Mr. CROWTHER. Well, the mechanisms with which the drug is prepared. I think the answer is that they specify such things as how long a drug compound must run in the centrifuge and at what temperatures. Also they require that the processes be tested to be certain that the compounds fall within certain tolerance levels. They are also concerned that each drug and the related manufacturing process meet the specifications. So, I think the answer——

Senator NELSON. I am very puzzled about that. You are talking about the disintegration rate?

Mr. CROWTHER. Yes, sir; that is part of it.

Senator NELSON. Now, the USP and NF have a disintegration rate. You mean to say that the Defense Department has experts who have decided on a different standard? I am not objecting, if it is better, but I would like to see the proof.

Mr. CROWTHER. Well, I cannot say that the specific example is used in each specification. Quite often the specifications refer to the standard that have been published but sometimes they add to those standards to gain consistent quality in the drugs they procure.

Senator NELSON. Has anybody taken a sampling of the drugs they procure and then a sampling that is procured for any good general hospital just using USP standards and determined that one is different or better than the other?

Mr. CROWTHER. Well, I believe the reverse has occurred. The Defense Department has determined that certain batches are unacceptable and they have been rejected because those batches do not meet their standards. There are several tests that each drug must meet and these tests are included in the specifications.

Senator NELSON. That is interesting. The Commissioner of the Food and Drug Administration was here yesterday saying that so far as the generic drugs and the brand name drugs that are in the marketplace are concerned, we have no cause and no evidence to believe that one is any better than the other. That is not an exact quote.

I would be very suspicious myself that what you are describing is what Colonel Breyfogle was referring to, that they set standards that only a certain brand name can meet so there is no competition.

USP will come here and testify that the best known standards in the world are USP standards. Now, you say that the Defense Supply Agency has a better standard. When you have a situation where 96 percent of the contracts are negotiated and the Federal Government is not using the law to check the cost behind those negotiations, I have a suspicion that the taxpayer is getting euchered out of an awful lot of money. I think the Veterans' Administration and the Defense Department ought to appear here with a panel of USP and NF experts and tell us what it is that they are doing that is so beneficial. If they are right, then USP and NF probably ought to adopt their standards and the FDA ought to go along with it.

But when I look at the high percentage of negotiated settlements and the fact that GAO has never been called upon to look at the costs to see if the prices are reasonable, I think there is some reason to be concerned about the possibility of excessive, wasteful expenditure of taxpayers money.

Does this strike you that way? I do not expect you to have the facts about these various standards the military talks about that