Mr. CUTLER. You are raising, Mr. Chairman, a fundamental issue of patent law; that is whether the information disclosed and published in the patent is sufficient to confer the monopoly granted by the patent or whether the inventor should be compelled to disclose a lot of additional information in order to get his patent.

It is an awfully complicated question and the job of the Patent Office is to see that the information disclosed is sufficient so that the benefits of the discovery will become available to the public after the monopoly period has expired.

Senator NELSON. But the argument here is that a particular company in such a case does some things better than anybody else does them. All I am saying is that after 17 years of protection, why should not, for example, the FDA make public all the information on the production of that product, and say to a firm, "If you want to produce this drug, following exactly the procedures followed by X company that has had 17 years of experience, 17 years to make back its investment and make a profit, we will furnish you all the production information, and you can go out on the market without further clinical testing. If, however, you want to do some additional experimenting, maybe to refine the product, try to improve the product, then you have to do clinical testing because we do not know what the result may be." I am just asking, as a matter of policy, why should not that be the practice?

Mr. CUTLER. It seems to me it would be a much simpler policy to require the second company to do the clinical testing. The point we are trying to make here is that there are some 40 or 50 chloramphenicol products on the market——

Senator NELSON. What kind of products?

Mr. CUTLER. There are some 40 to 50 chloramphenicol products on the market today and judging by tests that Parke, Davis has conducted on three of those products in addition to its own clinical tests, the other products do not come up to the clinical effectiveness of the Parke, Davis product, Chloromycetin or, indeed, what is in their own labeling. It would be simple enough to require those companies to make the tests.

Senator NELSON. We know in this case, assuming your experiments are correct, that this is a case where the FDA standard is not adequate. I just repeat for the record that we have hundreds of cases of drugs on the market that meet the FDA or USP standards which are adequate to produce an effective drug. I am just saying why should not a company that has had the benefit of the protection of a patent for 17 years then make public all the information that would allow another company to exactly duplicate that drug.

Dr. LUECK. I would like to comment briefly in regard to Chloromycetin in answer to your question.

During the 17 years that Parke, Davis Co., was under the patent rights for Chloromycetin, some more than 14,000 references or articles appear in the scientific literature on Chloromycetin. The very tests that we used to gather the information presented here today have been published by Parke, Davis scientists a number of years ago for anyone to use. It is our firm belief that the literature contains such information and the total amount of information that Parke, Davis & Co. has,