ingredients are absorbed from the gastrointestinal tract at substantially the same rate and to the same extent as indicated by the time-course of their concentration in the blood. They are said to be therapeutic equivalents when they produce the same therapeutic effect with no difference in toxicity or side-effects.

Now it is a well-known and well-publicized fact that a number of studies, involving the products of a score or so of drugs, have shown that there were differences in the concentration of the active ingredient in the blood following the administration of chemically equivalent products from different sources. Clearly, this means that the standards for such products, or the enforcement of the standards, or both, were inadequate to assure the bioequivalence of those products.

It is very important to point out, however, that two drugs may differ in bioavailability, that is be bio-inequivalent, but may still be therapeutically equivalent. It is entirely possible, and, in fact, frequently true, that the concentration in the blood produced by two products may differ substantially, yet, for both, that concentration may fall well within the range between that required for the desired therapeutic effect and that at which unacceptable toxic effects are produced.

On the other hand, it is also true that in a very few instances, differences in bioavailability have led to well-documented therapeutic failures. The rarity with which such failures have been documented should not mislead one into believing that they are rare occurrences. There are so many other variables that affect the response observed when a drug is administered that it may be difficult to distinguish bioavailability as the source of the problem unless a careful study