are so many well- poor- and medium-qualified people making drugs. Because you have to be able to say therapeutically equivalent today, tomorrow, and next week—because they do not always do the same job every day.

Now, we did not make this problem, and we are not trying to complicate it. It just evolves from the nature of the situation that exists.

Mr. GROSSMAN. Can I assume then you would feel that the USP standards, the standards they now have, are not adequate?

Mr. STETLER. USP standards—in other words, the USP does a fine job as far as they have gone. They recognize as we recognize, that there probably should be other standards developed, and they are now being developed with the cooperation of the manufacturers.

What we say on USP standards is not intended at all to be critical of that book, and it is not. But USP is not the whole answer.

There are other standards, and they are being revised now. When those are in the book, USP standards will mean more than they mean now. Whether they will ever answer completely the problem, I cannot say.

Mr. GROSSMAN. We can probably say, then, as soon as Dr. Goddard's study is completed, we will be in no better position than we are now.

Mr. STETLER. Well, we will be in a better position as to what he finds on those 12 or 50 products. But I don't think, after he studies the 12 or 50, that he can say across the board all products bearing the same generic name are equivalent—no; he cannot say that.

Mr. GROSSMAN. Thank you.

Senator NELSON. All right. Go ahead.

Mr. STETLER. On that point—if you would like—I would read just one statement here. This is from Dr. Feldmann, of the National Formulary.

> This brings up a closely related matter that is a national limitation of the compendia. Many people in pharmacy have the mistaken notion that if a product meets all the specific tests and requirements detailed for the article in the USP or NF monograph, then that particular product has to be perfectly satisfactory. While I wish this were true, I am sorry to say that it is not, and the nature of the problem is such that we can never hope to develop compendium monographs which will give complete assurance of any product's complete and absolute suitability.

Mr. GROSSMAN. Could I ask you one last question.

With regard to the USP, I understand their tests are essentially physical; is that correct?

Dr. SLESSER. Yes.

Mr. GROSSMAN. Could you then recommend their tests be extended to biological areas, and to animal testings like that?

Dr. SLESSER. Mr. Grossman, according to Dr. Miller a committee has been appointed for this very purpose, and they are exploring this particular matter, and hopefully some time in the future they may come up with tests which will come much closer to doing what you have indicated here than the present compendia are able to do.

Senator NELSON. In establishing the USP standards, it is not purely a chemical matter, really, is it? That is, the consultants involved in setting standards include not only the industry but also the expert physicians who have used this drug around the country. So there is a cumulative clinical knowledge about this compound and its effect that