stantial differences in 'therapeutic equivalence' between two comparable drug products (also referred to as generic or brand equivalence). Consequently, while we must recognize that this factor exists, currently available evidence indicates that only very seldom is there a difference in clinical performance if the official compendia standards are met by both drug products."

In subsequent testimony both FDA Commissioner Goddard and USP Director of Revision Miller, among others, also commented to the effect that differences do exist in the case of some drug products, but that there are relatively few documented cases in literature references,, indicating that from a clinical standpoint this problem has been greatly exaggerated. In your March 5, 1968, letter to me you also quoted from my statement made to your Subcommittee that:

"* * * I would be hard pressed to name more than a few—less than five—well-conducted clinically acceptable studies which have demonstrated significant differences between two or more products clinically where they have met all the chemical and physical standards as provided by the official compendia."

The references which remain after eliminating those that are inappropriate may include a few such studies, but the number certainly does not exceed five and probably is even smaller than five.

Consequently, it appears that the above-quoted statement from my testimony is actually confirmed by a review of the compilation of references which you supplied to me, and concerning which you requested my evaluation and opinion from a scientific viewpoint.

Sincerely,

EDWARD G. FELDMANN, Ph. D., *Director.*

Mr. GORDON. How many of the drugs in the 211 studies you cited did not meet the required standards set for them by the USP or the National Formulary?

Dr. SLESSER. Mr. Gordon, I do not know the answer to that question. But let me state this.

The existence of USP or NF standards does not by any means assure that every product on the market will meet them. The fact of the matter is there are products on the market that do not meet U.S.P. and NF tests, and there probably are a great number of them. The evidence is certainly in that direction

There are products that do meet the USP and NF tests which do not function properly therapeutically. And these are covered, of course, either directly or indirectly by scientific literature in these 211 references.

Senator NELSON. Do you know of any drugs on the market that do meet USP standards or NF standards and do not function appropriately therapeutically which are not on the list of the 14 or 15 to which Dr. Miller and other witnesses testified? In other words, do you know of more than the 14 or 15 that are cited as exceptions by Dr. Miller and other pharmacologists and experts in the field?

In other words, if you know of some that ought to be added to the list, we ought to have the USP advise us about them, because they are not aware of any more than 15 or so.

Dr. SLESSER. Senator, perhaps in this connection you might be interested in inviting to some future session of this committee—I do not know whether he will consider this as an honor or not—my recommending him, I am talking about—not appearing before this committee—but Capt. Solomon Pflag who is Chief of the Technical Operations Division, Director of Medical Materiel, the Defense Supply Agency. In a talk he made on November 20, a little over a week ago—perhaps you are interested in what the military feels about this particular point.

Let me read very briefly from his talk.