Senator NELSON. Does this happen to be one of those rare drugs where the only test of equivalency is in fact a clinical test, or a biologic test, at least?

Dr. LEE. That is correct. In the case of chloramphenicol we have found that a biological test is required. We believe, however, that it is not necessary to have an additional clinical test in the treatment of disease when equivalent blood levels have been produced.

Senator NELSON. What I am getting at is whether the companies have now been admitted back to the market?

Mr. GOODRICH. By presenting evidence showing an adequate blood level response to the formulations. Now, this is not a situation such as we had some years ago with intrinsic factor in which you required a biological test for each batch. To the contrary, this is a formulation examination, some sharpening of the chemical standards, and on top of that, a requirement of the study of biological availability to make sure the drug was getting into a proper blood-level situation.

Senator NELSON. But those chloramphenicols were removed from the market and in order to come back on the market, they had to present a test of biological equivalency, and they have done that?

Mr. GOODRICH. Yes, sir.

Senator NELSON. Have you been able to establish an objective test out of all this? What have the firms done to their production methods that made the drug more quickly available physiologically, and if they have done something specific, could that be put into the standard?

Mr. GOODRICH. We should have our scientific people answer that in detail. I would be afraid to try to give you the exact details. I do know that some formulation changes were made, and that the tests of biological availability were required.

Dr. LEE. I think it is important also, Senator Nelson, to add that the FDA also requires good manufacturing practices and quality controls, so that we can assure the public that the steady flow of the drugs into the marketplace continues to meet the standards. To assure compliance the FDA carries out plant inspection and also test drugs obtained in the marketplace.

It isn't just meeting the standard. If we didn't have these other factors built in through the Food and Drug Administration I think it would be difficult to give the kind of assurance that is necessary.

Senator NELSON. Doctor, I will have to leave for 10 minutes. The Interior Committee has some important measures to dispose of, and they need me to constitute a quorum. So we will recess for 10 minutes, and I will be back.

(Recess.)

Senator NELSON. Please go ahead, Doctor.

Dr. LEE. Mr. Chairman, before returning to my statement, in your absence I reflected a little bit on the question that you and Mr. Gordon raised earlier with respect to the compendium. There is a point that requires more clarification. This has to do with the most commonly prescribed drugs and why we shouldn't list and describe them in a single volume and then list and describe the rest of the drugs in a second volume. The assumption behind this proposal is that this first volume would be the most frequently used by the physicians, and would be less bulky and more easily used.