Senator Nelson. There are several documents here as well as letters by Dr. Weinstein, Dr. Ley, Dr. McCleery, and others; and since they explain this situation in some detail, and specify the kinds of violations that the FDA believes do occur, and give examples of them, I would ask that they be printed in the record at the appropriate place.1

Dr. McCleery. I would like to turn now to the third element of the promotional campaign with which we had to deal, and that concerns the medical journal advertising to the medical profession by Merck

Sharp & Dohme.

We have already supplied for the record copies of two major kinds of ads 2 which have been used by the company, one characterized by a submission which you have in your hands dated July 18, and which is identical in content to the issues of the same ad in July 4 and August 15, 1966, issues of the Journal of the American Medical Association. There is a second ad, with some minor changes, which you also have a copy of, and bears a handwritten inscription called the "The" Ad, which was published in November 1966, and I want to make comments on both ads.

Mr. Gordon. Which ones are these?

Dr. McCleery. The first ad, you have a copy of the JAMA dated July 18, 1966. We happened to act in our memos on an issue dated July 4. All of these ads are identical. They are just prints of the same ad in different issues. The one you have at hand is marked with the hand inscription "A." The "A" ad is July 18, 1966. As I go along, we will deal with the features which are common to the second ad, marked November 1966, in the American Journal of Medicine.

Senator Nelson. Are you referring now to the AMA Journal?

Dr. McCleery. Right.

Senator Nelson. In looking at the ad, it shows a radiograph of a left foot and says, "Indomethacin is a drug of choice in acute gout." Is that correct?

Dr. McCleery. Are you reading correctly?

Senator Nelson. "Indocin is a drug of choice in acute gout." Dr. McCleery. I just wonder what your question is. Senator Nelson. Is it a drug of choice, do you know?

Dr. McCleery. One of the reasons we have submitted both this ad and the ad of November is because the author said "the drug of choice." You will note in the JAMA ad there is a bracket around the "a" which the company at this time inserted in place of the author's own statement that it was the drug of choice.

Senator Nelson. Who inserted the "a"? Dr. McCleery. The company and its advertising agency. We have assumed this was in a mood of good instinct and caution that the company changed the author's quote from the word "the" which is correct, and which is in the view of many a far less defensible statement concerning the value of the drug. The complexities of what the statement says with the word "a" in instead of "the" is the problem. In any event, in answer to your question, in my opinion, and in the opinion of many who are expert in this field which I am not, indomethacin is a good drug for the treatment of acute gout—it had not reached the level of "the drug of choice" for acute gout.

¹ See documents and letters beginning at p. 3246, infra.

² See supplemental information beginning at p. 3221, infra.