Dr. Theodore Schwartz.[1] The tension, the pulling and hauling, the major differences of opinion that led to that final decision, must all be taken into account in trying to interpret the meaning of that decision. It was judged likely that tolbutamide was toxic; but the evidence was not considered conclusive.

So I do not think we can say that there is a clear, flat conclusion that comes out of this, and I think reasonable people may come to somewhat different conclusions.

The CHAIRMAN. Clear conclusions about what?

Dr. MEIER. About whether tolbutamide should be abandoned by all physicians in the treatment of diabetes.

The CHAIRMAN. That really is not the issue, is it?

Dr. MEIER. I think the issue is what we ought to do, not whether we have reached a firm conclusion. I do not think we have reached a completely firm conclusion as my statement will show. I deplore the fact that we are not in a position to reach a firmer conclusion than we now have, but I would support the final statement of the Biometric Society committee's report, which suggests that a new study might be conducted. I think it would be ethically legitimate to conduct a new study. I myself think it is not ethically legitimate to continue to use the drug without a new study.

The CHAIRMAN. The issue is not whether you should prohibit its use under any circumstance on any patient in any situation. The question is, as a general proposition, should you use it in those cases where the patient situation can be managed by diet?

For example, Dr. John Davidson said that at the Grady Memorial Hospital it was finally concluded after the study—I think they had some 6,500 patients, which I believe was the largest group in the country—that they would take them off the drug and if my recollection is correct their patients were better managed on diet. He said it was tough medicine to swallow because they had lived with oral hypoglycemics, thought they did well, studied the UGDP study, which, they concluded, was right.

Then, in a more precise answer—I believe I am correct, and if I am not, I will correct the record—he thought that maybe in a very, very small percentage of cases, I think he said it might be 1 percent or less, an oral hypoglycemic would be indicated to be used. He did not state what that case was, so I do not know whether that was an insurance policy statement or not.

But in any event, is that not the question: Not whether you should abolish these drugs, but whether in those cases where diet can manage the problem, it should be used? And is it not the conclusion of the UGDP study, as well as Dr. Davidson at Grady Memorial Hospital—and the doctor from Mayo will address himself to this question also—that there is a very, very small percentage of cases in which it is indicated, but that it is widely used in cases where it is not indicated.

Is that a fair generalization?

Dr. MEIER. I think the question really is whether the evidence is of such overwhelming clarity that the conclusion reached by these gentlemen should be a regulation imposed by law upon the medical

[1] The Tolbutamide Controversy: A Personal Perspective (Annals of Internal Medicine, 75, pp. 303-306, 1971).