

Mr. BURROWS. That is right.

Senator NELSON. Is there any difference, so far as you know, between your brand name, if it meets the USP standards, and any other prednisone that meets USP standards?

Mr. BURROWS. I don't know of any significant difference. On the positive side, however, I do know something about the drug that Parke, Davis manufactures, and I do know something about the quality controls that we introduce during the steps of manufacture that we are responsible for.

I can speak for Parke, Davis quality, but I don't think I am in a position to speak for the quality of other manufacturers. By that I don't mean to imply that other manufacturers have some lesser standards or lesser accomplishments of quality than does Parke, Davis. I only am capable of speaking for our own controls.

Senator NELSON. You are familiar with the Medical Letter which was published June 2 of this year, in which it reports on tests of 22 prednisones. Your company's product was among the 22 that was tested. Are you familiar with that?

Mr. BURROWS. Somebody handed me a copy of that Medical Letter just as I left Detroit, and I have read it.

Senator NELSON. In the Medical Letter it states that all of the 22 brand or generic prednisones that were tested met the USP standards, and yours was among those that met USP standards.

If drugs meet USP standards, doesn't that mean that those that do are, according to USP anyway, equivalent drugs?

Mr. BURROWS. They are equivalent in terms of those standards. Again, I am not a scientist, but I understand that the results in individual patients for drugs that meet USP standards may not necessarily be identical results. Even in this Medical Letter you will see a recitation on page 2, and I don't know what significance this has, of variations in the percentage of cortisone found in the various prednisone drugs of other manufacturers. The variations are all within the limits of the standards, but you will note that to the extent of the variations apparently all the drugs are not identical.

Senator NELSON. No; it isn't possible, I suppose, for any two drugs to be identical or even any two tablets out of the same batch to be identical, if we use the word "identical" in the strictest sense of the word.

The representative of the USP who testified here said that they established the highest standards in the world for drugs. Based upon their careful studies, they set limits within which there may be variations, and the variations may not exceed these limits and comply with USP standards.

As they stated to us, their standards are the highest in the world, and they set a variation tolerance which is narrow enough so that, in their judgment, all drugs that meet the standards are equivalent. As you will notice, and as I am sure you know, the USP standards are set as a consequence of the deliberations of very distinguished pharmacologists, pharmacists, clinical physicians, the representatives of the drug industry.

Mr. BURROWS. That is right.

Senator NELSON. And it may very well be that Parke, Davis has a representative on the council that establishes the USP standards.