

In fact, in one study, it caused more miscarriages than the placebo, so that the fact an individual doctor might prescribe the drug does not mean it works.

What the study showed is that a woman who had a miscarriage in a previous pregnancy and who got the drug might have had a miscarriage anyway, even if she had not gotten the drug.

That points out what you are saying; we need to have well-designed, well-controlled studies, whether it is on the effectiveness of DES to prevent miscarriages to see that when a drug is first marketed it is effective.

Once the effectiveness law was passed, Darvon was reviewed, and certainly there were some questions raised about its effectiveness, particularly studies which showed that the drug was more effective than a placebo, but less effective than aspirin. That, in and of itself, would be grounds for marketing it, on the question of effectiveness alone.

I think here we have a double problem, not only is it less effective, or no more effective than a number of other painkillers, it also is considerably more dangerous.

Since we have been discussing the comparisons between Darvon and other painkillers, I have a chart on table IV, which examines the total number of deaths as measured by the drug abuse warning network system.

[The information follows:]

Drug	Deaths, 1977 ¹	Deaths per million prescriptions ²
Darvon.....	590	19
Codeine.....	255	5
Aspirin ³	150	<1
Acetaminophen ³	77	<1

¹ DAWN Quarterly Report January-March 1978.

² 1977 prescriptions filled from National Prescription Audit, I.M.S.

³ 1977 retail sales of aspirin of \$500,000,000 and acetaminophen, \$150,000,000—assume average cost of \$1 for aspirin, \$1.50 for acetaminophen and use deaths per million bottles.

Dr. WOLFE. In 1977 for Darvon and codeine, if you divide the total deaths by the number of prescriptions for aspirin and acetaminophen, all we were able to obtain were marketing figures for aspirin, retail sales, so for these two, we were able to figure out how many deaths per bottle sold there were, one index of aspirin and acetaminophen toxicity. For Darvon, there were 590 deaths during that reported period as listed in the Drug Abuse Warning Network Quarterly Report, January of 1978, and the rate of deaths per million prescriptions was 19.

Codeine was 255 deaths, or 5 deaths per million prescriptions.

Aspirin was 150 deaths, less than one per 1 million bottles, and for acetaminophen, it was 77 deaths, or also less than one death per million bottles sold—the same as for aspirin.

I note in looking at the Justice Department's testimony, that they point out that barbiturates, at least several of them, have a higher rate of deaths per million prescriptions.

An earlier report they put out in 1976, at least looked at one barbiturate, and they looked at the death and in that case the death rate was lower than for propoxyphene. In today's testimony they show the death rate per million prescriptions of barbiturates such as