

13508 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

The UGDP reported that patients treated for 5 to 8 years with diet plus a fixed dose of tolbutamide (1.5 grams per day) or diet plus a fixed dose of phenformin (100 milligrams per day) had a rate of cardiovascular mortality approximately twice that of patients treated with diet alone or diet plus insulin.

Total mortality was increased in both the tolbutamide- and phenformin-treated groups, but this increase was statistically significant only for phenformin. Despite controversy regarding the interpretation of these results, the findings of the UGDP study provide adequate scientific basis for this warning.

Although only one drug in the sulfonylurea category (tolbutamide) and one in the biguanide category (phenformin) were included in this study, it is prudent from a safety standpoint to consider that this result may also apply to other oral hypoglycemic drugs in these categories, in view of the close similarities in mode of action and chemical structure among the drugs in each category.