the standards, did any representative of Parke, Davis participate with the FDA in establishing these standards?

Dr. LUECK. No, sir; they did not change at that time.

Senator NELSON. What do you mean?

Dr. LUECK. There was no change in standards at the time the patent expired.

Senator NELSON. In other words, the FDA accepted the standards that had been established at the time the New Drug Application was approved for Chloromycetin?

Dr. LUECK. Yes, sir; Mr. Chairman.

Senator NELSON. What year was that, about 1949?

Dr. LUECK. 1949, but I wish to point out again that those standards have changed through the years and improved since 1949.

Senator NELSON. And did FDA adopt the improved standards?

Dr. LUECK. Yes.

Senator NELSON. And was your company aware that the standards adopted by FDA would not produce a product that measured up to Parke, Davis' Chloromycetin?

Dr. LUECK. No, sir. At that time we were not in any position to render that judgment at all, except to say, Mr. Chairman, that it has been our policy for many years that one can't rely on laboratory tests to ascertain therapeutic efficacy. This is the case in question, I think, of extreme interest to you and your subcommittee, whether laboratory testing alone can suffice to guarantee clinical effectiveness. In all cases, it certainly can't.

Senator NELSON. I do not think anybody disagrees with the proposition that two drugs which meet USP standards do not always produce equivalent therapeutic results. I do not think anybody before our committee has asserted that it would in all cases. What is at issue here is that there are exceptions. Is that not the case? And out of these rare exceptions, the manufacturers like to make the rule.

Dr. LUECK. I do not know if these exceptions are rare exceptions, Mr. Chairman. Exceptions come to our attention and they have come to my attention in Parke, Davis & Co. When we are in the process of researching a new compound, we have seen differences that we can create in the laboratory and we are cognizant of those differences. I do not know if these exceptions are rare.

Senator NELSON. Well, the assertion by Dr. Miller of USP is that it is rare. The assertion by Dr. Feldmann, of the National Formulary, your classmate at the University of Wisconsin, is that they are rare. The assertion of Dr. Modell, a very distinguished pharmacologist and M.D., is that they are rare. The assertion by many witnesses before this committee who are highly distinguished doctors, researchers, and professors, is that they are rare. Dr. Miller's assertion is that there are perhaps 15 or 18 cases known in all of the United States, versus all the drugs on the market where a drug meets USP standards and does not produce therapeutically equivalent results. And this happens to be one of them. And this is a case that does not include USP standards. If there is any fault, it is FDA in this case.

But you are talking about a drug whose patent expired in 1966 and you are able to select this one case to add to a list that involves 15 or 16