Mr. GORDON. How about intrastate manufacturers? Aren't there intrastate manufacturers?

Mr. STETLER. There are literally thousands.

Mr. GORDON. They do not come under the FDA regulations, do they?

Mr. STETLER. As for FDA controls, the answer is no. If they go across State lines, yes, but if they strictly manufacture and do an intrastate business, the answer is no.

I would like to go back just to the one concept, and that is I think personally, before we can get to the point where we can approach this problem differently, instead of looking every day at every manufacturer, how he does his job, we are going to have to establish some credentials and qualifications for being in the business of drug manufacturing, and to check that from time to time to make sure that they are still able to do the job.

Now, concomitant with that, I think the Government should stay away, at least on a day-to-day basis, from policing that qualified company, and let him assume, as he should, some of the responsibility for doing a good job. But if we start off with people that have had to comply with certain basic criteria to be in the business, then I think we have come a lot closer to ending up with products that deserve to be on the market.

Now, that is a personal view.

Mr. GROSSMAN. You do force the small businessman out.

Mr. STETLER. No necessarily. But, I do not want a small businessman or a big businessman making pills for me if he is not qualified for the job.

Mr. GROSSMAN. You see, the problem in a broad view from my point of view is that if we want to know about airports—I am talking about the committees of the Senate or the Congress—we usually get the Department of Transportation up here and they talk about it. If we want to know about something in another field, we usually get an executive agency to talk about it, and they tell us what they think.

Now, we call on the FDA, and they come up here and say there is therapeutic equivalency.

Mr. STETLER. Actually Dr. Goddard has not really said that. What he said is, "We cannot today say there is therapeutic equivalency. We hope soon to be able to say that with assurance, I have an idea there is and I am trying to validate it." I do not think if you were to ask him that question specifically that he would say, "We, the FDA, say there is therapeutic equivalency in drug products."

Mr. GROSSMAN. And this is the designated agency to oversee this job?

Mr. STETLER. Yes. Now, I do not want to say I am critical of them. I think that is an impossible job given today's circumstances for the FDA or anyone else.

Mr. GROSSMAN. Thank you.

Mr. GORDON. And yet according to the Sainsbury Committee recommendations, England might be getting a similar type of organization.

Mr. STETLER. That is right. But you have to look at what they have now, and what their problems are, and contrast it with what we have and what our problems are.