

Senator NELSON. Well, I certainly want to commend you for moving in that direction. I had thought maybe there was a legal question, and I had had the counsel draft a bill to accomplish the same purpose, which we introduced yesterday, but which your action will make unnecessary.

Is there any legal problem about the authority of the FDA to require a user package insert?

Mr. GOODRICH. Not if a finding is made as to the product here that is necessary for the safe use of the drug. The legal point being raised, I suppose, has to do with the ordinary rule that prescription drugs dispensed to the user do not themselves carry the warning of hazards, but that information is normally directed to the physician himself, and the law requires that the package dispensed contain such warnings as the prescriber requires in his prescription.

In this case, upon a finding that this kind of information cannot be safely left to word of mouth, that it must be communicated in a more orderly way, this is a safety factor that enters into the new drug decision and can be required, in my opinion.

Senator NELSON. We missed that aspect of the law. I had assumed that it would take some additional legislation, but I am pleased to hear that it does not.

Pardon me for interrupting, Doctor. I had another question I might as well ask right now, because it comes within the next sentence of your prepared statement.

In reading your sentence below, the one we just discussed, "Women whose history and present medical condition include thromboembolic disorders, impaired liver function," as you were reading it, you inserted a "family history of diabetes." This is not in my text.

Dr. EDWARDS. No, I inserted it.

Senator NELSON. So it would read "impaired liver function, family history of diabetes"?

Dr. EDWARDS. Strong family history of diabetes.

Senator NELSON. "Known or suspected cancer of the breast."

This is the question we discussed yesterday with Dr. Cutler, in which he would use, I guess, about the same language you would as to diabetes. We asked him this question, whether the package insert which I believe uses the language "known or suspected cancer of the breast," whether that was adequate. He feels, if I recollect his testimony correctly, that it ought to say about what you said, about diabetes, but that if, as he put it, a sister, mother, or an aunt had cancer of the breast, it should be a contraindication.

Would you agree with that?

Dr. EDWARDS. No, I would not. I would not be quite that forceful in my statement. I think certainly there is an area that we have to keep a very careful eye on, but at this point in time I do not think that our information, our data, would substantiate a statement of that magnitude.

Senator NELSON. So you would not be inclined to even use the words "family history," as you do with diabetes?

Dr. EDWARDS. Not at this point in time. Again, this is one of those areas I think we have to watch very, very carefully, and very shortly we might have to add that.