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Perspective
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Bioequivalence & Bioavailability; Some Perspectives

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Perspective

The term "bioequivalence" refers to pharmaceutically equivalent products where the extent of bioavailability of the actives are not significantly (in the statistical sense) different under scientific conditions usually following the rules of scientific sampling. As a student of the famous W.E. Deming (1900-1993) these words are common knowledge to people and researchers like me. To those not attuned to scientific sampling, these methods and the term bioequivalence would have no meaning. With strong backing by agencies involved in the testing of new pharmaceuticals and retesting of established drugs (both generic and proprietary) created by "perfect" law, the results will always be sound and scientifically justifiable.

In the United States, agencies of government are working to keep the creation of new pharmaceuticals safe and useful in both the diagnosis and treatment of a huge number of health treatment and diagnostic problems. In the common sense of the term bioequivalence, society would feel confident that two or more pharmaceuticals are equivalent if their characteristics and purpose of curing the same treatment or diagnosis in the very same manner. Two or more pharmaceuticals if examined scientifically may show results that cannot be found statistically different. If that occurs the two or more drugs would be bioequivalent. Perfect law would have the purpose of establishing the scientific system for such a process. Those who dispute this have several arguments. Law may not be "perfect" and imperfect law creates conflict in the interpretation of the law and its eventual execution. We live in a society where law governs and to which we call "living law." Hence, science advances the development and creates bioequivalent pharmaceuticals. Also, creates and develops testing methods employed by agencies of government to produce safety in usage and effects of pharmaceuticals and also in the use bioequivalent products. Last, using phrases like increase bioequivalence makes no sense from a sampling and testing point of view. Borrowing from previous scientific work, we can if two products are equivalent in every manner they cannot be different in anyway. If sampling differences are found, then we must determine if the difference is sufficiently large as to conclude that sampling variation cannot explain the small differences in the samples observed and analyzed. Monitoring results of tests is important to make certain that two products that found to be different come from separate and not equal populations.

Bioavailability refers to the extent to which a pharmaceutical reaches its site of action or a biological fluid such as blood that can access to its site of action. The two terms bioequivalence and bioavailability do not mean the same. Bioavailability is a subcategory of absorption and is the percentage of an administered dose of a product or drug that reaches circulation. This is a property of a drug and is part of principal pharma kinetic characteristics of pharmaceuticals. By definition, when a medication is administered intravenously, its bioavailability is 100%. Hence bioavailability and bio equivalence have different meaning and one can speak in terms of percentages of bioavailability but one cannot speak in terms percentages of bioequivalence. These are important concepts to understand whenever one analyzes large data sets sampled from populations.