tolerances allowed were a range of 90 to 110 percent of the stated label potency.

Now, this was not presented as being a statistically significant survey. That has been talked about a great deal, and I think the facts still speak for themselves. There were 245 manufacturers represented in these 4,573 samples examined. Three hundred and seventy-one of those samples, or 8.1 percent, were classified as being outside the potency limits defined as I have mentioned.

We did make available the detailed findings, both to the public and to the industry, after repeated requests from the drug industry. Thirty-eight of the manufacturers to date have requested additional information concerning the code and batch number, method of analysis, and quantitative finding. Now, upon receipt of this information, some of these manufacturers examined portions of the same code or batch and in one instance, the manufacturer said "Yes, you were right, we confirmed your findings."

In 16 instances, the manufacturer reported different results within the acceptable potency range.

In six samples involving five firms, after the review of the original data, we did concede that we had made an error.

Now, in three of these six samples involving two firms, the NDA potency limits were incorrectly tabulated. In the other three samples, the examining laboratory had not followed the prescribed methodology and the letter acknowledging the effort were sent to five firms: Geigy, Norwich, Parke-Davis, Lederle, and Searle.

Now, the other original findings, I still say, are correct. We stand behind those as long as it is understood that this is not a representative sample of the market place. The compliance action——

Senator NELSON. It was a random sample, so to speak?

Dr. GODDARD. No, it was not random. The compliance actions resulting from this survey were six seizures, 15 citations, 41 product recalls, 11 products discontinued, two prosecutions filed, two injunctions granted, and four voluntary destructions.

Now, I do not know what else we can say about this survey.

Mr. GORDON. I do not think you have to say anything else.

Senator NELSON. I am happy to have that in the record.

Dr. GODDARD. Later, the reports from the National Center, combined with those from our 17 district laboratories, will give a good picture of manufacturing and quality control of drugs throughout the Nation.

One indicator we now have is our weekly recall list, a list of those products recalled from the market, either voluntarily by the manufacturer or distributor or at the request of the FDA, during each 7-day period.

Drug recalls have risen over the past year. During fiscal 1966, out of 538 recalls of all foods, drugs, cosmetics, devices, and hazardous substances, there were 446 drug recalls. Out of 900 total recalls in fiscal 1967, there were 651 drug recalls, an increase of 45 percent for drug recalls. Some of the factors to consider in evaluating this rise in recalls are the following:

An increased ability—through better programing—of our agency to sample the drug supply and turn up defective products.

An increase in hospital, clinic, physician, and patient reporting leading to product investigation by either the manufacturer or our agency.