is reported to be widely abused by adolescents since propoxyphene preparations have been reformulated to eliminate the pellets in the propoxyphene in capsules. Abuse by intravenous injection seems to be on the decline. The possibility of convulsions increases as the dose is increased. Dependent persons require large doses to obtain the desired effect and this dose may be the lethal one for certain individuals. The margin of safety is narrow when doses exceeding 100 mg are used.

According to recent information released from the Drug Enforcement Agency, propoxyphene leads all other restricted prescription drugs in the United States in drug related deaths. Because propoxyphene is of so little value as an analgesic and becoming more widely abused and is not as safe as has been assumed, it is urged that the drug be controlled more strictly and placed in Schedule II or removed from the market. According to a report prepared by the Health Research Group (200P3 N.W., Washington, D.C.) during 1977 alone there were 589 propoxyphene related deaths reported to this group which collects data from areas covering only ⅓ of the population of this country. This number is greater than the number resulting from the use of heroin. Since the question of safety is now before us and since there is so much doubt about its efficacy as an analgesic, the following conclusions, suggestions and recommendations can be made concerning propoxyphene:

1. The drug could be under stricter controls and placed in Schedule II.
2. It is possible to maintain standards of good medical practice without propoxyphene; therefore, manufacture could be discontinued.
3. There is no medical justification for continuing its use as an analgesic because it has no therapeutic advantage over other drugs of similar potency that merit its being prescribed for relieving pain.

Senator NELSON. Next, we will hear from Dr. William T. Beaver, associate professor of pharmacology and anesthesia at Georgetown University.

It has been hard to hear Dr. Adriani from that microphone. Perhaps you can push it about 6 inches back.

## STATEMENT OF WILLIAM T. BEAVER, M.D.—Resumed

Dr. BEAVER. I will do the best I can, Senator. I appreciate being invited back to talk after the almost 10 years since I was here last.

During the last 15 years, I have had repeated occasion to review the literature on propoxyphene. In 1965, I wrote a review of the clinical pharmacology of the mild analgesics, which included a substantial section on propoxyphene. In 1966 and 1967, I served as a member of the Panel on Drugs for Relief of Pain, Drug Efficacy Study of the National Academy of Sciences-National Research Council and was the primary reviewer on propoxyphene and its combinations for the Panel. On November 24, 1970, I appeared before this subcommittee to discuss the relative merits of various mild analgesics in the relief of pain, and a portion of this testimony was devoted to a critique of propoxyphene, or Darvon.

From 1969 to 1976, I served as a consultant for the Food and Drug Administration, primarily on matters related to analgesic drugs and the design and interpretation of controlled clinical trials for drug efficacy. While serving as a consultant for the FDA, I prepared a special critique of the efficacy of propoxyphene based on my review of the published literature and the New Drug Applications for various propoxyphene products. This critique, submitted to Henry E. Simmons, M.D., Director, Bureau of Drugs, plus recommendations for revision of the propoxyphene labeling served as the basis for the re-