AMERICAN MEDICAL ASSOCIATION

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March 25, 1975

The Honorable Gaylord Nelson
Chairman of the Monopoly Subcommittee
of the Select Committee on Small
Business
United States Senate
Russell Senate Office Building
Washington, D. C.

Dear Senator Nelson:

This letter will confirm the earlier oral communication to your staff indicating our inability to participate in the hearings before your Subcommittee. In response to your letter inviting the American Medical Association to present its views concerning the proposed Maximum Allowable Cost (MAC) regulations recently published by HEW, we would like to submit the following comments.

In brief, the new system created under the proposed regulations of November 15, 1974, issued by the Secretary of Health Education and Welfare would generally limit Federal reimbursement for drugs furnished in programs under the Department's jurisdiction to actual acquisition cost plus a dispensing fee. Special provisions relate to certain multiple source drugs. A Pharmaceutical Reimbursement Board would be created -- a five member group composed of five regular departmental employees devoting part-time to this activity. For drugs identified by this Board as having multiple sources, for which "significant amounts of Federal funds are or may be expended," and for which "there are or may be significantly different prices charged by various product formulators and labelers" the Board would determine the "lowest unit price at which the drug is widely and consistently available to providers throughout the nation." This unit cost would become the MAC.

For drugs having a MAC, the reimbursable amount would be the lower of the MAC or the actual acquisition cost, plus a dispensing fee.

The Food and Drug Administration has a very limited role. It would only be required, upon request of the Board, to provide a written statement advising of "any pending or anticipating regulatory activity, including the establishment of a bioavailability requirement, which would warrant delay in establishing a MAC..."