The important point, however, is that not more than a dozen drugs have presented problems with respect to physiological availability. Thus to damn the entire Pharmacopeia of some 2,000 drugs for the failure of a mere handful is unscientific in the extreme.

As I understand his statement it is that drugs that meet USP standards are equivalent, and that, to his knowledge, there are only a dozen proven cases of two drugs meeting USP standards and having different therapeutic results.

Mr. STETLER. I think you are entitled to that conclusion from what was said. But I think really what he said is that—he estimates—12 drugs where there is proof of lack of equivalence. But the burden has always been shifted to the proof of lack of equivalence. Nobody has come up with proof of equivalency. This is a very spurious assumption that is made because USP has standards. Whether or not they exist, whether or not they are followed, and what they mean in the final analysis in terms of therapeutic effectiveness is still a question.

Now, he talks about 12. I think Dr. Goddard and FDA are currently testing about 50 products. We have some others here that we will talk about when we get around to it.

But the important thing which cannot be forgotten is that there is not absolute proof of effectiveness for the 3,000 products. There is lack of proof of therapeutic equivalence for many or most of those products. It is a question of where the burden of proof lies in this matter.

Senator NELSON. But I would suggest that if Dr. Miller is right, that there are about 12 proven cases—not just testimonials—proven cases, that the burden would rest, it would seem to me, in my approach to the matter, on those who say that this is not the exception that tests the rule.

Now, if it is the other way around, that the burden is on USP to prove that if they meet USP standards they are therapeutically equivalent, the doubt that is cast is cast equally upon all brand names and all generic names.

So what you have done is eliminated the whole argument. There is no use in pressing the point at all, because since you do not have any evidence to the contrary, there is no basis for selecting one drug over another, brand name or otherwise, since there is no positive proof that they are equivalent—you would end up just a guess anyway.

Mr. CUTLER. If I could just say one thing, Senator. A new drug under the food and drug law—and most of the ones we are talking about I think are new drugs—must be proven to the satisfaction of the FDA to be safe and effective. You cannot have your New Drug Application approved if you offer evidence that there is no proof that it is unsafe or ineffective. You cannot get by with a double negative. You must prove the positive. And many of the drugs that you are speaking of, particularly those developed by the innovative manufacturers, have survived that test.

Under the 1962 law—they have been proven to the satisfaction of the FDA to be safe and effective.

Senator NELSON. Yes. I do not quarrel with that. So if you take any of the drugs to which the 1962 statute applies, and the compounds on the market manufactured and produced by 20 companies meet USP standards, they are considered to be safe and effective.