in joint size to be significant, there was no difference in 17 patients, five were better on indomethacin, but also four were better on phenylbutazone. And they go on to conclude that this difference between the drugs' effect is not statistically significant. But it is significant that the number of patients showing reduction in their joint size was almost equal between the two drugs, and that there also was a positive effect for phenylbutazone noted in the same study that showed a positive effect on some cases with indomethacin.

Senator NELSON. That is from the second study.

Dr. MCCLEERY. Yes, sir. Whether these results have any connection with its lack of desirability, or are related to the company's decision not to use it as a source of reference, I do not know. But those are the authors' conclusions in the second paper.

Now, there are several other claims made in the JAMA ad to which we objected in detail in our internal memos. For example, one of the most serious of all was this matter of a drug of choice, to which I referred. Whereas in the earlier ads the company did change these quotes to tone them down by inserting the bracketed letter "a," the last ad in the series, later, in November, quoted it unadorned, unchanged, as "the drug of choice."

I might say in passing also that the Hart and Boardman article used in regard to the treatment of gout, which is the most right block of the ad, was based entirely on the indomethacin formulation that was not marketed, the tablets. Furthermore, the dosages used by the authors, which gave the results that led to "the drug of choice" opinion, were far in excess of the upper approved safe limit when the drug was marketed in this country in capsule form. Outside of all these features I would have to agree that the use of the quote is proper.

Now, Congress has already recognized that it is dangerous to promote a new drug with inadequately based claims for greater safety and comparatively greater effectiveness than established competitive products. Safe promotion can be based only on adequate clinical data, and then only with a complete awareness that the limited experience with the new drug as it enters the market, accumulated during its investigational state, may change rapidly and significantly when the drug is released for general use by physicians at large. Also experience will dictate changes from time to time as you have seen in the testimony yesterday, and for as long as the drug is marketed, very possibly.

Indomethacin was recognized from the first as a drug with significant capacity for adverse effects. We believe its promotion over the first year of its approved marketing improperly presented the drug to the medical profession—both as to the range of its effectiveness and as to the margin of its safety.

Mr. Chairman, this emphasizes, for us at least, the need for our continued special attention to the advertising of newly released drugs as they enter the marketplace, as well as that for older prescription drugs, to help provide assurance—and, I might add, I would like to insert the word "help" for the record here as a qualifier, which we so often insist that our opponents in advertising use—so with your permission, and with some seriousness, may I request that you insert the word "help" after the word "to"—to help provide assurance that they are fairly presented to the medical profession under the approved conditions of marketing. Further it demonstrates a need for constant sur-