

Senator NELSON. Well, are you saying after the drug was taken off the market in 1952 and then went back on to the market that the package did not include a package insert to the pharmacist between that period and 1962?

Dr. HEWSON. That is correct. First, I do not believe the drug ever was actually taken off the market and then the warning that was required by the FDA, and this was a Parke, Davis defense, too, stated that the warning was not required in the oral preparation and so was never put in until it was required by the FDA in 1961. The inference I get was that the FDA did not have the power or the authority to require it to be in the oral preparation until 1961.

Senator NELSON. There must have been some form of package insert that described the use of the capsule in the package to the pharmacist; was there not?

Dr. HEWSON. My understanding is that no package insert was required in the oral preparations. At least the warning was not required in that type, if there was one.

Senator NELSON. That puzzles me a little bit. It would seem to me that some insert would have to be in there to explain what the drug was used for even if it did not contain a warning.

Dr. HEWSON. Of course, this is a prescription drug, Senator, and a physician has to prescribe the use for it. The pharmacist, of course, should be aware of correct dosage, but in general it is on the prescription as the physician writes it.

Senator NELSON. So now, there is a package insert required and the package insert contains the warning; does it not?

Dr. HEWSON. Since 1961. Also the boxes, the small individual packages, had a one-sentence warning on it even as far back as 1952.

Senator NELSON. Now, if the doctor is not dispensing it himself out of his own office, how does he get the warning as to the side effects of this drug?

Dr. HEWSON. Well, first, most physicians do not dispense oral preparations of the drug in the office and they do not use the injectable form. I believe Parke, Davis did send out letters to 200,000 physicians in 1952 about the FDA investigation. Another source of information can be the advertising. Also, it can come from detail men. It can be from the Physicians' Desk Reference, which is sort of a bible to the practicing physician, although it really contains the literature on a drug as the drug company itself presents that information. It is really an advertising mechanism essentially. The wording does not come from an objective source. It comes from the drug companies. Probably the best and most reliable source is the objective medical literature, case reports, et cetera.

Senator NELSON. So the doctor who prescribes the drug does not regularly see the warning on a package insert because he does not see the package?

Dr. HEWSON. That is correct.

Senator NELSON. So, his source of information is medical literature and/or the advertising by the company and the detailing by the detail man; is that correct?

Dr. HEWSON. Correct. Yes, sir.

Mr. GORDON. Dr. Hewson, do you know of any cases where Parke,