The analysis was carried out in both the district labs and Washington headquarters lab. All these labs are equipped and staffed to handle very sophisticated scientific analyses.

b. You have stated during the past few months that you have some doubts or question about the sampling technique used in this survey, or the way in which the study was conducted. Would you please explain.

You would not want to project the results of this test to the nation's entire drug supply?

Yet on at least one occasion you did say that the study showed that "one out of every 14 products in our nation's drug supply was violative on the basis of potency alone." I gather you would not make that statement today based on the 1966 test.

See the prepared statement submitted for the record "Market and Manufacturers Survey-Potent Drugs—1966" and Dr. Goddard's summary of same, pages 1321 and following of the transcript.

c. It has been stated that some companies have complained about the results of the tests and that on re-testing you have found errors. How many times has this occurred? Have you notified the companies? Have you corrected the results of the study and republished the new figures?

See prepared statement submitted for the record, "Market and Manufacturers Survey-Potent Drugs—1966," and Dr. Goddard's summary of the statement, pages 1321 and following of the transcript.

d. I understand that the samples used in the survey have been destroyed by FDA. Isn't this unusual, particularly when serious questions were being raised by the industry re the results?

The samples were retained or destroyed in accord with standard procedures used by FDA. Samples on which no legal actions are recommended are routinely destroyed usually 30 days after analysis.

e. I am told that the companies keep identical samples and that the tests could be reconstructed. Would FDA be willing to work with company scientists in this effort? Would you permit an independent laboratory to do the testing?

Some companies collect duplicate samples at the time of FDA's collection. Some companies retain a portion of one batch as "reserve" samples. There are variations within batches of drugs and variations can be caused by conditions under which samples are stored and handled after leaving the manufacturer. We do not believe the tests can be reconstructed in those instances where the FDA sample was disposed of. We have discussed the analyses of the survey samples with company scientists on several occasions. We do not believe there are any benefits to be obtained through an independent laboratory analysis.

f. It seems to me you would want the tests validated, or the results set aside, if the survey is questionable or was improperly conducted, as you have stated (inferred).

As it is now, the study is continually being referred to as proof that there is no difference in drugs regardless of the identification of the manufacturer or their source. This, in my opinion, should not be permitted to continue. Dr. Goddard states on page 1322 of the transcript: "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 marketplace."

(Whereupon, at 3:10 p.m., the hearing was concluded.)

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