Finally, the warnings section makes explicit the clear implication of the finding that tolbutamide and phenformin may carry a risk not associated with insulin: "(Drug) 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 (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 as safe and effective. We have also concluded, however, that this patient population is a limited one. The proposal to limit the treatment population to patients in whom insulin cannot be used has been opposed in the past on the ground that it interfered with the practice of medicine. We recognize that drug labeling has an impact on the practice of medicine. For this reason the Food and Drug Administration has an obligation to ensure that labeling is as correct and accurate as possible. It must, however, meet the statutory standard of describing the conditions of use under which a drug may be considered safe and effective. If a known hazard or potential risk leads to the conclusion that a drug may be used safety only in certain patients, this limitation on use must be expressed in labeling.

The indications section, in addition to describing the population in whom these drugs are indicated, points out that "in considering the use of (drug) in asymptomatic patients, it should be recognized that