

13484 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

the analysis was conducted according to an approach called the survival modeling method, which takes into account the proportion of time each patient received the assigned medication, women in the tolbutamide group had a statistically significant increase in both cardiovascular and total mortality. This does not mean that the study necessarily showed the drug to carry less risk in males. On this point the committee concluded: "The data do not support the same conclusions for men, but one possible reason is that the smaller number of patients in the male group results in lack of sensitivity to detect differences of moderate magnitude."

In the final section of its report, the Biometrics Society committee summarized its conclusions:

Although we have concerned ourselves almost entirely with issues related to the possible toxicity of tolbutamide, we wish to point out that one of the valuable aspects of the completed UGDP trial will be the provision of data on the long term treatment of adult-onset diabetes with insulin. It is already clear that the benefits from this treatment are not dramatic, and the only worthwhile information about them will have to come from the relatively precise methods of a controlled clinical trial. In this sphere, the UGDP trial has no competitor* * *