accordance with official compendial standards and current good manufacturing practice regulations. These standards and regulations, as the Office of Technology Assessment's Drug Bioequivalence Study Panel has made clear, do not ensure quality and uniform bioavailability for drug products.[5/] In these circumstances, it would be superficial -- and perhaps dangerous -- for the government to include any drug in the MAC program merely on the basis of the criteria specified in the regulations.[6/] Needed in addition is a searching investigation as to assurances of quality respecting all involved manufacturers.

B. The Invalidity of an Assumption of Bioequivalence

HEW's assumption of bioequivalence among differing versions of a chemically equivalent drug product is, if anything, even less justified than its assumption that FDA can provide assurances of uniform quality. In January, 1973, FDA stated without equivocation that:

> "it has now been established that different formulations of the same drug may produce differing concentrations of drug in body tissues or fluids when tested under standardized conditions even though the formulations may meet current standards for in vitro testing.
>
> * * *
>
> "It is not possible to specify at the present time the frequency with which lack of equivalence in bioavailability of chemically equivalent formulations may occur."[7/]

In proposing the MAC regulation, HEW points to no new evidence which would cause it to dissent from this earlier FDA position. Indeed, incidences of bioinequivalence among chemically equivalent formulations of the same drug seem to have increased recently, as has informed opinion that such differences may have significant therapeutic consequences.