it needs to illuminate those issues."[56/] If the procedure adopted does not adequately develop "the materials requisite for a rational decision", the proceeding is legally defective even though the regulatory statute under which it was conducted does not specifically require a more elaborate hearing.[57/]

As noted above, the Medicare-Medicaid statutes require that in establishing a MAC for any drug product, a "hard look"[58/] must be taken at the issues of quality assurance, bioavailability and therapeutic equivalence. Since the considerations to which those issues pertain occupy a central position in the overall scheme of the federal health care legislation, they possess great substantive importance. In the current state of the science of biopharmaceutics, these issues are ones on which evidence may be both difficult to obtain and subject to varying interpretations. At least until further progress is made in assessing them, they will remain unusually complex and resistant to confident resolution on the basis of a simple comment procedure. If the Board is to be presented with all of the materials "requisite for a rational decision", it will be necessary to ventilate these issues in a proceeding that is more adversary and adjudicative in nature.

In this connection, it is instructive to note that, in important respects, a MAC determination would be closely analogous to rate regulation. To be sure, a MAC proceeding would not result either in a determination that any particular supplier's price is unlawfully high or in the setting of a different price which the supplier must charge in the future. Yet while a supplier would, strictly speaking, remain free to charge any price, this freedom might be largely illusory,