

12338 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

itself, "meet requirements for priority attention". It is worth recalling that the Task Force had noted that equivalency studies on some of the products it had identified were underway. For two of the three drugs tested, significant problems were demonstrated (chloramphenicol and diphenylhydantoin). Differences were identified in the third drug, sulfisoxazole, but the researchers were unable to determine their clinical significance. Dr. Christopher Martin, who directed the project, was quoted as saying that "Our findings raise serious doubts about the equality of different products of the same drug in the treatment of disease". So far as we are aware, further bioavailability studies in man under FDA auspices have not been published. In any case, the Task Force list did consist of products about which questions had been raised, and about which questions persist. We believe our allusion to that fact is both accurate and justified.

I would be grateful if you would place this letter, and the enclosures, in the printed hearing record.

Sincerely yours,


C. Joseph Stetler

Enclosures