Mr. GORDON. Dr. Berliner, is it not true that what we are really interested in is therapeutic equivalence, and the differences in bioequivalance that are not reflected in therapeutic equivalence are not significant?

Dr. BERLINER. That is quite true.

Mr. GORDON. I am really summarizing some of the points you presented in your prepared statement.

Is it not also true that for most drugs differences in bioavailability, even substantial differences, have no therapeutic or clinical effect?

Dr. BERLINER. That is also true.

Mr. GORDON. You stated that this group of drugs constitutes 85 to 95 percent of the drugs on the market.

Is that correct?

Dr. BERLINER. Well, I guess we did say that. I am sorry that we did because it was a figure that was sort of plucked out of the air by the members of our panel who were sort of forced to answer the question. We do not really know what the number is but it is a large fraction of the total.

Mr. GORDON. It is the vast majority of drugs.

Is that correct?

Dr. BERLINER. That is our impression, sir.

Mr. GORDON. If I understand your testimony correctly, these drugs do not need a demonstration of bioavailability.

Dr. BERLINER. I would agree to that, yes.

Mr. GORDON. You say that the classes of drugs for which demonstration of bioavailability will be necessary constitute a small minority of all drugs.

Dr. BERLINER. Correct.

Mr. GORDON. You stated on page 2 that "in a very few instances differences in bioavailability have led to well documented therapeutic failures."

How many such cases have actually been documented?

Dr. BERLINER. Well, there are differences of opinion. We heard Dr. Schmidt answer that he thought there were more than the two that we referred to. Those were the only two clearly documented ones we could find in the literature.

However, as I said in my statement and as I would like to emphasize, I do not think that means that they are all that rare. It takes a very careful study to demonstrate this, a carefully controlled study, so that all of the other factors which influence the response to drugs are controlled at the same time, and then you can detect the difference between two products. And if you do not do it in that way, you are just going to be guessing as to whether it is the drug that caused the problem or the patient.

So I think that in those classes of drugs for which we have said bioequivalence studies ought to be required, there would be a large number in which careful studies would reveal real therapeutic inequivalence.

Mr. GORDON. But as far as you know, there are only two documented cases?

Dr. BERLINER. Those are the only two that I could cite as clear examples.