Department on its own motion, particularly in view of the Committee's broad based representation, can only serve to facilitate communications between the Department and those interest groups most directly affected by the proposed regulations.

A major pitfall in the proposed MAC regulations is the failure to provide in Section 19.5, or elsewhere, that the Pharmaceutical Reimbursement Board may require the submission of actual drug product sales price information by drug manufacturers and wholesalers. APhA has, for years, focused attention on the utterly chaotic marketing practices of the drug industry which make it virtually impossible for pharmacists or third party program administrators to know the real cost of a drug product dispensed in a specific prescription. Unless and until true price information is required of manufacturers and wholesalers by the government, any effort to establish a MAC for any drug on the basis of "the lowest unit price at which the drug is widely and consistently available" is doomed to be an utter and complete failure.

Unless the proposed regulations are amended as APhA suggests, the Board will experience incredible frustration, which will surely come when it attempts to determine its first MAC. At that point, APhA predicts, the Board will either throw up its hands at an impossible task or will develop proposed MACs on the basis of fictitious price information, thereby perpetuating the very situation the Department is seeking to end. If this results after the months of planning and effort which purportedly have been devoted to this project, the MAC program will become a laughing stock. Certainly, the "price information" aspect of the MAC program, for which the Department has expressed great expectations is totally dependent on the obtaining of current true price information. Without it, the game goes on.

An economic study by the Council on Economic Priorities, released January 3, 1974, notes that while several drug manufacturers cooperated in providing true sales price information for that study, other manufacturers resisted disclosure of such information. In fairness to all drug manufacturers, a mandatory disclosure requirement should be included in the regulations and evenly applied.

In addition to the necessity of obtaining true price information, there should be an additional principle that a MAC should be established at the lowest price level at which a drug manufacturer sells a particular quantity of a specific drug product without regard to the nature of the purchaser. In other words, any effort by the Department to identify "the lowest unit price at which the drug is *widely and consistently available*" is also fated to be an exercise in sheer futility. By its very nature, and the nature of drug industry pricing practices, even if government sales are eliminated from consideration, the phrase "widely and consistently available" clearly requires a purely subjective interpretation by the Board. Just as clearly, however, the lowest price for a specific quantity of a drug product at which a manufacturer actually sells, is a purely objective fact readily determinable from actual sales records which a manufacturer can and should be required to provide. There simply is not apparent a more equitable way in which all sellers and purchasers of drug products can be treated by the government and no more realistic way to bring order out of present drug manufacturer pricing chaos.

The MAC program is not a situation in which the government can turn its back on private sector practices and accept whatever goes on in the marketplace as "competitive." In this situation, it is government money obtained from the taxpayers which is being spent and the taxpayers have every right to expect that the government will not only make the most prudent use of that money, but also that the government *will know* that it is making the most prudent use of that money.

APhA takes the position that application of the MAC limitation merely to multi-source drugs is inadequate, because, even for single-source drug products, selling prices by manufacturers and wholesalers vary widely and irrationally. Implicit recognition of this fact is contained in Section 405.433 (b) (2) and (3) of the proposed Medicare regulations. These provisions make "prudent and cost-conscious" buying practices the rule for Medicare and make this rule applicable even to single-source products. The other proposed regulations should be consistent and do the same.

If it wishes the continued cooperation of practicing pharmacists, who are now being asked to accept changes in the means for determining their professional fees, the government must assure pharmacists they will not be required to carry the double burden of a continued lack of fair treatment and a continuation of chaotic marketing practices in the drug industry. If this assurance is not forthcoming in the final formulation of the referenced proposed regulations, pharmacist cooperation likely will not be forthcoming and there will be little that this Association, any other pharmacy organization, or the government will be able to do. Now is the time for the Department to assure the continued goodwill of the nation's pharmacists.

DRUG PRODUCT QUALITY

As previously indicated, APhA and its members have an enduring interest not only in the economic issues raised by these proposed regulations, but also in the professional and scientific issues which have been widely discussed since Secretary Weinberger's December 19, 1973 testimony.

APhA supports the provisions of Section 19.5(b) calling for review by the Food and Drug Administration of each drug under MAC consideration and "clearance" by the FDA for any drug which would be subjected to a MAC limitation. The Academy of Pharmaceutical Sciences, a subdivision of APhA, has offered the Association a summary of its viewpoints regarding these proposed regulations, pertaining specifically to matters of drug product quality, and the composition of the Pharmaceutical Reimbursement Advisory Committee. APhA believes that these viewpoints can best be evaluated if this summary is presented *in toto:*

Drug Quality

The Academy of Pharmaceutical Sciences is concerned over the dependence placed by the HEW on the current standards, practices and regulations of the FDA and USP/NF to assure the equivalent quality and performance of drug products to be placed on the MAC list. We urge HEW to pay greater attention to the recommendations of the Office of Technology Assessment Report which clearly stated, that "Current standards and regulatory practices do not assure bioequivalence for drug products." Similarly the Academy, in its list of drugs submitted through APhA to HEW, specifically stated that before drugs are actually included on a proposed MAC list, that at least equivalent in-vitro *performance to an established prototype product be demonstrated by discriminating methodology. We urge HEW to implement these added assurances through the wording of the final regulations.*

Pharmaceutical Reimbursement Advisory Committee

The APS wishes to recommend that the responsibilities proposed for this Committee be broadened. Their responsibilities should include the ability to give advice on the adequacy of the standards, which will be applied to the drug products for the MAC list, in order that equivalent quality and performance is as-