

Mr. GORDON. One other question, Dr. Miller. If a drug meets USP standards, can we rely on the drug to do the job it was intended to do?

Dr. MILLER. We think so, by and large with very few exceptions. I have to qualify to that extent. Now, prednisolone is one of the cases.

Mr. GORDON. I am talking about prednisone.

Dr. MILLER. All right, prednisone. Yes, it was prednisone. Prednisone is a drug that is effective in very small amounts. One milligram is enough to do the job. A firm, a very highly respected firm, was putting out 1-milligram tablets of prednisone. The Food and Drug Administration discovered that within a given bottle some of those tablets had only a half a milligram of prednisone. Others had a milligram and a half. On the average, there was a milligram per tablet. But we considered that poor practice, and we now have a test that rules that out. We have a test in the USP which applies to prednisone tablets that prevents that happening again.

Mr. GORDON. What do you mean by exceeding USP standards?

Dr. MILLER. If I used the word exceeding USP standards I apologize because we don't recognize—

Mr. GORDON. You didn't use it.

Dr. MILLER. Oh, we don't think that there is such a thing as exceeding USP standards, because the USP standards are so written that anything—we say “not less than” a given percentage, and in the case of aspirin, for example, aspirin shall be not less than 99.5 percent pure. Now, that other half percent does not allow very much leeway for being better than USP standard.

Senator NELSON. I have seen some industry literature critical of USP in the sense that they say their drug exceeds USP standards. Are you saying that any further purification and any further this or that has no clinical or chemical meaning so far as the drug and its use is concerned? Is that what you meant?

Dr. MILLER. Yes, that is partly the view, but the main point is that anything between the minimum that we state and 100 percent is still USP, and when I have time, whenever I see one of these ads, I generally call the attention of the firm to our position, and as a rule, the advertising changes.

Senator NELSON. Thank you very much, Dr. Miller, for coming over here today. Your testimony has been very helpful.

Dr. MILLER. We appreciate the chance to come. Thank you.

Senator NELSON. We will adjourn until 10 o'clock tomorrow morning.

(Whereupon, at 3:50 p.m. the subcommittee was recessed, to reconvene at 10 a.m., Wednesday, June 28, 1967.)