Dr. MILLER. Yes; this laboratory is wholly independent and it responds to the needs of the three sponsors. It is concerned with the products that are put out by the pharmaceutical industry, but the testing it does is at the request of the sponsors. It has a small staff, and a small budget, but up to now it has met its needs rather adequately.

Proposals for revision are submitted to a two-layer screen of approval within the revision committee. A revision can be processed in a matter of weeks where a clear course is apparent, or may require years of study.

We take seriously the responsibility of keeping the studies in motion and in seeing that the results are translated into tests and standards as promptly as possible. In the 29 years since the passage of the Food, Drug, and Cosmetic Act in 1938, six entirely revised editions of the Pharmacopeia have appeared and numerous supplements have been published.

Admittedly, the mechanics and apparatus of the USP revision program are very simple; our headquarters staff is small. Although we must depend greatly upon voluntary efforts, our resources are substantial. We submit that the system has worked, is working, and will continue to work in providing the standards for drugs that are not exceeded anywhere in the world.

WHAT ASSURES DRUG QUALITY?

Great stress has been placed on drug quality in these hearings to date. The importance of quality in drugs is beyond debate, for in scarcely anything else in everyday use is the attribute of quality so vital and so difficult to measure, even for experts.

The elements that determine quality are several, but identifiable. This holds true for drug products made by large and small manufacturers or those compounded locally in the community pharmacy or hospital. The first requirement is the will to make a good product and the unswerving adherence to a creed that ranks high quality above all other considerations. Second is flawless procedure, usually called good manufacturing practice in the drug factory or good technique in the pharmacy. Then, in order of utilization and certainly in importance, come high standards of purity and potency; these are necessary to insure that only the best materials are used and that the final product comes up to expectation. It goes almost without saying that high standards are valueless unless they are put to use in a vigilant and rigorous testing program. Finally, once a product of high quality has been obtained, it must be protected by proper packaging, handling, and storage.

These, in broad outline, are the minimum elements needed to assure a quality drug product. The neglect of any one will almost certainly result in an inferior drug product.

Of all these elements, the most objective and most amenable to precise specification are the standards of purity and the conditions of proper packaging and storage. To provide these is the function of the U.S. Pharmacopeia and its sister compendium, the National Formulary. As a result, these books are recognized as "official compendia" in the Food, Drug, and Cosmetic Act.