them with therapeutic failure.

Of additional significance is the fact that the long awaited regulations of the Food and Drug Administration on bioavailability, proposed on January 5, 1973, have still not been published in final form.

In sum, scientific evidence demonstrating drug bioinequivalency is overwhelming. While the estimate of the number of drugs with such problems may vary, the fact remains that many multiple-source drugs are already known to exhibit significant bioinequivalencies, and many more may present problems which have not yet been recognized. Certainly, the FDA -- which, as we have shown, cannot even provide adequate assurances of drug quality and chemical equivalence on the basis of its present regulatory requirements and surveillance procedures -- is in no position to provide satisfactory assurances as to the more sophisticated parameters of bioequivalence.

C. Specific Criteria to Establish Quality and Equivalency

Until HEW is in a position to assure the uniform quality and effectiveness of the drug products to be included in a MAC program, there is no proper basis for the institution of such a program. When and if questions of quality and bioequivalency are adequately resolved, and effective protection can be provided against drug products of uncertain quality or effectiveness, any program that might be instituted should require that FDA provide certain basic information to the decision-making authorities. Such information should, at a minimum, include the following:

1. Firms known to produce or supply the drug product for the U. S. market.