product meets the appropriate criteria of identity, purity, quality and strength. Compliance with these standards constitutes generally reliable presumptive evidence that such a drug product will be clinically effective and safe.

Clinically effective and safe.

So I think Dr. Feldmann is saying the same thing about the issue with which we have been in dispute with the drug companies. If drugs meet the USP standards, it is presumed they will be clinically safe. That is the heart of the issue on which we differ, but a substantial body of authority in this country does agree with Dr. Feldmann's presumption.

Dr. SLESSER. Dr. Feldmann presumes this to be true and certainly he has a right to make this presumption. I think the body of scientific evidence would take issue with this presumption and I hope to bring that out more thoroughly as I proceed with the balance of my statement.

Senator NELSON. I just wanted Dr. Feldmann's statement in the record in proper juxtaposition.

That is a rollcall. Do you have any objection if Mr. Gordon sits and listens while you present your statement, or do you want to wait until I get back?

Dr. SLESSER. I would be happy to wait.

Senator NELSON. I have read your testimony so I know what is in it, and I have a few questions on it. I will do whatever you prefer.

Dr. SLESSER. I prefer to wait.

Mr. CUTLER. If it is just as short as the others, Mr. Chairman, why not wait?

(Short recess.)

Senator NELSON. The hearing will resume.

Dr. Slesser, go ahead.

Dr. SLESSER. Thank you, Mr. Chairman.

Senator NELSON. It appears we will have a continuous series of rollcalls. So I guess we had better move along.

Dr. SLESSER. That is perfectly all right.

Senator NELSON. Is that going to be part of an exhibit you have in your testimony?

Dr. SLESSER. Yes.

Senator NELSON. When you get to it identify it for the record.

Dr. SLESSER. This is chart No. 3, Mr. Chairman.[1]

Now, I think that a brief, a very brief presentation on how clinical effectiveness is established is probably worth while before going into the rest of the chart.

The capable innovator manufacturer will make sure that for the research and development formula, the pilot formula, or formulas, that all tests necessary are run to prove safety and effectiveness. The only way in which this can be done, of course, is by clinical trials on human subjects. So that safety and effectiveness have been established by clinical tests on this particular product.

Now, I think a great deal of misunderstanding about the significance of laboratory testing lies in this particular fact.

It is presumed that—I am using tablets as an example, but they do

[1] Charts 1, 2, and 3 appear as attachments to Dr. Slesser's prepared statement of Nov. 16, 1967, and begin at p. 2275, infra.