

some day. All they had was a different blood level achievement in a different period of time.

Dr. ALFANO. There is a study on oxytetracycline, I think. I can send you a copy of that.

(Material not received.)

Senator NELSON. But the evidence was that there was no therapeutic significance to the difference.

The following is a line of questioning of Dr. Lee, former Assistant Secretary of HEW, on this question of equivalency.

Mr. GORDON. I have one nitpicking question. You say there are only two or three which demonstrate an initial lack of equivalency and one of them has no practical clinical importance. Are there two or three? Which is it?

Dr. SILVERMAN. There are two. One of them, as you probably surmised, is chloramphenicol.

The second one is tetracycline. In the article in this publication, the scientists that wrote this article pointed out quite clearly that although differences were detected, this was not of any clinical importance.

Dr. ALFANO. That is tetracycline?

Senator NELSON. Yes.

Dr. ALFANO. There is one on oxytetracycline, a new one.

Senator NELSON. In any event, the USP, the formulary, and the FDA, can cite only one of two cases.

Dr. KRANTZ. May I speak to this, because it is very apropos of this?

Senator NELSON. Yes.

Dr. KRANTZ. The Department of Defense a few years ago, after having bought these brand name items at low price as generics, brought me 19 of them that did not show complete therapeutic efficacy. These are these drugs: Reserpine, thiopental sodium, tolbutamide, tedral, tubocurarine chloride, Warfarin, Heparin sodium injection, oxytocin injection, diphenylhydantoin sodium, digitoxin or digoxin, phenolsulfonphthalein, pentaerythrityl tetranitrate, succinylcholine chloride (Anectine), bromsulphalein solution, sustained release tablets, methenamine mandelate (enteric coating), Dexamy.

Senator NELSON. We will check the record further. Counsel advises me that the task force on these drugs went into this and found out that—

Dr. KRANTZ. They came to me for the purpose of finding pharmacological data which would show the generic equivalency of these drugs.

Senator NELSON. Were these drugs you cited here—I have not read that report—were these drugs that did, in fact, meet USP standards?

Dr. KRANTZ. Oh, yes; they put them through the USP test. This is very simple for them to do.

Senator NELSON. Did they meet the USP standards or fail them?

Dr. KRANTZ. Met the USP standards but the diphenylhydantoin did not control epilepsy. The meprobamate did not produce sedation. The thyroid did not change the metabolic rate.¹

Senator NELSON. You are certain that these are cases where the drug met the USP standards, not failed the standard tests when tested?

Dr. KRANTZ. The pharmacopeia standards are only standards of identity, purity, and also the rate of tablet disintegration.

Senator NELSON. Potency?

¹ See pp. 4555-4557 of Dr. Krantz' testimony.