

Senator NELSON. Well, you had the case of chloramphenicol.

Dr. CROUT. Correct.

Senator NELSON [continuing]. In which the brand name product Chloromycetin achieved a higher peak level much more quickly than all of the others, with the blood level dropping off much more quickly. When you look at the charts, one of the other products looked like a bell curve while the other one went up quickly—with a high peak and went down precipitously.

Dr. CROUT. Yes.

Senator NELSON. Now, at the time the FDA required the other companies to comply with the blood level achieved by the Chloromycetin; and there has been no evidence, and I have heard of none since, that the Chloromycetin was more effective therapeutically than the others. But since it had been in the marketplace for many years; physicians had dealt with it; and it was an effective drug for the purpose for which it was indicated, therefore you required the others to achieve the same blood level.

If it had been the other way around, that the Chloromycetin had a bell curve level and the others achieved a higher level and went down, I assume you would make the same decision, make them meet that same blood level—not based upon the evidence that one was more efficacious than the other, but based upon the fact that you knew one was effective and had been in the marketplace.

Is that correct?

Dr. CROUT. Correct.

Mr. GORDON. Concerning the extra requirements that the DPSC has for some of the drugs which you examined, would it be fair to say that some of the requirements there, which may not have medical significance, tend to undermine competition? For example, the use of certain expensive equipment, which may not have any medical significance, would at the same time exclude many small companies from supplying drugs to the DPSC?

Dr. SCHMIDT. In looking over the requirements I would think that some of them would have the effect of limiting those that could meet the standards, yes.

Mr. GORDON. Even though they may not have medical significance?

Dr. SCHMIDT. Yes.

Senator NELSON. Thank you very much, gentlemen, for your very valuable testimony.

Dr. SCHMIDT. Thank you, sir.

(Whereupon, the hearing in the above-titled matter was recessed at 1:05 p.m., to be reconvened the following day, Thursday, Feb. 21, 1974, at 10 a.m.)

[Testimony resumes at page 10163. The information referred to by Senator Nelson follows:]