That is really why we waited so long for that report, and believe it is so important.

The CHAIRMAN. Go ahead.

Dr. SCHMIDT. Our warning also points out that, although only one sulfonylurea and one biguanide were included in the UGDP study, it is prudent from a safety standpoint, in view of the similarities in chemical structure and mode of action of drugs within each of these two categories, to consider that the UGDP findings may apply to the other drugs in each category. The warning has thus been applied to all sulfonylurea drugs, and the one biguanide drug marketed in this country.

Finally, the warning section states that the clear implication of the finding that tolbutamide and phenformin may carry a risk not associated with insulin; the drug, the label will state: "Should be used in preference to insulin only in patients with maturity onset diabetes whose symptoms or blood-glucose level cannot be controlled by diet alone and only when the advantages in the individual patient justify the potential risk (see Indications). The patient should be informed of the advantages and potential risks of the (drug) and of alternative modes of therapy and should participate in the decision to use this drug."

We have concluded that a patient population exists for which these drugs, properly labeled, can be considered safe and effective. We have also concluded, however, that this patient population is a limited one.

The CHAIRMAN. This is part of the warning, is it?

Dr. SCHMIDT. Yes, sir.

The CHAIRMAN. The label states that the patient should be informed of the advantages and so on, and should participate in the decision to use the drug. I am wondering what you are getting at there. If in fact you have a patient, who cannot manage it for whatever reason, psychologically, mentally, physically, or what have you; could not use insulin or could not be kept on a diet, and the doctor concludes you should reduce the blood sugar level, that is a case for which, I would assume, there is general agreement that an oral hypoglycemic would be indicated. Is that correct?

Dr. SCHMIDT. Yes, sir.

The CHAIRMAN. Well, now, then, when you say they should participate in the decision to use one of the drugs, are you then talking about that very large number of people whose problem can be handled effectively by diet? Are you saying to the physician that before you put them on an oral hypoglycemic, they must be notified it is the belief of the physician that their problem can be handled by diet; that it would be better to use the diet, and that the doctor should attempt to persuade him to do so, and understand that the use of the drug may have adverse effects, and that the patient would be better off on a diet. Is that what you are talking about?

Dr. SCHMIDT. No. I think that this is really quite explicit. The warning says that the drug should be used in preference to insulin only in patients with maturity-onset diabetes, who cannot be controlled by diet alone, and only when the advantages in the individual patient justify the potential risk. Now, this narrows it down to that