

13466 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Specifically, he believes the study of modes of treatment for adult-onset diabetes conducted by the University Group Diabetes Program requires the addition of a warning about possible cardiovascular complications associated with the use of such drugs. Because of the importance of this matter and the concerns it has generated among physicians and their patients, the Commissioner has concluded that it is appropriate to invite exploration of the issues in a public forum before reaching a final determination on the wording of the labeling, including the warning.

The scientific and legal issues relating to the labeling of oral hypoglycemic drugs have been the subject of protracted public debate. To resolve the many complex questions that have been raised, it is essential that the important issues be identified and that public comment be directed to these issues. The following discussion is presented to summarize the history of the oral hypoglycemic labeling controversy, to identify the issues that have arisen during the controversy, and to explain the position of the Food and Drug Administration on these issues.

II. ORIGIN OF THE LABELING CONTROVERSY

Although insulin and the oral hypoglycemic drugs are both effective in lowering the blood glucose level in patients with maturity-onset diabetes, it is not clear that this reduction of blood glucose has a beneficial effect on the long term vascular complications of diabetes. In an attempt to answer this question, the National Institute of Arthritis,