than 85-percent chloramphenicol in 10 minutes, not less than 93 percent in 20 minutes, and not less than 98 percent in 30 minutes. None of the other chloramphenicol products which we tested met these standards.

Because the dissolution rate test is a laboratory test, in vitro and not in man, it alone cannot be considered to be sufficient to establish whether there was a lack of efficacy for these chloramphenicol products. A question of efficacy can only be answered with established clinical data. Consequently, we applied to the Food and Drug Administration for permission to conduct clinical studies on these same products to ascertain if human subjects would absorb the drug in a manner that could be correlated with the results of the dissolution rate test.

The Food and Drug Administration granted Parke, Davis permission to proceed with these clinical studies. The studies thus approved were to be conducted on normal human subjects, each of whom was to receive a single 500-mg. dose of one of the chloramphenicol. The tests of (1) the blood plasma levels of chloramphenicol and (2) the urinary excretion rate of chloramphenicol were to be determined for each subject.

The first clinical study, designated on the charts as "Study 1," was carried out on five normal subjects who received FDA-certified Chloromycetin capsules and on five normal subjects who received presumably an FDA-certified sample of product A. Both samples, as previously stated, were obtained from a retail pharmacy.

Chart 2 shows the results of the blood plasma level tests.

Senator NELSON. Do we have the names of the other companies in the sample comparative tests?

Dr. LUECK. No, you do not, Mr. Chairman. The names and the lot numbers have been turned into the Food and Drug Administration.

Senator NELSON. Do you object to giving the committee the names of the other companies?

Mr. CUTLER. Mr. Chairman, Parke, Davis would certainly prefer not to furnish those names to the committee. But they have been furnished, together with all of the protocols and results of the tests, to the Food and Drug Administration. So they would be available to you, I assume, on a confidential basis, from the Food and Drug Administration.

Senator NELSON. Is there any reason why information of this kind should be confidential?

Mr. CUTLER. Well, these are very serious charges addressed to the other drugs, Mr. Chairman, and Parke, Davis would prefer not to be naming the makers of the other products. It has turned its evidence over to the Food and Drug Administration. The Food and Drug Administration will presumably seek to verify the results found by Parke, Davis and take whatever action it deems to be appropriate.

Senator NELSON. Do any of the companies involved, without naming them, produce brand-name products?

Dr. LUECK. Yes, sir.

Senator NELSON. How many of them?

Dr. LUECK. I think it would be divulging the companies' names if I went any further than my statement.

Senator NELSON. Why would that divulge their names?