

13656 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Mr. Chairman and Members of the Subcommittee

I am pleased to have this opportunity to participate in these hearings on the oral hypoglycemic drugs. Over 5 years have now elapsed since the initial presentation of the findings of the University Group Diabetes Program indicating an increased risk of death from cardiovascular disease in patients treated with tolbutamide or phenformin. Since that time there has been considerable debate and controversy in the medical profession as to the validity of these findings and their implications with respect to the treatment of diabetic patients. My discussion will focus on the following areas: (1) Those aspects of the pharmacology and clinical applications of the oral hypoglycemic agents in which there is fairly uniform agreement among proponents as well as opponents of the UGDP study. (2) The impact which the findings of the UGDP study have had on medical practice. (3) The mechanisms by which the prescribing habits of physicians may be altered.

Virtually all experts in the field of diabetes agree that the oral hypoglycemic agents are drugs of convenience. They are convenient because they may be taken orally as opposed to the injections of insulin. More importantly, they are convenient because they do not require the self discipline and compliance inherent in a weight-reducing dietary regimen. In contrast to the effects of insulin in the patient with diabetic coma, the oral hypoglycemic agents are not life saving drugs. Furthermore, no convincing evidence is available which indicates that regulation of blood sugar by oral agents retards or prevents the long term degenerative complications of diabetes which may affect the eyes, kidney or nervous system. It is thus clear that these drugs are useful in a very limited number of patients with adult-onset diabetes: namely, those with symptoms due to an elevated blood sugar in whom dietary measures have failed and in whom insulin is impractical or refused by the patient. While some experts would include patients with an elevated blood sugar who are asymptomatic, there is universal agreement that these drugs are overprescribed in the United States.