the generic name of the product, excepting, of course, in cases where a doctor has a specific reason for instructing that the generic name not be on the bottle.

Does the PMA endorse that idea?

Mr. CUTLER. That is the recomendation as I understand it of the AMA, and the PMA supports that proposal. The PMA also thinks that the manufacturing sources should be identified and the brand name when there is one in addition to the generic name.

Senator NELSON. You have no objection to the appearance of the generic name?

Mr. CUTLER. No, sir.

Senator NELSON. That concludes all the questions I have, Doctor. I appreciate very much your testimony. It was very constructive, very informative, and useful to the committee.

Dr. SLESSER. Senator Nelson, thank you so much for allowing me to appear.

(The complete prepared statement and attachments submitted by Dr. Slesser for presentation on November 16, 1967, follows:

STATEMENT OF A. E. SLESSER, PH. D., ASSOCIATE DIRECTOR OF QUALITY CONTROL, SMITH KLINE & FRENCH LABORATORIES

Mr. Chairman and Members of the Committee, I am pleased to have the opportunity to supplement Mr. Stetler's statement on the matter of therapeutic equivalence of drug products.

Through my activities in the pharmaceutical industry I know something about the factors that can affect drug performance. There was a time when pharmaceutical manufacturing, like many other industries, was relatively simple. During that era there was a bare handful of drugs, few of them of known composition or specificity in treatment of disease. However, now we have a great number of highly sophisticated drugs, many of which are chemically complex and quite specific in disease treatment. As a consequence, the technology of manufacturing consistently safe and effective medicines today is not simple.

Control of the quality of the medicinals prepared from today's drugs is a complex operation. There was a time when quality control pretty much began and ended in an analytical testing laboratory. But, Mr. Chairman, that time is long past.

It is simply wrong, in the light of the present state of the art and science of pharmaceutical manufacture and the inadequately manned government agency, to contend that all drug products of like generic names are equal.

I submit we are not likely to have that assurance soon despite the efforts of all involved. Recent figures on FDA inspections, for example, do little to encourage optimism in this regard. The Agency made 3,651 inspections of drug plants in 1966; impressive as that figure may seem, it is 150 inspections less than the 1965 figure, and 341 less than the number for 1964. I do not recite these figures to criticize the FDA, Mr. Chairman. Their inspections of necessity are becoming more complex and time-consuming, and FDA personnel shortages are persistent. Nevertheless, fewer inspections are being made, not more. It seems to me, therefore, that it would be imprudent to rely heavily or solely on this mechanism as "the method" of assuring drug quality.

Even if we make the incorrect assumption that all manufacturers are capable of passing an FDA inspection, we are still in no sense out of the dilemma of therapeutic equivalence.

There is the matter of conforming to USP or other standards. The question is not whether drug products should conform, but whether each batch and each tablet, capsule and dose of every drug product does conform. The fact that standards exist—and that companies put "USP" or "NF" on drug labels—does not establish that in fact the companies actually have adequate control procedures, or that they follow them. In short, the real question is, do drug products conform to the standards they claim to meet?

In all candor, as one who has long followed and participated in the work of the USP and NE, I must also note that the standards of the USP and NF do not