

Mr. GORDON. Are any of these duplicate studies? How many drugs are involved? You said, I think, that there are not 211 drugs involved although you refer to 211 studies. Now, they may be concerned with only one, two, three, or four drugs.

Dr. SLESSER. No—they are concerned with a lot more than one, two, three, or four. I do not know the exact number. But I can tell you they are not duplicate studies. They may be on the same drug in some instances. There may be some on the same drug, yes. But exploring different facets of this particular drug.

In other words, there will not be two that have to do with the fineness of division of drug X let's say in a particular product.

Mr. GORDON. But you do not know offhand how many drugs are actually covered in the 211 studies?

Dr. SLESSER. I have not counted them. Do you know, Dr. Adams?

Dr. ADAMS. Well over 25.

Mr. GORDON. Now, how many are based on clinically controlled double blind studies?

Dr. SLESSER. I do not know the number, Mr. Gordon. I will state this. It is not always necessary to run a so-called double blind study. If you are comparing a drug—for example, in the type of study that Parke, Davis conducted on their Chloromycetin versus so-called generic equivalent chloramphenicol products, this need not be done in a double blind fashion.

Mr. GORDON. You do not know how many are based on controlled clinical double blind studies. Is that correct?

Mr. CUTLER. Could Dr. Van Riper answer that question?

Mr. GORDON. Surely—anybody.

Dr. VAN RIPER. Mr. Chairman, the importance of a double blind study depends on the drug that you have under study. One does not do a double blind study in a situation where he may have a fatal illness, where you would be giving a placebo, a blank.

Now, in this particular instance—I am not familiar with these studies, but the possibility and the probability is that these are run as therapeutic equivalents—one drug is studied against another, in a blind method, whereby the clinician who is doing the study is not aware of whether he is giving drug A or drug B. But he does know that both drugs under study are active.

Mr. GORDON. I can understand that. But I am asking about the 211 studies. Do you know how many of those are of the type you just mentioned?

Dr. VAN RIPER. I do not.

Mr. CUTLER. Mr. Chairman, could we offer these 211 studies for the record? They are all from published medical literature, as I understand it. And then they will speak for themselves.

Senator NELSON. All right. Depending upon how much value we determine there would be in printing them in the record as such. But you let us have them and we will decide that.¹

Mr. CUTLER. At least the references could be printed in the record. (Subsequent correspondence between Senator Nelson and Dr. Feldmann re 211 studies follows:)

¹ Retained in committee files.