

13468 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

A report on the findings of the UGDP was submitted to the Food and Drug Administration in March 1970. The report concluded that "the findings of this study provide no evidence that the combination of diet and tolbutamide therapy as described and used for mild non-insulin dependent diabetics is more effective than diet alone. Moreover, the findings suggest that tolbutamide and diet may be less effective, at least insofar as cardiovascular mortality is concerned, than diet alone or than diet plus insulin." The Food and Drug Administration reviewed the report and convened an ad hoc meeting of experts on May 21, 1970, to evaluate the findings. The report was scheduled for presentation at the annual meeting of the American Diabetes Association on June 14, 1970. The program and abstracts for the meeting of the American Diabetes Association were disseminated in May, however, and the general findings of the UGDP study became widely publicized in the press. In view of this publicity, FDA released a statement to the press on May 22, 1970, indicating that the agency agreed with the UGDP's stated conclusions and would require labeling changes for the oral hypoglycemic drugs to reflect results of the study.