not constitute the only type of dosage form by any means—it could apply to any pharmaceutical product.

It is presumed that by applying laboratory tests, whether they are USP, NF, or any other authority, to a certain number of tablets from a batch, or to a certain number of bottles in a shipment of a batch, without knowing anything else, one can then, depending on the results of these analyses, state unequivocally that this product does have safety and effectiveness.

Now, I hope to show wherein the fallacy of this line of reasoning lies.

Quality control, Mr. Chairman, makes sure that what comes out here as a finished batch is a duplicate, insofar as safety and effectiveness is concerned, of what was tested at this particular point.

In other words, I am suggesting that quality control has to be viewed as a chain, that it cannot simply be viewed as beginning and ending in an analytical laboratory, or a testing laboratory wherein, unfortunately, many people believe is the beginning and end of quality control.

So if I may, I would like to show the factors which are responsible for the safety and effectiveness as determined by clinical tests on the prototype formulas.

First of all, the specific components, both the drug and nondrug.

Now, you will notice that I underline "specific" in each case, because this is very important.

The drug itself, we know that such matters as the fineness of the particles of the drug—most drugs are crystals or powders—depending on particle size—you may get differences in the rate of absorption, as well as the magnitude.

There are other physical factors that can enter into the behavior of the drug in a drug product. One of them is described as polymorphism, which is simply a difference in the crystalline structure.

If you were to analyze such a drug by the formal chemical tests, Mr. Chairman, you could not differentiate polymorphic form A from polymorphic form B or polymorphic form C. Special types of tests are necessary, such as infrared spectrometry or X-ray diffraction—and there again is a fallacy in relying upon simple laboratory tests. And, of course, the significance of this is polymorphic form A, B, or C may very well show differences in physiological availability of the drug and the drug product.

Now, the nondrug components. They are also important. The capable, qualified manufacturer is just as interested in who supplies these components as he is in how they test in a laboratory. And he takes precautions to make sure that he deals only with capable, reputable vendors, with whom he has had a history of successful quality in the past.

Specific specifications are set up for drug and nondrug components. Written directions for sampling each incoming shipment exist. These are updated and precautions taken to make sure they are followed.

The ratio of the drug to the nondrug components, and of the nondrug components to one another is important.

Then we are talking about a specific formula. USP clearly indicates that the formulas and methods for manufacturing the dosage