

Dr. MILLER. Oh, yes.

Senator NELSON. By the firm?

Dr. MILLER. Absolutely, tested all along the line. The raw materials are tested when they come to the door of the plant before they are used, and the components as they are manufactured are tested at various stages, and then if the product is USP the USP tests are generally applied in the finished form, and all of that testing is done in the course of manufacturing.

Now, it may not be. If a man is willing to cut corners for various reasons, he can get along without testing to a remarkable degree, but he will be risking putting out an inferior product.

Senator NELSON. The law does not require, then, that the manufacturer test each batch of drug?

Dr. MILLER. No.

Senator NELSON. But the law does require that it meet the USP standards?

Dr. MILLER. Yes.

Senator NELSON. If it is in the Pharmacopeia?

Dr. MILLER. Yes.

Senator NELSON. Is that correct?

Dr. MILLER. Yes.

Senator NELSON. Then how do we know that they do reach the standards, if there is not inspection of each batch by the manufacturer or by somebody else? How can the public be sure that a drug of improper potency is not being put on the market?

Dr. MILLER. By seeing that the Food and Drug Administration has the facilities for testing as often as it feels it is necessary and where it feels it is necessary, where the risk is greatest of the products that are offered for sale. Now, the expansion of the FDA testing that will be possible by the setting up of this new central testing laboratory in St. Louis will go a long way towards achieving this purpose. They will be increasing, if I have the figures correct, the amount of testing by about 10 times that which has been done in the past, and that will accomplish much in giving the public a chance to be perfectly confident that the drugs that are offered are right up to standard.

Senator NELSON. I don't know how important this really was, but in any event, you recall the publicity a few weeks or months back of the test of some 4,600 drugs by FDA?

Dr. MILLER. Yes.

Senator NELSON. And on that what they said was that 7-plus-percent of the generics were subpotent or maybe excessively potent and 8-plus-percent of the trade name drugs, so they were pretty close together. Are those significant percentages, and how do they get onto the market if they were subpotent or too potent, if the controls by the generic manufacturers and trade name manufacturers were adequate?

Dr. MILLER. Well, I would suggest that you get Commissioner Goddard here to discuss that, but the facts are coming out with respect to these 4,600 or 4,800 analyses, and there have been some reports which this committee may want to look into, that the work was done by summer help—but it couldn't have been summer help because the work was done from March 1 until about June 1 last year—to give the Commissioner an idea of just what the market situation was.