

Dr. FELDMANN. Getting information from the DPSC has been a very tortuous task, Mr. Chairman. It is very difficult to get information from them. I have seen very little except for these statements that were referred to earlier about so many percent of unnamed drug manufacturers, so many percent of drug products.

Now, in the information that you mentioned a moment ago that you obtained from DPSC, and which you provided to me prior to our appearance here today to examine, one section did ask them, under question 15(e)——

Senator NELSON. Under which one?

Dr. FELDMANN. Fifteen (e).

You quoted—a statement made by Mr. Feinberg, “We develop definitive product specifications which often exceed official or commercial standards.” You asked them to please name each product for which such specifications have been developed, the significance for each product of these extra requirements, and the medical purpose served by these extra requirements.

I examined the answer that they provided, and there are a number of drugs which are either in the USP or the NF listed in their response. Knowing that Dr. Banes will be testifying later, I will not address myself to the USP drugs. But there are four NF articles that are listed in their response.

One of these is Glyceryl Guaiacolate syrup NF. This is cough syrup, an expectorant. They list three additional tests. One of these is a “taste palatability test.” Well, the matter of taste is a subjective matter, Mr. Chairman, at least in my opinion. This can be a matter of preference for the patient, but I would hardly say that this falls into a critical medical consideration.

They have a so-called “accelerated aging test.”

Senator NELSON. Accelerated aging?

Dr. FELDMANN. Yes, which simply means that the product is subjected to intensified environmental conditions to see whether it will stand up. Well, the NF specification is such—the “general notices” in the NF require—that an article meet the standards during its entire shelf-life. So this is, in a sense, really already covered by the NF monograph.

They then have a requirement for “color value, specific gravity and refractive index.” Well, in our opinion, Mr. Chairman, in the opinion of the official compendia, the NF and USP, these types of specifications are totally inappropriate. They are appropriate for an active ingredient, something that will go into the formulation, to ascertain its purity; but to apply to a formulation which is a mixture of ingredients, they are inappropriate. It would appear that such specifications may be largely geared or skewed around one particular formulation.

Senator NELSON. Well, that is the issue or suspicion, to use a more accurate description, of what may be going on. That is to say that they may be taking a drug, in this case a cough syrup, and deciding they want to buy it from a particular manufacturer, so they take all of the manufacturers’ specs and then ask for a bid, and there is