c)"...the results of this observational study suggest that the findings of the UGDP may be generalized to other diabetic populations." (III-23)

2. FDA-Sponsored Study of the Effect of Tolbutamide on Development of Coronary Artery Disease in Monkeys

This study, FDA contract #72-114,was done by researchers headed by Dr. Robert Wissler, Professor of Pathology at the University of Chicago. Begun in 1972, the final report was submitted to FDA in February, 1975.

Monkeys were placed on an "Average American Diet" and one-half were given tolbutamide at a dosage comparable to that taken by diabetics. The study was continued for two years with the following findings:

a) Coronary artery disease was found two times more often in animals taking tolbutamide than in animals on diet alone.

b) The coronary artery disease caused by the drug was three times more severe than that developing spontaneously from the diet alone.

Although the UGDP and Joslin studies showing increased death in humans from cardiovascular disease due to these drugs are clear enough, the Wissler study is the first experimental confirmation of the mechanism whereby the human deaths ahve occured. Since it has been known for more than 30 years that most diabetics die from cardiovascular complications, such animal studies should have preceded marketing.

3. A Study by Dr. C.R. Wu,, et al., of New Jersey Medical School, presented May 3, 1975 in Atlantic City at the American Federation for Clinical Research meeting also looked at the effect of tolbutamide on the heart of diabetic dogs. At therapeutic doses (equivalent to those taken by diabetic patients) the function and structure of the heart was worsened by 1 year of treatment with tolbutamide.

4. Unpublished Study of Joslin Clinic Patients Showing Lack of Efficacy of 4 Oral Diabetes Drugs.[4]

In addition, we have just obtained a copy of a study by researchers at the Joslin Clinic which clearly demonstrates that the oral antidiabetic drugs fail to achieve their intended "beneficial" purpose, namely lowering of blood sugar.

365 adult-onset diabetics were placed on an individualized diet and given either a placebo, tolbutamide (ORINASE), chlorpropamide

4. The Effects of Long Term Therapy with Oral Hypoglycemic Agents on the Oral Glucose Tolerance Test Dynamics in Chemical Diabetics (Tan, Graham, Bradley et.al.)