

11836 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

AMERICAN PHARMACEUTICAL ASSOCIATION

The National Professional Society of Pharmacists

March 11, 1975

Honorable Gaylord Nelson
United States Senate
Subcommittee on Monopoly
Select Committee on Small Business
Washington, DC 20510

Dear Senator Nelson:

I am replying to your letter of March 3 requesting my comments on the interoffice memoranda dated October 31, 1974 and October 4, 1974 of Abbott Laboratories on the subject of bioavailability studies conducted by the Upjohn Company.

I have reviewed these memoranda and have studied the Upjohn Company reports to which they relate. Without going into a detailed or item-by-item response, it is my opinion that the criticisms and objections made in the Abbott memoranda are all accurate and valid.

This is not to say, however, that the Upjohn studies were necessarily improper or completely without merit. Specifically, a major -- if not the major -- objection on the part of the Abbott staff was the fact that the Upjohn studies did not compare the bioavailability of "chemical equivalents" but rather compared the bioavailability of drug products from three pharmaceutical manufacturers containing distinctively different drug entities. Moreover, they were distinctly different dosage forms and contained different amounts of the active drug moiety.

Such studies may serve some useful purpose in assessing the fundamental effectiveness or safety of one drug entity compared to another. However, when and if such studies are used in an effort to assess bioequivalency, this is entirely improper. Not only does it violate the accepted definition of the term, but it is highly deceptive and unethical. Consequently, use of such studies by the Upjohn Company either to claim or even imply relative superiority of their product is reprehensible and deserving of the critical comments made by the Abbott staff.

On the other hand, in fairness to the Upjohn Company, it should be pointed out that at least they have made scientific and technical information pertaining to their products publicly