In recent years, an impressive number of noted physicians, pharmacologists and pharmacists, both in academia and in practice, have pointed to the importance of existing data in this field.[8] For example, a 1969 "White Paper on the Therapeutic Equivalence of Chemically Equivalent Drugs" prepared by a subcommittee of the National Academy of Sciences-National Research Council stated that:

> "variations [in serum levels of equal doses of drugs marketed by different manufacturers] indicate that therapeutic equivalence, or equal biological activity, cannot necessarily be inferred from equivalence in the chemical constitution of different formulations of the same drug."[9]

In the same year Alfred Gilman, Professor and Chairman of the Department of Pharmacology of the Albert Einstein College of Medicine said:

> "Trying to brush the problem of equivalency under the rug by calling it a rare occurrence is not succeeding. It may be a rare occurrence, in vitro. When it's a matter of crossing the mucosal barrier, that is another issue."[10]

In 1970, Dr. Charles C. Edwards, then-Commissioner of the FDA, warned that:

> "It has become increasingly apparent that drug products which purport to be equivalent and which may satisfy chemical and other analytical tests of equivalence, may not be therapeutically equivalent. . .. We have found that comparable bioavailability frequently does not exist for products that are otherwise, so far as currently available methods [of assay] are concerned, identical."[11]

Perhaps the most concise summary of the situation was given by Denis N. Wade, Director of the Department of Chemical Pharmacology at St. Vincent's Hospital in Sydney, Australia, when he stated that:

> "the plethora of evidence linking therapeutic performance of drugs with their pharmaceutical formulation indicates that different preparations of a drug should be assumed to be different therapeutically until proven the same."[12]