You have not made any final decision on what you might do about requesting examination of books and so forth?

Mr. STAATS. That is correct.

Senator NELSON. All right. We will hear from you at a later date on that; is that right?

Mr. STAATS. We will be very happy to keep in touch with you on it, as we have, I hope. And we are glad to know any thoughts that you have. But there are many factors, as I say, which have to go into this decision and we are considering them.

Senator NELSON. Well, at some later date, when you have decided one way or the other, we will have a hearing on it and you can advise us what judgments you made and why.

Perhaps the people investigating for you are very knowledgeable about this whole field of pricing structures and bidding and so forth, and maybe they are not. If they are not, I think it would be worthwhile for them to get informed sufficiently so that they can get at the question I have been raising. If we are purchasing drugs for use by the Veterans' Administration, the Department of Defense, and other Government agencies for use in this country, and the companies or the Government are insisting upon standards higher than USP or NF, then I would be very suspicious of them. And No. 2, they really ought to have to justify them so that we are not in the position of being forced to buy on a noncompetitive basis.

Mr. STAATS. I believe we are in full agreement on this part.

Senator NELSON. If you would pursue that question, then at a later date, we would have further hearings.

Has the GAO completed its study of the Food and Drug Administration?

Mr. STAATS. Have we completed our study of the Food and Drug?

Senator NELSON. Yes.

Mr. STAATS. We have several studies on the Food and Drug Administration. I do not know which one you have reference to.

Mr. CROWTHER. We just recently completed one on sanitary conditions in food manufacturing plants. We have several others underway. We have one, for example, dealing with the legal constraints that FDA is under for performing their efforts, and several others.

Senator NELSON. I have not seen your studies. I understand that the GAO has found out that the FDA has, in a period of 3 years, been refused data of various kinds from drug manufacturers 10,000 times, which included such requests as refusal to allow the FDA entry into a plant; refusal to supply formula data respecting a drug; refusal to show production control records; shipping records; refusal to show complaint files.[1]

Is that correct?

Mr. CROWTHER. Yes, sir; that is correct. That particular review has not been completed. It is still underway, but the figure that you quoted is the number that we have obtained. There have been more than 10,000 refusals for FDA access to various things needed for FDA to exercise its authority and the items range from refusal of entry to refusal of access to formulation data, and refusal of other related requests for specific data.

[1] See Appendix V, p. 9067.