

Senator NELSON. Any other questions?

Senator WEICKER. I would like to point out one thing that might be helpful to describe the relationship between the pharmaceutical manufacturer and the medical profession itself. I am afraid it comes across, at least it did to me in these hearings, that the relationship under consideration is one between a very sophisticated institution such as the pharmaceutical manufacturer and the public as a whole, which might not be in the possession of the knowledge needed to evaluate the product. Yet, in fact, it seems to me that there is a pretty extensive filtering system or jury on the product itself, in terms of the medical profession which must prescribe the drug.

Now certainly there can be no lack of degree or sophistication attributed to that body of society. At the same time, what is the procedure for the use of a drug? Is there a considerable comment made by the physicians themselves—do they ask questions of the manufacturer?

Can you describe that process to us? It is entirely left out of the impression given at these hearings. The general question of safety and efficacy of a drug is an important one. But one must realize that the drug goes out into a marketplace that is comprised of very knowledgeable and sophisticated persons, that is, doctors, who are able to make the types of judgments on the product commensurate with their knowledge.

Can you comment on that?

Dr. FURMAN. In every piece of package literature and every advertisement and every communication where these products are mentioned, we—almost without exception—provide the product labeling which carries the recommended dosage, the indications, the contraindications, and information on treatment of overdose. These are continually reviewed. As I indicated, we are now in the process of strengthening the part of the package that deals with the management of overdose.

We bring this to the attention of the physician. Instances of overdose, fatal or not, and overdose information also appear in medical literature.

This literature is scanned by our in-house physicians. We have commercial survey companies that keep their eye on newspapers and other news media for any example of a misuse of propoxyphene.

We make every effort to followup each one and get information. As new evidence of pharmacologic action—good, bad, or indifferent—is received by our scientists and other research laboratories, it is evaluated and shared with the FDA, reported at open scientific meetings, and, when judged appropriate and necessary, is put in the package piece.

Reference was made in one of the hearing days last week that the Physicians' Desk Reference is distributed free of charge by the Pharmaceutical Manufacturers Association. That is not correct. It is distributed by the publisher. The information in the Physicians' Desk Reference is information on products that are approved by the FDA and is in full conformity with FDA requirements as to labeling.

We feel that there is a continual flow of information and resource material available to the physician for the adequate, proper, and safe use of these agents.