desired, the same effect as the prescribed drug or will it provide less than the desired effect. Since the doctor is not sure that the medication received by the patient is doing the job properly he will have to see the patient more frequently. Thus the savings in the cost achieved by the use of the generic drug will be more than offset by the extra visit or visits.

Under our present system the physician prescribes a drug which is known to him and manufactured by a known reputable firm. More important however, the physician has personal knowledge and experience with the particular product. He can advise the patient, anticipate results and accurately judge when he should see the patient again. The doctor has a working knowledge of the particular product. Under the present system of generic drugs the doctor can never gain a working knowledge of the product.

Under the generic system each time a patient has a prescription filled for the same drug he could receive a drug produced by a different manufacturer. Each of the products can react differently since each manufacturer has his own method of producing the finished product. This problem is compounded by the fact that it is not possible to identify the manufacturer. Under these circumstances no physician can gain a working knowledge of a generic drug.

The most significant point of all, I believe, is the fact that a chemically equivalent drug does not mean it is therapeutically equivalent.

Senator NELSON. What evidence do we have of that specifically?

Dr. ALFANO. Well, studies of Max Sadove, an anesthesiologist in Chicago. He has done a study of the generic versus the trade-name drugs. Then there is a study of Pfizer on oxytetracycline. There is a difference which, I believe the FDA has confirmed.

Senator NELSON. We have not been able to get any convincing evidence from the manufacturers or anybody else that drugs that met USP standards are not therapeutically equivalent.

Dr. ALFANO. You have no evidence?

Senator NELSON. The best ——

Dr. ALFANO. Well, I will send you the material concerning these studies that there is a difference.

(Material not received.)

Senator NELSON. We have those studies. They have been refuted.

Dr. ALFANO. When were they refuted? I do not recall seeing this.

Mr. GORDON. In one of our earlier volumes, specifically volumes 1 and 2.

Dr. ALFANO. Was it not the chloramphenicol, too, that there was a difference?

Senator NELSON. That is the only drug we are aware of and there is no proof yet. Dr. Lee testified on that recently. There is no proof that the different blood level achievement of Chloromycetin versus the other chloramphenicols, indicates that one was any more efficacious, that there was any difference in therapeutic effect. There may be, but what happened was that in the tests, the brand name, Chloromycetin, achieved a higher blood level more quickly. The FDA took the other two, I believe, off the market because they did not achieve the same blood level. They wanted uniformity in blood level achievement. Dr. Lee says there is no evidence that either or any one of these was a more efficacious or a better drug than the other. They may find this to be so