that the two drugs with the same compound did not have the same clinical result and they discovered that some different excipient was used in one and that caused it and USP had missed that point, that would be an exception to the rule. But when we have never been able to find more than one or two such cases in history. It would seem to me that this is the standard to rely on.

Dr. ANNIS. Senator, here is an area I would like to ask Dr. Hayes about. He is much more knowledgeable in this area. Do they set up USP standards after the extensive basis of clinical testing?

Dr. HAYES. Of course, this is a problem which has engendered a great deal of discussion amongst interested parties. In fact, several learned bodies have spent considerable time studying it. Two come to mind, the Academy of Pharmaceutical Sciences and the Drug Research Board of the National Research Council. They have recently, as a result of their study of the problem, called for some improvement of the standards for assuring physiological availability or biological equivalence, as it were, of all drugs reaching the market. I believe that both the USP and NF at the present time are reevaluating their testing procedures in order to develop tests which will more properly evaluate the biological equivalence of all drugs reaching the market. So I do not think it is possible to say that the existing standards—although I know the people in the NF and the USP, that they are sincere, dedicated scientists, and the fact that they question their own testing procedures and look to improve them—that the matter can be settled as to whether, under existing standards of the USP and the NF, that they, in themselves, will assure biological equivalence. I think that more work has to be done. I think that work is being done.

Dr. ANNIS. Senator, may I add, too, that in this connection—I thought this was true, but I was not certain enough to testify. Recently the Drug Standards Laboratory had to come back to us; they needed more money. They are suffering from something known as inflation, too. The American Medical Association feels so strongly about this kind of testing that you are referring to that, without hesitation, when the Council recommended to the Board that additional appropriations be made, we did so.

This is an area where we are concerned. But we are even more concerned that it goes beyond what can be done in that chemical or pharmaceutical laboratory, because ultimately the laboratory of a drug for a person who is ill is in that patient's body. This is why that biological testing that Dr. Hayes refers to and other groups apparently feel must be upgraded, too, is so important. Here again is an area where we would want to be assured before testifying along that line.

Senator NELSON. I just want to say on this point that Dr. Miller of the USP and a representative of the NF have not testified that their standards were perfect. They have testified that they are the best standards existent in the world today and that they can be improved, and, of course, they will be. But the question arises, after accepting the USP standard or NF standard in some clinical testing we find out a year later that the standard omitted something, then they would correct it. But as of the date that standard is there, it is the best standard there is. Therefore, if a generic drug meets that standard and a brand name meets that standard, on what basis does an individual practitioner say or the PMA, in particular, say that one is better than another?

Dr. ANNIS. I would agree if standards are all the same they could