Dr. EDWARDS. But the manufacturer does not have to provide us with a list of those products that he is manufacturing.

Senator NELSON. He does not?

Dr. EDWARDS. Does not. That is why, when looking at this from a little longer range, I think that the Food and Drug Administration eventually will have to have at least the opportunity to certify all drugs. That does not mean that we, in fact, would want to certify every drug through a certification program, but rather to selectively certify, and I think that some kind of a registration program is certainly necessary.

Senator NELSON. Well, in effect, you have that authority now, do you not? That is to say, you go into the marketplace or go into the factory and select a sampling of drugs and have them assayed to see whether they meet USP standards. If they do not, you have the authority to say you cannot put them on the market or if they are already there, you must take them off.

Dr. EDWARDS. We certainly do.

Mr. GOODRICH. We have the authority as you say, to go there and obtain samples and analyze the samples. If the product is not under new drug or antibiotic control it can be distributed and if we find it in violation, we have the legal mechanisms to take it off the market. But there is an opportunity, if we had the resources, to expand our inspection authority which would concentrate on these points of drug manufacture where the importance of the performance to the patient is the highest and the likelihood of failure of the drug is the highest, something comparable to the certification, without having that express authority.

Yes, we do have that ability if we had the personnel and the funds to carry it out. We have recently had an episode with digoxin, which Dr. Edwards will discuss, in which we found it necessary to examine the products of all manufacturers to bring them all into compliance.

Senator NELSON. I was just trying to get it clear, Doctor, what you were saying about this.

Dr. EDWARDS. I really was not referring so much to certification per se as the registration process as such. I think that while we have to inspect them once every 2 years, we have very little to say in terms of what they are manufacturing.

Mr. GOODRICH. And the other point he had in mind there was that with certification the burden is on the company itself to make an analysis, submit that analysis plus the sample to us.

Now, with our existing mechanisms we would have to go in and obtain the sample, make our own analysis, and, of course, we could check the analysis that the company made under its Good Manufacturing Practices requirements. But certification has advantages in that the company must submit batch by batch the product to us rather than our sending inspectors out to obtain the sample, and they would be under an embargo from shipping the drug until they got back the results of our certificate.

Those are points of difference.

Senator NELSON. Is it correct that under present law a firm could go into the business of manufacturing drugs, and if they were an old established drug, could put them into the marketplace and the