SE WESTERN RESERVE UNIVERSITY · CLEVELAND, OHIO 44106

August 21, 1975

Hearing Clerk
Food and Drug Administration
Room 4-65
5600 Fishers Lane
Rockville, Maryland 20852

Dear Sir:

I regard it as a privilege to have this opportunity to discuss the proposed FDA labeling on the use of oral hypoglycemic agents. It is indeed appropriate that such direct action has finally being taken if the scientific basis for medical practice is to have any real significance. The heated discussions that followed the publication of the findings of the longest and largest prospective controlled clinical trial in the history of therapeutics serve only to point up the critical issues involved in the practice of medicine today. These issues involve the crucial question as to the basis for the judgement of the physician for choosing the optimum treatment for the patients entrusted to his care. Is the decision to be based on "clinical impression", anecdotal stories and wishful opinions, or will it be based on substantial evidence from adequate, well-controlled clinical investigations? If modern medicine is to have a firm foundation in basic and clinical science the wisdom of the Drug Amendments of 1962 resulting from the thalidomide disaster becomes crystal clear.

The scientific design, merit or validity of the UGDP study has been amply confirmed by the most intensive and extensive reviews in the history of medicine. When the evidence of excessive cardiovascular mortality first surfaced after several years of the trial, outside consultants were brought in to review the data independently. After the report was made public at the A.D.A. meeting in St. Louis in June of 1970, separate peer review committees appointed by the American Diabetes Association, the A.M.A. Committee on Drugs and the Medical Letter accepted the basic conclusions of the study. Because of the alleged contradictory findings from other studies, none of which approached in any way the magnitude or relevance of the UGDP study an elite committee of the internationally based Biometrics Society over a period of two years reviewed all these controlled trials and in their report published on February 10, 1975 the J.A.M.A. came up with essentially the same conclusions and recommendations. This report like the UGDP reports will stand as monumental and classical papers in the history of clinical medicine.

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