C. Specific Comments on the Proposed Regulation

1. Absence of a Requirement for Specific Findings on Quality Assurance, Bioavailability and Therapeutic Equivalence

Another major flaw in the regulations is the absence of a requirement that quality and bioavailability issues be considered at any stage of the proceedings or that findings on those issues be made by the Pharmaceutical Reimbursement Board before finally adopting a MAC for a particular drug.[42/] Under Section 19.5(b) of the basic MAC regulation, it is possible that FDA might raise a bioavailability issue if a regulatory action were pending with respect to that drug. But nothing in the regulation suggests that FDA must or should comment on quality or bioavailability issues in the absence of pending or anticipated regulatory action. And the fact that no regulatory action is pending at FDA can hardly be taken as an assurance that no such problems exist for the drug under consideration.

Similarly, it is possible that the Pharmaceutical Reimbursement Advisory Committee might raise quality or bioavailability questions on its own initiative when a proposed MAC is submitted for review under Section 19.5(d). But the Committee is certainly not directed, let alone required, to do so. Most important, under the proposed regulation, the Board itself need not consider these issues and, accordingly, need not make findings on them. As a result, it is entirely possible, if not likely, that MACs will be established for drugs that may vary significantly in quality and bioavailability from one supplier to another.

As discussed above, several provisions of the Medicare-Medicaid statutes are designed to preclude such a result. Thus while the Secretary may establish reimbursement limits at the level of a low