these basic questions are not answered, and so long as the undesirable effects on physician and pharmacist prerogatives and services and industry innovation persist, adoption of the proposed MAC program would be both unfortunate from a public policy standpoint and, in a number of respects, inconsistent with the requirements of the law.

The Equivalency Assumption

These regulations, as published, appear to be based on the assumption that multi-source drug products, regardless of the maker, are equivalent. In our opinion, this position cannot be sustained. A program like MAC must be designed so as to require the selected suppliers of drugs to submit proof of their ability to perform effectively and proof that their drugs are in actual conformance to reasonable standards of bioequivalency. In reality, the present regulation goes in the opposite direction. It proposes, in the absence of published bioavailability regulations, to allow a MAC determination to be made entirely on the assumption that products covered are satisfactory, even if some formulations of those products are marketed without the knowledge or approval of the FDA. Put another way, HEW proposes that unless there is proof of inequivalency, equivalency will be assumed -- a totally unscientific approach. The MAC determination would be made without knowledge of the ability of the supplier to conform to current standards of quality control, or assurance of a capability to recall defective products from the marketplace. Under such circumstances, it is clearly over-sanguine for FDA to offer equivalency assurances.