availability of the drug in the urinary tract on an around-the-clock basis.

In the testing of drugs used for the treatment of seizures, one of the generically equivalent drugs was absorbed more rapidly and had a higher blood level than the brand name drug. In this case it might be necessary to do clinical studies to determine if that is clinically equivalent, clinically effective when you find these biological differences.

There are some statistically significant biological differences that we did not consider clinically important and which Dr. Ley, in commenting on this report, did not consider significant. At the time of the publication of the report the implication was made that you could generalize from the study of these three drugs.

Mr. GROSSMAN. It says, "Already the statistics have shown that two grams of the drug may have the same chemistry and behave differently in the human body." And the whole emphasis of the article is to show that, with a big picture of Dr. Ley setting next to you right here.

Dr. LEE. We can provide you with Dr. Ley's statement made at the time, because I think that clarifies it. It is difficult recalling from memory the content of an article published 2 months ago. But I would be glad to supply more detailed information on those three particular drugs.

Mr. GROSSMAN. I would appreciate that. Thank you.

Mr. GORDON. As I understand it, as far as the sulfa drugs are concerned, the differences were not clinically significant; is that correct?

Dr. LEE. That is my impression, Mr. Gordon. I believe that the differences were not statistically significant. To be certain, however, we will provide that for the record. I don't want to try to recall this from memory when we do have and can provide you with specific information.

(The subsequent supplemental information submitted by Dr. Lee follows:)

In late 1967, Parke Davis and Company presented data to the Food and Drug Administration indicating that several brands of chloramphenicol on the market gave lower blood levels than those produced by the preparation for which the Parke Davis' new drug application had been previously approved. Under its contract with Georgetown University, the FDA arranged for blood level studies on chloramphenicol, and a number of other drugs, including sulfisoxazole, and sodium diphenylhydantoin.

Dr. Christopher M. Martin and associates at Georgetown administered chloramphenicol capsules to healthy volunteers in a group of studies comparing the blood levels of Parke Davis' Chloromycetin with those of two generics. Georgetown concluded that the generic chloramphenicol capsules gave significantly lower blood levels than Chloromycetin and the drugs could not be considered therapeutically equivalent to the Parke Davis product. FDA then conducted further experiments on chloramphenicol capsules from other manufacturers, and its conclusions were similar to those of Georgetown.

Similar experiments, also on healthy volunteers, were conducted at Georgetown with three different manufacturers' sulfisoxazole tablets and three manufacturers' sodium diphenylhydantoin capsules. The FDA's review of these data led to the conclusion that there were no significant clinical differences between the three sulfisoxazole products. The data developed from the diphenylhydantoin experiment, are indefinite, and do not permit a conclusion of any clinical significance with respect to these drugs at this time.

Data from the Georgetown work have been useful to the FDA, but these studies provide no basis for concluding that generic products "work less well" than the brand-name product.