(DIABINASE), phenformin (DBI) or acetohexamide (DYMELOR). At the end of four years on diet and either placebo or one of the four drugs, there was no evidence that any of the four drugs improved glucose tolerance more than diet and a placebo.

This study, although completed more than 2 1/2 years ago and presented in summary form at a meeting of the American Diabetes Association June 23, 1973, has never been published. It is likely that one or both of the following factors are responsible for its non-publication:

1. The Joslin Clinic is the center of advocacy (aside from the drug companies) for the use of these diabetes drugs.

2. The study was supported by Upjohn (makers of Orinase and Tolinase), Lilly (Dymelor) and Pfizer (Diabinase).

The degree to which the Joslin Clinic adheres to their "faith" in these drugs despite all the evidence--including data from their own patients--to the contrary can be seen in the testimony of Joslin Director Dr. Robert Bradley before the Senate hearings last fall:

"Data from the UGDP Study have thus far contributed nothing to the controversy regarding the effectiveness of blood sugar control and...the results cannot at present be extrapolated to the diabetic population at large." Select Committee on Small Business (p. 10986).

If the UGDP study didn't convince Dr. Bradley, surely the combination of increased mortality and lack of efficacy of these drugs in his own Clinic should.

WARNING LABEL AND MALPRACTICE

At the heart of opposition by both drug industry and doctor opposition to the proposed warning label is the question of medical malpractice. A strong label, warning against using the drugs unless an adequate trial on diet therapy has been attempted and making doctors (and patients) aware of the increased risk of cardiovascular death, would likely become grounds for malpractice if these caveats were not heeded.

On April 15, 1978, we commented on the way FDA had already weakened the warning label proposed for comment on Jan.28, 1974 from the earliest draft published in the FDA Drug Bulletin, May 1972. (See enclosed).

In testimony before Senator Nelson last fall, Dr. Thomas Chalmers, Dean of Mount Sinai Medical School discussed labelling:

"The new FDA labelling should be strong enough to warn all physicians that they are distinctly putting their patient at risk by using oral agents when diet or insulin will suffice. The wording