such severe inherent problems that, unless the controversy is indicated, it will be misleading to the public and to the physicians who are responsible for treating this problem.

I mentioned this article in the Globe. Dr. Bradley will tell you how many people have called the Joslin Clinic in the last few days, and have been so upset. I have heard similar statements from other physicians, telling me how many of their patients become upset by the press releases which have occurred. I do not blame the Biometric Society. They said things such as the following—I am reading now from the Biometric Society: "There remains the question whether tolbutamide, although ineffective in a fixed-dose regimen, might be an effective therapy as ordinarily used." That is right in the Biometric Report, Senator. In other words, if they used the drug properly, maybe it would be effective therapy. Very interesting—that is why I say, it is not these reports per se that are causing the problem for the public. It is what people are doing with these reports.

The CHAIRMAN. I think it should be known you are reading excerpts.

The fact of the matter is that the members who did the study agreed with the UGDP study results. The fact is that one of the greatest clinics in the world, the Mayo Clinic, has accepted the report. It is accepted at Grady Memorial Hospital in Atlanta. Those were two of the witnesses.

So sure, there are scientific disputes, but this society which was independently chosen of very distinguished people, have concluded that it was a valid statistical study, but the record is clear on that, anyway.

Mr. CHAYET. The record is not that clear, I would like in closing to summarize my position for the record if I may, Senator.

The CHAIRMAN. Sure.

Mr. CHAYET. I think we need new labeling right away. I would like to dispel any doubts at all that we are standing in the way of new labeling. We need it, and I am sorry we do not have it up to this particular point, and I hope we will have it soon.

I also——

The CHAIRMAN. Excuse me for interrupting. The committee counsel tells me that the FDA is going to testify very soon on the question of labeling. I did not realize it was already scheduled.

Mr. CHAYET. Fine.

But I think we need this labeling very badly, by that I mean labeling that will be fairly balanced and indicate the scientific controversy. This raises the question of what do we do about the controversy. Although I heard what the doctors said before about the difficulty of launching another study like this, I really do not see any way of avoiding it, unfortunately, at the present time, because what we have at the moment does not answer the critical and crucial questions raised. Regardless of an additional study, I think there ought to be balanced labeling so that doctors will use this drug properly and be aware of the controversy while, as quickly as possible, we ought to have additional studies. I would say, Senator, there ought to be at least one study that is as lengthy and as fully