A Code of Good Manufacturing Practices and other criteria with a licensing system and registration for all individual pharmaceutical products is essential. All drugs would then meet the same standards. This, of course, would be imposing the same requirements on all firms manufacturing drugs equally and would do much to solve the problem and obviate the objection which allegedly exists that some drugs are chemically equivalent but not biologically equivalent. This is not an impossible problem to resolve.

The fixed formula concept included in a National Drug Formulary would negate the licensing requirement and would accomplish the equivalency of official drug products.

Thank you. If there are any questions that you would like to ask, I would be perfectly willing to answer them.

In summary, we recommend that:

(1) HEW registered drug manufacturers in possession of approved New Drug Applications should be acceptable to all Federal agency drug bidders' lists for all products.

(2) Duplicative inspections, specifications, and requirements not having any medical or other significance should be eliminated so that competition may be encouraged.

(3) Inclusion of the fixed formula concept within a National Drug Formulary would assure that all official drugs are chemically as well as clinically equivalent.

(4) Resident drug plant inspectors now detailed by the Defense Personnel Support Center should be incorporated within the ranks of the Food and Drug Administration.

(5) The Food and Drug Administration should be adequately funded so that drug inspectors, trained as specialists, are not subject to diversion by food recalls.

(6) Payments for drugs delivered to Federal agencies should be made promptly to encourage the smaller drug manufacturers to submit their bids.

We appreciate this opportunity to submit our testimony before the Subcommittee on Monopoly of the Senate Small Business Committee, and trust that you will consider our recommendations.

Senator NELSON. How many small manufacturers does the National Association of Pharmaceutical Manufacturers represent?

How many manufacturers?

Mr. BARROWS. We have a membership of a little over 80 members, consisting of manufacturers and distributors. And at this time I would like to submit our roster of membership to the committee.

Senator NELSON. The committee will receive it.

[Testimony resumes at page 10253. The information referred to follows:]