

The superiority of aspirin over Darvon was statistically significant, and by that I mean that the odds are 20 to 1 that this difference did not occur by chance alone.

These results were quite startling to us because at that time Darvon led the market in prescription drug sales.

It can reasonably be argued that although interesting, these results really are not a fair evaluation of Darvon.

Although Darvon is sold in pure form, it is usually marketed in combination with aspirin or APAP, or with APC as the so-called Darvon compound.

In our second study we, therefore, looked at aspirin alone compared to aspirin plus a variety of other drugs that are commonly marketed in aspirin containing drug combinations.

This study involved 100 patients in 1,000 separate drug evaluations.

In this chart, table 2, you can see that again aspirin showed a significant advantage over placebo. The addition of a full dose of Darvon to aspirin, however, provided essentially no improvement in pain relief. You can also see that within this same study it was demonstrated that two prescription drugs did provide better relief than aspirin alone, and these are the combinations of either Talwin—pentazocine—or codeine with aspirin.

Senator NELSON. These are drugs containing aspirin?

Dr. MOERTEL. This is a combination of Talwin plus aspirin, or a combination of codeine plus aspirin, and also a combination of Darvon plus aspirin.

Senator MORGAN. What is Talwin?

Dr. MOERTEL. Talwin is a trade name. It is a narcotic antagonist, which has been found to have some analgesic activity as well.

It was demonstrated that the standard and time-honored codeine-aspirin combination also showed a statistically significant advantage to the Darvon-aspirin combination, again the odds better than 20 to 1 that this difference did not occur by accident.

Based on our results we would have to conclude that if Darvon alone has any pain-relieving effect, this is trivial and simply does not match up to common, inexpensive over-the-counter drugs.

We must also conclude that the combination of Darvon with aspirin holds no advantage to aspirin alone, and if a patient requires a stronger analgesic the physician should prescribe some other more effective drug regimen.

These, however, are just the results from a single institution; and although we feel our studies were of sound design and conducted meticulously and analyzed without bias, it is possible that there could be some unrecognized distorting quirk in our methodology or that cancer pain is not representative of other types of pain.

We only really feel comfortable with clinical experimental results when they are confirmed by others.

Over the remainder of my testimony I would like to review all of the published medical literature of which I am aware that pertains to the clinical evaluation of Darvon as an analgesic agent.

Here I am only going to refer to the controlled, randomized, double-blind studies.