as dizziness, polyuria, etc. the drugs are not effective in treating short-term symptoms. Some diabetes doctors believe that they prevent long term symptoms of diabetes such as vascular deterioration. However, there is no scientific substantiation of this belief.

3. The label should state that there is substantial evidence that these drugs are not effective for the prevention of the long-term symptoms of diabetes. FDA has proposed new regulations for all prescription drug labels which contains the following requirement:

> If there is a common belief that the drug may be effective for a certain use or if there is a common use of the drug for that condition, but the preponderance of evidence related to such use indicates that the drug is ineffective, the package insert shall state that there is a lack of evidence that the drug is effective for that use. s. 1.112 (3)(d). 40 Fed. Reg. 67, 15392ff.

The UGDP study demonstrated that these drugs are ineffective in preventing the long-term effects of diabetes.

4. The Warning section should state that these drugs are associated with increased cardiovascular mortality, without referring to the UGDP study. The proposed warning states that the drugs may be associated with increased cardiovascular mortality and that "This warning is based on the study conducted by the U.G.D.P." together with details of that study. If the UGDP reference is retained, the other studies which confirm the UGDP findings must also be cited. Otherwise, the warning will give the false impression that the UGDP findings are isolated and unique, which they are not.

Since the UGDP study, laboratory studies have pinpointed the mode of adverse action on the heart. This mode of action has been confirmed in humans by catheterization studies. Another study has described a significant rise in ventricular fibrillation in patients on these drugs. Two epidemiological studies have shown an abruptly increased mortality among diabetics since these drugs were introduced. Three retrospective clinical trials confirm the UGDP results, as do two cohort studies, the Kanarek study, based on patients at the Joslin Clinic, and the Palumbo study based on patients at the Mayo Clinic.

5. The Warning section should not include a statement that there is controversy as to the need for the warning. The FDA proposed warning says: "Despite controversy regarding the interpretation of these results, the findings of the UGDP study provide adequate scientific basis for this warning," thereby including a statement of controversy. The 1972 lawsuit, Bradley v. Weinberger, raised this issue. Bradley, who had the habit of prescribing these drugs, sued to prevent FDA from putting a warning on the label, or, if that failed, to get a statement in the warning that there was a difference of opinion among experts concerning the need for a warning. The case was never decided on the merits. However, FDA contested Bradley, stating that warnings should not contain disclaimers which would encumber and dilute the warning. Now FDA is reversing its position and including a "controversy" statement. We agree with FDA's earlier view that this statement is unwarranted and from a health point of view, counterproductive.

Without these changes in labelling, the addition of informed consent and immediate finalizing of these improved regulations, the FDA, to the delight of the drug companies, will be condemning American diabetics to a continuation of the needless death and waste of precious health dollars.