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BIOAVAILABILITY DATA—USEFUL OR USELESS?

We are confused! The "we" here is an editorial "we" and is not intended to reflect upon anyone beyond the writer of this column—although there appears to be ample justification for many of our colleagues and associates to share in our confusion.

Readers of this Journal know that bioavailability has been a leading subject of interest within the pharmaceutical sciences community for at least the past 10 years. Numerous articles have been published on the subject, several conferences have been conducted, various reports have appeared, a number of symposia have been presented, and, in general, reference to drug bioavailability has regularly appeared in speeches, testimony before congressional committees, and filings made to regulatory agencies.

The APhA Academy of Pharmaceutical Sciences was largely responsible for the definition which seems to have won general acceptance; namely, bioavailability means the rate and extent to which the therapeutic moiety is absorbed from a drug product and becomes available to the site of drug action.

Consequently, determination of bioavailability can be an important factor in evaluating the effectiveness and expected performance of a drug product. By the same token, determination of the respective bioavailabilities of two or more different products can be an important means of objectively and critically comparing the effectiveness and expected performance of such products.

On the basis of this approach, or strategy, in comparatively evaluating drug products, APhA launched its "Bioavailability Project." This program was developed with the active assistance of both the scientific and practitioner components of the Association membership. Moreover, the background chapter and individual drug monographs that have been published to date seem to have been well received by all elements of the profession.

More recently, the Food and Drug Administration indicated that it, too, regards this general approach as a viable and valid one in determining the suitability of a drug product and the equivalence of multiple products. This was clearly revealed in the agency's proposed regulations published in late June pertaining specifically to "Bioavailability" and "Bioequivalence." APhA and its Academy of Pharmaceutical Sciences reviewed these proposed regulations and gave them a solid vote of approval.

So far, so good. It looked like everyone finally was on the same track and now in agreement on this long-debated, emotionally charged issue.

At least, it looked that way until we saw a recent full-page advertisement proclaiming in big bold print: "Bioavailability Data is Useful . . . as a measure of the absorption of a drug product . . . but not as a measure of equivalence between two or more products."

If bioavailability data are not useful as one of the factors to be considered in comparing, evaluating, and measuring the equivalency between drug products, then we have somehow been misled. And it seems to us like a lot of other people and groups concerned with drug quality have likewise been fooled.

The source of this ad is a major pharmaceutical firm with a large battery of highly qualified scientific personnel.

So we are confused. Does this company really mean to say that bioavailability data aren't useful in comparing product equivalence? Or is this company actually trying to discourage or dissuade pharmacy practitioner readers from utilizing bioavailability data in making product comparisons now that competing firms are releasing such data and inviting objective comparisons based upon hard data rather than catchy slogans?