not know that the standards adopted by the FDA would not produce a therapeutically effective drug.

Dr. LUECK. We are not aware of any laboratory standards, Mr. Chairman, that will beyond any reasonable doubt, determine the therapeutic equivalency or therapeutic effectiveness of the drug. This is the point in question, that you cannot rely on laboratory standards to do this job for you.

Senator NELSON. But you did not know that the standards set would not do the job?

Dr. LUECK. No; by means of the standards set in the antibiotic regulations, plus the care and experience that Parke, Davis & Co. had with chloramphenicol and Chloromycetin, and based on our clinical experience, we maintained a product of excellent quality through the years. We had in the United States no means or no way of comparing Chloromycetin to another product.

Senator NELSON. I am still getting at the point that your experts did not know that the standards established were not sufficient to duplicate the same therapeutic effectiveness in chloramphenicol that Parke, Davis produced in theirs; is that correct?

Dr. LUECK. That is correct, and we do not know of any laboratory standards at this moment, Mr. Chairman, that would provide that information for Chloromycetin that was not proven in the clinic.

Senator NELSON. There is another rollcall on the Senate floor.

(Short recess.)

Senator NELSON. I apologize for the interruption.

As I understand your last statement, it was that, in your view, a company should not be permitted simply to copy the drug of another company and put it on the market without performing additional clinical tests.

Dr. LUECK. Mr. Chairman, I could probably clear up a few questions that you might have by just very briefly reviewing the information that Parke, Davis & Co. submitted to the Food and Drug Administration. I can do that very briefly and this may answer some fo your questions.

Senator NELSON. Very well.

Dr. LUECK. Back in 1947, 1948, and 1949, when Chloromycetin was first discovered and researched, of course, Parke, Davis & Co. submitted to the Food and Drug Administration clinical evidence of its safety and effectiveness. Tests were adopted at that time by the Food and Drug Administration to form the basis of a New Drug Application. The approval of the New Drug Application was on the basis of clinical effectiveness and adequate controls to maintain quality of the product in Parke, Davis' manufacturing facilities.

Now, to illustrate further, in 1964, Parke, Davis & Co. changed the synthetic process for manufacturing Chloromycetin and at that time, we were requested by the Food and Drug Administration to run animal tests, human tests, and chemical tests to verify the safety and efficacy of our product. We did all of these things at extreme lengths so that Chloromycetin has been of excellent quality at all times through the years. The controls established for Chloromycetin have been based on studies in human subjects, that the drug is effective.

Now, in 1966, when the introduction of competitive products to Chloromycetin was imminent, Parke, Davis & Co. suggested to the