Senator NELSON. The prescription would include how many tablets?

Dr. LEWMAN. It is not limited to my knowledge.

Senator NELSON. So then you are saying the doctor may give a prescription which may be renewed five times, with the doctor deciding how many tablets would be included in each prescription?

Dr. LEWMAN. That is right, and have no knowledge of when or if it is refilled. We have 30 to 34 million prescriptions a year for this drug that can potentially be refilled up to five times.

That I submit has a potential for a lot of abuse. Why do I think most of these deaths are accidental?

First, I want to state I have not seen a case of anybody dying from this drug when it is taken as recommended. The real nitty-gritty of this problem, I think, is that these are accidental deaths, and this results from the breakdown product of the drug.

After propoxyphene is taken, it is broken by the liver, into a series of compounds, which we will refer to as metabolites, or breakdown products, and the most significant of these is nor-propoxyphene.

Nor-propoxyphene is significant because of its long half-life. It has about a 40-hour half-life. The parent drug, propoxyphene, has a life of about 8, 10, 12 hours. If a patient has taken several of these pills every 4 to 6 hours, the parent drug (propoxyphene) is being rapidly broken down. The nor-propoxyphene metabolite, however, is accumulating for almost 2 days and eventually can reach toxic or lethal levels.

The metabolite problem is not addressed in the package insert data and there is a minimum amount of information in the literature. I am certain that prescribing physicians and the patients taking it are unaware of the significance of this toxic metabolite.

I do not think the propoxyphene deaths, in fact, I am sure they are not unique to the State of Oregon.

I will echo Dr. McBay's and Dr. Hudson's comments about Valium deaths and codeine deaths.

I have seen a handful of codeine deaths. I have never seen an overdose of Valium alone in years of investigating drug deaths.

I am sure it could happen, but I have not seen one.

I feel the data is wrong in that respect but I think the most significant thing about the DAWN data is that it does not reflect the majority of the country.

We have to remember that death investigation systems, in most States in this country, remain in an abysmal state.

In many States of this country, you still have an elected coroner system, which means you have funeral directors, gas jockeys, police officers, district attorneys, and so forth, anyone that can get 50 percent of the votes plus one, running around investigating deaths.

These people are simply not trained, they do not have the investigative background, they do not have the technical apparatus to accurately diagnose and report these deaths.

It is a complex investigational problem, and much of the country is simply not yet adequate to the task.

All I can do is estimate. I think we probably have 3,000 to 4,000 propoxyphene deaths in the United States every year. I arrive at this figure by simple taking the statistics from the good sound death in-