

report quoted in the Merck ad, we felt that Merck had no right to adopt the quotation in their 1966 advertising. The quotation from an article by Hart and Boardman in the BMJ, October 18, 1963, was used under the ad's caption "Rheumatoid Arthritis," and the quote that the company chose and chose to adopt as their own, was "The first noncorticosteroid agent which produced a predictable and measurable reduction in joint swelling in most cases of active rheumatoid arthritis."

Senator NELSON. That is a quote from the British Medical Journal from an article by Hart and Boardman.

Dr. McCLEERY. Yes, sir. Our comments with reference to this 1963 quotation are that, first, it does not represent a true statement of the effectiveness of the advertised product, Indocin. And in this regard, the company, we feel, is responsible for choosing and using an author's view; that it becomes in this effect their own, that they are responsible.

Senator NELSON. What you are saying is that they quoted Hart and Boardman accurately, but Hart and Boardman were incorrect?

Dr. McCLEERY. I do not think I will get around to my view on that if I can avoid it. I am saying that they quoted the article correctly. Whether it represented a correct view of the drug, other than in the mind of the authors, is a responsibility, I say, that the company has to assume—that when they choose a view expressed by an author in the scientific literature, that they have to stand on whether or not that represents a general view that is accepted widely by the medical profession at the time that they use it in an ad—that they must assume responsibility for making that view their own view.

Senator NELSON. All right.

Dr. McCLEERY. Now, the approved package insert for the product does not contain the promissory concept represented by "most cases" or "predictable," which were the views of Hart and Boardman.

Senator NELSON. Will you explain that. You are referring back to the quote from Hart and Boardman?

Dr. McCLEERY. Yes, sir; all of this will be in reference to that one quote—all that follows.

Senator NELSON. And you are saying that—

Dr. McCLEERY. That the approved package insert reflecting the agreed-upon view of the drug between the Government and the company does not contain the concepts of the features of the drug expressed by Hart and Boardman in their view—that the company thereby chose an opinion of someone else which was not, and has not, been approved for representing the drug in the package insert.

Senator NELSON. Are you saying that if the company requested to use the words "most cases," and "predictable" in the package insert, you would not have approved that language in the product package insert as of that date?

Dr. McCLEERY. That is not my responsibility, nor do I have enough information to make that judgment. I am saying that the package insert of record at the time the ad was printed did not contain these concepts, these promises. The companies are obligated in our view by the law, and the regulations written on it, to describe a drug, their drug, not beyond the terms included and approved in the official labeling for the drug. This is a baseline for the judgment of advertising,