Mr. GORDON. Let me say a few words here. Yesterday, Dr. Berliner, the chairman of the OTA panel, as well as the Commissioner of the Food and Drug Administration, admitted that there were only two cases of therapeutic inequivalence that has been documented, and they both admitted that was an excellent record.

Now what do you have to say about that?

Mr. TRYGSTAD. Mr. Gordon, I do not know what he considers documentation, but there are many, many cases reported over the years, perhaps even before we ever heard the word "bioequivalency" in which there were therapeutic failures with inequivalent drug products and the OTA report confirms that.

Mr. GORDON. Yes, they have been reported, and let me give you a case of one of them, of several of them, as a matter of fact, which come from the Abbott files. "The main point that we wish to make," and this is Abbott talking, not a government agency, "is that Upjohn," referring to Upjohn, and I presume it is the same with other companies, too, "is using bioavailability studies for promotional purposes. To do this they are designing their bioavailability studies to be biased in favor of their product and negatively biased toward competitive products. Certainly we feel this is a prostitution of the science of bioavailability and does little credit to scientists who allow such distortion to occur."

Well, there is no sense in my going ahead with this. You know what this is. Would you comment on that? Would you say that any industry bioavailability study is suspect in the light of what Abbott says?

Mr. TRYGSTAD. No; I would not say that any industry study is suspect.

Mr. GORDON. I said bioavailability study.

Mr. TRYGSTAD. Of course not. I do not know anything about Abbott's quarrel with Upjohn over their bioavailability study. Neither do I know which one they are talking about. But bioavailability studies have been made in universities and by other scientists and many of these were recognized by the OTA report. There are other sources of information about this. As a matter of fact, the American Pharmaceutical Association itself has had a very thorough study of the literature done on bioavailability studies, so that this is not something that was simply originated by one company and shot at by another.

Senator ABOUREZK. I want to ask you, Mr. Trygstad, what evidence do you have that what the Secretary said yesterday is not valid. What do you have to counter what he said—I mean specific evidence, not just a statement.

Mr. TRYGSTAD. I do not believe I can be responsible for what the Secretary said, nor can I comment on his entire statement.

Senator ABOUREZK. Well, the one I referred to, that is the one we are talking about. Would you want me to repeat it?

Mr. TRYGSTAD. Yes, please.

Senator ABOUREZK. He said:

Essential to the success of the MAC program is our ability to insure the drug products covered by the program all meet the same high standards of quality.

I would like to take a few moments to discuss programs that the Food and Drug Administration has undertaken and will undertake to provide this assurance.