publication of a warning label which would, if properly worded, cause most adult diabetics to be taken off these dangerous, ineffective, and expensive drugs.

During this interval of irresponsible delay by the FDA, approximately 250 million dollars worth of these drugs have been consumed in this country alone and, according to experts, 20,000-30,000 unnecessary deaths due to these drugs have probably occurred.[2] Of the 1.5 million people currently using these drugs, it is estimated that 80% to 90%, at least, could be controlled as well or better--and certainly more safely--by diet or, in a very small number of cases, insulin.[3]

Although the published medical literature contains ample evidence of the increased risk of death and lack of efficacy of these drugs, the FDA is aware of four additional studies the results of which have not yet been made known to the public. A brief review of these studies follows:

1. Unpublished Study on Mortality in Joslin Clinic Patients

Although many doctors who have been wedded to the idea that these pills benefit diabetics have attacked the findings of the UGDP study, none have been as vocal as the doctors of the Joslin Clinic in Boston. Aside from organizing the law suit against the FDA to block promulgation of the warning label three years ago, Dr. Robert Bradley (Joslin Director) and his cohort have devoted considerable time to presentations at drug-company-financed meetings around the country aimed at maintaining doctors "faith" in these drugs. It is thus all the more striking to find that a study of the Joslin Clinic's own patients yields results similar to those found by the UGDP.

A Harvard Ph.D. thesis by Paula Kanarek entitled "Assessing Survival in a Diabetic Population" and dated January 1973 was a retrospective study of 6300 patients at the Joslin Clinic. Begun after the UGDP study, its stated purpose was to study the effect of various types of therapy on the survival of diabetic patients, particularly to see "if individuals treated with tolbutamide (ORINASE) are more likely to die from cardiovascular causes..."

The results of the study showed that:

a)"For individuals who survive at least 5 years, however, the relative survival experience for persons receiving tolbutamide is worse in all cases than that of those on diet..." (p. III-16)

b)"...certainly in all risk categories, the probability of dying from cardiovascular causes in 5-10 years was consistently higher in the tolbutamide group than in the diet group (III-17)

2. Senate Hearings on Oral Hypoglycemic Drugs, Sept. 1974, p.10803.

3. J.A.M.A., 232, 854, May 26, 1975.