compendia and non-official drugs by procedures from the NDA. The assignment directed that regulatory action be instituted as usual where violations were encountered.

Samples were classified at headquarters as being outside potency limits if the results were beyond: Official compendia limits, NDA specifications, and (for other drugs) 90–110% of label declaration.

A total of 245 manufacturers were represented in the 4,573 samples examined. The Districts originally estimated 261 primary manufacturers of drugs in the 20 categories.

A total of 371 samples, or 8.1%, were classified as outside the potency limits defined above.

The detailed findings were made public, after the general findings were announced, on repeated requests from the drug industry.

As expected, a number of the manufacturers (38 to date) requested additional information concerning code and batch numbers, methods of analysis, and quantitative findings. On receipt of this information, some of the manufacturers examined portions of the same code or batch. In one instance, the manufacturer told us FDA findings were confirmed. In 16 instances the manufacturer reported different results within the acceptable potency range. In 6 samples involving 5 firms after review of the original data, FDA concluded that the original findings were in error. In three samples involving two firms the NDA potency limits were incorrectly tabulated. In the remaining 3 samples the examining laboratory had not followed the prescribed methodology. In such cases, a letter acknowledging the error was sent to the firm. These were:

Hygroton Tablets—Geigy Pharmaceuticals, Ardsley, New York
Furadantin Sodium Sterile-Norwich Pharmacal Company, Eaton Laboratories Division, Norwich, New York
Thyroid Tablets—Parke, Davis & Company, Detroit, Michigan
Methotrexate—Lederle Laboratories, Pearl River, New York
Aristomin Capsules—
Dartal Tablets—G. D. Searle & Company, Chicago, Illinois

The gravimetric method used on the sample of Suspension Tydrocortone TBA, manufactured by Merck, Sharp and Dome, West Point, Pennsylvania, was not sufficiently accurate to warrant the conclusion that the product did not meet potency limits. In other instances, it has not been concluded that the original findings were incorrect.

The following compliance actions resulted from this survey:

6 seizures
15 citations
41 product recalls
11 products discontinued
2 prosecutions filed
2 injunctions granted
4 voluntary destructions

Dr. GODDARD. In summary, this program was carried out between March 24, 1966, and the end of May 1966, when some 4,600 samples were drawn from manufacturers' available stocks. The repackagers and distributors were not included in this survey.

Senator NELSON. Just manufacturers' stock, not products already on the retail market and——

Dr. GODDARD. Those are the instructions that were issued. To my knowledge, that is the procedure that was followed.

Now, we wanted to get at least one sample of each dosage form in 20 listed categories from each of the primary manufacturers. Now, these 20 categories include drugs that commonly used such as digitalis and cardiac glycosides, corticosteroids, diuretics, nitrites, and so forth. The districts were given discretion to collect more than one sample from manufacturers, where they had a substantial production of a given drug or where there was a questionable compliance background.

Now, the procedures that were to be followed were the USP, NF, or NDA procedures and in the absence of a USP or NF standard the