

Dr. McCLEERY. Right. And which quote was not the opinion of the author at the time that the ad was created?

Senator NELSON. Yes.

Dr. McCLEERY. You might wonder, as we did, why the company might choose—if they chose, it may be a matter of inattention to the literature—but whether they chose to use the '63 paper and ignore the '65, I do not know. But I think I would like to offer you evidence from the second paper—just a few brief recountings of the results reported by the authors in the second paper which may suggest why the second paper was undesirable as a form of promotion. And I would like to read a few excerpts from the Hart and Boardman paper of 1965.

Senator NELSON. You say the company was aware of the second paper?

Dr. McCLEERY. I cannot say that. I can only assume that if they were not, that it was a matter of inattention which I would not find excusable.

Senator NELSON. Since it was a trial run on their own drug.

Dr. McCLEERY. And it was published in the same journal, and was in print available well before they created the ad, and since they were clearly aware of the research of Hart and Boardman, having been in contact with them from the days of the IND.

I would like to read some of the comparative results which this ad did not point to—which a doctor might see if he read the 1965 article.

The following from the article, not used by the company in its promotion, are some of the results found by the same authors.

As far as subjective signs are concerned, when they asked the patients at the end of the trial which one was found by the patients to be more satisfactory, "15 patients preferred phenylbutazone, 10 found them to be equally effective, and one preferred indomethacin. This difference is statistically significant with a 'p' value less than 0.001."

They go on at much greater length and deal with the question of pain as recorded by them for each patient during the month on each drug. And they found that the "improvement in pain"—that five on phenylbutazone, but only two on indomethacin found their pain relief better, and that 19 found no difference.

As far as "joint stiffness" was concerned, assuming a 25-percent difference to be significant, five were less stiff during phenylbutazone, and only one less stiff on indomethacin—20 patients found no detectable difference.

As far as the very commonly used parameter of judgment, "early morning stiffness," for drugs in this category, they found that in the first month on phenylbutazone seven patients were improved, and on indomethacin only three improved. In the second month, on indomethacin improvement occurred in three patients, and on phenylbutazone four improved.

As far as "grip strength" was concerned, I won't review the comments in detail, but there was no real difference between the two drugs on that parameter.

As far as the objective "change in joint size," which is a common feature of the 1966 ad, and is related to the authors' comment about the "first nonsteroid" to produce reduction in joint size, these are the actual figures given by the authors in their paper, which precede their conclusions. So they say—assuming a change of three ring sizes