

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 16573

The one use, now under investigation, for which the benefits of DPX may outweigh its risks is in the treatment of narcotic addiction. Because DPX is a narcotic, it has been used to withdraw addicts from other narcotics, such as methadone, its close relative. Since there is in existence an Investigational New Drug (IND) approval for DPX, this use would not be altered by declaring it an imminent hazard and stopping its marketing as an analgesic.

2. Reschedule DPX in Schedule II. If you believe there is a legitimate use for DPX as a pain-killer--despite its relative ineffectiveness for this indication--it could be placed in Schedule II for those people for whom both aspirin and acetaminophen and other less dangerous analgesics were not effective or not tolerated. I do not know how large a group, if any, this might be but I would estimate that it is less than 1% of those currently using DPX. The enclosed petition to the Drug Enforcement Administration seeks this rescheduling under the Controlled Substances Act, 21 U.S.C. §811(a). This act requires that the Secretary of HEW submit an opinion to the Department of Justice concerning any proposed scheduling or rescheduling of drugs.

Although I favor the imminent hazard route and this letter constitutes our petition to ban DPX as an imminent hazard to the public health, you must decide how best to protect the American public from this deadly drug which--in addition--is wasting more than 140 million dollars a year of health care resources.

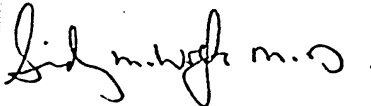
I look forward to a prompt reply.

Sincerely,

Sidney M. Wolfe, M.D.
Director Health Research Group

SMW:pm

Enclosure



NOTE: Legal and/or scientific research for the petition was contributed by Ellis Gordon, Michael Lipsett, an attorney now attending University of California, San Diego Medical School, and Deborah Schechter, staff associate of the Health Research Group. Staff researchers at the Department of Justice, Drug Enforcement Agency, were also helpful in providing data not otherwise available.