I do not quite grasp what you are protecting in the public interest by allowing this company to license freely. Its licensees have not done the clinical testing. On what grounds do you allow the licensees not to have clinical testing and yet you require tests from the biggest companies in America if they have not been licensed by the original company?

Dr. GODDARD. Senator, in the first instance, of the 25 companies, we do know that the drug, as they propose to produce it, has been proven to be safe and effective, because we have the manufacturing control data submitted to us in each of those instances.

Senator NELSON. Let's say there is just one supplier. All the firms are using exactly the same compound from the same source.

Dr. GODDARD. Right.

Senator NELSON. So the only question left is in the formulation of the tablet, is it not?

Dr. GODDARD. Yes.

Senator NELSON. If they all meet USP standards why decide that the drug of one of the biggest companies does not get a license when all the rest do?

Dr. GODDARD. Senator, in this instance, if company B's manufacturing process were identical with that of company A, I intellectually would not be able to defend any position here. I could not say that there is a lack of prior proof of safety and effectiveness. Now, the probability of the process being identical is, however, slight, I think. In that instance, then, with the variation in the manufacturing process, the Congress does require that we have proof of safety and effectiveness. The drug has to be demonstrated by the manufacturer to do that job.

Senator NELSON. But, doctor, you are undertaking what I think is a marvelous program. I want to commend you. You have done a great job in your position as Commissioner in behalf of the public interest without being unfair to private interests. You are undertaking a program now of clinical testing. You confront exactly the same question, because as I understand it, you will take a drug of which there are many versions on the market, and test a certain number of them. Then you will assume that if the rest meet proper standards, they will get the same clinical result.

Now, why can't you do that when company X comes in with a drug which meets all the chemical standards of the version of the drug that is on the market?

Dr. GODDARD. The burden is on the company in that instance, Senator Nelson. Also, we do feel that because of the Freedom of Information Act and past policies we would be turning business information over to these companies. And that has been our reason for not doing so. I am simply trying to raise before Congress the issue and say this needs to be discussed and our national policy on it examined. I do not happen to agree with it. I think in these instances that it is wasteful of scientific talent and that we ought to devise a better method of handling the problem than we currently have.

Now, maybe I am just a coward, Senator, because I am afraid to do this on our own initiative. But I have been advised by our General Counsel that we should not take this step and that it is something that the scientific community and Congress need to discuss along with the business community that is involved.