Without such a determination, the government will interfere unjustifiably with the physician's clinical experience and judgment and will abrogate the right of Medicare and Medicaid patients to be treated in the same manner as non-subsidized private patients. By intruding into the physician-patient relationship and substituting its judgment for that of the physician, the government assumes an obligation to assure that there is no therapeutic difference between the products it will pay for and those that would have been prescribed absent a MAC program. To date, no such assurances have been given that such determinations would be made.

The proposed program fails in several important respects to assure that Medicare and Medicaid patients will receive high-quality, effective drugs. The rules that would govern the establishment of MACs for drugs treat the problems of quality assurance and therapeutic inequivalence in a cavalier and off-hand manner. The multiple source drugs to which the MAC policy will apply are to be identified by a Pharmaceutical Reimbursement Board, with the advice of a Pharmaceutical Reimbursement Advisory Committee, on the basis of (a) dollar volume of actual or anticipated usage and (b) the existence of products from more than one source at significantly different prices. Provision is made for the Food and Drug Administration "to advise the Board of any pending or anticipated regulatory activity, including the establishment of a bioavailability requirement which would warrant delay in establishing a MAC for that drug." Nothing more. As a minimum, HEW should assure that all drug products eligible for reimbursement in a class for which a MAC has been established are