

16920 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

severe physical or psychological dependence required to place a drug in Schedule II. In fact, the HRG petition itself does not seriously contend that propoxyphene meets this requirement for inclusion in Schedule II. The petition states, for example (at page 17), that "case reports tend to substantiate the claim that the physical dependence produced by DPX is generally moderate; however, psychological dependence can be significant." Even taken at face value, this characterization of the dependence liability of propoxyphene would place the drug in Schedule III, which provides that abuse of the drug "may lead to moderate or low physical dependence or high psychological dependence."

HRG's statement, however, cannot be taken at face value. Extensive experience and clinical studies, which are described in detail in Tab J of the Blue Book, show that the incidence of physical and psychological dependence resulting from propoxyphene abuse is so low that it is not of significant medical concern.

Aside from the technical statutory criteria for including a drug in Schedule II, one must also consider the practical effects of doing so. The controls that apply to Schedule II drugs differ from those for drugs in lower schedules in two important respects: first, DEA is authorized to establish manufacturing quotas for Schedule II drugs, which it is not