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Appendix III—Additional Submissions by the Pharmaceutical Manufacturers Association

May 1, 1968.

MEMORANDUM

To: Senator Gaylord Nelson, Chairman, Monopoly Subcommittee
From: Benjamin Gordon, Staff Economist

During the course of the Subcommittee's hearings on December 19, 1967, the PMA was asked and agreed to supply certain information which was not available at the moment.

The attached material which was received by the Subcommittee on April 17, 1968, after the transcripts had already been sent to the Government Printing Office, will be included in an appendix of the printed record of the Subcommittee's hearings.

This new material was not subjected to scrutiny during a public hearing, nor was it checked for accuracy by the committee staff. A cursory examination, however, revealed that, on page 13, for example, the case of MER–29 was used to show the financial risk to the industry from unforeseen side effects of a drug. It is stated that this drug was withdrawn because of unexpected side effects.

The fact is that the company was aware of the side effects before applying for the New Drug Application and withheld this vital information from the FDA and the medical profession, as a result of which, on July 2, 1963, a special Grand Jury charged, in a twelve-count indictment, that the manufacturer of this drug had violated the Food, Drug and Cosmetic Act. On June 4, 1964, the firm was found guilty in criminal case #1211–63 in the U.S. District Court for the District of Columbia.

The PMA is well aware of the facts in this case, and the example casts doubt on the usefulness of the rest of its submission.

Pharmaceutical Manufacturers Association,
Washington, D.C., April 15, 1968.

Hon. Gaylord Nelson,
Chairman, Monopoly Subcommittee of the Senate, Small Business Committee, U.S. Senate, Washington, D.C.

Dear Senator Nelson: In the course of the testimony of witnesses on behalf of the Pharmaceutical Manufacturers Association before your Subcommittee on December 19, 1967, you or Mr. Gordon asked for certain additional material. Enclosed is a memorandum supplying such material, to the extent that we have been able to obtain it, for inclusion in the record.

Sincerely yours,

C. Joseph Stetler.