

Mr. GORDON. Are you saying that all drugs should be batch tested or no drugs should be batch tested? I am not sure I understand exactly what you mean.

Dr. MILLER. The USP position is that no drugs need to be batch tested. It is a very expensive way. At one time I calculated, as close as we can get the figures, that it costs about 30 times as much to administer the control testing of the antibiotics as it does for the other drugs, many of which are just as important to public health as the antibiotics.

Mr. GORDON. Does the USP have any means of knowing that its standards are being adhered to? How can we insure that all products conform to the USP standards except through batch testing or some other way?

Dr. MILLER. Well, you certainly have the reports of the Food and Drug Administration, of their results of applying the USP tests to drugs in interstate commerce. It is their job to see that they do measure up to the USP standards.

Mr. GORDON. How do they do that?

Dr. MILLER. They do it by spot testing.

Mr. GORDON. By spot testing?

Dr. MILLER. Yes, spot testing is the process of collecting samples on the open market and testing them for compliance with label claims. They do it to a very large extent by factory inspection. They have the option of going in to any factory in the country, and asking to see the results of the tests that have been applied. Now, that can be done without requiring that once having completed those tests in the factory, any place in the country, a sample be sent to Washington, the testing be done all over again, at the manufacturer's expense, which means in turn at the public's expense, because certainly the manufacturer is going to have to get that money back in the price of the drug. In other words, it is retesting to an extent that we feel is considerably unnecessary.

I am just as much in favor as anybody could be of ensuring that every drug on every pharmacist's shelf in this country shall be just exactly as potent as it is supposed to be, but there are ways to do it that do not include batch certification.

Senator NELSON. I am not informed as to how much testing of drugs is done. Are all drugs that go on the market at some period or another inspected by some independent agency or the Government? In other words, some company is in the business of manufacturing a particular drug, and the FDA has the authority to spot check. Now, if this compound is being manufactured by a company that is on the market year after year, how do we know that it complies with the USP standards, for example?

Dr. MILLER. Well, in the first place the manufacturer has the responsibility in introducing a drug in interstate commerce, assuming he is going to do that, to see that he meets the published standards, if such there be. He doesn't need to test to do that. He can risk his reputation, risk being thrown into jail literally, if he is willing to take the chance, in not carrying out tests before he ships the drug, or at any time. Very few manufacturers are willing to take that risk. I know of none.

Senator NELSON. Are you saying that each batch of drugs by any manufacturing firm is batch tested?