expending for comparable drugs because of this scheme taxes all our citizens.

A responsible drug association must not only advance criticism but suggest means which will ameliorate that which is obviously wrong and in doing so assist their Government.

We have advocated the adoption of the fixed formula concept, whether it be incorporated into existing compendia or instituted by the FDA, which would negate much, if not all, of the duplication now necessary by all drug manufacturers pertaining to clinical studies and bioavailability comparisons.

The fixed formula concept when related to official drugs locks in the specifications, standards and methodology of analysis of not only the finished dosage form, but also of all of the components, the procedures and equipment to be employed in the compounding of the drug.

The fixed formula concept applied to an official drug will assure that the same drug manufactured by any registered firm will be the same in composition; was manufactured in the same manner; and will be the same in efficacy. The bioavailability will be assured as the drug will be equated with its bioavailability—then and only then will the formula be fixed, and the official drug of one company will be the same as the official drug of another. Without the implementation of the fixed formula concept, the problem of therapeutic equivalence will always be argued.

We are proposing a national drug formulary which will incorporate the fixed formula concept. This will resolve the criticisms that the official standards are too simple and not sufficiently advanced or sophisticated to be meaningful; and too, that the official standards are merely chemical or physical tests that have no relevance to therapeutic equivalence.

We have urged the USP and the NF organizations to consider the fixed formula concept from the standpoint of achieving uniformity in product equivalence and consistency of bioavailability—and were informed that our proposal has considerable merit.

It is exactly the procedure followed by the single producer of a drug product, who develops, tests, evaluates, and then freezes his product composition and method of manufacture, often on a world-wide basis in their plants all over the world.

The identification of like products of a given drug compound through the publication and acceptance of a common composition and procedure for manufacture would surely be in the public interest.

The concept of fixing compositions and manufacturing details for a number of established and important drug products is an extension of the standardization process and a way of assuring the equivalence of official drug products.

Before this very committee on May 20, 1969, Dr. John Adriani appeared and entered this statement into the record, and I quote: