

Dr. LUECK. Because I think they could decipher which products we had tested if I continued any further along that questioning. There are brand-name products.

Senator NELSON. Are any of them companies that produce only generic drugs?

Dr. LUECK. Yes, sir.

Senator NELSON. These are going to be public anyway.

Dr. LUECK. Yes. Both types of products, both brand names and generic, are represented in the study.

Senator NELSON. Are any of the brand-name companies that produce an inadequate chloramphenicol tablet members of the Pharmaceutical Manufacturers Association?

Mr. CUTLER. I do not believe any of them are, Senator Nelson.

Dr. LUECK. To respond to that, I think one member is an associate member.

Is that right?

Mr. CUTLER. I don't know the answer to that, sir, but we will find out and let you know.

Senator NELSON. Well, all right, go ahead. It will become public at some stage, anyway.

Dr. LUECK. Thank you, Mr. Chairman.

Continuing on page 5, a plasma-level test consists of measuring the amount of the drug present in the blood at a given time. The plasma level of an antibiotic is considered by experts to be a measure of the amount of drug that has been absorbed by the bloodstream and, is therefore, indicative of the amount available for eliciting a therapeutic response. It is important to note that physicians require that an oral antibiotic product give as high and as rapid a blood level as possible per given dose. This is because quick absorption of the antibiotic into the bloodstream is necessary in order that the drug may be immediately transmitted to the site of the infection.

As can be seen from chart 2, the blood plasma levels of chloramphenicol for the two products, Chloromycetin and product A, are markedly different. To illustrate the significance of this difference, please note the following statement appearing in the labeling—package insert—of both products:

Chloramphenicol administered orally is absorbed rapidly from the intestinal tract, producing detectable concentrations in blood within one-half hour after administration and peak concentration in from one to three hours. Peak blood concentration is roughly proportional to the dose.

It can readily be seen that product A is not absorbed as rapidly as Chloromycetin nor is the peak concentration in the blood as high as that found with Chloromycetin.

The second test conducted in this study was the urinary excretion rate of chloramphenicol. The test was performed on the same subjects taking part in the blood-plasma-level test.

The excretion rate of a drug is determined by measuring the amount of the drug in a sample of urine taken at various time intervals after administration of the product. It is pointed out that before a drug can be present in the urine, it must be absorbed from the gastrointestinal tract into the bloodstream of the patient, and thence partially metabolized and found in the urine. This test, therefore, ascertains how much