The NF, on page XLIII, echoes the essence of the USP statement under the caption "Therapeutic Authority Disclaimed," as follows:

> The inclusion of a drug in the N.F. is not intended as an endorsement of its therapeutic value.

Total quality control, Mr. Chairman, involves much more than any compendium can cover. Not too long ago, the chairman of the NF Committee of Revision, Dr. Edward G. Feldmann, discussed natural limitations of the compendia as follows—this is a direct quotation and we have copies here for you:

> Many people in pharmacy have the mistaken notion that if a product meets all the specific tests and requirements detailed for that article in the U.S.P. or N.F. monograph, then that particular product *has* to be perfectly satisfactory.

The word "has" was italicized.

To continue with the quotation:

> While I wish this were true, I am sorry to say it is not and the nature of the problem is such that we can never hope to develop compendia monographs which will give complete assurance of any product's absolute suitability.

The detailed specifications that are needed to produce a quality drug product under good control procedures are so extensive and so all-encompassing as to defy inclusion in compendia of any sort. Quality control measures, records, and reports used in leading drug firms for each batch of even the simplest drug product are massive. These begin with the raw materials and end with the consumption of the product. Details of the manufacturing and control procedures utilized for only a few products of a capable manufacturer would constitute a book in itself.

We all know that safety and effectiveness of a drug product are determined by well-designed, properly controlled and correctly executed clinical tests. Such tests are run by the manufacturer on one, sometimes two, rarely on more than two batches of the product. Now, having proved the safety and effectiveness of the product, we must ask ourselves this question: To what factors are the product's safety and effectiveness due? For an answer to that question and an explanation of how quality control functions, I would like for this subcommittee to take a look at a chart that I have prepared for this purpose.

Before doing this, however, let me state, Mr. Chairman, that contrary to common belief, the drug component in most tablet products comprises less than 10 percent of the makeup of the tablet and that the number of components other than the drug itself may vary from two or three to as many as 20 or more. I mention this because this should be taken into consideration when we are talking about a drug versus a drug product, which is the form of the drug which is marketed and administered to the patient. This is the area in which the effect of know-how or lack of know-how can be demonstrated in a very important fashion.

Senator NELSON. You just quoted Dr. Feldmann. In part 1 of these hearings of the Subcommittee on Monopoly of the Select Committee on Small Business, I quote from Dr. Feldmann:

> A good quality control system will minimize the differences between batches of the same drug product. The official compendia standards are designed to enable the testing of the final product to ascertain that a given lot of a drug