

earlier in the hearings, confirm that propoxyphene-related deaths are due to misuse and even such deaths are decreasing."

As Dr. Furman testified, company spokesmen called attention to a national survey, released last week, which showed that nine out of ten physicians said they regarded propoxyphene to be safe when used as recommended. The doctors also said they were aware of the dangers of the drug when used in excessive amounts and in combination with alcohol and other drugs.

"Like any drug, propoxyphene can be abused," Dr. Furman told the Senate subcommittee. "The vast majority of patients who receive Darvon use it properly. But there are some people who take Darvon in excessive doses and who take many drugs at one time—often along with alcohol. Frequently, their motives are suicidal. This kind of drug abuse is a medical and social problem that transcends the abuse of any one drug. If Darvon suddenly were to become unavailable, the problem would remain the same."

Dr. Furman stressed that "Lilly is deeply concerned about this problem of drug abuse. The company believes that further study and educational efforts are needed to understand the problem and to help correct it. The larger societal problem—of which propoxyphene abuse is only a part—remains, and Lilly is committed to work with the government and the medical profession in further efforts in resolving any questions regarding the safety and effectiveness of Darvon."

Senator NELSON. I raised this question with Commissioner Kennedy and I would ask you the same. As you noted from the testimony last week of Dr. Moertel, in his double-blind studies the conclusion he reached was that adding a full dose of propoxyphene to aspirin did not increase its effectiveness. I also raised this question with Mr. Kennedy.

Do you know of any well-controlled studies that meet the requirements of the 1962 act that would indicate that, in combination, propoxyphene added to aspirin is more effective than aspirin alone?

Dr. FURMAN. Well, one comes to mind right away, Mr. Chairman. It is a study by a physician, Dr. Bauer, in some 600 postoperative patients with wound or incisional pain. This study demonstrated that the combination of propoxyphene—I believe this was napsylate—with aspirin produced a greater analgesic effect than aspirin alone.

Senator NELSON. I was asking for references to any studies. Please submit that to us.

Dr. FURMAN. I will be glad to.

[Subsequent information was received and follows:]

ELI LILLY AND COMPANY,
Indianapolis, Ind., February 16, 1979.

HON. GAYLORD NELSON,
Chairman, Select Committee on Small Business,
U.S. Senate,
Washington, D.C.

DEAR SENATOR NELSON: I am pleased to respond to your request, made during the recent hearings you conducted on propoxyphene, that I submit the reference to the study by Bauer comparing aspirin with aspirin-propoxyphene combinations.

The reference is as follows:

Robert O. Bauer, Arthur Baptisti, Jr., and Charles M. Gruber, Jr., Evaluation of Propoxyphene Napsylate Compound in *post partum* Uterine Cramping, *J. Med.*, 5:317-318, 1974

Enclosed is a Xerox copy of the Bauer publication.

During the hearing Senator Levin also requested information on comparative studies. Enclosed are these references, listed under the following headings:

Clinical Studies Showing a Superiority of Propoxyphene Compound over APC.

Clinical Evaluation of Propoxyphene: Compared to Codeine.

Clinical Evaluation of Propoxyphene: Compared to Aspirin.

Clinical Studies Showing a Superiority of Propoxyphene with A.S.A. Over A.S.A.

Clinical Studies Showing a Superiority of Propoxyphene with Acetaminophen Over Acetaminophen.