

Mr. GOODRICH. Yes, we do. And we find that some of it does not comply for many different reasons. We have had instances in which the company claimed that a paragraph was left out inadvertently. It is entirely possible that might have been so. There have been other instances in which the writeup was shortened unduly. There have been instances such as with the Merck Sharp & Dohme here this morning, in which a message that we thought was quite clear, that the drug did cause ulcers, is translated into a lesser language that ulcers have occurred. We find all types of this. The surveillance over prescription drug promotion is a full-time job for an active person—for several active persons who have a great interest in this problem.

Senator NELSON. Dr. Ley?

Dr. LEY. The material which will be presented in subsequent hearings will give the concrete example of a preclearance operation of a promotional ground for the detail man's use in the physician's office. I think this review will answer many of the questions that you are directing at us today as a concrete example.

Senator NELSON. We will leave the rest of the questions on the detail men until subsequent hearings.

Mr. GORDON. As I understand it, then, FDA really does not know what the detail man is saying about Indocin; am I correct?

Senator NELSON. Or any other drug.

Mr. GOODRICH. We know what his company tells him to say. Now, we do not know what he says when he goes to Dr. X's private office and talks with him about the drug. The only way we could know about it is if the doctor tells us. This is a delicate part of surveillance in which we have no mechanism of carrying it forth, except as the doctors tell us.

Mr. GORDON. I believe we have had testimony in the past that the oral presentation is probably the most important presentation of all to the doctor; that the doctor very seldom, if ever, reads the promotional material, printed material, that is left with him; that he relies to a large extent or mostly on the oral presentation.

Now, you will also recall that in the *Love v. Wolf* case, the court held that the activities of the detail men in the case of Chloromycetin washed out the warnings in the printed material. Do you recall that?

Mr. GOODRICH. Yes.

Mr. GORDON. Even if you had adequate staff, and you were to revise your regulations, would this be enough to protect the public?

Mr. GOODRICH. Well, I know that certainly the drug companies feel that detailing is an effective means of promotion. But I could not accept the idea that the tremendous amount of money and effort and the elaborate outlays of printed material have no impact on the prescriber. I think myself that an ad, such as the one you have before you, has a tremendous impact on the doctors prescribing.

Mr. GORDON. I do not say it would not be helpful in protecting the public. But would other measures be necessary. Would this alone be enough?

Mr. GOODRICH. I do not know what you are suggesting, Mr. Gordon. It certainly would be fine with us if doctors who considered the detailing they got was wrong would communicate with us, we would be much interested in that. We would be prepared to take action if we found violations. But that is the only mechanism we have for getting at that, beyond assuring everyone that all the printed material,