

Senator NELSON. There was one other quote in Bulletin 74 referring again, referring this time to older patients and calling them "The real crocks and cruds." Now that quote is:

Now, how many older patients, the patients with most of the aches and pains, the real crocks and cruds seen in everyday and daily practice, just how many of these patients do not have some degree of cardiac decompensation and some degree of edema?

For a great and distinguished company to be referring to elderly citizens as "the real crocks and cruds" gives you some idea of the level of their attitude toward the patients. And apparently the attitude of the detail men and all the rest of them. The approved package labeling which I have here is dated effective May 1965; is that correct?

Dr. McCLEERY. Yes, sir.

Senator NELSON. Is a copy of the package labeling sent by the firm to all the detail men?

Dr. McCLEERY. Presumably so. It is required. We have no way of knowing for certain the intimate detail.

Senator NELSON. But the FDA does require that that be done?

Dr. McCLEERY. With every sample of drug that the detail man is given to give to doctors, there is required to be a package insert.

Senator NELSON. So, then, the 1965 instructional bulletins to detail men were issued after the package labeling had been in effect, is that not correct?

Dr. McCLEERY. Yes, sir.

Senator NELSON. Do you have a listing of all of the unapproved claims made by the company in the various bulletins examined?

Dr. McCLEERY. I don't have one before me. We have made one, and I have mentioned a number of them in my testimony. I think that that attitude is perhaps exemplified best in the early period of enthusiasm, which might be understandable if not condonable, in the period when a new drug comes on the market. However, it is less understandable in the year 1967, long after that introduction, and after our contacts on the principle of proper promotion of Indocin had led to agreement between the Commissioner and the top officer of Merck. I think the bulletins in 1967 are much more impressive in the way they express the value and indications of Indocin, and also what uses are suggested in this language, presumably by a regional sales manager, to develop copy for oral assertion by individual detail men to the doctor. This is much more subtle than the kind of language in the introductory period, but I think it is also quite instructive of the problem.

I would be glad to point out one or two instances of what I mean if you wish.

Senator NELSON. Please go ahead.

Dr. McCLEERY. You had made reference just a moment ago to a statement in Bulletin 74 dated September 5, 1967, on the "real crocks and cruds." In the same bulletin in which that statement is made, there is a reference on the second page which runs through, in a very subtle way, the whole pattern of promotion by this method in the time period of 1967. I will quote from it, Mr. Chairman. On page 2 it says—

Senator NELSON. Is that September 5, 1967, Bulletin 74?

Dr. McCLEERY. Yes, sir; on page 2. It says: "Wherever there is pain, inflammation and swelling in or around the joint with a resultant limitation of motion as there is in rheumatoid arthritis, rheumatoid