If the figure is 1 million and a half and if you take even Dr. Bradley's estimate of only 20 percent, Dr. Bradley is saying that 80 percent of a million and a half people—about 1,200,000—should not be using them. In the view of Dr. Davidson, only 1 percent should be taking them which means that almost the whole million and a half are exposed to needless risks. Only 150,000 diabetics are taking them for proper indications. Is that correct?

Dr. SCHMIDT. It would be hard for me to believe that anymore than, say, one out of five or two out of five, at the absolute outside, of people who are now getting these drugs by these indications should get them.

The CHAIRMAN. Well, if you go above one out of five you are above Dr. Bradley, who has been one of the most vocal critics of the UGDP study.

Dr. SCHMIDT. I have really no sound basis on which to pick a number.

Dr. CROUT. I seem to think you are emphasizing the importance of this relabeling and what it means to the practice of medicine. I would also emphasize that we are talking about the United States and point out that these drugs are used worldwide. No country has yet, to my knowledge, put a warning of this type on the labeling, and, yet, we do know that when the Food and Drug Administration of the United States does something it tends to cascade worldwide. These drugs are used enormously in Europe. I am told, for example, that the number one selling prescription drug in Germany is not a tranquilizer as it is in the United States, but an oral hypoglycemic drug. So this particular action will, I think, have world impact, and we are sensitive to that. It is also why it is so terribly important to the drug industry because it is multinational.

Mr. GORDON. In an article in the Journal of the American Medical Association, Dr. John Davidson stated:

> There has been a striking increase in death rate and decrease in life expectancy in maturity onset diabetics in America, Europe, Asia, Africa, and Australia during the last 20 years. These changes have paralleled the increasingly widespread neglected diet therapy and the almost unbridled enthusiasm among many physicians and patients for the use of sulfonylureas and treatments of choice. They seem to parallel the rise and the uses and increase in these drugs and increase in the death rate and the decrease in life expectancy among diabetics.

Do you have any comments to make on that?

Dr. CROUT. We have not reviewed that situation, and I would not want to engage in the sensationalization of putting those two things together. That statement may be true or not true. I do not know.

The CHAIRMAN. Go ahead.

Dr. SCHMIDT. The limitation of the treatment population to patients on whom insulin cannot be used has been opposed in the past on the ground that it has interfered with the practice of medicine. We recognize that drug labeling has an impact upon the practice of medicine, and I think it should for this reason. The Food and Drug Administration has an obligation to ensure that drug labeling is as correct and accurate as possible. It must, moreover, meet the statutory standard of describing the conditions and use under which