It was a crash program. We have seen data made available by some of the manufacturers involved which contradict, refute completely, the data on these very same lots that are supposed to have been found in violation. So the least we can say is that the subject is quite controversial at the present time, but I think it will be safe to predict that there will not be much difference between the two general groups of the manufacturers that you just mentioned, those that sell under brand names and those that sell under nonproprietary names. But I think all the facts are not in yet as to the result of this comparison. But there is a lot of difference between a substantive violation, that is one in which the potency was down far enough to be a worrisome thing, and a violation just beyond the line. Now, that too will have to be looked at. Where the USP lower limit was 95 percent and a product was found to be 94½ percent that technically would become a statistic on the violation side. Surely it is something that no one wants. But a product that is 94¼ percent is certainly not in as much violation as one that is 75 percent, and how many were down in that 75-percent range has not yet been revealed. In fact, the data themselves have not been reported with very satisfactory completeness.

Mr. GORDON. Dr. Miller, the Food and Drug Administration has supplied us with information to the effect that there are about 1,300 drug recalls in the past couple of years.

Dr. MILLER. Yes.

Mr. GORDON. Some of which caused death and serious injury. How can we insure that that does not happen?

Dr. MILLER. I wish I knew, because I am just as deeply concerned over an injury or a death by a subpotent drug as anyone can be.

Mr. GORDON. Don't you think batch testing could help?

Dr. MILLER. No. You will find that there have been just about as many recalls among batch-tested drugs in proportion to the number that are on the market as there were of those that were not batch tested. No, batch testing is not the whole answer.

Mr. GORDON. Is it a partial answer?

Dr. MILLER. It is a partial answer.

Mr. GORDON. A partial answer.

Dr. MILLER. If the American public is willing to pay the price that will have to be charged for testing every drug twice, every batch of drugs twice, then that is the way we perhaps should go about it. We don't think it is necessary.

Mr. GORDON. One more point. As I understand it, in this batch testing it is the FDA who sets the standards, is that correct?

Dr. MILLER. Yes, that is the thing of course that annoys the USP, because it took the authority away from us. It is just a matter of professional pride, but we think with almost 150 years of experience, we have a background of setting up standards that should not have been disregarded.

Mr. GORDON. Are the FDA standards lower, higher, or just about the same as the USP standards?

Dr. MILLER. Actually I think they were lower in many cases. The FDA was willing to settle for 85-percent penicillin, and our committee men never wanted to see less than 90, and yet the 85-percent figure prevailed.

Senator NELSON. You still list the antibiotics?