vite them to go to FDA, they can do it. This is not going to be a very prevalent practice in the industry.

Senator NELSON. I believe Dr. Goddard testified that they could do this. I will have to check the record.

The question I raised with the FDA was that a company with a New Drug Application approval can authorize 20 other companies to manufacture the drug, with the approval, as you say, of FDA. None of them need to be any of the known brand name companies. And yet the best known brand name companies who have not received a license from the one who received approval cannot go on to the market with it, even if he duplicated it from analysis as perfectly as it could be done, even if you could take his tablet and mix it up with all the rest and never tell the difference.

Mr. STETLER. I really think on this point, we are proceeding on a wrong premise. I would suggest we check that testimony.

Senator NELSON. I will read that testimony again.

I had a long colloquy with Dr. Goddard on this exact point. I will read it and bring it up at a later date.

Mr. GROSSMAN. I would like to ask a question, Mr. Stetler.

With regard to the equivalency question again—we had testimony from Dr. Goddard last week that "The drugs are therapeutically equivalent until proven otherwise." And I specifically asked him whether this was an assumption or what we could call it. And when I asked him if the purpose of the present FDA study into equivalency then is to corroborate the position he now holds as to equivalency, his answer was "Yes."

In other words, he is conducting the study to corroborate a position that the FDA I assume now holds?

Mr. STETLER. This is an assumption he has stated. If you look back where this has been discussed by Dr. Goddard from time to time, I think he has said rather specifically that the FDA is in no position to guarantee equivalency between drug products.

He has said "I personally believe that when products are chemically equivalent, usually you can assume they are therapeutically equivalent, * * * to prove whether we are right or wrong, I am in the process," he says, "of conducting a test on X products." I understand that testing is being done at Georgetown University, and it will be helpful. But there is no valid assumption on that at the moment. As a matter of fact, our position is diametrically opposed to that assumption.

Mr. GROSSMAN. Have you been consulted at all with regard to this study?

Mr. STETLER. No. Well, there may be people in the industry that have discussed it from time to time. But the protocols for the study and the way it is being handled and the selection of the drugs being tested is pretty much a project between FDA and Georgetown University.

Mr. GROSSMAN. The problem I see here is that we are going to have an endless series of these studies. You will do a study and prove there is an example where they are not therapeutically equivalent. Dr. Goddard will do a study that proves they are. And we are going to go on for years and years. What is the end of all this?

Mr. STETLER. Although it would be a nice, handy, easy thing, to be able to say "We have proven equivalency" the facts of the matter are that nobody will ever be able to make that statement as long as there