Senator NELSON. Clinical tests.

Dr. GODDARD. Very rarely.

Mr. GOODRICH. But we say in every instance, Senator, that you can refer to and use in your New Drug Application scientific data in the open published literature as part of the New Drug Application. We want to be sure that these drugs are safe and effective and we believe that as a general rule, there should be at least some clinical testing of all new drugs by whomever put them on the market.

Senator NELSON. Well, I understand the Commissioner to say that the New Drug Application is almost better than the patent.

Dr. GODDARD. That is what I am told, Senator.

Mr. GORDON. It is better.

Senator NELSON. Now, when company A makes a New Drug Application which meets the standards of clinical and other testing and you issue the New Drug Application, is there anything to prevent company A from licensing company B to produce that drug?

Dr. GODDARD. Company B would then have to provide proof that they had obtained such permission and also get an NDA approval by FDA. This would be done on the basis of incorporating by reference in their NDA the material submitted by company A.

Senator NELSON. So we are in the most unusual position where a private company has more authority to delegate the right to manufacture a drug than is exercised by the FDA?

Dr. GODDARD. Yes, sir; in a sense.

Senator NELSON. That is an incredible situation.

Dr. GODDARD. We hold the final approval authority. Now, that is a business arrangement, the licensing arrangement, over which I do not believe we should have any control. Now, we do, however, control the NDA that the second firm may get.

Senator NELSON. If you require that company B makes a New Drug Application for exactly the same compound for which an NDA has already been granted to company A, the basis for your position that there has to be some clinical testing is, I assume, the protection of the patient. Why is it that then company A, fine as it may be, which has no official public responsibility, can take the New Drug Application that the FDA gave them and license B, C, D, E; if you look at prednisone there are at least 22 companies that Schering licensed. You say you do not have any right to interfere in licensing. This is not a licensing question, it is a health question.

Dr. GODDARD. Oh, we do have the authority to make certain that the health of the public is being protected in this fashion. Each one of those 22 firms then has to get an NDA approved by FDA.

Senator NELSON. But you allow them, if I understand you correctly, Doctor, to incorporate the testing that was done by company A.

Dr. GODDARD. The clinical testing.

Senator NELSON. Yes.

Dr. GODDARD. The manufacturing controls and manufacturing procedures and submission of samples and the factory inspection, however, are carried out de novo. The labeling is also under our jurisdiction, and thus the advertising is controlled. The only thing that is omitted in that instance is the animal toxicity study and the clinical testing on humans.

Senator NELSON. But why can't you have confidence in company B taking a compound that is available to everybody in the market, and