Dr. LONG. I think therapeutic equivalency is an entirely different matter than chemical equivalency.

Senator NELSON. Do I understand you to say that the USP standard did not mean very much?

Dr. LONG. It does not mean very much with respect to therapeutic results. Let us take the old common aspirin, for example, aspirin grains five, USP. You can find on the market lots of different kinds of aspirin, some at 9 cents a hundred, if you will, and some at 49 cents a hundred. And in some instances there is no difference, perhaps, between the 9 cents and 49 cents. But in other instances there is. Because there is a difference in the way the tablet is compounded, the disintegration rate, the permissible—even under USP standards the permissible variations in quantities of something other than pure acetylsalicylic acid may be permitted up to certain tolerances of purity. So that, therapeutically, equivalency is a good deal more important to the physician than the term USP alone. So I think perhaps I should change my statement to say that USP does not mean anything. It means a good deal, of course, because it does tell you about the chemical quantities that are in there, and the tolerance limits that are permitted for impurities, if you will, within a given product. USP does provide for that. But in addition to that, one needs to know something about biologic or therapeutic equivalency, which may be affected by many many things, as you know.

Senator NELSON. It is the position of the USP as well as many others, including Dr. Modell who testified here, that if a drug meets USP standards it is therapeutically equivalent until they find some evidence to the contrary. In other words, the best knowledge that the profession has, physicians as well as pharmacologists, is put into the USP standards, they may not have all the knowledge, but when something new is discovered they put it into the standard. So their position is that if it meets the standard it is therapeutically equivalent according to the best available expertise.

I notice you are shaking your head.

Dr. LONG. I do not agree, Senator.

Senator NELSON. Do you have a specific example of a case where two drugs meet the USP standards and were proven not to be therapeutically equivalent?

Dr. LONG. Oh, yes. FDA has that, for example, in chloramphenicol.

Senator NELSON. As an example, the FDA does not say they were not therapeutically equivalent. They just did not reach the same blood level. Dr. Ley will tell you that they did not have any test to find Chloromycetin vis-a-vis the two that did not meet the Chloromycetin level. There is no test to say that they are not therapeutically equivalent. So apart from that, FDA simply says there is no proof on therapeutically equivalency. Do you have another example?

Dr. LONG. I think there are many examples. I did not research this subject because I did not come prepared to testify on that particular line of testimony, Senator. But I can tell you, on the basis of my own experience, and on the basis of experience of many of my colleagues with whom I visited, that there are situations in which there is not therapeutical equivalency.

Senator NELSON. You say in your own experience. Do you have a case in which you had the drugs assayed, two drugs, and they both met USP standards, and they were not equivalent?