

16712 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

phencyclidine and methaqualone. We will be looking for data of a similar nature in the study on propoxyphene now underway to determine whether it meets Schedule II criteria. In addition, HEW's recommendation is required as part of the scheduling process.

The majority of DAWN ER propoxyphene mentions center around legitimate prescriptions. While Schedule II prescriptions are not refillable, an average propoxyphene prescription is 40 dosage units and the experts tell us it takes approximately 20 dosage units to cause death--probably less in combination with alcohol or other drugs.

If HEW (FDA) determines that removal from the market is not appropriate, it seems to us that there are additional options within FDA's purview over drug usage which directly address the toxicity problem. These include:

- A labeling change, perhaps a boxed warning, which would strengthen the warning to physicians of the toxicity problem and of the use of the drug in suicides.
- A curtailment of the indications for use which would limit the drug's use to those conditions where it is clearly superior to other less toxic substances.