Senator NELSON. I was asked whether it was intentional. I can only repeat what the FDA said. This is a July 8 memorandum of the FDA. Here are three ads that ran in JAMA on June 29, 1964.

Dr. ANNIS. Senator, we do not deny that we have ads that you have indicated. In retrospect, I can think of a lot of things that have been wrong in the past.

Senator NELSON. Let me just read here. You raised the question of whether there was ever any intent. I shall just read what was said. These are on Pree MT. This is just one, June 8 and June 29, 1964. This is a July 8 memorandum, 1964.

To the Bureau of Regulatory Compliance, Joseph F. Sadusk, Jr., M.D., Medical Director—

Through him from Robert S. McCleery, M.D., section on advertising and promotional labeling—

1. We believe the faults—

What happened here was that they ran two ads, the first two. When they got to contraindications, they printed in the ad, "None known." Then when they got the complaint, they ran one on the 29th and they did not put contraindications in at all. They left it blank. So they had "None known," and there were contraindications, and they knew it. Then on the third ad, they did not put in the contraindications.

Dr. ANNIS. Were they prosecuted by the FDA?

Senator NELSON. Counsel advises me that the company was prosecuted and found guilty.

1. We believe the faults of the ad and the attached mail pieces are significant and that we can help you support any action you deem advisable. We are deeply concerned that the action chosen might also have as a consequence the immediate cessation of this type of promotion which can mislead the reader into using the drug in a manner that could jeopardize the safety of his patients.

2. An interesting and disturbing event has occurred since our interest in the Pree MT ads began on June 9. (See attached copies of June 8 and June 22 issues of Modern Medicine and June 8 and June 29 issues of J.A.M.A.)

Note that the heading "Contraindications" has disappeared from the June 22 and the June 29 ads.

The June 29 ad was in JAMA.

This kind of change is very easy to accomplish technically. It could have been handled by a telephone call from the company or the agency to the printer. In a few minutes the printer could knock off the offending type, without the need to produce new plates. The only difference is that the J.A.M.A. printer was not an expert. As a consequence, he also damaged the type for the word "Dosage."

a. The fact of the change is an obvious admission by the company that it had been wrong.

That is leaving out the contraindications entirely.

b. The cynicism of the company is disclosed by its willingness to continue the ad and merely change an error of commission to one of omission.

c. Since Section 502(n) of the Act requires a true statement of contraindications, they have not really removed the basis of our complaint. Further, the other errors, pointed to in our June 10 memo, still stand.

d. The act of the J.A.M.A., re: the June 29 issue, raises an important point. Its Council on Advertising could be perhaps excused, on the basis of ignorance, in accepting the June 8 ad copy. However, their agreement to delete the line, "Contraindications: None Known," makes it appear that the Council became a knowledgeable participant in an act of omission contrary to law.

This is FDA speaking. Now, I suppose somebody in JAMA might have an argument to respond to that. But again, they run an ad that is important. They run one in June——