very small group of patients we have talked about before, who for whatever reason cannot be controlled by diet or cannot take insulin. So first of all, we are talking about just this small group, and then second, we are saying that the patient must be knowledgeable. Good medical practice dictates that the patient is knowledgeable about the options of control by diet, control by insulin, and if the choice by the physician is to be the oral hypoglycemic agent, we are saying that the patient should be knowledgeable about the risks of this drug to which he may be subjected.

Now, I could use another analogy that may help a little bit. If one has hypertension, he really ought to avoid salt. Now, I do not know if you have ever tried a salt-free diet, but a salt-free diet or low-salt diet is an extremely difficult, and in many respects uncomfortable sort of trial. When drugs came along that increased the renal excretion of sodium, there was a very strong tendency on the part of the patients to say, this solves my problem. I can now eat salt again, and have tasty food, and take the drug, and everything is fine. I will be just as well off as I was when I was on a salt-free diet. Physicians found it much easier to prescribe a pill than it was to fight—and believe me, it is a constant struggle with patients to keep them on a salt-free diet, or to control a diabetic by diet. So, taking the pill was really kind of a step toward the brave new world.

Now, when I used to inform my patients that, yes, they could lower their sodium with this drug, and not be as strict about their diet; but when they took a drug, they were running these risks. Sometimes for the first time, I got compliance on the part of my patients with this sodium-free diet, the low sodium diet. Now, what I am talking about is simply good medical practice that would be accepted as good medical practice by anyone. And we are saying, in this labeling, that patients, for the reasons I just illustrated with my analogy, must be informed of this possibility of increased risks; and as part of their management, they must know the options of insulin and of their using dietary control.

The CHAIRMAN. Well, then, if I understand the whole paragraph quoted there, it is addressed to a very narrow spectrum of patients.

Dr. SCHMIDT. Quite so, yes.

The CHAIRMAN. And, if I interpret it right, you are saying that if, as a practical matter, the patient's blood sugar can be controlled by diet, the doctor should not give him the drug.

Dr. SCHMIDT. That is our opinion, yes. But, as I indicated, we do believe that there is a small patient population for which these drugs, properly labeled, can be considered safe and effective, and we have also concluded though that this patient population is quite limited.

The CHAIRMAN. I have forgotten the figure of the estimate of the number of patients per year that were receiving prescriptions for oral hypoglycemics? Was it 1.5 million?

Dr. SCHMIDT. About 1½ million patients is a rough estimate.

The CHAIRMAN. You testified a few months ago that there has not been any careful studies to show what percentage of those receiving oral hypoglycemics are receiving them for properly indicated reasons.