refer to the drugs meeting U.S.P. tests. Those doctors are available to testify. And their findings are reported in medical literature.

Senator NELSON. Name me one of the 211 that met U.S.P. standards and was found not to be clinically effective.

Dr. SLESSER. Chloramphenicol.

Senator NELSON. That is on the list. We know about that one. Name some in addition to the dozen or so that Dr. Miller has mentioned, and Dr. Feldmann has mentioned, and that have been in the literature.

Dr. SLESSER. I do not know the ones they have mentioned. I have not seen them in the testimony.

Senator NELSON. If anybody has combed that record better than the industry, I would be very surprised.

Dr. SLESSER. I read their complete testimony before your committee, Senator, and I have not seen any names.

Mr. GROSSMAN. Dr. Slesser, has the PMA ever made any efforts to deal with the U.S.P. standards? Are you trying all the time to upgrade these standards? We have heard so much about how the standards may not be adequate. What are you doing about it?

Dr. SLESSER. The industry has been for many years, Mr. Grossman—the industry has been—PMA has been cooperating with the compendium officials, with Food and Drug Administration, through the quality control section, which meets twice a year, for the specific purpose of establishing standards and specifications for drug products.

Mr. GROSSMAN. Let us pin this down a little bit. Do you think the U.S.P. standards are adequate, as far as quality control? In other words, we have heard so much talk—let us have a yes or no.

Dr. SLESSER. They are adequate for pharmaceutical—in a pharmaceutical sense, Mr. Grossman, not in a clinical sense.

Mr. GROSSMAN. I am a lawyer. Could you explain that to me?

Dr. SLESSER. Well, there has to be some proof of biological effectiveness.

If you look at any monograph in the U.S.P.—these are the tests and specifications for the U.S.P. and N.F. products—and if you examine each of the tests which are stipulated in those monographs, you will find, except for insulin, where there is a fasting rabbit blood sugar level lowering test—that there will be no test for therapeutic performance. It is simply assumed, erroneously by many, because there are disclaimers in the U.S.P. and N.F. to this effect—nevertheless it is assumed that so long as a product meets these tests, ergo, U.S.P. or N.F. test—ergo it has to be therapeutically effective. This is disclaimed by the compendia themselves. If you are asking me do I know of a substitute for a clinical test, the answer is no.

Mr. GROSSMAN. The U.S.P., then, is not doing enough. I mean yes or no?

Dr. SLESSER. Insofar as therapeutic—I can only answer your question this way. I am not trying to be difficult, believe me.

Insofar as spelling out clinical performance, there is no such specification—except in the one instance that I mentioned, in the U.S.P. or N.F.

Mr. GROSSMAN. Now, on another matter, you make a very, very strong allegation on page 11 of your testimony where you say, "The inability of the FDA to assure even the competence of all drug firms,