

Mr. GROSSMAN. Let me ask you this for information. You say you reached the conclusion that except in rare instances drugs which are chemical equivalent, et cetera. Is this conclusion based on what you have done in the past, or what you surmise will continue in the future, or how does this work?

Dr. NOVITCH. It is based largely on past experience. But also, the goal of FDA's present efforts is to seek new standards which could make it possible eventually to use laboratory tests in place of the biologic availability studies that are now required with chloramphenicol. The major goal is to achieve some sort of correlation between prospective new standards and the clinical studies that are now underway.

Dr. LEE. Of course, this also involved a review of the available information and the literature on various studies that had been done.

Mr. GROSSMAN. My problem is, you say this is your conclusion, and I assume based on a thorough, complete, final study.

Dr. LEE. As new drugs emerge, new studies will be required. Thus it has to be a continuing study. This has now been established as a continuing activity within the Department.

Mr. GROSSMAN. Am I correct in saying that as far as all drugs that are presently on the market are concerned, you would make this conclusion or statement?

Dr. LEE. Yes, you can draw that conclusion from our statement.

Mr. GROSSMAN. And have all drugs in fact been tested for this purpose?

Dr. LEE. For clinical equivalency, no. But you think that, based on the evidence that we examined, both from the literature and from the clinical studies and from the biological studies, from the standards that have been developed over a number of years, our conclusion was that there are relatively few where there will not be clinical equivalency when you have chemical equivalence.

Senator NELSON. Meeting USP—

Dr. LEE. Meeting the standards. And, of course, we are updating the standards. Efforts are currently underway to update those standards.

Mr. GROSSMAN. Dr. Lee, I think it was in the New York Times of Tuesday, July 16—I remember when this came out, because there was a big furor about it—and since that time I have heard different reports as to what the truth was of the article which appeared, I think, in the Washington Post, implying that the FDA had found that there were differences in drugs in equivalency.

I know it mentions chloramphenicol specifically, but it also mentioned other drugs. There was a lot of confusion, and I heard this was a false report, and somebody let this out when it shouldn't have come out. Can you clear this up for us?

Dr. LEE. I am not exactly certain of the study to which you referred, but I believe it was the study that was conducted at Georgetown University. And if I recall correctly—we can provide you a more detailed statement for the record—there were three drugs. One was chloramphenicol, and one was a sulfa drug, and the other was diphenylhydantoin, which is used for the treatment of epilepsy.

In the drugs that were tested the requirements differed. The sulfa drugs, which are used primarily to treat urinary tract infections, required the careful analysis of the urinary excretion rates and the