APPENDIX IV

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., May 26, 1969.

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

DEAR SENATOR NELSON: This will acknowledge your letter of May 14, extending an invitation to the Pharmaceutical Manufacturers Association to appear before your Subcommittee to discuss certain drug efficacy studies on fixed combination drugs, conducted by the National Academy of Sciences-National Research Council. Since your letter arrived on the day I was leaving the city to attend the PMA's Annual Meeting, this is the first opportunity I have had to reply.

Inasmuch as you have already conducted two days of public hearings and have other witnesses scheduled to appear on the subject of antibiotic combinations, it would be impossible for our Association or individual companies, whose products are involved, to appear *first*, as your letter suggests. In any event, we do not desire to appear for the reasons stated below.

According to recent testimony before the House Subcommittee on Intergovernmental Relations, various panels of the National Academy of Sciences-National Research Council have, since 1967, submitted to the FDA 2824 reports covering approximately 3700 drug formulations manufactured by 237 different companies. The NAS-NRC itself, has estimated that its review to date has required at least 10,000 therapeutic judgments.

I wish to note that not one of these NAS-NRC reports, until such time as notice of it is published in the Federal Register, has been made available to the PMA or to the manufacturer of the drug under study. Further, according to the testimony before the House Subcommittee, only 182 of the 2824 reports have been the subject of a Federal Register notice to date. Whether these published notices encompass all or some, a majority or minority, of the fixed drug combinations which were under review, we have no way of knowing.

For the purposes of this reply, it is immaterial whether the studies you propose to discuss before your Subcommittee include all "fixed combinations" or only those of "fixed antibiotic combinations." Neither the PMA nor individual companies has seen nor had an opportunity to study the reports of the NAS-NRC on "fixed combinations" or on "fixed antibiotic combinations." We are as a consequence, in no position to discuss them.

But whether the PMA had or had not made a study of these reports, we would still decline your invitations on the ground that the issues raised by the NAS-NRC panel studies involve medical and scientific matters to be decided under established laws and regulations.

It is our considered opinion that the safety and efficacy questions which have been raised with respect to combinations, should be decided in the medical and scientific forum, which functions within the FDA and the Department of HEW. This decision making should embody a judicious evaluation of all of the evidence and should be as free as possible of public and political non-scientific pressures, of disputations of scientific facts by non-medical individuals, or of the written or oral statements by non-professionals.

We feel strongly that the status of "fixed combination drugs" or any other category of drug products should be decided through the procedures now prescribed by the Federal law and implementing regulations. The administrative and legal remedies which the law and regulations authorize should be permitted to follow their course without prejudging of the issue in a Committee hearing or in the press.

Sincerely yours,

C. JOSEPH STETLER.