

Dr. GODDARD. Yes, this has been clearly known to the Pharmaceutical Manufacturers Association and the Drug & Allied Manufacturers Guild.

Senator SCOTT. At this time, your agency can't assure physicians that the chemical equivalent drugs now on the market are therapeutically equivalent, but is it not a fact that you are working toward that end, that you are seeking to be able to do that?

Dr. GODDARD. Yes, sir.

I do not think anyone can provide absolute assurance that therapeutic equivalency exists for every drug in the marketplace. But by the same token, I have not seen any good evidence from any firm, large or small, that their drugs are superior to anybody else's. I hear the statement made time and time again. I have challenged representatives from firms who have made this statement to show me the evidence that its drugs are superior. Generally now, we are talking, you understand, about the pre-1962 drugs, where effectiveness did not have to be proven.

Senator SCOTT. Is that not where the proverb applies that one man's Anacin is another man's Empirin?

Dr. GODDARD. I have not heard that proverb before.

Senator SCOTT. It is an old eastern proverb that I just made up.

Dr. GODDARD. There are two instances of lack of therapeutic equivalence known that have been cited in the literature. With one, tetracycline, that was sugar coated, involved all the producers of tetracycline. I do not think that size is any assurance of freedom from worry in this field. We are going to begin some clinical trials on those drugs that are available from more than one manufacturer on those 200 most frequently prescribed drugs. At some place down the line, I think we are going to have to make a hard nosed business decision in the Government. I am not opposed to doing that, either.

Senator SCOTT. I would applaud you for doing that.

Dr. GODDARD. If we find in group after group that there is therapeutic equivalency and we have gone down this road 30 times with 30 different drugs, I think I would be derelict in my duties if I did not cut off further clinical studies. Also, I would not want to expose unnecessarily the patients to the risks that can be involved.

So this kind of a question, we think, can be answered in about 18 months.

But make no mistake: I think the examples of lack of therapeutic equivalency are in the minority. The possibilities are actually that only in very few instances does therapeutic equivalence not exist. Among ourselves, physicians would argue as to whether or not it would be noticed in the intermittent therapy that is given in the private practice of medicine without continuous supervision. That is a valid point. That is why we are going ahead and carrying out these trials.

But as I say, I have not seen good data from any company, large or small, that says that their pre-1962 drug is more effective than anybody else's.

Senator NELSON. We have had testimony from a number of witnesses who have said that the burden ought to rest on those who assert that they are not therapeutically equivalent to come forward with the evidence. We had the Schering Co. president here last week. We read