

Clearly, the issue perceived by the Board then was the relative efficacy of propoxyphene. Because it clouded this perception, the Department of Defense spent \$526,050 on preparations containing propoxyphene in fiscal year 1977, and \$359,690 in fiscal 1978, through central purchasing. Local purchases by individual services may have added to those figures.

Since the hearings 8 years ago, propoxyphene has been given a hard look by the experts who evaluate drugs for physicians and pharmacists. Here are three of these copyright evaluations:

1. A March 1972 monograph prepared for the formulary service of the American Society of Hospital Pharmacists declares:

A limited number of controlled studies indicate that 65 mg. of propoxyphene hydrochloride is no more effective than 30 to 45 mg. of codeine or 650 mg. of aspirin and may be inferior to these drugs.

In a discussion of side effects, the monograph advises:

Side effects following administration of the recommended dosage of propoxyphene include dizziness, headache, sedation, somnolence, paradoxical excitement and insomnia, skin rashes and gastrointestinal disturbances (including nausea, vomiting, abdominal pain, and constipation). Euphoria may occasionally occur.

2. In 1976, the U.S. Pharmacopeial Convention, Inc. published the National Formulary and the USP Guide to Select Drugs—a first-of-its-kind list whose “major importance to the practitioner and student is in highlighting those drugs that should receive attention and be used as preferred drugs.”

Drug selection was accomplished by the Subcommittee on Scope through a system of expert advisory panels. Scope is a subcommittee of the USP Committee of Revision, whose members are elected by the members of the U.S. Pharmacopeial Convention. The Subcommittee on Scope comprised 18 physicians, 1 dentist, 1 toxicologist and 8 pharmacists.

The explanation to the guide declares:

In summary, there are two reasons for using the drugs listed in this book: (1) They have been judged best from the standpoint of medical merit; and (2) their standards of pharmaceutical quality are generally publicly known and more readily assured.

Propoxyphene was not listed in the National Formulary and the USP 1976 Guide to Select Drugs.

3. In its chapter on mild analgesics, the American Medical Association Drug Evaluations (Third Edition, 1977), prepared by the AMA Department of Drugs in cooperation with the American Society for Clinical Pharmacology and Therapeutics, says of propoxyphene:

On the basis of several controlled studies using single-dose assays to determine analgesic efficacy, it is estimated that the milligram potency of propoxyphene hydrochloride is about one-half to two-thirds that of codeine; 65 mg. of propoxyphene hydrochloride is no more effective, and usually less so, than 650 mg. of aspirin.

In addition to the lack of significant effectiveness over placebo, recent data have shown that Darvon has greater abuse liability than was originally believed, and leads all other prescription drugs in the United States in drug-related deaths.

Accordingly, Public Citizen's Health Research Group has petitioned HEW Secretary Califano to remove this drug from the market