Dr. GODDARD. The difference there would be that there would be a body of established literature after 17 years that would permit the truncating of the New Drug Application. The individual firm then involved could submit a shortened NDA, a short form NDA, in essence, citing the world's literature with respect to clinical safety of the drug and so on. It would still have to submit, however, the manufacturing procedure, the quality controls, the labeling that is to be used and in some instances, even some clinical studies showing that the drug manufactured by that process would produce the effect that to be claimed. This is particularly true in the antibiotics field.

Senator NELSON. Did I understand you correctly that once the patent expires, Food and Drug does not require any manufacturer of the drug on which the patent has expired, to repeat through all the clinical testing.

Dr. GODDARD. Not all of it, no. As I say, some of the information to support an NDA that the manufacturer sends in can be drawn from the existing world literature. But there is still some duplication, Senator, make no mistake about this. Some of the toxicity studies would have to be repeated on animals and some of the clinical studies may have to be repeated—not in every instance, though.

Senator NELSON. Is there any reason for requiring any extensive testing of prednisone which has been on the market for 17 years and is being produced by 50 companies? Along comes a company which wants to produce the drug and if they meet the requirements of USP, is there any reason why they should go any further?

Dr. GODDARD. We think there is a reason they should submit a New Drug Application in order that we may control the labeling, the advertising that surrounds the drug, have knowledge of the manufacturing process that is going to be employed. We feel that the drug should come in under the NDA procedure.

Now, the part that Congress itself has never discussed, Senator, is whether or not this information that we hold in our files should be made public and thus avoid duplication of scientific effort and repetition of certain kinds of experiments. And it is not only for the drug that is now coming out of the patent protection status after 17 years. This holds true for those drugs that are not patented and thus could be marketed by additional firms at any time. In other words, those in which 17-year exclusivity is not involved.

Now, in most of those instances, the complete work has to be duplicated. All the clinical trials, additional subjects studied, all the preclinical animal data has to be duplicated. I think this is a question that Congress must examine, however, with respect to the policy of FDA. In the 1962 amendments, the language, the legislative history, shows no consideration of this at any time.

Senator NELSON. But there is no statute that sets out this requirement——

Dr. GODDARD. No, sir.

I think that with regard to a policy that has been in effect as long as this one has by the Food and Drug Administration, I would, as an administrator, be guilty of overturning what amounts to——

Senator NELSON. A bad rule.

Dr. GODDARD. I do not mind overturning a bad rule. But this is something that I think the Congress itself has to study. This is an established policy, it is an accepted policy. I think it needs debate and