without any clinical testing at all, produce tablets to go on the market—B, C, D, E, F, G, H, the whole series of companies—just because Schering, say, licensed them? You say, well, if Schering licensed them, they are able to incorporate Schering's clinical research into their application and that excuses them from going this long route, which you have testified takes as long as 7 years.

Dr. GODDARD. That is correct.

Senator NELSON. I do not get an answer that rings any music in my ears.

Dr. GODDARD. We are having trouble communicating, Senator.

What I are trying to say is we are protecting the public's health in that instance by making certain that the company is capable of producing the drug and producing it properly, with the right manufacturing controls, quality controls, under sanitary conditions, without contamination of the tablet. Now, we yield and say, yes , company A proved this drug to be safe and effective. We don't need any further proof than that because Schering, or company A, has on a business arrangement permitted all these other companies to use the clinical information they submitted.

Now, we accept that, just as we will accept use of the world's literature to prove safety and effectiveness for drugs that are not patented. It is the same situation, Senator.

In those instances——

Senator NELSON. Did you say same or strange.

Dr. GODDARD. Same.

Senator NELSON. I just wanted that in the record. Well, it is a strange situation to me. It seems to me that you have a situation where——

Dr. GODDARD. Well, I think I can see why you feel it is a strange situation. I also feel that there is some unnecessary duplication involved in these activities, and that is why the question comes up. I think properly that the question should be discussed by Congress in terms of the scientific community and the business community involved. Congress should get down to the issues involved here and see whether or not the interest of the public at large might better be served by a public policy which permitted disclosure of the clinical, the scientific information incorporated in New Drug Applications.

Senator JAVITS. Would the Senator yield?

Are you prevented in making that public now?

Dr. GODDARD. Senator Javits, we think we are. I as an administrator think the past policy of not revealing this type of information in effect binds me not to change the policy until there is proper discussion by Congress.

Senator JAVITS. Well, why do you say discussion? Do you want law by Congress, do you want a recital in the congressional report? What do you want?

Dr. GODDARD. I think it would require law in this instance—a change in the law.

Senator JAVITS. So though the law does not actually foreclose you, you still want affirmative law to release you, is that right?

Dr. GODDARD. That is correct, sir.

Senator JAVITS. Because you say the practice has been such that it makes you feel you cannot do it?