

Now, I refer to the Medical Letter of June 2, 1967. As you know, the Medical Letter is a very highly esteemed professional publication. A number of witnesses, pharmacologists, physicians, medical spokesmen have referred to it as a very reputable high-quality publication. The Medical Letter asked the Fitelson Lab in New York to test 22 brands of prednisone, some generic and some brand name products. In the Medical Letter, on page 41, they state that none of the variations of the 22 products tested are outside of Pharmacopeia limits or are of sufficient magnitude to have an adverse effect in the treatment of conditions requiring the use of corticosteroids:

The disintegration test measures only rate of disintegration and not rate of dissolution or rate of physiological availability. There is nothing, however, either in the report of the clinical trials or in the experience of Medical Letter consultants to suggest that variations in formulation are causing any problems in the treatment of patients.

Then on page 42 the Letter continues under the heading "Prices":

The great price spread among tablets purchased from different pharmaceutical companies suggests the desirability of prescribing by generic name and specifying at least for patients of limited means that the prescription be filled with low-priced prednisone tablets.

You state on page 14 that you think yours is the best product. Now, have you any clinical evidence to demonstrate that your product priced at \$17.90 a 100 is a better product than Upjohn's Deltasone priced at \$2.25 a 100?

Mr. CONZEN. Available clinical testing still does not allow us to say just how much the drug products of one manufacturer differ from those of another. The clinical evidence does indicate that current quality control testing cannot guarantee that two supposedly identical drug products deliver the same amount of drug chemical at the same rate to the patient.

There are three medical papers which have reported experience in patients treated with two prednisone products. In each instance one product was effective, the other failed.

Senator NELSON. May I interrupt a moment. Were these double blind tests?

Mr. CONZEN. I cannot answer that.

Senator NELSON. Do you know the names of the products? Would you name them?

Mr. CONZEN. The names of the products were not disclosed in the studies. I refer to the Journal of Pharmaceutical Sciences, volume 52, page 605, in 1963, by Drs. Campagna, Cureton, Merigian, and Nelson; and the other one by Drs. Levy, Hall, and Nelson in the American Journal of Hospital Pharmacy, volume 21, page 402, published in 1964, which established these data. I will be glad to make copies of these publications available to the subcommittee.

Senator NELSON. We have those studies. Unless my memory is incorrect, Dr. Feldmann, Director of the National Formulary, said they were not double-blind tests.

Mr. CONZEN. I cannot, from personal knowledge, state whether these were double-blind studies or not.

Senator NELSON. If my memory is correct, he also said that they were testimonials and not scientific clinical studies.

Mr. CONZEN. These studies by these scientists state that they provide additional evidence to previously published work suggesting that the