the abuse of any one drug. If Darvon suddenly were to become unavailable, the problem would remain the same.

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. Available information indicates that the extent of propoxyphene abuse has, in fact, declined as physicians have become better informed about its abuse potential and since the drug was placed in schedule IV under the Controlled Substances Act in 1977. However, 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 to ameliorate the problem.

The facts do not, however, support the health research group's contention that propoxyphene products should be subjected to the more stringent controls of schedule II, much less that they should be banned as an imminent hazard to the public health.

Propoxyphene is an analgesic for the relief of mild to moderate pain. Physicians prescribe it, either alone or in combination with other analgesics, such as aspirin, for pain of the kind and severity that follows surgery and tooth extractions and that accompanies lower back injuries, cramps following childbirth, and many other medical conditions.

It must be kept in mind that before Darvon was developed there was perceived a need for it. Lilly developed propoxyphene as the result of a national program of research, instituted in 1948, to find a synthetic substitute for the opium-derived analgesics—such as codeine—that would offer the therapeutically desirable properties of those drugs without causing addiction of drug dependence.

After extensive study, including clear-cut demonstration of pain relief in laboratory animals, Lilly introduced Darvon in 1957. Since then, the company has continued to improve its propoxyphene products, study their effects, monitor their use, and disseminate information concerning them to physicians and pharmacists.

Over the past 21 years propoxyphene has been extensively studied. More than 865 scientific papers concerning the drug have been published.

Clinical research, as well as long experience in actual medical practice, has shown that propoxyphene products are safe when used as directed. Therapeutic doses of propoxyphene provide a wide margin of safety to the patient. Lilly has sold more than 20 billion doses of propoxyphene over the last 21 years, and the company does not know of a single instance in which the use of its propoxyphene products in accordance with their labeling has caused death or serious injury. Propoxyphene's dependence liability is less than that of codeine.

Senator NELSON. How is a dose of propoxyphene described? Is that one tablet, one prescription?

Dr. FURMAN. It means its use, either single or multiple doses, in accordance with proper medical use.

Senator NELSON. You say 20 billion doses in the last 21 years. How would you define that?

Dr. FURMAN. That would represent several millions of patients using it.