USP distintegration time test should be reevaluated as a method to predict correctly physiological availability in vivo.

Senator NELSON. What I am getting at is that the Medical Letter stated that from their consultants, pharmacologists, clinical physicians, they can find no differences or variations in formulations that are causing any problems in the treatment of patients. They advise that the doctor prescribe generically especially for the patients of limited means. What I am asking is does the Schering Corp. have any double-blind clinical test to prove that the therapeutic efficacy of its prednisone is better than any other one of the 22 prednisones listed in the Medical Letter?

Mr. CONZEN. No, sir.

Senator NELSON. Is there any evidence at all that it is better than Upjohn's Deltasone in terms of its therapeutic efficacy?

Mr. CONZEN. We have no such comparative clinical studies.

Senator NELSON. Then looking at the test, as a matter of fact, Upjohn's is a purer drug than Schering's. Upjohn has only a trace of foreign bodies in it, that is cortisone. Schering's has five-tenths of 1 percent. So if you are using the question of purity, Upjohn's at $2.25 a 100, if that is as important as many drug companies insist, is a better drug in that respect than Schering's. And then Merck's has zero cortisone in it. Schering's has five-tenths of 1 percent. On the basis of purity then, Merck's prednisone, selling at $2.20 a 100, is of higher quality than Schering's selling at $17.90. Although I do not think that is a fair argument, the drug companies use it consistently by saying that they do more refining and produce a higher quality product. These are USP standards, and USP says the variations listed here really do not make any difference. If the drug companies are going to stand on the proposition that they do more work than some other company and get more purity, and that USP standards are not high enough, then Schering's drug is not as high a quality as the two drugs listed here, so far as purity is concerned. There are two with only a trace, and there are several, five that have the same amount of impurity, cortisone, in them. What is your observation about that?

Mr. CONZEN. My observation on this is that, in my opinion, the acid test as to the value of the quality of a product lies when the physician treats his patient, and how this drug acts and is effective in the patient himself. These physical or analytical tests in the laboratory are not the only criteria by which equivalency should be judged.

Senator NELSON. If that is the case, I again ask what proof does Schering have that their drug is a better drug from a therapeutic standpoint than any one of the 22 drugs listed in the Medical Letter?

Mr. CONZEN. We have no proof that it is better, but we have abundant proof that it is the best documented drug on the market, through these thousands of independent clinical studies, and the fact that physicians continue to prescribe our drug.

Senator NELSON. The fact that a physician prescribes it does not make it a better drug, does it?

Mr. CONZEN. It means that he considers it, for his patient and this particular indication and case, the best he should prescribe.

Senator NELSON. What is your response to the Medical Letter's statement that there is nothing, however, "either in reports of clinical trials or experience of the Medical Letter consultants" who are better