I might add that it would also be helpful to know where the drug product pick-up occurred, because different results could be expected if the product sampled was resting in the shipping room of the original manufacturer, or in a warehouse in another part of the country, or in a retail pharmacy.

If it is not possible to disclose the names of companies producing the drug samples tested, it would be helpful to know the names of the drugs, or at least the therapeutic categories of the drugs involved. I am thinking here of nonproprietary drug names such as penicillin, and therapeutic categories such as antihistamine, tranquilizer, etc. To be of maximum usefulness to the industry, any tabulation should also give some idea of the type of manufacturer involved, in the event the name of each manufacturer cannot be disclosed. By type of manufacturer I refer to whether the manufacturer is a member of P.M.A. and some idea of whether the company has its own quality control and research facilities.

It would be most helpful if studies of this kind could furnish some of these necessary details. To summarize, I would suggest the following information:

(*a*) The name of the drug, or at least the therapeutic category.

(*b*) The name of the manufacturer, or the type of manufacturer as defined above.

(*c*) The nature and extent of the alleged defect found in the drug.

(*d*) The source of the drug sample tested (manufacturer, wholesaler, retailer).

Sincerely yours,

KARL BAMBACH.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., August 31, 1966.

Dr. KARL BAMBACH,
Pharmaceutical Manufacturers Association,
Washington, D.C.

DEAR DR. BAMBACH: I have your letter of August 25 in connection with your request for data on the results of analyses of 4,200 samples recently collected in an FDA survey.

I am forwarding a copy of your letter to the Commissioner's Office since, as you related to me and also indicated in your letter, Mr. Stetler wrote Dr. Goddard on August 22 concerning this same subject. I am sure that you will be hearing from this office on this subject within the near future.

Sincerely yours,

FRED J. DELMORE,
Director, Bureau of Education and Voluntary Compliance.

PHARMACEUTICAL MANUFACTURERS ASSOCIATIONS,
Washington, D.C., October 27, 1966.

JAMES L. GODDARD, M.D.,
Commissioner of Food and Drugs, Department of Health, Education and Welfare,
Washington, D.C.

DEAR COMMISSIONER GODDARD: As you know from past correspondence, reports from officials of the Food and Drug Administration on the alleged low quality of drug products are a matter of increasing concern to the pharmaceutical industry and particularly to the Pharmaceutical Manufacturers Association. In my letter to you of August 22 I referred to your comments at a meeting of the Drug and Allied Products Guild that one out of every fourteen drug units is violative with respect to potency, according to an FDA analysis of 4,200 drug samples. I asked for details of this study, hoping to receive information on the 4,200 samples involved, including the names of products and manufacturers and the types and degree of deviation from labeled potencies. In the event this could not be furnished, we at least expected to receive a tabulation of instances involving members of PMA.

This same study was mentioned by Gen. Fred Delmore at the seminar conducted by the University of Wisconsin at Hershey, Pa., and on August 25 Karl Bambach of our staff wrote to General Delmore requesting similar information.

On September 1 Deputy Commissioner Winton Rankin acknowledged these letters, stating "We are considering your request and will be in touch with you later." No further reply has been received.