

advertising of Indocin that had come to our attention. Later, you made available for our review and comment a number of sales bulletins on Indocin.

These bulletins appear to have been sent to Merck detail men by the district supervisor in one of the firm's sales regions. Their form and contents suggest that they are internal communications to the detailing force, not intended for distribution beyond control of the firm.

I would like to add here, Mr. Chairman, for the record, that the following comments are based on the assumption that these are indeed statements by responsible officials of the company, and all I have to say hereafter will be based on that assumption.

Senator NELSON. You are referring to the instructions?

Dr. McCLEERY. Right.

Senator NELSON. Just so the record will be clear at this stage, a detail man sent the bulletins to us. At the top it says, "To all western district associates from H. Glassner," who is the district manager of that area, and it is these bulletins upon which we raise the questions—

Dr. McCLEERY. Right.

Senator NELSON (continuing). With the FDA, and it is on these bulletins—

Dr. McCLEERY. That we are making comments.

Senator NELSON (continuing). That you are making your comments.

Dr. McCLEERY. Yes, sir; that is correct.

Before dealing with specific features of the instructions to Merck detail men, I should point out that the methods recommended in the bulletins for increasing sales of Indocin seem typical of methods used to promote a variety of products which ordinarily do not have such serious public health implications, as does a drug like Indocin.

And on the whole we regard these sales bulletins as seriously misleading.

Senator NELSON. Doctor, may I interrupt a moment?

If the detail man did, in fact, follow the instructions in the bulletins, he would be making some claims for this drug that were not approved by the FDA; is that correct?

Dr. McCLEERY. I would say yes.

Senator NELSON. And if the doctor got his information and relied upon the detail man, he would then be using this drug for purposes not approved by the FDA; is that correct?

Dr. McCLEERY. If he were not only influenced by some of the statements here, but derived a large part of his basis for judgment on the drug, that is why we are saying that they were misleading.

Senator NELSON. You say seriously misleading in your statement.

Dr. McCLEERY. I did. The extent to which the sales instructions were followed or what extrapolation the Merck detail men may have given to the instructions in their oral presentations are unknown to us. As to the effect of the instructions on medical practice, there seems little reason to doubt that they would contribute to the prescribing of Indocin for unapproved uses.

Mr. Chairman, we found that the bulletins could be grouped for comparative study into two time periods. Six bulletins, dated between July 12 and August 4, 1965, were representative of the group of instructions issued during the period of the introduction of Indocin to the marketplace. Six other bulletins, typical of the second group, were