

Dr. McCLEERY. I am saying that in our view it is not, although the subject is discussed. I would like, if I can go on just for a moment, to point your attention to the way that the ad differs from the package insert in these respects.

We believe that these that follow exemplify what might be called the euphemistic style of revealing warning information. The ad's "brief summary" translated the package insert's warning "Indocin itself may cause peptic ulceration * * *" into the area of causal doubt in this manner: "Ulceration of the stomach, duodenum, or small intestine have been reported. * * *"

Senator NELSON. I do not see that in the ad. Is that the July 18 ad?

Dr. McCLEERY. Yes, under the "Precautions." "Ulceration of the stomach, duodenum, or small intestine have been reported."

Senator NELSON. Is this under the warning section in the package insert?

Dr. McCLEERY. It is under the contraindications section—but it is in the ad's precaution section. Under the contraindications section in the package insert is the statement that I read first, which is a plain statement which carries the idea that the company has agreed with the Bureau of Medicine to say "Indocin itself may cause peptic ulceration." We are saying that in no way is that statement in the package insert properly reported to the physician in the ad by the statement "Ulceration has been reported." This is a style of statement about side effects that is traditional in ads over the years. It only means that many side effects are reported to be associated with the use of a drug, which may be by chance, and to say merely that it has "been reported" in no way suggests that it is "caused by" the drug in question. On the other hand, the package insert is very clear.

Senator NELSON. Where does this precaution appear in the package insert?

Dr. McCLEERY. Under the contraindications section. It is a piece of information under the contraindications section.

Senator NELSON. It does not appear under the warning section?

Dr. McCLEERY. I cannot tell you whether it also appears in the warning section. But it does appear in the package insert in the contraindications section.

Senator NELSON. There is also a warning section in the package insert, isn't there?

Dr. McCLEERY. Yes.

Senator NELSON. Those warnings do not appear in the warning section of the package insert?

Dr. McCLEERY. I frankly cannot tell you. I do not know that well enough by heart.

Senator NELSON. I wish you to submit for the record the package insert that was being used by the company at that time. I would like to have that in the record at this stage of the testimony.

(The information to be furnished for the record follows:)