

If they all contain the same amount of drug, and if that particular drug is identical and is pure in each tablet, I can only assume all have the same effect.

Mr. COUGHLIN. Is there any way in which you would also test for therapeutic equivalency?

Dr. FITELSON. No, sir; I have no way of testing.

Mr. COUGHLIN. So this is an assumption you draw?

Dr. FITELSON. That is right, an assumption based purely on chemical tests.

Mr. COUGHLIN. Thank you.

I was also curious, Doctor. Are you affiliated with a hospital?

Dr. FITELSON. No, sir.

Mr. COUGHLIN. Thank you very much.

Mr. GORDON. These tests were based on USP standards?

Dr. FITELSON. We followed the U.S. Pharmacopeia test; yes.

Mr. GORDON. And is that not the assumption of the USP also, that if they fall within the USP standards, they should be clinically equivalent?

Dr. FITELSON. I think Dr. Garb is better qualified to answer that.

Dr. GARB. I will go further than that.

That is not only the assumption of the USP, that has been the assumption of the medical profession ever since the beginning of modern medicine. If you have a chemical on the one hand which is the same as the chemical on the other hand, and if they are not identical in their actions, there has to be a reason for it.

Senator NELSON. May I interrupt? You can complete your answer.

That is a rollcall. I am going to have to leave. I think that I have asked all the questions, but I want you to conclude your answer, and I want to say to both of you, I appreciate very much your coming here. The testimony of both of you is very valuable to our hearings and to this record. Thank you very much.

Dr. GARB. The conclusion of my answer is that if we cannot assume this, then we cannot practice any kind of rational medicine. We have to assume, for example, that a study which was done on phenobarbital 10 years ago still applies more or less to phenobarbital today, unless there is a reason for it being changed, and there can be reasons. There are changes, for example, in the antibiotics, as the bacteria adapt to them.

But this is a fundamental assumption in medicine, that unless there is reason given to the contrary, we must assume that an equivalent amount of a particular chemical at one time will do the same as the same chemical at another time.

Now, it is conceivable to be sure that there may be differences, but we have to start out on the assumption that there are no therapeutic differences when there is chemical identity, unless somebody comes forward with objective evidence to prove that there is a difference.

There have been a few rare cases in which differences have cropped up, but they were unusual situations in which a drug manufacturer used a particular chemical in the tablet, and in so doing he neutralized part of his active ingredient.

Mr. GORDON. That was calcium tetracycline?