Thank you for your attention. I will be happy to try to answer your questions.

The CHAIRMAN. Well, on the question of bioequivalence, until such time as a careful study and evaluation by some appropriate standard is established, then no one can assert that the blood level achievement of one-half dozen of the same compounds is any different than the other one, can they?

Dr. BERLINER. Not unless somebody has studied it, sir. Unless someone has examined the question directly, there is no way of predicting in advance.

The CHAIRMAN. So if the drugs are in the marketplace and as of any particular day an average of 22 compounds, an average fo 22 drugs made of the same compound in the marketplace, and no study has been made, there is no justification for an assertion that a particular brand or generic name drug that achieves a certain level is better than any one of the 21 others that achieve any different levels; is there?

Dr. BERLINER. Well, that is not necessarily entirely true because the original drug product, the one for which the New Drug Application was obtained, has been required to demonstrate therapeutic efficacy, and this is not a requirement for the additional products that come on the market.

Now I do not mean to imply that there are necessarily going to be such differences, or if there are such differences, that they are going to be of therapeutic significance. But it is true that the first drug marketed in a particular class is the one for which the efficacy and toxicity data have been required by the Food and Drug Administration and they do not require similar information for most drugs introduced when the patent runs out or whatever the situation may be.

The CHAIRMAN. Well, nevertheless, the company that puts a drug into the marketplace and that drug achieved certain blood level in a certain time schedule, it may very well be that another company puts one into the marketplace that achieves a different blood level on a different schedule over a different time period, and a carefully controlled test might show that that one is better than the one that was first in the marketplace; might it not?

Dr. BERLINER. That is correct sir. That has happened.

The CHAIRMAN. As I understand your report, your own opinion is that when additional drugs are to be admitted to the marketplace, that the original developer of the drug should be required to disclose publicly the blood level achieved by its drug. Is that correct?

Dr. BERLINER. We recommended that manufacturers be required to make available for those people who are setting standards, information the manufacturers may have in their files that relate to drug product composition: information about those factors which they have explored and which they have found to relate to bioavailability.

The CHAIRMAN. I regret there is another roll call and I have to go to the Senate floor. I have three or four questions which Mr. Gordon will ask, if you do not mind responding to his reading of my questions.

Dr. BERLINER. Not at all, sir.

The CHAIRMAN. Thank you very much. I am sorry about these interruptions.

Dr. BERLINER. That is quite all right.