name of the company. Some drugs and chemicals are manufactured by the ton. It seems doubtful that such drugs, as for example—aspirin, doriden, or thalidomide, vary in potency but in these competition keeps the price down. On the other hand, potency can vary in the preparation of antibiotics and probably in hormonal drugs and other synthetic preparations. Minor variations on manufacture may make a major difference. I believe in a very real sense the Food and Drug Administration can only demand a certain standard. Under most circumstances where standards are set, most persons or manufacturers try to produce a superior product. It matters not whether it is minimal standards for a nursing home, for the care of laboratory animals, or for drugs. By and large the persons involved try to do a superior job, especially where superiority brings profits. In the competitive world the pharmaceutical firms try to produce superior products. This is highly desirable and should be encouraged and therefore together with the generic name, the company's name should appear on the product. The medical profession in turn should be encouraged to try the various products and try to determine which is most effective. The doctor should know which preparation he is using, but above all he should know the various ingredients of the preparation he is giving. Therefore I firmly believe that not only the generic name of the drug (or a simplified generic name) should appear on every bottle but also the manufacturer's name. The pharmaceutical firms would, I believe, derive certain benefits by having the generic name of the drug on the bottle. For example, if the generic name was on the bottle it would prevent a less scrupulous company from marketing a product which did not contain the essential ingredient and giving the product such a closely similar name that people believe it is the same product. For example, *Softenon* was the trade name under which thalidomide was sold in Spain. I was unable to find out whether or not *Softenil* contained thalidomide.

The pharmaceutical firms would also derive another protection by having the generic name on the label. Were such a procedure common practice, it would prevent the less scrupulous companies from studying the formula, manufacturing the drug and selling it under a different name. Although such a procedure is illegal, nevertheless, this occurred in the case of thalidomide. Moreover, only if the sale is of sufficient magnitude does it pay the original manufacturer of the drug to sue the other company. Our Food and Drug Administration regulations, I believe, prevent the stealing of a formula on any wide scale in the United States but the F.D.A. has no control over what happens within a state and "support your local product" is a common slogan.

We cannot control drug manufacturers throughout the world nor should we attempt to do so, but we can and should keep our own house in order.

This brings me to another problem which should be of vital concern to your committee, namely, the quality control of the drugs which are exported from the United States. My interest and concern in this problem was aroused last May (1967) when President Johnson gave me the privilege to attend the World Health Organization in Geneva as an Alternate Delegate. One of the major subjects of discussion was the quality control of drugs. This subject had been under study by the World Health Organization for several years but little had been achieved. The Official Record of the World Health Organization, Volume 157. Executive Board report of the 39th Session in Geneva 17–27, January, 1967, (EB.39.R8) on the Quality Control of Pharmaceutical Preparations:

"Having considered the report of the Director-General on the quality control of pharmaceutical preparations:

"Noting that this matter has been the *subject of repeated discussion at previous sessions of the Executive Board and the World Health Assembly;*

"Bearing in mind *resolution WHA 18.36, which invited governments to take the necessary measures to subject pharmaceutical preparations, imported or locally manufactured, to adequate quality control:*

"Recalling particularly resolution WHA 19.47, requesting the Director-General to continue his assistance to Member States for the improvement of the quality control of pharmaceutical preparations, and for the establishment of quality control laboratories for national or regional purposes, as well as the establishment of general *principles for the quality control of products entering into international commerce.*

"Noting with concern that the requests of Member States that drugs should not be exported without having been subject to the same quality control as those issued to the same market in the country of origin are not yet generally applied, and that in many cases pharmaceutical preparations are continuing to circulate without such control;