At the onset, we wish to state, for the record, the position of the Committee on the Care of the Diabetic with regard to the UGDP study. First it is important to stress what we are not seeking to bring about. We are not asking that the FDA ignore the UGDP findings completely or that these findings not be reflected in the labeling accompanying these drugs. In fact we find it difficult to understand why, some 19 months after this matter was decided by the Court of Appeals for the First Circuit, the FDA has not acted definitively to bring about new labeling. We are seeking new labeling to insure that this study and other relevant studies will be made known to physicians and their patients. However, such labeling must indicate the fact that there is great controversy surrounding this subject and that a material weight of scientific and medical opinion does not accept the results of the UGDP study. In short, what we are seeking is fair balance in the governmental handling of this matter. I realize that nearly eight million dollars is a great deal of money and ten years is a very long time, and criticism of such an effort is neither to be given nor taken lightly; nevertheless, costly mistakes in research, as in all human endeavors, have been made before, and will be made again, and criticism and controversy will not disappear merely because those who seek to justify this study pretend that it either does not exist or is of no account.

We have set out in this testimony some of the fundamental problems confronting analysis of the UGDP as a study and the Biometric Society's report on that study.