Assumption of equivalency and quality care.

Underlying the program is the assumption by the Department that drugs which are chemically equivalent are equivalent in other respects, such as bioavailability and therapeutic response. Contrary to what one might expect, the regulations create for the FDA, the nation's chief health agency having greatest accumulated governmental drug expertise -- a relatively minor role, a role almost of a totally passive nature. The FDA, upon request of the Board, would be required merely to advise the Board as to "any pending or anticipated regulatory activity, including the establishment of a bioavailability requirement, which would warrant delay in establishing a MAC for that drug." Apparently, in the absence of any such regulatory activity, equivalence in all essential respects is presumed. We submit that any such presumption is unwarranted. Any presumption should be to the contrary, that is, that drugs are not generally equivalent.

We are convinced that many disparities exist in so-called equivalence of drugs that can result in a significant difference in therapeutic effect. It is for this reason that the American Medical Association must question the proposed MAC program as it relates to quality medical care.

There are many parameters that must be considered in evaluating the equivalence of drugs:

(A) Chemical equivalence - do the drugs meet prescribed standards of chemical purity?

(B) Quality control - do the drugs meet acceptable standards of wholesomeness with respect to non-therapeutic ingredients?

(C) Bioavailability - are the drugs absorbed in such a manner as to produce consistent blood levels?

(D) Therapeutic equivalence - can the drugs produce similar pharmacologic actions in the same patient?

(E) Stability - do the drugs deteriorate "on the shelf" at a similar rate?

(F) Patient acceptability - will the patient "take" either drug with equal adherence to instructions?

Instances are known where so-called "equivalent drugs" failed to meet one or more of the foregoing criteria of equivalency. For example, recent evidence has been presented to show gross differences in the rate at which different brands of digoxin are absorbed. Because this cardiac drug is extremely potent, even small increments in bioavailability can mean the difference between no discernible effect, a satisfactory therapeutic response, or dangerous toxicity. Likewise, every practicing physician is familiar with peculiarities in patient acceptance that can profoundly affect willingness to follow a prescribed drug regimen. Such factors as differences in taste, color, size, or shape of tablet, or the dosage form, can be critical in determining whether the patient will "take" the prescribed medication.