growth of a test microorganism. As can be seen from chart 6, product A demonstrated less inhibition of the microorganism, as measured in terms of micrograms of chloramphenicol per milliliter of blood sample tested, than did the Chloromycetin, Parke, Davis.

At this point, it was evident that a significant difference did, indeed, exist between product A capsules and Chloromycetin capsules, Parke, Davis.

The final clinical study, designated on the charts as Study III, was initiated to compare additional chloramphenicol capsule products with Chloromycetin, Parke, Davis. This study was performed in a manner identical to that described in Study I and Study II above. However, to improve the statistical significance of the study, 10 normal subjects were used per product in Study III.

Samples of Chloromycetin capsules, Parke, Davis, and product A different batches, were again obtained from pharmacy stocks on the open market. Also, samples of product B and C, in commercial distribution by two other companies, were obtained as above. Chart 9—and, Mr. Chairman, chart 9, for your convenience, is displayed over on your left. Number 5 you can see that product A and particularly product C showed very different dissolution rates as compared to Chloromycetin, the product depicted on the left.

Senator NELSON. Did product A meet FDA standards?

Dr. LUECK. Yes, sir; so far as we know, all of the products tested in these studies met the requirements of the antibiotic regulations or the laboratory tests of the antibiotic regulations.

Senator NELSON. Is this a case where the FDA set the standard and USP adopted it?

Dr. LUECK. No, sir.

Senator NELSON. Does the USP have a different standard from FDA?

Dr. LUECK. No, sir; in this case, this is a certifiable antibiotic and the standards that prevail are the ones included in the Federal regulations on the antibiotic regulations. They supersede the USP.

Senator NELSON. That is what I said, the USP simply accepts the FDA standards.

Dr. LUECK. Yes.

Senator NELSON. This is not a case, then, of the USP establishing a standard itself?

Dr. LUECK. No, sir.

Senator NELSON. When did the patient expire on Chloromycetin?

Dr. LUECK. The patent expired October 1966.

Senator NELSON. October 1966?

Dr. LUECK. Yes, sir.

Senator NELSON. Did any representatives of Parke, Davis participate with the FDA in setting the standards to be met?

Dr. LUECK. Yes, sir; initially, when Chloromycetin was approved for marketing, the standards were established on the basis of information submitted by Parke, Davis & Co., to the Food and Drug Administration. They, through the years, have been improved and changed, but standards were set largely on Parke, Davis information, corroborated by the Food and Drug Administration.

Senator NELSON. At the time the patient expired and the FDA set