therapeutically equivalent. No assurances of such intentions are given in the present proposal.

In the preamble to the proposed rules, the Department acknowledges the existence of questions about differences in the quality and effectiveness of different-price drugs. It also acknowledges its obligation to see that all drugs "are formulated to be safe and effective and are manufactured under optimal conditions to assure consistently high quality." But it is a well known fact that all drug products on the market are not manufactured under "optimal conditions," nor are they of uniform quality. Although HEW has acknowledged its obligation to Medicare and Medicaid patients to provide quality drugs, the Department makes no commitments to assure that this obligation will be carried out. HEW appears to rely on the assertion that, if the Food and Drug Administration permits a product to enter and remain on the market, it is acceptable.

NPC understands that HEW proposes to exclude from its MAC program only those drugs in which bioavailability is considered to be an important factor, or for which unresolved problems of bioavailability are known to exist. The remainder would be eligible for immediate inclusion on the MAC list. Good reason exists, however, to believe that our present knowledge of bioavailability and therapeutic equivalence is deficient for many drugs. The necessary scientific studies have simply not been conducted. An assumption that drugs are equivalent based on the mere absence of data is unwarranted. Even as bioavailability problems are discovered, they cannot be effectively eliminated by government-imposed standards