It is not enough to have labelling -- albeit strengthened -- on a product which the patients' doctor has already decided to prescribe. Patients must be given information in the doctors office which will allow them to participate in the serious decision to use these drugs. Specifically, future use of oral diabetes agents should be preceded by a written informed consent form including, but not limited to the following information:

INFORMED CONSENT FOR USE OF ORAL DIABETES DRUGS

1. I have participated in a program of dietary control and physical exercise including at least 25 hours of instruction.

2. This program did not succeed in weight reduction or control of blood sugar and Dr._____ told me that insulin was the preferred drug if one had to be used.

3. I refuse (or am physically unable) to take insulin.

4. I am aware of the increased risk of cardiovascular death from taking oral diabetes drugs and of the animal study showing that one of them (Tolbutamide) causes a significant increase in coronary artery disease and that therapeutic efficacy has not been proven.

In light of the above, I agree to take _____ (oral diabetes drug).

_____ _____

Date Patient's Signature

Recommendations for the Label

1. The antidiabetic drugs should be indicated only for patients with symptoms from high blood sugar, whose symptoms cannot be controlled by diet or insulin. They should be used by patients who cannot be controlled by diet only if such patients also cannot inject insulin.

The label as proposed by FDA approves use in a broader group of patients -- those whose "symptoms cannot be controlled by diet alone and in whom insulin cannot be used because of patient unwillingness, erratic adherence to the injection regimen, poor vision, physical or mental handicap, insulin allergy, employment requirements or other factors." The FDA label essentially condones use in symptomatic patients when insulin is merely inconvenient to use. Mere inconvenience is not a legitimate reason, in our view, to sustain the known risks of these drugs. The FDA label also indicates use in patients without symptoms.

2. The label as proposed by FDA grants an indication to patients with high blood sugar who do not have symptoms. The Food, Drug and Cosmetic Act requires that all indications be supported by "substantial evidence," evidence from "adequate and well-controlled investigations, including clinical investigations." Obviously, since these patients have no short-term symptoms of diabetes, such