or even suggestive, would not the absence of the beneficial effect on the long-term complications of diabetes mean that the benefit-to-risk ratio for these drugs is unfavorable.

Dr. SCHMIDT. Well this comes back again to that same point of separating out treatment of the symptomatic diabetic who cannot take insulin, or who is not normalized by diet, that small group of people. Clearly, the benefit-risk ratio for that small group of individuals is such that we believe the drugs are safe and effective for them and should be available for their treatment.

Mr. GORDON. Only for lowering blood sugar—is that right?

Dr. SCHMIDT. That's right.

Mr. GORDON. And for a limited period of time?

Dr. SCHMIDT. And for symptomatic patients. Now if you are talking about asymptomatic patients, then my belief is that the drugs simply should not be used.

Dr. CROUT. I would agree with Dr. Schmidt as a physician. On the other hand, the asymptomatic patient is what the argument, the true argument, is all about. So, I think when you see estimates, or hear estimates of whether the oral drugs should be used in 1 percent, or 10 percent or 20 percent or 50 percent of the people now taking them, what you are hearing are differences of medical opinion on whether or not the lowering of the blood sugar in asymptomatic patients may stave off long-term cardiovascular disease.

And I think an important point to realize is that we do not view the UGDP study as conclusive on that point. Nor did the biometric study review the study on that point. The point we feel considerably more secure about is the evidence that the drugs may increase cardiovascular mortality. Whether the lowering of blood sugar staves off such mortality and is a compensating benefit for these drugs is an unanswered question, and the labeling reflects that point.

The CHAIRMAN. Is it not also correct that the study concludes that the purpose can be accomplished by diet better than the use of the drug—except for that rare small number you are making reference to?

Dr. CROUT. I think a number of physicians, including ourselves, would draw that interpretation from the study.

Your question was, did the study per se show that? And the answer is, not precisely. But that would be the conclusion people would draw from the study and it is an important point. Because the question has been asked, if usage of these drugs goes down, does that mean that usage of insulin will automatically go up? And in our opinion, and I think in the opinion of a number of physicians, the answer to that is no.

The best alternative therapy for the great majority of patients now on these drugs is diet. We believe that the changes in the practice of medicine that ought to occur at this point in time will focus more on the value of diet than on replacement of oral hypoglycemic drugs with insulin.

The CHAIRMAN. Dr. Davidson at Grady Memorial Hospital said in his testimony[1] that he thought perhaps the oral hypoglycemics

[1] See testimony of John K. Davidson, M.D., Ph. D., director, Diabetes Unit, Emory School of Medicine and Grady Memorial Hospital, in hearings "Competitive Problems in the Drug Industry," part 25, pages 10838–10854.