firm might be in business for two years before it had any contact with the FDA?

Mr. GOODRICH. Possibly. We do have internal instructions on how to deal with a newly registered firm which bring the inspection as soon as the district can handle it, but it does not assure that there will be an inspection before the company makes its first batch of pills or before it makes its first interstate shipment. We certainly should strive to have that carried out as an internal matter.

Senator NELSON. Would it not be sound law to simply require that nobody can put drugs into the marketplace until there has been an inspection?

Mr. GOODRICH. Yes.

Dr. EDWARDS. That is really what I primarily had reference to. We have to have some control over these products before they actually get into the market, more than we have now.

Mr. GORDON. Do you also envisage registration of each drug? In other words, as it is now, you merely register the plant but do you envisage having each drug registered? Is that what you are aiming at?

Dr. EDWARDS. This again, is what I was referring to. In other words, we register the plants.

Mr. GORDON. That is right.

Dr. EDWARDS. We have to have some inventory, if you will, as to what the plant is doing. The only way we can do that is by having some idea of the particular products that are being manufactured by the plant.

Mr. GORDON. As it is now, you do not know who is manufacturing what, is that it?

Dr. EDWARDS. Well, in some cases we do, in some cases we do not actually.

Mr. GOODRICH. Anything that is an antibiotic or new drug, of course, we know. The products that we may not know about are the products for which there is no requirement that they inform us in advance. Those drugs that were under the basic grandfather clause of the 1938 Act, that is, any drug produced prior to that date did not require new drug clearance, and there are some grandfather provisions in the 1962 Kefauver-Harris amendments.

We are litigating in that area to narrow those exemptions as much as we can, but to answer quite specifically, yes, there are some producers of phenobarbital and thyroid and other products that we do not have a full inventory of and we do not have a full inventory of their labeling or of their medical justification for putting the particular labeling into the marketplace.

There was no requirement for that and we have an after-the-fact enforcement responsibility on those drugs.

Dr. SIMMONS. Mr. Chairman, you asked what control does the FDA have on a new drug. On any New Drug Application that comes in, before that drug can be manufactured we do inspect the plant to make sure that they can turn it out as they claim they will in the New Drug Application.

In addition to that, we have a continuing surveillance mechanism whereby we have a regular inspection system nationwide. We will