Thus, as a matter of law and of sound administrative policy, a more meaningful opportunity for participation than is presently provided by Section 19.5(e), (f) and (g) of the regulation would seem to be required in MAC determinations.

Perhaps most important, a hearing on a proposed MAC should be held in all cases, and at such a hearing, the Board should present its evidence and arguments. All interested parties should then be permitted to present their own evidence and arguments either supporting or opposing the MAC. Opportunity for cross-examination should be provided at the request of any party if the written submissions demonstrate the existence of substantial and material disputed issues of fact regarding the critical points of quality assurance, bioavailability or therapeutic equivalence.60/

V. CONCLUSION

In the preceding discussion, we have shown that existing evidence undercuts the critical assumptions of the MAC proposal. The program, as proposed, would not be workable or lawful. It rests on a foundation that is unsupportable in science, defective in economics and capricious in law. It would unmistakably work against the public interest because: (1) chemically equivalent drug products are not always therapeutically equivalent; (2) FDA cannot assure the quality of all formulations of currently marketed drugs that would come under the program; (3) professional prerogatives are not protected; (4) research and quality-based manufacturers and other responsible element of the pharmaceutical complex cannot operate as efficiently and innovatively under a "lowest price" reimbursement system; and (5) direct and indirect