

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. These are the combinations of either Talwin (Pentazocine) or codeine with aspirin. The 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 doesn't 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'd 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'm only going to refer to the controlled, randomized, double-blind studies. When your endpoint of a study is as subjective as pain relief, these are the only kind of studies you can believe.

In all, we found 34 such studies involving various types of pain and these are listed in the bibliography which I have supplied. In Table 3 I've displayed the results of the 23 studies in which standard doses of Darvon alone were compared with placebo. You can see that none of the studies favored sugar pills. In four of the studies there was essentially no difference between Darvon and sugar pills. In seven the results favored Darvon but the difference was not statistically significant. Our first study is included in these. In 12 of the 20 studies Darvon was favored and the result were statistically significant. Based on these overall results it is reasonable to conclude that Darvon alone does have some analgesic activity although its not very striking. If, for example, aspirin alone had been tested in the 23 study populations of patients with relatively mild pain, it could be reasonably anticipated that aspirin would have been strongly favored in all 23.

In Table 4 I've displayed the results of 14 studies in which Darvon alone at standard doses was compared to common over the counter drugs—aspirin alone, acetaminophen or APAP alone, or APC. Among this group there were no studies favoring Darvon, in one study there was no difference, and in the remaining 13 of the 14 studies the over-the-counter drugs were favored over Darvon. In seven of these the differences were statistically significant.

In Table 5, I've shown the studies involving standard doses of Darvon in combination with aspirin, APAP, or APC compound. The results of these combinations are compared to the results of the over-the-counter drugs used alone without the addition of Darvon. Three studies favored Darvon combinations, three favored the over-the-counter drugs used alone, and 6 of the 12 studies showed no difference. It's of interest that there are two other studies of this kind that have not appeared in the medical literature although they have been highly publicized in lay media. It seems that some ad men at a proprietary pharmaceutical company must have been looking at the overall Darvon literature and decided they could make a real good sales pitch by showing their over-the-counter analgesic was just as good as Darvon compound. So they proceeded to contract out for two clinical research studies and that is exactly what the studies showed. Perhaps you remember the subsequent ads that appeared on the media displaying an Anacin tablet side by side with a Darvon compound capsule and accompanied by the advertising claim that Anacin had been shown in two medical studies to provide just as much relief as the high priced prescription item.

In Table 6 I've shown the results of ten studies in which combinations of Darvon plus over the counter drugs were compared to combinations of codeine or Talwin (pentazocine) plus over-the-counter drugs. Eight of the 10 comparisons favored either the codeine or the Talwin combinations.

In short, the results of our Mayo Clinic studies are entirely consistent with preponderance of the studies done by other investigators. It can be concluded that Darvon does have some pain relieving activity but this is very minor and