I have served on the study section of endocrinology and metabolism, Grants Division, National Institute of Arthritis and Metabolic Diseases, and have served as a contributor and an associate editor of the journal "Diabetes." I think that is probably enough.

My connection with the Committee of the Biometric Society was that of a consultant diabetologist, and I attended most of the meetings. I was struck by the thoroughness with which the members of the committee made their investigation. I detected no bias for or against the UGDP study. The committee listened to more who criticized the study than to those who were less opposed or favorable. The committee did not hesitate to ask the coordinating center in Baltimore for raw data when a point was in doubt, and members made trips to the center and to several participating clinics to check methods, procedures, and results. No uncertainty was too small to leave unresolved.

I should remind you that the UGDP was set up to determine whether various treatments for diabetes would minimize the mainly vascular complications that notoriously accompany that disease. It is ironic that a full report dealing with complications has not yet been published because, in the third and fourth years of the study, an alarming preponderance of deaths had accumulated in the tolbutamide group. The investigators, then, per force, had to turn their attention to mortality and survival.

I was not a participant of the UGDP study, but I followed it closely. Despite some imperfections, I think that the results and conclusions of the UGDP have shown tolbutamide and phenformin, and probably their cousins, to be dangerous drugs, especially when taken for extended periods of time. I stand by my opinion of 4 years ago, expressed with the help of a committee of the American Diabetes Association in the editorial statement accompanying the first report of the UGDP. I quote: "The UGDP mortality study shows that death rates were essentially the same in the IVAR group"—I suppose I have to explain that.

Mr. GORDON. Is that the insulin variable group?

Dr. RICKETTS. Yes. I will explain that later.

The UGDP mortality study shows that the death rates were essentially the same in the people who had various dosages of insulin and which maintained more nearly normal fasting blood glucose levels than in the more poorly controlled groups of the placebo and the other groups.

This would appear to mean that efforts to establish good control of hypoglycemia in the kind of population studied had no effect on mortality.

The real lesson of the data is that if diet plus insulin does not reduce mortality below that experienced with diet alone, it is highly improbable that oral hypoglycemic agents will do so.

There is indeed no doubt about the reality of the greater number of cardiovascular deaths observed in the TOLB group as compared with all other treatment groups. Inquiry into the reasons for this has been both intensive and extensive. Aside from the most proximate explanation, that tolbutamide may have been directly and solely responsible, the possibility that the tolbutamide population, by chance and despite randomization, entered the study with more or greater risk factors than the other populations had to be scrupulously investigated.

Although this possibility has, in the opinion of the ADA Ad Hoc Editorial and Advisory Committee, not been excluded, the weight of statistical analysis