

Dr. MILLER. If you ordered diphenhydramine hydrochloride, you might not get Benadryl but if you bought it from Parke-Davis the chances are pretty good you would get exactly the same product that they sell under the trademark Benadryl. To clarify my statement here, what I am trying to say is that abolishing trademarks and trying to make names simpler so doctors will remember them and things like that actually may be desirable for some reasons, but it should not be approached from the standpoint of trying to make drugs cheaper, because I don't think that will necessarily follow. We have too many examples, like the aspirin situation, where they are sold under the same name, and price differences do exist. Here you have price differences in that Medical Letter list, where they are sold under prednisone as such but they are all prednisone tablets. If you took away the ones where they are sold exclusively under trademarks and just looked at the ones that are sold under the nonproprietary name prednisone, you will find price differences there, and that is the point I am trying to make, that price differentials will exist, because of the differences in manufacture, differences in costs of other sorts, differences in distribution, differences in service. Some of the firms that sell for the least do not have a distribution system. You can buy them in only a half-dozen places in the country, and to make it available in 36,000 places in the country is expensive, a very expensive thing.

Mr. GORDON. Who has been complaining, as you previously stated, that the USP standards are too lax, too few, and cannot do their job? Who made that statement?

Dr. MILLER. One of our friends up in Buffalo, Dr. Gerhard Levy, is one of those who says that the USP standards do not guarantee clinical equivalency, and yet many times I have asked him for help in improving the USP standards, and his answer always is "Well, that becomes a research project," and he has never been very helpful in providing us better standards. We are working hard on it within our committee. We have one of the country's experts.

Mr. GORDON. You disagree with Dr. Levy; don't you?

Dr. MILLER. I don't disagree with him completely. I think he is overemphasizing these few shortcomings.

Mr. GORDON. Yet you say here on page 4 that "The USP standards for drugs are not exceeded anywhere in the world."

Dr. MILLER. That is true. Nobody else has any of these standards that he complains we should have. We have standards that no other pharmacopeia in the world has, and yet he thinks we should still be better. We agree with him on that. We wish we were better. But he among others has not been able to provide us with objective methods that FDA could go into court with, to improve, to make certain, doubly sure that these products were clinically equivalent and absolutely physiologically available.

Senator NELSON. Is the question of clinical equivalency considered in establishing the USP standard?

Dr. MILLER. Oh, yes.

Senator NELSON. Then, do you do clinical tests yourself?

Dr. MILLER. We do not.

Senator NELSON. Or do you rely upon the literature?

Dr. MILLER. We rely upon the literature, we rely upon experts on our committee, and we do have tests that have been shown in the past