Mr. GORDON. Dr. Goddard, I have no further questions, but Senator Hatfield would like to have some of his questions answered for the record. I shall submit them to you.

Dr. GODDARD. Be happy to do so.

Mr. GORDON. Fine. I think that will be all.

Dr. GODDARD. Thank you.

Mr. GORDON. Thank you very much.

(The information referred to, subsequently received, follows:)

RESPONSE BY FDA TO SENATOR HATFIELD'S QUESTIONS

1. Dr. Goddard, we have heard a great deal about generic and therapeutic equivalency. I notice when you appeared before a subcommittee of the House Interstate and Foreign Commerce Committee some months ago that you agreed that comparing generic and brand name drugs was like comparing a Model-T Ford to a Cadillac. Is this still your view?

Dr. Goddard never stated agreement to this comparison. Prior to a question from Congressman Nelson, the Congressman himself made the above mentioned comparison. Dr. Goddard noted his agreement with the Congressman's question, which followed the earlier comparison statement.

So that there will be no misunderstanding, the text of this exchange, found on pp. 230–31, "Agency Hearings" before the Committee on Interstate and Foreign Commerce, House of Representatives, March 1, 1967, is as follows:

> Mr. NELSON. It has come to my attention that, for example, to compare drugs by generic name would be like comparing a model T to a Cadillac and that the effectiveness of drugs with similar generic names may not be exactly the same.
>
> Then when you get into the prescription of a drug, is it true or is it not true that there may be a variation as to the effectiveness of drugs of the same generic name ignoring the trade or brand name?
>
> Dr. GODDARD. Yes; this is unfortunately true. I say unfortunately, because it means we are not performing our functions as well as we have to. We view our goal as being one where the physician can prescribe any drug that is in the marketplace on any basis he wishes, using brand names or generic names, and be assured that those drugs are all effective and they are all safe. Now, this is not the case today; there is this variation. The Defense Supply Agency in its procurement program for drugs has clearly demonstrated differences between different manufactures' drug brands and we have also seen some of this.
>
> So we do have a considerable task to undertake and this is one of the reasons, of course that we are trying to set up the National Drug Testing Center. Of course, other methods as well must be used, but it is clear that the differences do exist with as many drugs as we have in the marketplace.

2. Legislation is pending in the Senate which would limit the present ability of a doctor to prescribe drugs to beneficiaries under the Social Security Act. As a physician, do you believe such limitations are proper? Should they be accomplished by Government fiat?

We have reviewed the legislation referred to and support in principal the objectives of paying drug costs under medicare. However, the subject is filled with tremendous complexities, and is presently being reviewed in depth by the Secretary of HEW's Task Force on Prescription Drugs of which I am a member. I have seen many hospital formularies which are adequate and accepted by the physicians practicing within the limits of that formulary system. We shall have to defer consideration of such measures until the entire subject has been adequately studied and a report submitted by the Task Force.

3. If two drugs meet U.S.P. or N.F. standards, are they therapeutically equivalent?

See pages 1325–6 of the transcript; page 9 of Dr. Goddard's prepared Statement.

4. In June, Senator Sparkman of this Committee introduced into the record of this hearing some material which cast serious doubt on the validity of the so-called "drug potency study" conducted by the Food and Drug Administration in 1966.

> a. Were the analyses of drugs conducted in your central laboratory or in the field? Are you equipped with technical personnel and facilities in your field offices to conduct intricate tests of this type?