hundreds and thousands of physicians, I am persuaded that there is something else besides chemical equivalency that has to do with therapeutic results in the treatment of patients.

Senator NELSON. I think the USP will say that. Of course chemical equivalency—that includes coating and tablet pressing and all that?

Dr. LONG. That is what I mean.

Senator NELSON. But USP insists, they take all the best available knowledge, based upon all of their consultants, and put into the standard, the best knowledge that is known today. They will concede that some better knowledge may come later, and then they will put it into the standard. But as to the standard today, until additional evidence is produced they say that if drugs meet USP standards they are therapeutically equivalent. And only in the rarest of circumstances has this not been true.

Dr. LONG. I wonder why the statement is always put that way? Why would you not say that they are not therapeutically equivalent until it is proven that they are?

Senator NELSON. The experience of the consultants and clinicians, pharmacologists, and authorities when they establish the standard is that if they meet the standard, they are equivalent.

Dr. LONG. I think this is not the consensus of the opinion in my experience, or in my contacts with practicing physicians who have been taking care of sick people day after day and week after week and month after month. That consensus of experience is that therapeutic equivalence and chemical equivalence are not always identical, that with the same dose of a given drug in the same patient for the same disease, that brand X, let us say, the therapeutic results are not the same as with brand Y, if you will. Now, this may be true in many instances, that X and Y will result in the same. But I think there are many other instances in which this is not true.

Senator NELSON. You see, the drug companies will argue, well, the coating will make a difference, the excipient will make a difference, the size of the granule will make a difference, how hard the tablet is pressed will make a difference. Everybody knows that.

Dr. LONG. Yes.

Senator NELSON. Including the USP. So they set a standard for dissolution, and the excipient, and so forth. And the amount of the active ingredient can only vary, depending upon again the consultation with the experts, it has to have X percentage of the active ingredient, and in aspirin it is 95 to 105 percent pure aspirin. And their consultants advise that if you get within that tolerance you get the same result. All I am saying is, we have been asking for proof of instances where they meet the standard and were not equivalent, and we have received testimonials, but we have received nothing scientific from the drug industry or from any clinician or anybody else, except what they state what their personal experience has been. Well, in that kind of case it might be very well true that maybe they did not meet USP standard. None of the testimonials we have had, in the case where the drug was assayed to see whether it met USP standards first—that is our problem, trying to get that kind of a case.

Dr. LONG. I think maybe if I read a little further I may answer your question in part, and then perhaps we will come back to it if you wish.