Dr. SCHMIDT. That is correct. The committee concluded that there were no data that refuted the principal conclusions of the UGDP study, and we agree with that.

Mr. GORDON. But setting aside, for the moment, the cardiovascular deaths, have the opponents of your proposed labeling supplied substantial evidence—as required by law—that the oral hypoglycemic agents have a beneficial effect on the long-term vascular complications of diabetes? In other words, I am talking about efficacy in treating diabetes.

Dr. SCHMIDT. Yes, I see; I have a little problem with your question because it implies that what is required by law would be that these drugs would have a beneficial effect on the long-term vascular complications of diabetes. And in fact, we have no substantial evidence on that point.

Mr. GORDON. But, that is required by law, is it not?

Dr. SCHMIDT. Well, no, because it depends upon the claims made and if the claim for these drugs was that they influence the long-term mortality, then they would indeed need substantial evidence. But, if the claim is that they lower blood sugar or relieve symptoms—in other words, if they have that effect and there is substantial evidence for that, then that is what is required by law for that labeling. And we do have substantial evidence that these drugs lower blood sugar and that they relieve symptoms.

Mr. GORDON. Well, does it state that the purpose is merely to relieve symptoms and that is all?

Dr. SCHMIDT. Well, no, but you see, what you are doing is two things: one is you are pointing out the need for revised labeling, and we firmly agreed with this. In times past, as I believe I said last time I was here, it was believed by most physicians that lowering the blood sugar in the diabetic would have a beneficial effect upon the long-term mortality figures of diabetic patients. We analogized this to the idea that lowering blood pressure would prolong the life of individuals with hypertension. And what we are determining by some substantial evidence is that lowering blood pressure in hypertensives does prolong lives in those individuals that have high blood pressure.

We are learning things about the lowering of the blood sugar in diabetics that surprise us. And so we are in a different position now than we were in the past when the labels may have been silent on the issue of whether or not lowering glucose prolongs the life of a diabetic.

We may have applied this cause and effect relationship. What we need to do now is to separate out now clearly the treatment of people in order to relieve symptoms, which is very important.

I have taken care of many diabetics. And you can be sick if you are a diabetic. You can feel terrible when you are a diabetic. And in symptomatic diabetics, the normalization of blood sugar, which relieves symptoms as it does in some, is a very important thing. But we have to separate that and substantial evidence for that and that claim from the effect that that might or might not have on longevity of individuals with diabetes.

Mr. GORDON. Now, even if the results of the UGDP study were not conclusive—let's assume they are not conclusive—but are likely,