assumption that the least expensive nationally available version as revealed in the invoice audits, was used to fill all prescriptions. Applying the analysis to Medicaid out-of-hospital drugs, the "saving" approximated $13 million for the 25 drugs.26/

From what has already been said, we are convinced that the administrative costs alone would exceed the promised savings.

Before such a radical change in drug distribution practices and drug development is suggested, particularly at a time when the President has called for a moratorium on new programs involving additional costs, HEW should offer convincing evidence that it will provide a clear net benefit or a saving. It appears to us that the MAC proposal would not survive such a critical review -- even without a consideration of medical risk from non-equivalent drugs and with no weight given to the other negative factors previously identified.

IV. LEGAL ISSUES AND SPECIFIC COMMENTS

In the preceding discussion, we have argued that implementation of the MAC proposal would be a serious error from a scientific, economic and public policy point of view. In the pages which follow, we show that the MAC proposal cannot lawfully be promulgated unless and until FDA is able to assure the quality and equivalency of the products of each supplier of any drug included in the program. We also offer comments on other legal problems raised by the regulations.

A. Inconsistency with Medicare-Medicaid Statutes

1. Quality of Care

Throughout the Medicare-Medicaid statutes, Congress has repeatedly