The most recent, and for present purposes, the most persuasive statement on bioavailability comes from the Report of the Office of Technology Assessment. The very first conclusion in the Report is that "current standards and regulatory practices do not insure bioequivalence for drug products".[13] In the words of the Report:

> "[T]here can be no dispute about the fact that well-documented and significant differences in bioavailability have been demonstrated in chemically equivalent products representing a number of drug categories."[14]

Among the partial list of scientific studies which the OTA Panel cites in support of its conclusion are those dealing with tetracycline,[15] chloramphenicol,[16] digoxin,[17] phenylbutazone, [18] and oxytetracycline.[19] The OTA Panel also pointed out that its partial list of studies demonstrating bioavailability problems should not be taken as a conclusive listing, since "[p]roblems of bioequivalence have received serious investigative attention only during the past few years". In short, the OTA Panel was satisfied that "the problem of bioinequivalence in chemically equivalent products is a real one. . ." and that there is:

> "unequivocal evidence that neither the present standards for testing the finished product nor the specifications for materials, manufacturing process, and controls are adequate to insure that ostensibly equivalent drug products are, in fact, equivalent in bioavailability."[20]

All of this would not have been so disturbing to the OTA Panel if it were not "also a fact that <u>therapeutic</u> inequivalence has been observed among certain chemically equivalent drug products".[21] And the Panel found little reason to doubt that "other therapeutic failures and/or instances of toxicity [due to bioavailability problems] have escaped attention".[22] The Panel is undoubtedly correct on this point, since most of the studies undertaken to date have been designed to show differences in bioavailability without necessarily correlating