the psychological impact of schedule II as seen with substances we have placed there. Many prescribers prefer to write for a lesser scheduled drug, and, of course, there is also the practical factor that prescriptions must be in writing and no telephone prescriptions would be allowed. However, even though there would be a lessening in terms of the prescribing of the product; the majority of the propoxyphene mentions center around legitimate prescriptions as already mentioned here this morning by others.