Senator NELSON. To be manufactured by anybody else?

Mr. STETLER. No, sir.

Senator NELSON. This is contrary to the testimony we had.

Mr. STETLER. Normally, if it is still a new drug, the second manufacturer will be required to go through the NDA procedure at Food and Drug. But a drug can become an old drug, either by being declared so by the FDA, or by becoming generally recognized as safe and effective. When that happens, another manufacturer can produce it, without going through the new drug procedure.

Senator NELSON. We will check the testimony. I think Dr. Goddard said when a New Drug Application is granted, the company that is granted the New Drug Application may then license X, Y, Z to manufacture the same drug forthwith.

Mr. STETLER. I think that is incorrect.

Mr. CUTLER. The first company, Mr. Chairman, could provide its clinical data to the second company it licenses, and FDA then in its discretion might decide to approve the second company's application based on that data. That is a possibility.

Mr. STETLER. No, but that is different. They still have to go through the FDA procedure. FDA makes that decision, not the company.

Senator NELSON. As I recall, Dr. Goddard said that if X gets the New Drug Application approved, and supplies his data on experiments to companies 1 through 10, they can then manufacture the same drug and put it on the market without doing the experiments that were required for the drug that received the original approval, is that correct?

Mr. STETLER. They can do that. But still it is within the discretion of the Food and Drug Administration whether they want to approve that application or whether they want to let that manufacturer put that product on the market.

A company that has a New Drug Application processed does not make that decision for the Food and Drug Administration. If they want to give their data, that is all right. But even if they give it, the FDA is going to look very carefully at the capabilities of the new manufacturer, as they should. I could get a lot of data, but it would not qualify me to manufacture drugs. So unless I have the capabilities to duplicate all of the protocols of this first manufacture, and can demonstrate that I can do that, I have no right to be in the drug business. And the FDA has to check that.

Senator NELSON. You are putting in the reservation that the right to license has to have the approval of the FDA.

Mr. STETLER. This is not a licensure procedure. The company does not license an NDA.

Senator NELSON. What do you call it?

Mr. STETLER. They license if they have a patent for the drug.

Senator NELSON. I have been using the term license as it relates to a patent. The patent holder may make an agreement to permit other companies to manufacture this new drug?

Mr. STETLER. Not without the authority of the Food and Drug Administration, sir.

Senator NELSON. Well, I am not talking about that.

Mr. STETLER. If they want to, if they have a New Drug Application approved, and if they want to pass over to some manufacturer all of the testing and research and clinical work they have done, and in-