community generally. If we were solidly convinced that tolbutamide were poison, there would be no doubt about it, and if the benefit-risk ratio was definitely proved to be unfavorable, then I think we would seek regulation to prevent its general use.

What I am saying is that I do not think the evidence is that clear. I think that some investigators have come to the kind of conclusion that you described, and not being a physician, I have no independent opinion about whether their experience is one that could be generalized to all physicians. I think there is enough room for doubt that I would be hesitant to seek regulation to determine absolutely that the drug may not be used except in that 1 percent of cases. I do think that there is enough evidence against it that even though we might allow the community to use its judgment with relatively little restriction, that it would only be appropriate to do that as long as we are setting about immediately to settle the remaining doubts.

I am sorry that the state of affairs does not lead me to a feeling that we know all the answers. I think there are important answers we do not yet know, and therefore I would be reluctant to go so far as to say that the use of tolbutamide should by law be restricted to the 1 percent subgroup.

The CHAIRMAN. I do not think anyone is dealing in absolutes here, and of course there are all kinds of medicines in the marketplace which are widely used for nonindicated cases. This, it seems to me, from what I have heard from the experts is what we are talking about here.

The conclusions reached at Grady Memorial Hospital was that there was a very, very small number of cases in which the oral hypoglycemics were indicated, that the large percentage was better managed by diet, and that their results after more than 3 years showed that the patients were better than they were before, and this is what the UGDP study indicates.

I assume you agreed that the study was statistically valid although being a scientist I am sure you want to say that nobody can be absolutely sure, which is of course true. Nobody is absolutely sure about anything, but you do endorse the position of the Biometric Society in their evaluation of the UGDP study, is that correct?

Dr. MEIER. Let me say that I wholeheartedly endorse the report that the Biometric Society Committee put out, and I will discuss that further in my statement.

The CHAIRMAN. Dr. Palumbo, did you want to comment?

Dr. PALUMBO. May I?

As a physician and clinician who is involved in the treatment of diabetic patients, I think that we have to make a reasonable judgment on the basis of a randomized clinical trial such as the UGDP as to what we are going to do for the patient who sits in front of us; and the decision here is based upon the first principle that each physician is committed to; and that is—if I may use the Latin phrase, "primum non nocere," which translated means, "do no harm."

And therefore, it has to be clear that our treatment is not doing harm to the patient. Now, we may, under unusual circumstances, elect for a risk-benefit ratio, but I think for the majority of our