

Dr. KRANTZ. Identity and purity.

Senator NELSON. The committee is well aware of that, Doctor. What I am saying is did each one of the drugs named under test meet the U.S. pharmacopeia standard or did they fail to meet the standard?

Dr. KRANTZ. I was so informed by the colonel who brought them to me, that they had met the pharmacopeia standards.

Senator NELSON. I would question it for this reason. We have discussed this question with the Directors of the National Formulary and U.S. Pharmacopeia and they flatly state that they cannot find any cases, excepting one or two, in which a drug met USP standards or U.S. Formulary standards and was proven not to be therapeutically equivalent. Now, I will take these and recheck them, but this has been the testimony by the Director of the FDA, by the U.S. Formulary, the U.S. Pharmacopeia, and by a number of distinguished pharmacologists. If they met the standard, there have been only one or two cases where that was proved not to be therapeutically equivalent. If there is further evidence of exceptions, of course, the committee would like to have it.

Dr. KRANTZ. Well, this came from the Army source of supply in Philadelphia. The colonel came to see me in my laboratory about a year ago and asked me if we could develop pharmacologic tests which could prove their pharmacologic activity in addition to the fact that they had already proved their chemical identity.

Senator NELSON. Dr. Lee testified for the Department of Health, Education, and Welfare on December 23 respecting the Task Force Report. I will read what I said to him and what he said:

Just on one point of your conclusion—

that is the conclusion of the Task Force Report—

that when drugs are chemically equivalent and meet all the chemical standards, they are therapeutically equivalent except in rare instances, as you are aware. We have had distinguished pharmacologists and clinicians appear before this Committee and give the same testimony I assume that when you refer to the fact that you have relied upon the literature, and clinicians, and past experience and so forth, that that also involves the rather vast experience of the Defense Supply Agency, the Veterans Administration, and general hospitals and others who buy on competitive bidding. And on one occasion they get one brand of prednisone and one brand of another drug.

Dr. LEE. Tetracycline.

Senator NELSON. And their experience over the years has been that if they meet the same standard and have the same chemical composition, that they are therapeutically equivalent; is that correct?

Dr. LEE. That is correct. Because this is a highly charged and controversial area, the task force made a very extensive study. The task force study has been going on for well over a year. We consulted with the leading experts in the field; our staff reviewed the literature; we had the special studies carried out; we reviewed the experience of the Defense Supply Agency and other agencies who have had just the kind of experience that you have described. Our conclusions really are based on a detailed examination of the information that is available today.

Senator NELSON. Thank you.

I have to go vote, but the committee counsel tells me that he cannot find anything in your material, Dr. Krantz, that says these drugs, in fact, met USP standards. Could you show him where that is?

I will be back as soon as possible.

(A recess was taken.)