forms which are official in the USP are not a function and cannot be—included in the monographs for the official products that are listed therein. So that with a given drug, a manufacturer who may use the same drug or active ingredient—but then varies in some other respect, and does not use the specific formula—could alter the safety and effectiveness of the resulting drug product.

Specific manufacturing procedure—this is extremely important. A statement has been made that it does not matter—or there is a feeling that exists, that it does not matter how a drug is made as long as it meets standards. This is certainly not true of the pharmaceutical industry. The pharmaceutical industry knows from experience, and the FDA knows, too, that you cannot rely upon the doctrine I don't care what the kitchen looks like, as long as the soup tastes good. This is not at all valid, and there is a very definite relationship between the kitchen and how it looks—namely the pharmaceutical plant, the capability of the people who work there, the facilities with which they work, the know-how, the physical plant itself, and the quality of the product.

Now, throughout the course of every batch, specific in process tests, assays, checks, and inspections are done. Mr. Chairman, these number literally in the hundreds for each batch, and sometimes may number a thousand or more. And it is important that these be done because these are an important part of the chain of quality control which will insure that on a batch-to-batch basis, every batch will be the same in safety and effectiveness a the initial batches which were tested in the clinic.

And finally, other specific in-process controls—one function of which is to make sure that these other four links in the chain have actually been executed, have been effective, have been properly conducted. One function takes the form of a stack of finished reports of data, results of inspections, tests, analyses, and so forth, which for even a single batch may number a great many pieces of paper. They show the complete history of the manufacture of that batch.

Now, once a knowledge of the control of all these things—these links in the chain—is known, then and only then do the laboratory tests have meaning, because if the batch has been made with the links of this chain under control and unbroken, then we know that the finished batch will meet all the USP or NF or other required tests.

So what I am trying to say, Mr. Chairman, is that if this chain has actually been effectuated, and has been capably applied, then the finished batch will meet USP tests. However, I want to emphasize this—the reverse is not necessarily true. In the absence of knowledge that this chain was in fact operative, capably applied and so forth, laboratory tests to establish that the finished batch or a sample of it is safe and effective may not be meaningful.

Now, that is the crux of the basis for the concept of total quality control. Lest there be any misunderstanding that this is solely something which the industry is trying to use as a smokescreen, I would like to quote Dr. Earl Meyers who for many years was in the new drug branch of the Food and Drug Administration—in a speech that he made before the American Pharmaceutical Association, at the fifth