

Other than narcotic detoxification, not yet an "approved" indication for use of the drug, its use as a pain-killer or analgesic is clearly an accepted medical use even though, as discussed above, it has led to widespread abuse and, as will be seen, is much less effective than generally believed.

We would agree with the statement in the January 3, 1970 Medical Letter that "65 mg dose of DPX has mild analgesic effect and can be tried in patients in whom the usual doses of analgesics such as aspirin or acetaminophen (as in Tylenol or Datril) are not effective or not tolerated."

We would add, however, that the number of such people is extremely small and were the use of DPX limited to this population, the number of prescriptions would be more like 300,000 per year than 30 million (1/100 as much use as now).

VII. Criterion 3 - Dependence (Addiction)

The last finding that must be made regarding DPX is that its abuse may lead to severe psychological or physical dependence.* 21 U.S.C. § 812(b)(2)(c). This disjunctive language of the Controlled Substances Act indicates that a finding of either severe psychological or physical dependence resulting from DPX abuse will justify its inclusion in Schedule II. There is substantial evidence that DPX can produce strong psychological dependence and, sometimes, significant physical dependence.

Clinical trials have shown that DPX can produce physical addiction, as manifested by withdrawal symptoms. Although this apparently does not occur at recommended doses for relief of pain,⁷⁴ patients undergoing narcotic withdrawal using DPX-Nap have become physically addicted to the latter.⁷⁵ In 1956, Fraser and Isbell

* As used herein, physical dependence refers to a condition of latent central nervous system hyperexcitability induced by frequent administration of a drug. Signs and symptoms of abstinence or withdrawal appear when drug administration suddenly ceases. (In the case of opiates, a withdrawal syndrome can be precipitated by administration of narcotic antagonists such as naloxone and nalorphine.) Psychological dependence on a drug can develop along with, or in the absence of, physical dependence. A salient characteristic of psychological dependence on a drug is the tendency for the latter to provide positive reinforcement for repetitive drug use by direct action on the central nervous system.