PHARMACEUTICAL MANUFACTURERS Association

C. JOSEPH STETLER
PRESIDENT

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The Honorable Gaylord Nelson
Chairman, Subcommittee on Monopoly
Senate Small Business Committee
United States Senate
Washington, D.C. 20510

Dear Senator Nelson:

During the course of my testimony before the Monopoly Subcommittee of the Senate Small Business Committee on May 16, I promised to supply certain material for the Record.

First, at page 357 of the transcript, I asked for an opportunity to supply a chronology and commentary on the deliberations of the Drug Research Board on the so-called substitution resolution. That comment is enclosed.

Second, I requested, and you agreed, that our submission dated February 14, 1975 to the FDA Hearing Clerk on the Maximum Allowable Cost plan would be made a part of the printed Record; it is also enclosed.

Finally, I wish to correct the implications of a colloquy between Mr. Gordon and myself (pages 368-69 of the transcript) concerning what Mr. Gordon called a misleading PMA "summary" of the Office of Technology Assessment Report on Drug Bioequivalency. Mr. Gordon was of the opinion that we distributed the summary in question, when in fact we did not do so. People who responded to our ad were sent the full report, not a summary. We did assemble a detailed commentary and critique of the OTA Report, having promised one to the OTA. But we sent that document only to a very limited number of individuals, primarily those in OTA, in concerned government agencies, and to our own member firms. There is no connection between the PMA ad and that document. No distribution of a general nature was made, and indeed it is plain from the nature of the document that it is of very limited use to someone who has not already read the Report.

As to Mr. Gordon's assertion that the reader of our critique will be misled to believe that the HEW Task Force on Prescription Drugs considered a specific list of drugs to present "bioequivalency problems", I think our statement is correct and that the matter is very clear: We said, in listing the Task Force candidates for equivalency testing, that those drugs, in the words of the Task Force