program are of uniformly acceptable quality and equivalence in terms of bioavailability and therapeutic effectiveness. The MAC proposal is based on the claimed capability of the Food and Drug Administration to provide such assurances. Unfortunately, this is wishful thinking. We stated our objections to this assumption on December 19, 1973, the day MAC was first proposed. We are equally firm in rejecting it today.

The lack of such a present capability in the FDA, and the almost unanimous opinion of the scientific community that the bioequivalency of drugs cannot be assumed or assured, presents a powerful argument against the proposed regulations.

A. The Inability of Government to Assure Uniform Quality

A prerequisite for any government program that would restrict and infringe upon the professional judgment of physicians or pharmacists is a demonstrated ability on the part of the government to assure quality and equivalent therapeutic effectiveness. Moreover, such an assurance must be based upon affirmative evidence of an effective and reliable government monitoring program. It cannot rest upon generalized assumptions based merely on an absence of known quality control or bioequivalency problems.

Thus it is patently insufficient to base a MAC determination merely on an FDA statement that no regulatory action, including bioavailability, is pending or anticipated with respect to a candidate drug. An informed decision cannot be made without far more information covering, for example, the recall history of the drug, the names and qualifications of suppliers and the record of relevant inspection problems that have been associated with the drug or its suppliers.