in terms of quality control, I take it, are procedures to assure that U.S.P. standards are in fact met. Isn't that what we are talking about?

Dr. SLESSER. What we are talking about, Mr. Chairman, is this. That quality control, properly exercised, begins at the R. & D. stage, and that when properly exercised on a batch-to-batch basis—the only way a manufacturer can assure that every batch that he makes and every tablet and every capsule in that batch is as safe and effective as the original clinically tested batches, is by the implementation and the execution of this chain of quality control in the manufacture of each batch. So in effect, quality control serves as a substitute for the clinical test on a batch-to-batch basis.

Now, this is really what quality control is, and what it does, after you have done clinical testing. If you have not done the clinical testing, I state it is a scientific fact that laboratory test results alone may mean absolutely nothing.

Senator NELSON. Well, I hope we are not running around in a circle. But the U.S.P. standards are the highest in the world, and the U.S.P. consults people from the industry, as well as the best clinicians in the country from all the various specialities, to set the standards. It seem to me all you are talking about in quality control is that you must have a first-rate method of assuring that you really come out meeting those standards. If you know of some drugs that meet the U.S.P. standards but are not therapeutically effective, I would like to have the names of them, because Dr. Miller has given us the names of all those he knows, 15 or so known among all the drugs on the market. Now, do you know of drugs in addition to those that Dr. Miller knows about that meet U.S.P. standards and are not therapeutically effective?

Dr. SLESSER. Mr. Chairman, the fact of the matter is that there are such drugs on the market.

Senator NELSON. What kind of drugs do you mean?

Dr. SLESSER. There are two categories. There are drugs which do not meet U.S.P. and N.F. specifications.

Senator NELSON. Those, we will all agree, should not be on the market and are not at issue here at all.

Dr. SLESSER. There is another category of drugs that do meet these specifications, but are not clinically effective.

Now, the U.S.P.—Dr. Miller certainly has something to do with the U.S.P. On the page that I referenced, he stated that there is no—at the present state of knowledge, the monograph specifications cannot assure pharmacological availability. And that is what we are talking about. That is the guts of this issue. And the Defense Department recognizes this, and therefore they are going beyond U.S.P. or N.F. specifications. And I suggest that Captain Pflag could probably reveal reasons why they had to go to this particular kind of activity.

Senator NELSON. There wouldn't be any reason for you to be aware of this, but I believe I have asked every industry witness that has appeared, "Do you know of any drugs that meet U.S.P. standards that are not therapeutically effective?" They do not give me any examples.

Now, what amazes me, just absolutely astonishes me, is that I say this week after week after week, but witnesses merely give me a lot of other material that is peripheral.