While these provisions approach the quality issue from different perspectives, their sum and substance, as stated by the House Committee on Ways and Means, is to insure that the beneficiaries of these federal health programs receive "the best of modern care."[29/]

As indicated in Part II above, a number of sources have already provided careful documentation of significant differences in bio-availability among chemically equivalent products. The developing literature in the field of biopharmaceutics has identified a number of instances of therapeutic failures,[30/] and the absence of documentation of additional failures cannot be taken as an indication that such failures do not exist, but only as a symptom of the fact that adequate, well controlled experiments directed toward this problem have been undertaken only recently.

Finally, it cannot reasonably be argued that present compendial standards, GMP guidelines and FDA regulatory procedures provide assurances of quality or equivalency for drug products regardless of source. Again, these points have all been recognized in the OTA Report[31/] and the conclusions of the OTA Study Panel should not be lightly disregarded by HEW.[32/]

In these circumstances, it is clear that implementation of the MAC proposal at this time could jeopardize the quality of drug therapy available to federal health care beneficiaries, contrary to the express congressional intent underlying the Medicare-Medicaid legislation.

2. Interference with the Practice of Medicine and Pharmacy

The inability of FDA to provide assurances as to quality or therapeutic equivalence also means that the MAC proposal cannot be squared with provisions in the Medicare-Medicaid statutes which