12386 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY which may be held at the discretion of the Board. If such a hearing is held at all, it may be restricted both as to the number of participants and the types of issues.

Hence it is entirely possible that the rights of interested parties to participate in a MAC determination may be limited to the bare minimum required by Section 4 of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553, for rule-making proceedings, viz. the opportunity to submit written views without an opportunity for oral presentation. And even this skeletal form of participation would occur at a stage of the proceeding when the Board's views will have already been crystalized as a result of the input which it would have received from FDA and the Committee.

We recognize that there is no specific requirement in the Social Security or Medicare-Medicaid statutes that a MAC-type determination be preceded by a formal hearing on the record with full opportunity for presentation and cross-examination of witnesses. However, the fact that the formal evidentiary hearing requirements of Sections 7 and 8 of the APA, 5 U.S.C. \$\$ 556 and 557, do not apply does not mean that HEW can properly conduct a MAC proceeding on the basis of the minimum rule-making standards of 5 U.S.C. \$ 553. While 5 U.S.C. \$ 553 and 5 U.S.C. \$\$ 556 and 557 define the two poles of possible administrative procedures, they are not the only alternatives which may be employed. 53/In appropriate circumstandes, a proceeding which need not be conducted in accordance with the full panoply of adjudicatory safeguards set forth in 5 U.S.C. \$\$ 556 and 557 may still call for a more elaborate opportunity for participation by interested parties than is provided by 5 U.S.C. \$ 553.54/ This is especially likely to be the case

"when the issue presented is one which possesses great substantive importance, or one which is unusually complex or difficult to resolve on the basis of pleadings and argument."55/
In all cases, the agency should attempt "to realistically tailor the proceedings to fit the issues before it [and] the information [which]