

16572 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

He went on to say that although some DPX overdose deaths were, in fact, attempted suicides, "accidental overdoses of DPX" was the category "into which most of the DPX overdoses in Oregon appear to fall." In other words, the margin between the doses which achieve the desired euphoria and those which are harmful or even fatal is extremely narrow.

Dr. Lewman did not believe that education of physicians was adequate and suggested, in the same letter to FDA, that DPX be moved into Schedule II. (On November 7, 1978, Oregon Public Health Officer, Dr. Edward Press, redirected this request to reschedule DPX in Schedule II in a petition to the Department of Justice, Drug Enforcement Administration.)

In summary, DPX is the deadliest prescription drug in the U.S., has been related to the deaths of thousands of people in the U.S. (and elsewhere) and is even outdoing morphine and heroin in 14 U.S. cities in its relationship to drug deaths.

In my view, there are two possible courses of action:

1. Invoke the Imminent Hazard Section of the Food, Drug and Cosmetic Act, 21 U.S.C. §355(e), and immediately suspend the New Drug Application (and marketing) of DPX. If you determine that there is no legitimate use for DPX as a pain-killer or that the risks of DPX outweigh any benefits even as a pain-killer, and that the drug should therefore be eventually removed from the market, the magnitude of DPX deaths during the 2-3 years that would transpire before the "slow" banning procedures mandate use of the imminent hazard provision. The evidence of DPX-caused deaths is more than sufficient to prove that this drug is "posing a significant threat of danger to public health."

In the British Medical Journal, an editorial on the "Dangers of Dextropropoxyphene"¹ queried, "How good is the case for using the drug at all?" After discussing the lack of "hard data on its therapeutic value...compared with other analgesics", the Journal goes on to say that "any doctor prescribing the drug rather than a simple, less expensive and potentially less toxic preparation should be aware of the hazards and able to justify his choice."

¹ British Medical Journal 1, p. 668, 1977.