except experience. We cannot give another company experience. And to gain experience, it is my firm belief that a fundamental thing that the company must do is clinically compare its product with the standard that is in existence. In this case, the standard was clearly Chloromycetin. They could either make the product better or at least, they have to make it at least as good.

Senator NELSON. Of course, you testified a while back that even though your own experts helped develop the standard that FDA adopted, they either did not know or did not disclose to the FDA a sufficient amount of information to make it possible to produce a drug that would be therapeutically effective.

Dr. LUECK. No, sir, Mr. Chairman; I wish to correct one point.

Parke, Davis & Co. made available to the Food and Drug Administration all the information that we have on Chloromycetin and chloramphenicol. We recommended that clinical testing of the competitive products should be carried out before those products were allowed to go into distribution.

Senator NELSON. I know you recommended that. But is it not true that if a company took all your best experience and produced this tablet, using the same ingredients you do and following your procedures exactly, the company could produce the exact same product.

Dr. LUECK. No, sir; apparently that is not the case with Chloromycetin, Mr. Chairman.

Senator NELSON. Has anybody exactly duplicated your tablet? You do not know what the problem is. It may be that the coating on that tablet does not dissolve rapidly enough. But, if the manufacturer had known your formula and followed it exactly, then he would be capable of producing anything your company can produce, given the information, would he not?

Dr. LUECK. I assume so if they do the proper testing. Yes; if they research the product——

Senator NELSON. No; if you furnish them all the information.

Dr. LUECK. If we furnish the information and produce the product, then I would stand behind that product as being similar. If they produce the product in a different procedure or different facility, even using the same procedure, then our products such as Chloromycetin, in our opinion, should be tested for clinical equivalence. As a matter of fact, we have to reject some of our own material that we manufacture, Mr. Chairman. We cannot manufacture this product perfectly each time ourselves.

Senator NELSON. That is correct. Neither would any other company.

Dr. LUECK. That is right.

Senator NELSON. But you are testifying that if the best experts you have in your company advised any other high quality, brand-name company as to exactly how you produced a drug, that the other firm could not duplicate your product? It that what you are saying?

Dr. LUECK. We have a prime example before us to answer that question, Mr. Chairman. In my opinion, when Parke, Davis changed the clinical process to produce Chloromycetin in 1964, we did exhaustive animal tests, we did exhaustive human tests in subjects with typhoid fever, comparing the old process with the new process. And we did not rely only on laboratory tests.