such that if a firm follows these, it can reasonably be expected that they will produce an up to potency product batch after batch. This is what we aimed to achieve. We try to capture the best available techniques in drug manufacturing into these current good manufacturing practices.

Senator NELSON. I note that a number of producers—21 firms—are giving up the business because they could not comply. Is most of the production for most of the drugs in most of their dosage forms fairly mechanized and automated at this stage?

Dr. SIMMONS. By and large, yes.

Mr. GOODRICH. That is quite variable in terms of different methods. The regulations do permit the use of highly automated equipment, highly automated testing procedures, but they are not designed to require that degree of technology if drugs of adequate quality can be produced through other systems.

The Good Manufacturing Practices regulations deal with the nitty-gritty of good production, that is, a proper building, proper equipment, proper cleaning of the equipment, proper controls of the raw materials going into the mixing batch, proper control over the labeling, regulation of the type of personnel, and so forth. They are designed to be compliable by the small manufacturer as well as the large but there are certain minimum things that must be observed by all manufacturers to assure drug quality.

Now, the 21 firms that have not been able to comply either have not had the willingness or the finances to meet these minimum requirements and the public can accept nothing less.

Senator NELSON. Are there any requirements that must be met by a manufacturer of a drug prior to marketing his drug?

Mr. GOODRICH. Oh, yes.

Senator NELSON. What are they?

Mr. GOODRICH. Of course, if it is a new drug, then he has to make a commitment at the going-in stage of production that he will observe a protocol of manufacturing control that will assure reliability. If it is an antibiotic drug he must submit each batch to us for batch certification. If he is dealing with drugs that are not new drugs, that is, the old products, he must for all drugs meet the conditions of current good manufacturing practice and if he does not, the drug is adulterated and can be taken off the market, he can be enjoined or prosecuted.

So the good manufacturing practices are the basic rules that apply to every drug manufacturer, large or small.

Senator NELSON. But when somebody decides to go into the business of manufacturing drugs, at what stage do you become acquainted with this?

Mr. GOODRICH. He must register with us before he starts. We have to react with an inspection as soon as possible to make sure that he does have the knowledge of what it is all about and he is inspected against the standards of current good manufacturing practices.

The law requires one inspection at least every 2 years, which is far too infrequent, but we are putting the resources into this as we have been to improve on the performance. The Intensified Drug Inspection program is one that concentrates at points where we think the risks of violation are the highest.