The CHAIRMAN. Well, I hear what you are saying. The only reason—you recited the OTA report 3 minutes as your authority for a posture. I quote from the OTA report, and now you repudiate your authority. If you want to do that, fine. Let us move onto another authority, but you are repudiating the authority you cited a few moments ago to support your position.

Mr. TRYGSTAD. Mr. Chairman——

The CHAIRMAN. I am puzzled by that, and when you do that in a law court, you usually lose the case.

Mr. TRYGSTAD. I said in reference to this one particular section of the report that you referred to, that it was rather peculiar logic. I also said I would like to refer to several other points in the report which said there must be an improvement in the compendial standards which are now outdated and inadequate. They also said there must be an improvement in GMP's and in the procedures that are looked into in manufacturing. All of these the committee seemed to feel were essential, and I get the impression from this that they were making recommendations that these things be accomplished before we could feel confident about drugs being equivalent.

Mr. GORDON. Dr. Berliner yesterday stated that he sees no reason why MAC cannot go ahead. There is a group of drugs which do not present any problems, and there is no reason why we cannot go ahead. He stated this clearly. Now, are you saying the OTA said something else?

Mr. TRYGSTAD. I am only referring to what is stated in the report. If that was Dr. Berliner's opinion which he gave yesterday, I could not quarrel with his opinion, but the report enumerates the many things that need to be done before you can have complete confidence in the goals that we are attempting to reach.

Mr. GORDON. Well, Secretary Weinberger said these things are being done, and they will be done before the MAC regulations go into effect.

Mr. TRYGSTAD. Well, Mr. Gordon, he said some of these things are being done, and some of them, he said, will be done.

Mr. GORDON. Will be done, but they will be in effect before the MAC regulations. They will be done in the next couple of months.

For example, the bioequivalence regulations will be out in the next couple of months before the MAC regulations go into effect.

Mr. TRYGSTAD. I believe it has been about 2 years now since the FDA started talking about developing bioequivalency standards. We have not seen them yet. Dr. Novitch was called up here to project the accomplishment of some of these recommendations, and I believe he said that bioavailability standards will be "proposed" in about 2 months. That still does not put them into effect in that length of time.

The CHAIRMAN. Well, let me ask you—everyone knows of course that compendial standards can be, shall be, will be revised, upgraded, and they will be better 10 years from now than now and 20 years from now than 10 years from now, and 30 years from now than 20 years from now. However, the drugs are in the marketplace. They are at various prices. They are there under the distinguished brand names of a wide variety of drug companies, and they are there under generic names.