same authors published the results of a much better controlled and double-blind study on a larger population than the 1963 paper—here 26 patients crossed over on both indomethacin, and the competitive product, phenylbutazone.

(2) This was a study of the response to the marketed capsules within the limits of approved dosage, the authors ended the paper with a note of thanks to company personnel "for generous supplies of indomethacin," it was published in the same journal as the first article (British Medical Journal, 2: 1281, Nov. 27, 1965), and was available well before the ad was created and published.

(3) The overall patient response greatly favored the competitive product to an extent that was statistically highly significant, for example, when the 2-month blind trial was over "* * * 15 patients preferred phenylbutazone, 10 found them to be equally effective, and one preferred indomethacin."

(4) The authors' conclusions re Indocin were strikingly different (the key words "predictable" and "in most cases" no longer were included) after this study, that is, "* * * the first nonsteroid to produce a measurable reduction in joint size in selected cases of active rheumatoid arthritis."

Now, the phrase "the first nonsteroid" is common to both articles. It should be noted that the authors' retention and the company's use of the phrase "the first" is in my view highly questionable.

Within the authors' own results in the 1965 article, they included the observation that reduction in joint size occurred not only in patients on indomethacin, but also on phenylbutazone as well, and that taking into account both the number of patients improved, and the extent of reduction, differences between the two drugs were not statistically significant. And yet the authors were still using the phrase "the first nonsteroid," and so on.

It is difficult for me to see any validity or significance to the claim "the first" especially when the authors failed to find such difference in the reduction that they did find—to find any statistically significant difference between the amount of reduction.

Mr. Chairman, since your committee may wish to consider the Hart and Boardman papers in some detail, I have made copies of both papers available to you and for the record, and I have gone into some detail on this point, because it typifies several advertising practices which we regard as seriously misleading.

Senator NELSON. We will print those in the record. If I understand you correctly, what you have said is that the company quoted from an early study by these two doctors.

Dr. MCCLEERY. That study being of less quality than the later.

Senator NELSON. And was the second study which modified the position taken in the first study published and available at the time they ran the questionable ad?

Dr. MCCLEERY. Yes, and known to the company long before that, because they were in contact with the authors of the study and supplied the drug to the authors, so that they were well aware of the study going on.

Senator NELSON. So here you say there is a clear-cut case where they knew a subsequent study modified the original one; yet, they continued to use in their advertising a quote from the original study.