sured. The proposed regulations seem to stress the Committee's advice on policy and economic considerations of placing drugs on the MAC roster, but the Committee should also be utilized to advise HEW in the area of bioequivalency and quality assurance.

In order for the Committee to fulfill the above responsibilities, the Academy recommends that composition of the Pharmaceutical Reimbursement Advisory Committee include an expert in biopharmaceutics and an expert in clinical pharmacology. The Committee's ability to analyze the adequacy of current standards, that will be depended upon to assure quality and performance of the MAC listed drugs, rests upon adding these additional experts. We urge HEW not to rely entirely upon their own FDA in matters of drug quality and bioequivalence.

With respect to the issue of drug product quality, and specifically the report of the Office of Technology Assessment referred to in the above-quoted APS comments, APhA notes, as APS points out, that the OTA panel report concludes that "current standards and regulatory practices do not assure bioequivalence for drug products." By the same token, the OTA panel also concluded that "it is neither feasible nor desirable that studies of bioavailability be conducted for all drugs or drug products."

Affirmatively, the OTA panel recommended that an official list of interchangeable drug products be developed as rapidly as possible and that such a list distinguish between those drugs which might present bioavailability problems and those drugs "for which evidence of bioequivalence is not considered essential."

In response to this latter recommendation, the Association, with the full cooperation and assistance of the Academy of Pharmaceutical Sciences, proffered to the Department at its request a list of drugs intended to aid in implementing the OTA panel recommendation. Thus, it appears to APhA that events which have already transpired taken in combination with the "FDA clearance" procedure will provide the necessary assurance that establishment of a MAC for a particular drug will not represent a threat to the public health.

As the Association has repeatedly stated, and as the OTA panel itself implicitly recognized, there is no way, even through the expenditure of unlimited funds, that pharmaceutical scientists, the pharmaceutical industry, or the government can assure a "zero defect" level of drug product quality. What can be provided is a vigorous assurance that drug product quality in the United States is extremely high overall and that the incidence of inadequate drug product quality is extremely low. As a means of continuing this assurance, the Association urges the FDA to consider application of dissolution requirements in its "clearance" procedure, as previously recommended by the Association, as well as any additional available laboratory tests representing current technology.

The Association supports the APS suggestion that a biopharmaceutics expert serve on the Pharmaceutical Reimbursement Advisory Committee and notes that the proposed regulations are sufficiently broad to encompass such specific expertise. The Association assumes that the Committee will advise with regard to, among other matters, the quality standards to be applied to drug products under MAC consideration.

DRUG PRODUCT COST

APhA believes that the provisions of Section 19.6, which assure not only a regular review of MAC determinations, but also the right of any individual or organization to request imposition of, adjustment of, or termination of a particular MAC at any time is both eminently fair and capable of efficient administration. The Association notes, however, that a provision which is capable of efficient administration may be worthless unless it is, in fact, efficiently administered. In the absence of prompt administrative decisions by the Department, the entire reimbursement mechanism for pharmaceutical service in federally supported health care programs is in danger of failing. The final regulations should address themselves in Section 19.6 to two specific eventualities.

First, the Board should be empowered to make MAC determinations on an emergency basis without resort to the advisory committee procedure when such action is deemed necessary by the Department. A specific situation which might require such emergency action would be in the case of sudden and unexpected drug product shortages which, among other effects, might have abnormal disruptive effect on drug product prices. Such situations have already been experienced in the cases of quinidine, heparin and injectable ampicillin. A similar situation may be anticipated in the next one or two years in light of projected shortages of codeine.

Second, the final regulations must contain in Section 19.6, or elsewhere, provision for automatic retroactivity of upward MAC adjustments, once an initial MAC has been established for a particular drug, to compensate for possible delays in the MAC determination procedure and expected computer update delays at the state level. Downward MAC adjustments can be made concurrent or prospective in application.

Probably the most controversial aspect of the proposed regulations is the imposition of an "actual acquisition cost" reimbursement basis for drug product cost in all federally supported health care programs. This requirement is presently in effect in only a few states. Despite the fact that many pharmacists may not yet fully understand the following reasons for this decision, APhA is constrained to support this requirement as reflected in Section 19.3 of the proposed Departmental regulations and also in Section 250.30(b) (2) (ii) of the proposed Medical Assistance Plan regulation, Sections 50.502 (d) and 504(b) of the proposed Public Health Service Regulations, and Section 405.333(a) of the proposed Medicare regulations.

Imposition and *enforcement* of the actual acquisition cost requirement is deemed mandatory by APhA to protect the government, taxpayers and competing pharmacists against economic windfalls which accrue to large volume purchasers of drug products when drug product cost reimbursement is based on published "list," "average wholesale prices" or other fictitious price data.

It is well known among pharmacists, third party program administrators and government officials, that drug products cost reimbursement based on catalog prices is based on fictitious price information and that actual acquisition costs by pharmacists generally range below published figures. Depending upon the purchasing power of particular pharmacies and the proclivities of drug manufacturers and their salesmen, actual acquisition costs have resulted in "significant" to "gross" overpayment for the drug product component of prescriptions paid for, at least in part, with federal funds. Large volume and other "favored" purchasers such as dispensing physicians have been the chief recipients of special economic windfalls.

When the Pharmaceutical Reimbursement Board obtains true price information from drug manufacturers, the Board will learn that price concessions have frequently been granted to such purchasers to a level of 40-50 percent and more below published catalog prices. This fact is confirmed by the earlier referred to Council on Economic Priorities study. Reimbursement to such purchasers based on catalog prices, therefore, not only constitutes a "rip off" of the government