

Senator NELSON. Let me comment on your last statement:

Thus we have confirmed what experts have repeatedly said, that chemical similarity is not necessarily indicative of therapeutic equivalency.

I have never heard of anybody saying that it is. The statement is really, I think, Doctor, quite meaningless. Nobody says that. That is not the argument. The argument is, as you said earlier, whether or not in almost all cases, with a rare exception, if USP standards are met, the drugs are therapeutically equivalent. That is what the issue is.

Now, Parke, Davis, which is the manufacturer of Chloromycetin, has had on the Committee on Revisions of the USP, Mr. F. O. Taylor, from 1950-1960—

Dr. LUECK. Yes, sir.

Senator NELSON. And Mr. Marina from 1960 to date, is that correct?

Dr. LUECK. Yes, sir.

Senator NELSON. Now, when the USP adopted FDA standards, did these representatives of Parke, Davis give them the benefit of their advice as to what standards had to be set in order to produce a therapeutically equivalent or effective drug?

Dr. LUECK. I would like to comment on two things, with your permission, Mr. Chairman.

I would like to state for the record that Parke, Davis & Co. feel that the USP and NF and the FDA antibiotic regulations are the strongest standards in the world.

Senator NELSON. Every witness from every company has agreed with that.

Dr. LUECK. I would like to go on to say that this is evidenced by the distinguished people who have spent their entire careers in Parke, Davis who have contributed to the USP and NF over the years and who will continue to do so.

I would like to point out, though, for the chairman, that Chloromycetin or chloramphenicol is an antibiotic, Mr. Chairman, and is therefore not covered in the standards in the U.S.P. It is covered in the antibiotic regulations. The antibiotic regulations cover chloramphenicol.

Senator NELSON. I understand. Correct me if I am wrong about this: Does not the USP adopt, then, the FDA standards?

Dr. LUECK. No; they generally—

Senator NELSON. Or do they just do nothing about it?

Dr. LUECK. No; they just list the monograph, and in a few moments, I will find it. They just list the monograph in the USP and mention that this is under the antibiotic regulations. So Chloromycetin or chloramphenicol is not controlled by the monograph in the USP. It is controlled standardwise by the antibiotic regulations.

I would read from, Mr. Chairman, if you please, from the rubric of the USP on chloramphenicol, page 114:

Chloramphenicol contains not less than 90 percent—

It gives the clinical formula:

It conforms to the regulations of the Federal Food and Drug Administration concerning antibiotic drugs. See Antibiotics, page 768.