

13470 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

A statement published at the same time by The American Medical Association Council on Drugs (ref. 3) included the following recommendations:

Although some flaws exist in the UGDP study, it clearly demonstrates that every effort should be made by the physician to control the symptomatic, maturity-onset diabetic with diet alone. Should this fail, treatment with insulin or oral hypoglycemic agents should be undertaken. If oral hypoglycemic agents are selected for therapy the results of the UGDP study should be kept in mind. Therefore, the consideration of treatment with oral hypoglycemic agents should be secondary to the use of insulin.

In May 1971 the use of phenformin in the UGDP study also was discontinued because there was a significantly higher cardiovascular mortality in the phenformin group (12.7 percent or 26 out of 204) compared to the other treatment groups. The preliminary results with phenformin were published in August 1971 (ref. 4). An additional report by the UGDP published in November 1971 discussed the clinical implications of the UGDP study (ref. 5).

In June 1971 the Food and Drug Administration issued a Drug Bulletin outlining changes in the labeling for all sulfonylurea drugs. The Drug Bulletin stated that diet and reduction of excess weight are the foundation of therapy of diabetes mellitus, and that when the disease is adequately controlled by these measures, no other therapy is indicated.