APPENDIX V

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
1155 15TH STREET, NW.,
Washington, D.C., February 28, 1969.

HON. GAYLORD NELSON,
U.S. Senate, Washington, D.C.

DEAR SENATOR NELSON: Testimony presented to the Senate Subcommittee on Monopoly on December 18, 1968, by Dr. Paul Lowinger, Associate Professor of Psychiatry, School of Medicine, Wayne State University, has created the erroneous impression that various pharmaceutical companies have failed to comply with Federal drug laws and regulations. We believe that Dr. Lowinger did not intend to create this impression and that the Record of the Subcommittee's proceedings should be clarified.

In his testimony, Dr. Lowinger stated that during the period 1954–1966 inclusive, he had made 27 new drug study reports for 19 drug companies. Of these, he contended only 10 reports were subsequently submitted by the companies to the Federal Food and Drug Administration. Implicit in these statements is the charge that the alleged failure of the drug companies to submit the other reports to the FDA was in violation of Federal drug law and regulations.

In response to an inquiry in this matter, we have heard from 9 of our member companies, concerning 15 of the reports. Seven companies have stressed the important fact that the present reporting regulations concerning investigational drugs first went into effect in May, 1963. Prior to that date, there was no requirement that manufacturers keep the FDA informed of the progress of investigations of new drugs in humans during investigational new drug trials. Toxicity data developed from such investigations was to be submitted to the FDA only when new drug applications on such drugs were filed.

Three companies dispute Dr. Lowinger's allegation that he ever sent them such reports. In fact, two categorically state that they have no record that Dr. Lowinger did any work for them on their products he listed.

In the interest of clarifying the Record of the Subcommittee's hearings on the drug industry, I would, therefore, respectfully ask that you include this letter in the hearing record, immediately following Dr. Lowinger's testimony.

Sincerely yours,

C. JOSEPH STETLER.

CC: Members of the Subcommittee on Monopoly, Senate Select Committee on Small Business.

APPENDIX VI

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SPECIAL ARTICLE—FIXED COMBINATIONS OF ANTIMICROBIAL AGENTS*

National Academy of Sciences—National Research Council, Division of Medical Sciences Drug Efficacy Study

Abstract.—A review of the claims put forward for the use of penicillin-sulfonamides, penicillin-streptomycin and certain other fixed combinations of antimicrobial agents has convinced five panels organized under the auspices of the National Academy of Sciences—National Research Council that such combinations are "ineffective as fixed dose combinations." Although the individual active ingredients may be useful in specific entities, no greater effectiveness can be expected for the combination than for any one ingredient. Use of a proper dose of one ingredient may require excessive or inadequate doses of the other.

*This report was prepared by Anti-infective Panels II and IV of the Drug Efficacy Study, Division of Medical Sciences, NAS–NRC; the chairmen of these panels are Dr. Calvin M. Kunin and Dr. William L. Hewitt. Subsequently, the report was circulated to Anti-infective Panels (I, III and V) and was approved by the respective chairmen: Dr. Heinz Eichenwald, Dr. William M. M. Kirby and Dr. William B. Tucker. In its present form, therefore, the report has approval of all Anti-infective Panels of the Drug Efficacy Study. Members of Panel II are Drs. William McCabe, John Nelson, Edward L. Quinn, Jay P. Stanford and Ian MacLean Smith. Members of Panel IV are Drs. M. Glenn Koenig, Floyd W. Denny, Sidney M. Finegold, Donald B. Louria and Arthur C. White.

Address reprint requests to the Drug Efficacy Study, Drug Research Board, National Academy of Sciences—National Research Council, 201 Constitution Ave., N.W., Washington, D.C. 20418.