

What can you tell us about the quality of testing to establish efficacy of antiobesity drugs, and would you say in retrospect, that they met the standards envisaged by the law?

Dr. SCOVILLE. The ones that were used in the review, in the opinion of those that had the studies computerized, did meet the standards of the law.

I cannot give you details about individual investigators. I think we would have to go through case by case, if there were some suspicious things that anybody wished to bring up.

I would have to say that in the general approach, the FDA reviews the documents, and anything suspicious is looked at more carefully.

Occasionally field investigations are carried out.

Mr. GORDON. Here is a letter signed by Dr. Jennings dated February 19, 1970, that the drug Voranil was not approvable. He stated that "Bias has been introduced into the statistical analyses by deleting data from certain investigations in such a manner as to exclude unfavorable findings."

Can you recall how often you found this kind of tactic?

Dr. SCOVILLE. I do not recall.

May I ask the date of that?

Mr. GORDON. February 19, 1970.

Dr. SCOVILLE. The general approach when bias is detected is to inform the manufacturer of it, and a common response to such a statement is for the data to be resubmitted in a format determined by the FDA in a way in which the FDA tries to lay it all out so as to eliminate a potential for bias.

It is to eliminate potential for bias that we went over every patient report form.

Mr. GORDON. Did you find this is a common thing, this type of withholding of essential information, or using statistics in such a way that you get a favorable finding?

Dr. SCOVILLE. It is hard to be sure of motives.

In the case of inadequacy of statistical analysis, it is usually due to inferior motives or inferior abilities, and it is difficult to tell which.

Mr. GORDON. That is all.

Senator NELSON. Thank you very much, Dr. Scoville. We appreciate your taking the time to come and present your testimony this morning.

Dr. SCOVILLE. Thank you very much.

Senator NELSON. Our next witness is Dr. Eugene Jolly, president, Biometric Testing, Inc., Englewood, N.J.

Dr. Jolly, we appreciate your taking the time to appear here this morning.

Your testimony will be printed in full in the record.

You may present it however you desire.

**STATEMENT OF EUGENE R. JOLLY, M.D., PH. D., PRESIDENT,
BIOMETRIC TESTING, INC., ENGLEWOOD CLIFFS, N.J.**

Dr. JOLLY. Thank you, Senator.

Senator Nelson, Mr. Gordon, it is a privilege to be here with you today to provide a summary of my findings resulting from clinical investigations of amphetamines and related drugs used as adjuncts in