

Senator HATFIELD. Dr. Taussig, according to my understanding, the USP standards are more physical than biological. Do I understand from your statement here about drugs that they can and should be tested on a variety of animals before use for the infants, the pregnant mother, and so forth? Does this recommendation of yours go beyond what are present USP standards?

Dr. TAUSSIG. I don't know how specific the regulations are. I think a number of doctors are working on the problem, and I think the various standards would follow very quickly when the best methods and the best animals for trial are known.

There is a great deal of keen interest in trying to determine it today, which we have learned from sad experience is necessary, and until one really appreciated it, one hadn't started to study which was best.

I think with our present experience, a few preliminary things are clear. If a drug is obviously bad for a variety of animals, it is probably bad for man. If it doesn't hurt those, it should be tested more carefully.

Senator HATFIELD. Do you feel then that there should be a more extensive and comprehensive testing than is presently used to establish USP minimum standards?

Dr. TAUSSIG. I think they are trying to do a pretty good job right now. I think that the ideal, perhaps even the best, is really not known. As I say, I think you have got to be fair to both sides, and to realize that drugs are tremendously valuable, and that you don't want to discourage all production of new drugs, but you certainly want to get all known dangers eliminated.

Senator HATFIELD. Let me ask you another question. When you say that the drugs react differently upon different people, how do we get then to the so-called equivalency tests and other such problems in dealing with the generic or brand names?

Dr. TAUSSIG. As to age groups, I think there is a general understanding today in testing various drugs that are going to be used for children, on very young animals, and on newborn animals, that older people react differently, and it is only really after this that we have seriously taken into consideration what is the effect on the fetus, and testing that.

Of course, the danger may be something quite unexpected. For example, if it is so good as a sleeping tablet for older people, why is it not equally good for a younger person or for a pregnant woman?

Senator HATFIELD. Will drugs act differently on different people within the same age group?

Dr. TAUSSIG. Well, some drugs. Of course, the sensitivity varies, some drugs people find more effective than others. This is an individual variation.

Senator HATFIELD. But doesn't this then raise a problem as to determining equivalency, efficacy, and all these other measurements of drugs?

Dr. TAUSSIG. I think it raises a problem. I don't believe it raises insurmountable problems, to know what is its reasonable probability. One difficulty lay in the lack of regulation for a clinical test. The doctor just gave a sample and the patient responds, yes, he had a good night's sleep; or, no, it didn't give him a good night's sleep, and that was considered as a trial and virtually no records were kept.