the rule that there is not an equivalency among drugs that meet USP standards, when really it is the other way around. The exception just tests the rule. Once in a while the clinical and pharmacological knowledge about a drug is not sufficient at first to set foolproof standards. When more is known, modified standards are developed which incorporate the new knowledge. But this is an exceptional case.

So is it not really true that so far as we know, if drugs meets USP standards those drugs are equivalent therapeutically and you have to prove that they are not? As you know, we had this case recently of prednisone reported on in the Medical Letter. They tested 22 prednisones and accumulated scientific expertise around the country, and on this basis flatly stated that the present differential in price from 59 cents to $17.90 to the pharmacist is not warranted by differences in quality. This has never to this date been refuted by anybody in the industry.

Dr. GODDARD. We are trying to extend that to the drugs most frequently prescribed, those in the 200 most frequently prescribed list that are available by generic as well as by trade name. We are going to conduct that kind of test on human volunteers, you see, through Georgetown, with a contract there, through Public Health Service programs, and perhaps Veterans' Administration programs.

Now, let me point out to support what I have said, every instance that has come up, we and others have moved in on it, have studied it in depth, and it has resulted in a change in the standards. That is necessary. That is a role we must play and the scientific community engages in these kinds of studies to try to understand why the finished product of tetracycline, for example, was not performing at that point in time. When we understand it, then the standard can be changed. But it would seem to me that your point that the exception proves the rule is a valid one. The drugs are therapeutically equivalent until proven otherwise. But we do feel a burden to carry out further testing and get this thing wrapped up. We are going to improve the good manufacturing practices, too, Senator, which will also contribute to the improved quality of drugs.

Senator NELSON. You are going to what?

Dr. GODDARD. Improve what we call the good manufacturing practices, the requirements that manufacturers must meet.

Senator NELSON. You are going to increase the standard; is that what you are saying?

Dr. GODDARD. Yes, in effect.

Senator NELSON. You referred to testing 200 of the most frequently used drugs.

Dr. GODDARD. No, selecting from the 200 most frequently prescribed drugs those that are available in a generic name form. If it is a unique source, there is no point in checking, because of the unique source. Many of these drugs, by the way, came through the NDA procedure originally, so we have the information on clinical effectiveness already in hand.

Mr. GROSSMAN. Dr. Goddard, may I ask you, is then the purpose of the study they are conducting to corroborate the position you now hold as to equivalency?

Dr. GODDARD. Yes; to lay to rest these——