

Mr. GORDON. Is there any evidence that the physician bases his prescribing practices on the contents of the label?

Dr. EDWARDS. I think we have to remember that the Physicians' Desk Reference, which I believe is probably the most commonly used source of drug information by the practicing physician, is made up principally, or composed of, the labeling on various drugs. So, I think looking at it from that standpoint, I suspect that we could say that he does use the labeling.

How frequently the physician uses the package insert per se I do not know. I do not think we have any basis for a statement on that. Dr. Simmons points out, and it is an extremely important point, that the labeling does in fact indicate what may be in the advertising and promotional material for the drug. This is doubly important, not just for the physician per se, but also in terms of all promotional material for a particular drug.

Senator NELSON. I do not follow that. You are saying that they cannot promote the drug—make claims for the drug beyond what are authorized in the label?

Dr. EDWARDS. What is in the label, exactly.

Mr. GOODRICH. And they must make the same warnings and with the same emphasis and the same words in the promotion as in the package insert. So, the package insert sets the stage for all promotions and controls over promotion. That is, the journal advertising, the mail-outs, detailing, and so on.

Senator NELSON. Who uses the insert? The physician usually does not see it, does he?

Dr. EDWARDS. The physician or the pharmacist may or may not see it depending on what his own habits happen to be, but we hope the majority of physicians see it, particularly with more potent drugs.

Senator NELSON. Does the PDR print the whole package insert?

Mr. GOODRICH. In general, yes. They are not required to have some of the things in the insert, like animal studies and things of that kind, but the essential indications, contraindications, warnings, precautions, et cetera, all are required to be in the PDR exactly the same as in the labeling.

Senator NELSON. You say they are required to be in the PDR.

Mr. GOODRICH. If the drug is advertised in the PDR. There is no requirement that anything be put in the PDR but if the company desires to advertise by listing their drug in the PDR they must use the prescribed information.

Senator NELSON. It is required, then, that if a company places an ad in the PDR, that the ad must conform to the labeling FDA has approved for that particular drug. Is that correct?

Mr. GOODRICH. Yes.

Senator NELSON. And, therefore, if they are going to advertise, they have to include certain parts of the package inserts.

Mr. GOODRICH. Our position is that the PDR really serves the purpose of labeling on the physician's desk and, therefore, it must be in conformance with the labeling requirements. We do not allow in the PDR a brief summary that might be permissible in a prescription drug ad, but even in the prescription drug ads you are seeing