

it met any other standards, because I do not know where it was purchased.

Senator NELSON. We have a constant instance involving generic and brand names where somebody will testify that it proves that the generic is not as good, because here is a case in which it did not do such and such. Every single case we checked is the case of a drug that did not meet U.S.P. standards. Of course, when that happens, that is front page in all the medical press and the pharmaceutical manufacturers naturally say, "Here is another case that you cannot trust it."

We have cases in the files from the last hearing in which exactly the same thing happened to the brand names, so you might as well say you cannot trust brand names. In the cases I mentioned of the 4,600 drugs tested, with 8.8 percent of the brand name not being able to meet potency standards, that proves the case that you had better stick with generics, because generics meet it more often.

Dr. ANNIS. My point was just the opposite—that the mere generic equivalence in itself is not sufficient. If we were talking about building in additional safeguards, as I indicated earlier, many generic drugs prescribed come from satisfactory suppliers. We are not opposed to these. All we want is to be sure that when a physician prescribes a drug, he gets the drug that he prescribes and one that has the other qualities over and above its chemical constituency that are essential to its proper and expected action.

Senator NELSON. The point is made very frequently by USP, manufacturers and so on, that if the drug meets NF or USP standards, they are equivalent. Then the other side argues that they are not and they use chloramphenicol as one of their cases, in which there is no proof that there was any therapeutic difference between the Chloromycetin and the other two in the marketplace. They just reached different blood levels in a different period of time, but the FDA decided that they would make them uniform. They could have made them uniform to the other drug as far as any clinical knowledge of the therapeutic efficacy of either one of them is concerned.

But the problem is that every time you find a generic that fails a test—and the brand names appear to fail them just as often—that is publicity to all the doctors, who then say, "Well, you cannot trust the generic."

Now, the thing that we have to resolve, it seems to me, is how do we get adequate testing to assure the medical profession, whether it is brand or generic, that it does meet the USP or NF standards.

It seems to me there are two things: One of them is to give enough personnel to FDA so that they can make adequate quality control inspections. You will not get this unless distinguished groups such as the AMA appear before Congress and say this is critical to America. Not just say this in the journal but appear before the Appropriations Committee and say that it is going to be critical to the health and pocketbook of the consumer, and, therefore, we think you ought to give FDA more inspectors.

Would the AMA appear before the Appropriations Committee when the issue arises in support of inspection?

Dr. ANNIS. Senator, we would be happy to appear before the Appropriations Committee or anybody else to assure increasing quality standards for all these products made for the benefit of the American people.