

Senator NELSON. Since you have inserted the package labeling, that includes the full range of contraindications. Are there several more in addition to these here?

Dr. McCLEERY. No, sir; there aren't several more. We mentioned one by name in our testimony, and that was that the drug is contraindicated in children. That is not mentioned. There is another inflammatory disease of the intestinal tract which is contained in the package labeling as a contraindication and is somewhat similar to the ones that you were naming, called regional enteritis. That is not on this list. That is the other contraindication.

Senator NELSON. Of course the children—it covers a vast number of people in any event.

Dr. McCLEERY. Yes, I mentioned it was contraindicated in children.

Senator NELSON. Then the next sentence said,

These are not unusual signs as you know, Doctor, even aspirin causes some gastric complaints.

Isn't the intent of this sentence to play down the warning of the previous sentence?

Dr. McCLEERY. I would think so.

Senator NELSON. In Bulletin 84, July 14, 1965, it states:

Indocin equals or surpasses the effectiveness of Butazolidin.

Is that correct?

Dr. McCLEERY. If I may, I would like to avoid trying to give a definitive answer to that. The evidence of comparative studies of these two products are unknown to me. I do not know if they exist to an extent that would permit someone to make meaningful comparative claims against another product.

Senator NELSON. Continuing to quote from Bulletin 84, July 14, 1965, and this is the excerpt from the statement: "In therapeutic doses has a safety index comparable to aspirin." Is that correct?

Dr. McCLEERY. I would have to say that in my understanding of what I feel are the views of people that I have read who work in this field, aspirin, as varied within the dosages used, is really safer. But you are asking me a question, Senator, that I am not really an expert in.

Mr. GORDON. Do you know of any studies which indicate—perhaps you have already answered this—that Indocin equals or surpasses the effectiveness of Butazolidin? On what do they base that statement?

Dr. McCLEERY. I don't know what they base the statement on, but I must say I am not an expert in the field of these drugs. There are studies I have read, but I am not prepared to make a statement that would be—I am perhaps more reluctant to do it than the statements we are reading were reluctant to make the claims. I know of none that prove this.

Senator NELSON. On page 2 of the bulletin it is stated:

Lightheadness and dizziness occur occasionally with Indocin as with almost any other medication. For the most part these effects are very mild and very transient.

One of the leading physicians who evaluated Indocin for Merck, Dr. Rothermich, wrote to Merck on June 12, 1963:

The greatest deterrent to increase in dosage to effective level is the appearance of cerebral toxicity. This manifests itself clinically in excruciatingly severe headaches, dizziness, lightheadedness, disturbance of sensorium, a feeling that