FEDERAL TRADE COMMISSION,
OFFICE OF THE SECRETARY,
Washington, D.C., February 24, 1975.

HEARING CLERK,
Food and Drug Administration,
Rockville, Md.

DEAR MADAM: This letter is in response to your invitation to submit written comments as to the following proposed rules governing certain of HEW's prescription drug reimbursement programs:

"Maximum Allowable Cost for Drugs: Limitations on Payment or Reimbursement for Drugs," 39 Fed. Reg. 40302 (Nov. 15, 1974); and

"Reimbursement of Drug Cost—Medical Assistance Program," 30 Fed. Reg. 41480 (Nov. 27, 1974).

Please consider the attached statement of Federal Trade Commission Staff for purposes of comment to your proposed rules. This statement has not been adopted as an official statement of the Commission.

Very truly yours,

CHARLES A. TOBIN,
Secretary.

Attachment.

STATEMENT OF THE STAFF OF THE FEDERAL TRADE COMMISSION CONCERNING HEW'S MAXIMUM ALLOWABLE COST PROPOSAL

The Department of Health, Education and Welfare announced on November 15, 1974, by way of a proposed regulation in 39 Federal Register 40302 ("Maximum Allowable Cost for Drugs"), its intention to reduce expenditures for drugs in programs of the Department, principally Medicare and Medicaid. Actual implementation regulations which will change the existing reimbursement policies have been published as to Medicaid—39 Fed. Reg. 41480 (Nov. 27, 1974) ("Reimbursement of Drug Cost—Medical Assistance Program"). The Medicaid program, wherein the Federal Government provides funds to states, is the principal program dealing with reimbursement to out-of-hospital pharmacists. Others typically involve direct reimbursement to institutional providers for inpatient care, including the dispensing of drugs.

This comment discusses only the Medicaid program. The implementation regulations as to the Department's other programs were not issued in time to be considered in this analysis. The comment is designed to assist HEW in strengthening its proposals to better achieve certain pro-competitive goals cooperatively embraced by both agencies.

I. INTRODUCTION AND SUMMARY

It seems axiomatic that the Federal Trade Commission (FTC) should be interested in creating and sustaining effective competition throughout the prescription drug industry so that prescription drugs are available to consumers at the lowest possible prices. HEW's main thrust in its regulation concerning "Maximum Allowable Cost for Drugs" (MAC) is to assure that the government pays out no more in reimbursement for drugs under Medicaid than is truly necessary for those drugs to be provided.[1] As designed, the MAC plan is a utility rate regulation scheme which attempts to simulate, through determination of necessary costs plus a "fair" return, a competitive price.

The goals of the two agencies in this respect seem to be in complete alignment. Both agencies recognize that because of competitive problems in the pharmaceutical market, the prices currently prevailing may not be as low as they could be.[2] However, the position taken by FTC staff is that measures (other than a utility rate regulation approach) to strengthen competitive forces would be less expensive, more straightforward, and totally more satisfactory than a

[1] Staff understands that the total reimbursement to a pharmacist (via the state under Medicaid) for dispensing a prescribed drug is composed of two elements: (a) his acquisition cost of the drug; and (b) his charge for dispensing the drug.

[2] Numerous sources of competitive problems have been discussed in both the economics literature and in lengthy Congressional hearings. (*See, e.g.*, U.S. Senate, Select Committee on Small Business, Subcommittee on Monopoly, *Competitive Problems in the Drug Industry*, Hearings, Parts 1–25. 1967–1974 [See part 5 in particular for a discussion of economic issues].) Among those discussed are the abuse of patents and trade names, state antisubstitution laws, restrictions on retail drug price advertising and other laws affecting retail pharmacy operations.