Food and Drug Administration that before those products entered distribution in the United States, they, too, should be tested in the clinic, in human subjects.

So we did correspond with the Food and Drug Administration in 1966 relative to effectiveness of possible competitive products, but there were no changes made in the specification or the standards for the antibiotic at that time.

Senator NELSON. If a company licenses another company to produce its product, does the licensee have to do clinical testing before it can put the product on the market?

Dr. LUECK. Frequently, yes.

Senator NELSON. Do they always have to?

Dr. LUECK. It would depend upon the situation, what was licensed. If it were just the license of a procedure, a chemical synthesis, for example, Mr. Chairman, to be followed, it would be necessary, in our opinion, to do clinical testing to make certain that the proper controls were placed on that chemical procedure.

Now, if the company who owned the effective New Drug Application produced the product, it could be assumed that they would produce the same quality product. In other words, if you sold the bulk chemical to the next company, it could be assumed that clinical testing was not required. But if the chemical process was moved to another operation, conducted by other people, other technicians, then efficacy should be proven, in our opinion, in human subjects. This is what Parke, Davis did with Chloromycetin.

Senator NELSON. So that I understand you correctly, you are saying that if the bulk chemical itself were produced by the licensee holder of the New Drug Application, the firm who is granted the New Drug Application, and it licenses company A to produce the product and furnishes company A with the bulk product, this licensee may produce the tablet without conducting its own clinical testing?

Dr. LUECK. No; I think I misled you slightly. It would not be necessary, in my opinion, to check the quality measures of the synthetic process. But in my opinion, it would be necessary to check the efficacy of the product form produced by the licensee if there indeed was any difference.

Now, I would have to perhaps explain that a little further. The bulk chemical—suppose it was placed into a capsule with other diluent materials and so forth, it would be necessary, in my opinion, then, to perform sufficient clinical trials to prove that that product form, that capsule, was clinically effective.

Senator NELSON. The present law?

Dr. LUECK. It is up to the Food and Drug Administration, Mr. Chairman, to make that decision.

Senator NELSON. Is it ever the practice for the company that has been granted the New Drug Application to license other companies and furnish them with all the information they have concerning the method of production? Is that a common practice?

Dr. LUECK. It is my understanding that that has been done. I would like to remind the chairman that my concern in Parke, Davis & Co. does not include that area of our business and I am not the most familiar with it. But it is my understanding that arrangements like that have been made in the pharmaceutical industry.