lightly. But that is the way it is; nothing is going to make this study free from controversy. Nothing thus far has settled this controversy, and Dr. Chalmers can write editorials entitled "Settling the UGDP Study" as long as he wants, and it is not going to resolve the issue. I would like to now move on and state exactly what the Committee on the Care of the Diabetic is seeking to accomplish.

First of all, may I state that, when I began this matter I sought to restrict the UGDP findings on the label. I thought the study was so flawed, based on what I had learned from the physicians I represent that it should not appear on the labeling. However, I later filed an amended complaint in the Federal court, because there is the possibility that the study has some merit even though it is flawed. We are not saying that these drugs absolutely do not cause certain problems because we do not know. But the UGDP study did not give us the answer, and pretending it did does not help us at all.

What we are seeking is a label which reflects fair balance, which reflects the fact that there may be a problem with the drugs, which indicates the study results and the controversy surrounding them. There have been many eminent people supporting both sides. The evidence which has been presented clearly points up the existence of conflict and controversy which now must be admitted by all. To fail to indicate such controversy on the label is most inappropriate.

At this point, I would like to discuss the lawsuit, Senator. I believe that the action is unprecedented. It is the first time, to my knowledge, that a group of physicians and patients—and I emphasize that the plaintiffs include patients—in a class action representing all physicians and patients similarly situated—have sued the Government and the manufacturers to prevent the Government from forcing the label change along the biased lines that it sought and the manufacturers from buckling under to FDA pressures, for a variety of reasons, and voluntarily changing the label. It is on the basis of that lawsuit that we secured, in November of 1973, a preliminary injunction halting the Government from ordering the label change and halting the companies from voluntarily altering it. We have not sought to hold up labeling, and I do not understand why it has taken so long for the FDA to move forward with labeling. This case was before the court of appeals on July 31, 1973. Why is it that 18 months later, we still have no revised labeling? One reason may be the unrealistic expectation that the Biometric Study would settle the matter once and for all and then the labeling could proceed.

Well, that has not happened. And the Committee for the Care of the Diabetic will go back to court, and will take every step it has to take, to prevent a onesided, biased label from emerging; and the Biometric Society Study does not alter our resolve. I might add that we have had less than 2 days to review the Biometric Report. Why did we only have 2 days? Why was it not made available to men like Dr. Bradley, and the other members of the Committee on the Care of the Diabetic? I asked the AMA why it was not, and they said they could not allow this because the Biometric Society said not to release it to anyone; anyone except Dr. Chalmers, that is.

Why was the Biometric Society so secretive about this document? I would very much like you to find out, Senator; the answer probably is that NIH insisted on secrecy. The result is that a document is going