

earlier, do not reflect differences in therapeutic equivalence, and therefore, are not relevant to what we are really interested in. It is therapeutic equivalence and not bioequivalence.

As for the statement from Abbott, I am interested in how you got it. But nevertheless, it is nice to know that that apparently solid phalanx of the drug manufacturers is not quite as solid as it appears.

I think it is true that the drug manufacturers have tried to use the bioequivalence problem to suit their own ends, and sometimes their ends are internal as well as external, that is internal to the industry as well as outside.

I am aware of the studies that were referred to in the Abbott memo. Those are the ones that have been published and made a major issue, I guess it was by Upjohn. And it is true that Upjohn seems to have scheduled their tests in such a way as to make their product look more bioavailable than somebody else's, I presume Abbott's in particular; otherwise Abbott would not have been excited about it.

It is also true that they have gone around and collected data from the literature and come up with a long list of drugs for which differences in bioavailability have been shown. It is an interesting thing that the rigor with which that list has been assembled resulted in the same drug being listed under two different names as two different drugs. So as I say, the drug companies have used this to suit their ends and often this goes beyond what is, I think, scientifically a valid point.

Mr. GORDON. Dr. Berliner, here is an advertisement of the Pharmaceutical Manufacturers Association which appeared in Time magazine and also in U.S. News & World Report. It deals with and it quotes from the OTA report. I shall pass it up to you and ask you—

Dr. BERLINER. Well, I have seen it. I know what it says.

Mr. GORDON. Would you say it accurately reflects the tenor of the OTA report?

Dr. BERLINER. Well, the one sentence that it quotes is accurately quoted. We followed the usual practice in such reports of putting our conclusions at the beginning, and if one were to stop at the end of the first sentence, as they have—that is the first sentence of our report—we could have saved ourselves a lot of trouble because the rest of the report goes on to put this particular statement in perspective. I believe that statement is to the effect that—

Mr. GORDON. On page 22 of your report, it is stated that in most cases it does not make much difference.

Dr. BERLINER. But that particular sentence, I think, maybe we ought to indicate clearly what it says. You may want to read it because I said it was the first of our 11 conclusions.

Mr. GORDON. Yes.

Dr. BERLINER. And we went into considerable detail to point out that we were not particularly concerned about bioequivalence. What we were interested in was therapeutic equivalence and that differences in bioequivalence were not necessarily reflected in differences in therapeutic equivalence.