until the standards themselves have been validated and correlated with clinical observations. To say that bioequivalence is unimportant in many drugs (for interchangeability) because of a wide range between an effective dose and a toxic one does not follow the same logic that is applied in requiring the labelled amount of an active ingredient (within tolerance limits) to be present in a pharmaceutical product. This would fail to distinguish, as an important consideration, between minimum and maximum effectiveness. The health and safety of Medicare and Medicaid patients must not be jeopardized while FDA uncovers problems of therapeutic inequivalence and promulgates bioavailability standards that may or may not assure the uniform effectiveness of drugs that are marketed as chemical equivalents.

In the end, the quality of care must depend principally on the professional skill and judgment of the practicing physician. He alone knows the clinical performance of a drug product for each patient he treats. The proposed regulations purport to recognize the paramount role of the physician by permitting him to certify a patient's need for a particular brand of drug. But they allow for such certification only when a specific manufacturer's product is the "only" one that can be tolerated by or will be effective for a particular patient. No physician could properly make such a certification without testing every available product on each patient. The exception may thus prove illusory. Moreover, the enumerated criteria for certification ignores many other legitimate reasons that might underlie a prescription for a particular manufacturer's product -- such as the desire to maintain a uniform course of therapy or to assure consistency