The Senator may be aware of the fact that the AMA is one of the three financial supporters of the Drug Standards Laboratory here in Washington, D.C. We pay one-third of the budget to supply specific research and standardization of these drugs. Few people realize that. But this is just one other area, that indicates our long desire for quality drugs. We will be very happy to testify.

We have long felt that the Food and Drug Administration—and the record will show it came into being many years ago with a strong continued support of the American Medical Association—we have no battle with these men who are trying to assure quality products. The only time that we come into conflict with anyone is when they say that by virtue of a chemical similarity the drugs are the same. These other standards are absolutely essential. We would support such a stand for more dollars to enable the FDA to do an ever-better job.

Senator NELSON. Are you saying that you disagree with the testimony of a representative of the USP and the NF that if a drug meets USP standards, it is therapeutically equivalent?

Dr. ANNIS. No; I did not say that, Senator.

Senator NELSON. Oh, I see.

Dr. ANNIS. I did not read their testimony, and if this is indeed their testimony, I would suspect that it would deserve serious consideration. I have not seen it.

My point is that the general continuing argument has been against brand as opposed to generic, with the assumption that if a drug is generically the same, it therefore has therapeutic equivalence. If the valuations referred to by USP and NF include these other standards, the absorbability in certain areas of the intestinal tract within a certain period of time, so that when I give a drug I know it is going to be absorbed within the person's body, I have no quarrel. But this is shown by clinical testing. This will not show up sometimes in the laboratory. What is true in a guinea pig, or a dog, a cat, or rabbit is not necessarily true in a human.

So in many cases the laboratory alone, the chemist, the pharmacologist cannot give the whole answer. So our position is that we must look at the drug in its whole spectrum—from the standpoint of how it is compounded, its basic purity and the rest, including its reaction within the body—so that we can assure a physician when he prescribes the drug generically, nothing will be supplied his patient that falls short of these desirable physiological reactions and he will know the end result, then I am sure we would be on common ground.

Senator NELSON. But the position of the USP is, and it has been the position of a number of witnesses, including distinguished pharmacologists and clinicians, that if a drug meets USP standards, then it is therapeutically equivalent to any other drug that meets that standard and that in the whole history of this debate there have been—there has been I think one proven case where that was not the situation. That would be a case when all the distinguished people who set the standard happen to have missed the point—the clinicians, the chemists, and so forth—in evaluating the drug have established the standard and missed some point. But in the whole history of drug testing, there has been a proof of one or maybe two cases. Therefore, if we are going to use any standard at all, it would seem to me the USP standard is the one that we should use. If clinical evidence is developed