

The drugs procured commercially generally meeting USP standards, which are minimum in many instances——

Senator NELSON. But Dr. Modell says no.

Captain PFLAG (Continuing). Are not subjected to extremes in temperature and climatic conditions.

May I give you an example, a specific example, sir.

Several years ago we purchased reserpine tablets from a certain company on the west coast. These tablets met the NF disintegration test which at the time was 30 minutes, at the time of procurement it met it nicely. At the end of 5 months, as this material laid on our depot shelves, the disintegration time ranged from 30 minutes to 2½ hours, and had this been in the system any longer it might have even gone beyond that.

So we have to make absolutely certain that an item that we procure at one point in time is in a condition to be used on a patient several years later if it is stored in prepositioned war reserve stocks.

Senator NELSON. Or if it is an item that can be preserved that long without losing its potency.

Captain PFLAG. Yes. We have other instances where material is put on the beaches, for example, in Vietnam, i.e., dextran. When it is in an ambient atmosphere fluctuating from 120 degrees Fahrenheit to 50 degrees Fahrenheit, you get particulation in this material.

Senator NELSON. So you aren't saying, really, if I understand you, that you require standards higher than USP because obviously that drug that was on the shelves on the warehouse for 5 months and did not disintegrate for 2½ hours did not meet USP standards——

Captain PFLAG. Did not meet NF standards——

Senator NELSON (Continuing). At that time.

Captain PFLAG (Continuing). At the time we picked it up, but at the time we purchased it, it met NF standards.

Senator NELSON. That's right.

Captain PFLAG. And, sir, as a result of that, what we do is, we reexamine our specification and attempt to introduce tests and tighten specification so that we can prevent this from ever occurring again.

Senator NELSON. Yes; but what you are saying is that you wish to insure that it meets USP standards, not superior standards.

Captain PFLAG. That it would meet NF standards or USP standards.

Senator NELSON. Or USP.

Captain PFLAG. Yes, sir; at the time the drug is to be used.

Senator NELSON. Correct.

Captain PFLAG. Yes, sir.

Senator NELSON. But at no stage were you demanding that the drug meet a standard higher than NF or USP. You are just demanding that it meet the NF or USP standard, and under certain storage conditions, it didn't meet it. I would like to know what that standard is if it is higher than USP or NF.

Captain PFLAG. We have a case in penicillin, in a penicillin injectible, in which we require a color standard which is higher——

Senator NELSON. A color standard?

Captain PFLAG. A color standard; that the injectible be of a certain clarity, have an absence of yellowness or color.