Dr. SLESSER. Mr. Chairman, first of all, I would like to express my appreciation for your permitting me to appear and giving me the opportunity to supplement Mr. Stetler's statement on the matter of therapeutic equivalency of drug products.

Through my activities in the pharmaceutical industry, I know something about the factors that can affect drug performance.

Senator NELSON. We will print in the record Dr. Slesser's full statement.

Are we talking about the statement that is called supplementary?

Dr. SLESSER. Mr. Chairman, I did not have one that says supplemental testimony before the subcommittee. I think the original one had the wrong caption as far as committee identification is concerned.

Mr. CUTLER. That was when he was going to supplement Mr. Stetler's. That is his original statement.

Senator NELSON. What are we dealing with, then?

Is this the one he is making an abbreviated statement on?

Dr. SLESSER. Yes. I am trying to find a spare copy for you.

Senator NELSON. I would ask that that statement be printed in full in the record. Then we will take his summary statement and we will ask questions. If you have a copy of the summary, I can probably follow you more easily.[1]

Dr. SLESSER. I do have a copy of this brief summary, Mr. Chairman, which I do not believe you have, which we will find very shortly.

Senator NELSON. Go ahead while they are finding it.

Dr. SLESSER. Control of the quality of the medicinals prepared from today's drugs is a complicated operation. It is simply wrong, in the light of the present state of the art and science of pharmaceutical manufacture and the inadequately manned FDA, to contend that all drug products of like generic name are equal.

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?

Now, I would like at this point to stress the fact that the USP and the NF are indispensable compendia. There is no question about the importance of the standards that appear in these compendia. However, this is only part of the story. Actually, the USP itself points out on page XVII that the problem of providing objective standards and methods for USP drug products to measure physiological availability, which means the extent to which the active ingredient is taken up by the body in a useful form, "remains in the exploratory stage at this time" and adds, "Progress has been slow in developing such standards that would be suitable for U.S.P. use."

[1] The complete prepared statement and attachments submitted by Dr. Slesser for presentation on Nov. 16, 1967, begins at p. 2271, infra.