Senator NELSON. Do you have somebody here who can address himself to that point?

Dr. LUECK. I think we have members of the panel who can.

Senator NELSON. Who here could answer my question?

Mr. CUTLER. Mr. Chairman, I do not think we have anyone here who can answer that question for a variety of companies, but we can certainly try to get you the answer.

Senator NELSON. Is there anybody here who can answer it for any company as to what the law requires, and as to whether it is a practice that is followed by the industry at all.

Mr. CUTLER. I think I can answer as to the law, Mr. Chairman. There is nothing in the Food and Drug law or the patent law that would prohibit one company from turning all of its manufacturing and know-how information over to another company. It would then be up to the Food and Drug Administration, under the law, assuming the product is a new drug, to determine what evidence would be required from the second company.

Senator NELSON. Is there any reason at all why, after a patent has been granted by the public to a company for 17 years, that at the conclusion of the 17 years, all the processes, methods, and benefits accumulated by that company from its experience and public protection for 17 years should not be turned over to the FDA and then made a matter of public information?

Mr. CUTLER. Well, I believe all of the company's processing information is turned over to the FDA to the extent the FDA requires it. And, of course, all of the information that the company was required to disclose in order to obtain the patent is published in the patent itself.

Dr. LUECK. I would like to comment if I may——

Senator NELSON. But all the processes, I understand, are not.

Mr. CUTLER. If it is a process patent—well, there is no proprietary know-how not subject to patent that is kept by companies, by individual companies, each for itself. But the information on which the patent was granted is, of course, published.

Senator NELSON. What I am getting at is that the testimony repeatedly heard from representatives of the industry is that even if you include the same active ingredients, maybe even if you include the same inert ingredients, even if you do all kinds of things the same way chemically, you may not get the same result.

Mr. CUTLER. Right.

Senator NELSON. What I am saying is, as a matter of public policy, we could pass legislation to require the publication of all relevant production information. The American people have said, in order to encourage discovery, research, they will protect the patentable item in this field for 17 years. I do not have any reason to quarrel with this policy. I think it has produced some good results.

Now, once the 17-year period has expired and the company is dealing with a product which directly affects the public health, should not all the information on how they produce the product be made available to any other company so that any firm, once the patent period is over, will be able to use the same processes and duplicate the drug if they wish?