I might point out, in contrast to this very simple, limited advertising on one and two pages for old drugs, that the Merck introductory ad for Indocin in the JAMA (of which you have a copy) in November 1965, was a 10-page, very impressive, four-color ad. It ran for 6 months, approximately. The impact of this kind of ad, in this and many journals, I believe would be likely to be substantially greater than the 21 percent results from these rather limited ads.

Senator NELSON. What study was that?

Dr. MCCLEERY. It was an Alfred Politz study for Modern Medicine magazine.

Senator NELSON. Is additional discussion of that going to be presented?

Dr. MCCLEERY. I intend, if you wish it, to give you a copy of the entire study.

Senator NELSON. Yes. Do you intend to discuss it further at a future hearing?

Dr. LEY. If the Senator wishes, we may.

Senator NELSON. I would like to see a copy of it, and then appropriate parts of it might be printed in the record. But we ought to have a chance, as Mr. Goodrich says, to evaluate it.

I want to thank all three of you very much. You have made a most valuable contribution to the hearings. We appreciate your taking the time to come here and present this testimony.

(The information submitted by Senator Nelson follows:)

MERCK SHARP & DOHME,
West Point, Pennsylvania,
July 14, 1966.

H. I. WEINSTEIN, M.D.
Director, Division of Medical Review.
ACTING CHIEF,
Medical Advertising Branch/DMR.

Indocin (indomethacin)—Misbranding under 502(n).

I. "Indocin" article in July 1966 issue of *Pageant* magazine by Phyllis and Robert P. Goldman.

II. 3-page ad in the July 4, 1966 *Journal of the American Medical Association.*

III. Recommendation.

I. PAGEANT ARTICLE, TITLED "INDOCIN"

A. The subject article has come to our attention most prominently in connection with information accompanying a letter of June 21, 1966 from Mr. John E. Fletcher (Merck) to Mr. Cron. This was called to our attention by Mr. Goodrich, who also asked us to check Indocin's medical journal ads. Mr. Fletcher attached a copy of his note of June 17, 1966 to members of the Merck management admitting that the firm cooperated with the Goldmans in making information available for the article, but disclaiming any responsibility of Merck in the matter on the grounds that the article was not "promoted" or "sponsored" by the firm.

B. Thus, the question whether FDA has jurisdiction over the article must be settled before proceeding to deal with the question of whether its contents misbrand the drug.

Even taking Merck's admission and disclaimers into account, we believe that the *Pageant* article is subject to section 502(n) of the Act and that Merck is a responsible party for causing issuance of the article:

1. While section 502(n) excludes labeling defined by regulation 1.105(1), it includes all advertisements *and other descriptive printed matter* that is not determined to be labeling.

We believe that the Pageant article should be regarded as "other descriptive printed matter" that is not labeling.

2. Section 502(n) of the Act does not require material subject to the Act to be "promoted" or "sponsored" by a prescription drug manufacturer, packer or