labeling of drugs of essentially the same therapeutic effectiveness and safety is confusing and misleading to physicians and doesn't lead to informed patient care.

We agree with you that your firms have been helpful in developing the rules applicable to current good manufacturing practice. We acknowledge our role in the development for many of the package inserts that are now found to be inadequate and misleading. Under authority of the current law which permits regulation of claims of effectiveness, we hope to correct this problem.

Your letter of February 19 is disappointing to us. All of the points you have made have been argued strenuously before at least two Courts of Appeals and a District Court. There is no need for us to answer them here, as we have in Court. But what is important is to get on with the DESI project. We have been willing to accept NAS/NRC evaluations of claims as "effective," without insisting upon proof by adequate and well-controlled clinical studies. But where the evaluation is less than effective, the product must be withdrawn unless an adequate data base to support the claims can be developed. The sooner your companies turn to this task, the better it will be for all of us.

At Senator Nelson's request, I am forwarding a copy of this letter to him.

Sincerely yours,

CHARLES C. EDWARDS, M.D.,
Commissioner of Food and Drugs.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., March 10, 1971.

Hon. GAYLORD NELSON,
Chairman, Subcommittee on Monopoly, Select Committee on Small Business, United States Senate, Washington, D.C.

DEAR SENATOR NELSON: This is in reply to your February 23, 1971 request for comments on problems raised by letters sent to Commissioner Edwards on February 10 and 19, 1971, by the Pharmaceutical Manufacturers Association, Washington, D.C.

Answers to these letters are in preparation and we will respond further to your request after these replies have been formulated. If we can furnish any additional information, please let us know.

Sincerely yours,

M. J. RYAN, *Director,*
Office of Legislative Services.

U.S. SENATE,
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C., February 23, 1971.

Dr. CHARLES C. EDWARDS,
Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C.

DEAR DR. EDWARDS: Enclosed is a letter I received from the President of the Pharmaceutical Manufacturers Association, to which he attached his letters to you of February 10 and 19, 1971.

Since it is planned to place this material into the printed record of the Subcommittee's hearings, as requested, I would appreciate your comments on the problems raised by the PMA's letters. This is to insure a fair and balanced presentation of the subjects under discussion.

Very truly yours,

GAYLORD NELSON,
Chairman,
Subcommittee on Monopoly.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., February 19, 1971.

Hon. GAYLORD NELSON,
Chairman, Monopoly Subcommittee, Senate Select Small Business Committee, Old Senate Office Building, Washington, D.C.

DEAR SENATOR NELSON: At the time of the hearings of the Monopoly Subcommittee of the Senate Small Business Committee which were conducted on February 1, 1971, you circulated a statement dealing with correspondence from the