

in its October issue is to show the breadth of the November 1966 campaign containing the word "the" in place of "a," and you have copies of the October 26, I believe, issues of Modern Medicine, you also have copies of the November 1966 issues of the American Journal of Medicine, and Arthritis and Rheumatism magazine, all of which are the same. They are just prints of the same ad in different journals.

Senator NELSON. Did the package insert at any time include the same phrasing, "the drug of choice"?

Dr. McCLEERY. No, sir; it did not.

Senator NELSON. And the FDA did approve the package insert? So at the same time that the package insert is making a lesser claim, using different language, the company is running advertisements in the Journal of the American Medical Association and other medical magazines claiming that Indocin was the drug of choice in gout; is that correct?

Dr. McCLEERY. Correct.

Senator NELSON. So there was no question that the company knew what the viewpoint of FDA was as to the requirements for the package insert at the time they were running these ads in the medical journals.

Dr. McCLEERY. I should say not.

The so-called A ads that we have been discussing appears as identical advertisements in the Journal of the American Medical Association in many issues, but also in issues of July 4 and August 15. And these were found to be featuring under the major headline the theme that the drug "extends the margin of safety in the long-term management of arthritic disorders." At the same time—

Senator NELSON. Where are you, Doctor?

Dr. McCLEERY. The middle of page 3.

Senator NELSON. Please proceed.

Dr. McCLEERY. At the same time, the Office of Marketed Drugs, under Dr. Jennings, who appeared yesterday, was negotiating with Merck for changes in the package labeling to emphasize newly recognized hazards that had emerged during the first year of clinical experience since original approval of the drug.

The JAMA ads in July 4 and August 15, 1966, issues were analyzed and found to be defective, in our opinion, in several respects. I am going to mention only a few of them. I would not want you to believe we have exhausted our objections by what I point out today.

Senator NELSON. This is now in what edition of JAMA?

Dr. McCLEERY. The July 18 issue that you have in front of you.

Senator NELSON. That is the one you are going to discuss now?

Dr. McCLEERY. Yes, sir. I would like first to mention generally the major defects of the ad in our view, and then will be more specific regarding the details of our objections to certain of the features of this and of a later ad which appeared among others in the November 1966 issue of the American Journal of Medicine.

The basic theme of greater long-term safety in the ads was not supported by the clinical experience.

Mr. GORDON. You say "greater"?

Dr. McCLEERY. It is a kind of advertising technique which has a great deal of value because it says "greater" but does not specify greater than what, and goes in the advertising world under the delight-