the drug may be considered safe and effective. If a known hazard and potential risk leads to the conclusion that a drug may be used safely only on certain patients, this limitation on use must be expressed in labeling.

The indications section, in addition to describing the population in whom these drugs is indicated, points out that "in considering the use of (drug) in asymptomatic patients, it should be recognized that whether or not controlling the blood glucose is effective in preventing the long-term cardiovascular or neural complications of diabetes is an unanswered scientific question." This emphasizes the different benefit-risk considerations that obtain in the symptomatic patient who needs alternative treatment if insulin cannot be used, and the asymptomatic patient, whose need for alternative treatment is debatable. I think we have discussed this point at some length previously.

You asked that I comment on the promotion of these drugs. We cannot conclude that advertising for these products has been generally violative. It has, however, been based upon labeling that is in need of modification. It is clear that promotional materials must change radically to reflect the new warning and restricted indications. You can be assured that we will be monitoring the advertising of these products closely after the new labeling becomes final to see that they do, indeed, do so.

The CHAIRMAN. Do you permit reminder advertising, and how do you handle them?

Dr. SCHMIDT. Well, we permit reminder ads, yes.

The CHAIRMAN. With no claim?

Mr. MERRILL. This drug, Senator, carried a boxed warning. We have in preparation a final order that is responsive to a notice of proposed rulemaking published last year that would prohibit the use of reminder ads for any drug that carries a boxed warning.

The CHAIRMAN. I see, so any advertising would include the box.

Mr. MERRILL. It would include a brief summary—the full range of information.

The CHAIRMAN. I see, go ahead.

Dr. SCHMIDT. It is important to realize that the use of these oral hypoglycemics remains widespread despite the UGDP study and despite the rather limited ability of the drugs after a few years of use, even to lower the blood sugar. Total prescriptions for this class, according to the National Prescription Audit, have been stable between 19 million and 21 million since 1967 (except for an apparent dip in 1969.)

The CHAIRMAN. That is per year?

Dr. SCHMIDT. Yes.

The CHAIRMAN. What does that prescription mean in this context?

Dr. SCHMIDT. Well, any one individual would during the year receive more than one prescription.

The CHAIRMAN. Well, if 1½ million people were getting it, of course, it would not always necessarily be the same person.

Dr. SCHMIDT. Well, if these figures are accurate what that means is the average person would receive over 15 prescriptions or one prescription a month. I will not put my career on the line toward the