

yours covers the same area. That is the reason I raised the question to you.

Dr. LUECK. Yes.

Senator NELSON. All right, go ahead.

Dr. LUECK. The results of the blood plasma level tests, both chemical and microbiological, are shown in charts 10 and 11.

May we have chart 10?

Mr. Chairman, this chart refers to plasma levels as determined by the colormetric clinical test for Chloromycetin, product A, product B, and product C. In a glance at the chart, it is readily discernible that differences between these plasma levels, resulting from the administration of the respective products, are quite different.

May we have chart 11, please?

Chart 11 depicts the blood levels as determined by the microbiological analytical technique and we see again that appreciable differences are noted between the products, and these results compare very favorably with the colormetric analytical results and corroborate the fact that the testing procedure is being followed accurately.

Now, the results of the urinary excretion rate tests are shown in chart 13.

May we have chart 13, please?

It again can be seen that there is a significant variation between the products. I would like to point out that the official package insert for all these products reads that 70 to 90 percent of the drug should be excreted in the urine over a 24-hour period. That 70 to 90 percent is depicted in the crosshatch area at the top of the figure. You can please note that Chloromycetin is the only product that reached those levels in this test.

Now, our clinical consultants believe that the difference shown in Studies I, II, and III would be very significant in the treatment of infectious diseases. The higher and earlier blood plasma levels produced by Chloromycetin capsules, Parke, Davis indicates that more rapid and thorough absorption of the dose occurred than with the competitive chloramphenicol capsules. Indeed, the blood plasma levels indicated for products A and B are low and product C is disturbingly low. Their clinical efficacy is open to question.

The total urinary excretion of chloramphenicol and its metabolites was shown by the studies to be substantially less for the competitive chloramphenicol capsule products than that demonstrated by Chloromycetin capsules, Parke, Davis. The Food and Drug Administration approved labeling for all the chloramphenicol capsule products indicates that the chloramphenicol dosage should be absorbed into the human body so that 70 to 90 percent of the drug is excreted by the kidneys within 24 hours. It is evident from the urinary excretion data in chart 13 that none of the other companies' chloramphenicol capsules reached the proper degree of excretion as prescribed in the package insert which accompanies the drug. They all are below the labeled limits of 70 to 90 percent.