

Senator NELSON. No, what I meant was, what is a dose of propoxyphene—1 tablet of 65 milligrams?

Dr. FURMAN. Sixty-five of hydrochloride or 100 of napsylate.

Senator NELSON. So you are talking about in the case then of 20 billion tablets?

Dr. FURMAN. Or capsules, yes.

Senator NELSON. All right.

Dr. FURMAN. Propoxyphene is an effective pain reliever. Its efficacy has been demonstrated in controlled, double-blind clinical studies conducted in accordance with rigorous scientific standards. The Food and Drug Administration has repeatedly confirmed the efficacy of propoxyphene products, as has an expert panel of the National Academy of Sciences-National Research Council.

Several dozen companies have received new drug approval from the FDA to manufacture or market propoxyphene.

The efficacy of propoxyphene has also been demonstrated through its long history of successful use by medical practitioners in the relief of pain.

Mr. Chairman, I might point out that university-affiliated teaching hospitals generally have a formal pharmacy and therapeutics committee made up of faculty members who carefully review products for inclusion in their hospitals' formulary. These "P. & T." committees generally adopt only those drugs they consider appropriate for their institution's use. In a recent survey, we found that more than 90 percent of 466 university-affiliated teaching hospitals contacted have propoxyphene available in their formularies for their patient's use. We feel this is a good indicator of the acceptance of propoxyphene in such institutions.

Some studies have failed to demonstrate the efficacy of propoxyphene. Others have failed to show that it is any more effective as a pain reliever than aspirin. The same may be said, however, of other well-established pain-relief medications, including codeine.

Even Dr. Moertel's study mentioned in his testimony last week indicated that a 650-milligram dose of aspirin—two aspirin tablets—was superior to 65 milligrams of codeine; and in ranking analgesia according to patients' achieving more than 50 percent pain relief, propoxyphene 65 mg. was ahead of codeine 65 mg. (Moertel et al., *NEJM*, 286: 813, 1972, fig. 1).

It is often very difficult to demonstrate the efficacy of a pain reliever in a clinical study. This is so in part because the nature and cause of pain may vary and because the perception of pain involves an important, yet variable psychological component, the effects of which are difficult to measure or control in clinical studies.

For example, Beecher and his associates were unable to demonstrate the superiority of codeine, 60 milligrams, over placebo. (Beecher et al., *J. Pharm. Exp. Ther.*, 109: 393, 1953).

It is important to recall that studies using laboratory animals are not complicated by these psychological factors and that, in such studies, the pain-relieving properties of propoxyphene are consistently confirmed. In addition, many of the studies referred to earlier in these hearings compared propoxyphene with other pain relievers on the basis of a single dose. Our knowledge of the pharmacology of propoxyphene