> "The existing drug and manufacturing standards, our drug surveillance system, our batch testing requirements, and our selective bioavailability requirements make it possible to say that any drug that meets these requirements can be expected to produce safe and effective results."37/

That this assumption of quality and therapeutic equivalence underlies the MAC proposal was made apparent when the Secretary next remarked that:

> "in the absence of demonstrated differences in uniform quality and therapeutic equivalence, there is no reason why the Government should pay more for a drug than the lowest prices at which it is widely available, either in our direct purchase or our reimbursement program. . .."38/

Similarly, the preamble to the proposed MAC regulation notes that questions have been raised "about differences in quality and effectiveness" but goes on to assure that:

> "the existing drug and manufacturing standards, drug surveillance system, batch testing requirements, and other standards such as bioavailability requirements, where needed, will assure safe and effective drugs of consistently high quality."39/

In short, HEW recognizes that to be valid a MAC type proposal must rest upon findings of quality assurance and therapeutic equivalence. Yet as demonstrated in Part II above, the existing evidence on those issues simply will not support the required findings. To the contrary, the evidence suggests that differences may extend across a wide spectrum of drugs.

Until HEW comes forward with evidence which will support findings of quality assurance and therapeutic equivalence, adoption of a MAC program will lack the required "rational connection between the facts found and the choice made."40/ Since the evidence does not provide a factual predicate which will support the assumptions underlying the MAC program, implementation of the program would be arbitary and capricious.41/