ineffective drugs remain in our hospitals and neighborhood pharmacies. Public confidence must be built upon the firm foundation of adequate, scientific evidence clearly supporting the effectiveness claimed. The sooner this is accomplished the greater will be the public confidence in the entire medical establishment, be it the drug manufacturer, physician, pharmacist, or the Food and Drug Administration.

We sincerely desire to enlist the support of all members of the medical community to lend their support to the accomplishment of this objective.

Thank you for your interest in our consumer protection activities. Please let us know if we can be of further assistance.

Sincerely yours,

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

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U.S. SENATE,
SELECT COMMITTEE ON SMALL BUSINESS,
*Washington, D.C., January 26, 1971.*

Hon. CHARLES C. EDWARDS,
*Commissioner, Food and Drug Administration,*
*Washington, D.C.*

DEAR DR. EDWARDS: I would very much appreciate your comments on the attached letter which I have received from the President of the Pharmaceutical Manufacturers Association.

Kindest personal regards.

Sincerely,

GAYLORD NELSON,
*Chairman, Monopoly Subcommittee.*

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PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
*Washington, D.C., January 21, 1971.*

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

DEAR SENATOR NELSON: In connection with your present series of hearings concerning the Food and Drug Administration's review of the efficacy of medicines marketed between 1938 and 1962, there have been numerous statements in the press and before your Committee which, I think, tend to overstate the situation.

The primary example of this is the list of products made available late in November, 1970, by FDA, in which some 359 products are described as "ineffective." Newsmen and patients quite understandably were led to conclude that several hundred of the drugs their physicians were prescribing are useless.

In fact, as a result of a survey by PMA of its member firms, we can state that fully two-thirds of their products named on the FDA list had been withdrawn from the market before the list was released. Indeed, dozens of them have been off the market for over two years, some have not been offered for sale for a decade or more, others have never been marketed in the United States.

The number in real question, then, is small. For PMA firms, it is ninety-two; and were double counting, due to repetition of multiple forms of the same drug, eliminated, the number of actual products involved would be still smaller.

But there is a more important point than the number of products that are in question. That is the status of such products, in the legal sense. The regulatory procedures involved here permit the manufacturers of products judged "ineffective" to submit additional data in support of their claims, and call for FDA to make an evaluation of that data before issuing a final ruling.

With respect to most of the 92 PMA-firm products in question, we are advised that the manufacturers have submitted additional supportive infor-