Admiral ETTER. This next sentence, I think, also speaks to this.

Requirements specified include color limits for liquid products particularly for parenterals; expiration dates, refrigeration requirements for many items not required by the USP and NF; dissolution tests, animal tests, accelerated aging, and some clinical requirements. Also, special packaging is required for greater assurance of stability. These areas include inner and outer seals, leakage tests, special closures, label adhesion, tin plating, and vacuum packing.

In this regard, Senator, I would like to ask Captain Pflag if he has anything to add to this matter of exceeding the USP and NF standards.

Captain PFLAG. No, sir. I think, Admiral, that was covered in the statement in a very general way, unless the Senator wants some specific, more specific data.

Senator NELSON. Well, I am not exactly sure what the Admiral is saying, when you talk about packaging and the longer life because of a different method of compounding or formulating. We have made it clear that this does not make it superior therapeutically.

Frequently, the drug companies say, well, our drugs meet a higher standard than the U.S. Pharmacopeia and/or the National Formulary. The best expert testimony that we could get, not only from USP and NF, but also from outside experts, such as Dr. Modell, with whom you are familiar. Dr. Modell states:

> By and large, purification or modification beyond these standards—

That is, USP or NF—

> doesn't make any practical difference, but as I have already stated from time to time there are improvements made occasionally by the industry, occasionally by workers outside of the industry, and as soon as the USP learns of this, it changes its own standards and requirements.
>
> Thus, there may be a gap, but in general, there is no practical difference between all drugs that live up to USP standards.

Then on page 303 Dr. Modell states:

> They—

Referring to USP standards—

> they are not minimal standards by any means. U. S. Pharmacopeia has the highest standards of all pharmacopeias in the world. They are standards that are so high that further purification would provide nothing more than additional costs.
>
> The primary requisite is the establishment of the standards necessary for the most effective use in medicine. It is, therefore, explicit in the decision of the U. S. Pharmacopeia Committee to set specific standards for a drug that further purification or higher standards will accomplish nothing in medicine. If the industry wants for one reason or another to go far beyond this, of course, it has every right to do it, but it does not mean that it has accomplished anything in so doing.

This is the aspect that I was referring to, and I take it that you are not saying that you require standards higher than USP or NF in the context in which I was reading the statement of Dr. Modell? [1]

Captain PFLAG. Senator, we find it absolutely necessary that a drug be as potent at the time it was procured as it would be at the end of a long-term storage period. It might be, for example, 5 years.

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[1] See testimony of Dr. Walter Modell, Part 1, pages 283–305.