

13630 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

procedure--a contingency which might have grave implications for the credibility of the whole study... We were not able to find an assignable cause for the surprising allocation of the sexes to treatments but have no reason to think the study has been compromised by a breakdown of the randomization to the treatment groups." *

The Biometric Society could have considered other evidence of a possible breakdown of the randomization procedure if they examined the two-fold and even more than three-fold difference in total time at risk as between male and female patients, differences in compliance, autopsy rates, etc. Among the defects in the UGDP study, the Biometric report states, "The omission of a history of smoking was a blunder." This is praising with a faint damn as there were other blundering omissions such as the failure to identify patients on thiazides, as well as the failure to identify those patients with family histories of heart disease.

The Biometric Society mildly observed that the UGDP report "made use of some relevantly unfamiliar and exploratory techniques". These very techniques have, for several years, caused critics to raise the question of statistical manipulation of data.

* It is interesting to note that the calculation of age at death of the data presented by the UGDP shows that all tolbutamide patients, males and females, had a mean age of 65.2 and all placebo patients 61.5 and the difference at death between placebo females and tolbutamide females was six years, 59.8 for placebo and 65.8 for tolbutamide group.