As you can see from the chart, there are a large number of these products supplied to people over 60. Indeed, 33 percent of all the prescriptions written for Darvon and Darvon-containing products are written for the portion of our population over 60 years old.

Another third are written, you see there, that other high point is for another third or so of those prescriptions that are written for people in the age group 20 to 40.

Now, it is in the younger fraction of this age group that most of the deaths occur at a mean age of 25. Actually, that point represents the age intervals between 20 and 30 and there is another 22 percent or so of those deaths in that next point which represents the age range 30 to 40.

Now, you add those together so that you cover that 33⅓ percent of the prescriptions that are written for the entire age range 20 to 40 and you discover that over 52 percent of the deaths fall into that age group and yet, the people over 60 who account for an equal fraction of the prescriptions are only accounting for 8 percent of the deaths.

In other words, if I may be permitted a little liberty for the sake of description the young adults and people over 60 are equally likely to take a Darvon, but the people over 60 are only one-fifth as likely to do themselves damage as a consequence of that.

I would think that ultimately the public policy solution that we apply to this problem has to take account of the fact that the risks and benefits associated with the use of these products at least as we judge the risks (from the DAWN data) which are distributed very unevenly through our population.

Let me just summarize if I may, Mr. Chairman, the actions that FDA has taken over the past several years in response to problems associated with these issues regarding the efficacy and safety of propoxyphene products.

In 1972, because of misleading statements on the effectiveness of Darvon made to physicians in a letter from Eli Lilly & Co., we required the manufacturer to issue a "dear doctor" letter stating:

> There is no substantial evidence to demonstrate that 65 milligrams of Darvon is more effective than 650 milligrams of aspirin—two 5-grain tablets—and the preponderance of evidence indicates that it may be somewhat less effective.

In April 1976, FDA's Controlled Substances Advisory Committee recommended that propoxyphene and its salts and preparations be controlled in schedule IV of the CSA and as pointed out earlier, the DEA adopted that recommendation a year later.

Labeling for propoxyphene was further revised in 1978 to add a warning against the additive depressant effect of the products when used in conjunction with alcohol, tranquilizers, sedative hypnotics, and other central nervous system depressants, and to require additional information on adverse reactions, drug interactions, and management of overdosage. A warning against use of the products during pregnancy was also added because of the danger of causing addiction in the fetus and producing a neonatal withdrawal syndrome. That is a problem with any member of the narcotic family of drugs.

Now finally, I will just point out what you know very well that on November 22, 1978, the Secretary of the Department of Health, Education, and Welfare was petitioned by the Health Research Group to