

istration, and the Food and Drug Administration; from scientists in schools of pharmacy and medicine; from scientists associated with foreign pharmacopeias, foreign companies and foreign governments; and from unaffiliated scientists writing as private individuals.

It is my responsibility to review these comments, in concert with the responsible subcommittees of the USP Committee of Revision. We then incorporate those changes that are deemed scientifically valid and explain to proponents why certain changes they suggested have not been adopted.

In this manner, the USP evolves publicly scrutinized, objective, scientifically verified standards, and practicable tests and assays, through the collaborative efforts of disinterested scientists.

Senator NELSON. May I ask a question which we asked Dr. Apple also?

The Defense Department spokesmen have stated that they develop drug specifications that often exceed official or commercial standards.

What is your observation about that?

Dr. BANES. I have examined the responses sent to me by DPSC. When we circulate "Comment Proof" they respond as well as these other scientists I have mentioned. They sometimes say, we think certain standards ought to be adopted, see the specifications that we have put out. And they insert these specifications into our record for "Comment Proof."

My general impression is very similar to that narrated to you by Dr. Feldmann. For the most part, I would say they are trivial. In some instances, they are so exacting that you wonder why they were set up as they were.

For example, on the monograph for sulfasoxazole. (This is a sulfa drug. We have many such drugs in the U.S. Pharmacopeia with their standards, specifications and tests and assays.) I find in looking through the specifications sent by the Department of Defense that the tablets are to be examined by a method of analysis called X-ray diffraction. Now, this is an approach that requires a tremendous piece of apparatus costing in the neighborhood of \$50,000 or \$100,000. But when I examine the data to be obtained by this test, I see nothing that goes beyond what is already in the specifications. And here is a test to be applied which is superfluous, gives no more data than is already available from more readily procured equipment. And the question arises, what is the point of such a requirement? If I were to suggest to our committees of scientists that we add this specification, they would say,

What on earth for? We have already pinned down the identity and quality and the purity of the material by means of our simpler tests. Why should we go to this one?

On top of it, we have a specification for the sulfisoxazole that goes into the tablet, requiring a chloride determination. Well, chloride determinations are worthwhile in some instances, and they are provided in many of the monographs, but not for these sulfa drugs.

But in addition to this trivial requirement, the method to be applied and so specified in the write-up given by the Department of