

16594 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Although Dr. C.M. Gruber, one of Eli Lilly's medical spokesman, took exception to this conclusion,¹⁰⁰ his own published investigations have also shown that DPX is no more effective than placebo in single 65 mg doses.* 101

In 1977 Miller reviewed 13 double blind studies** of DPX's analgesic effectiveness, twelve of which had been published subsequent to his earlier review.¹⁰² Five of these thirteen studies purported to evaluate the relative efficacy of DPX hydrochloride and DPX napsylate, which was introduced in 1971 by the Lilly Company just before its patent on DPX hydrochloride expired. Miller's conclusion: "The introduction of the napsylate salt PRX [i.e. dextropropoxyphene] has not provided a more effective preparation, and the napsylate has no other clinically significant advantages over the hydrochloride."

Lacking proof of superior analgesic efficacy, the popularity of DPX Napsylate products (Darvon-N, Darvocet-N, Darvon-N with ASA, etc.) attests to the superior efficacy of the Lilly Company's promotional efforts.

The other eight studies reviewed by Miller once again failed to demonstrate that DPX had any analgesic advantage over the other less expensive medications. Indeed, as noted above, three of these studies suggested that DPX was no more effective than placebo.

Miller's review also discussed all the double-blind studies comparing DPX hydrochloride and DPX napsylate combination products with other analgesics. Considering the paucity of well-designed studies comparing combination drugs with single analgesics, the fact that most analgesic preparations prescribed are combinations is surprising. Miller found only one well-designed study comparing acetaminophen (the active ingredient in Tylenol, Datril, etc.), acetaminophen plus DPX (i.e. Darvocet), DPX alone, and placebo.¹⁰³

* Dr. Gruber's conclusion in his 1977 study (note 90) that DPX in multiple doses does provide significantly greater relief than placebo is suspect because he neglected to randomize the patients in his study.

** Including 2 of the 3 just discussed.