have you believe that no reliance can be placed on any drug unless it has been produced by a firm that is widely known. There are others who would have you believe that you can buy any drug in the marketplace and expect it to be therapeutically equivalent to others sold under the same name. I must reiterate that we do not have controlled clinical studies to decide the issue in all cases. We are preparing to have the necessary studies made on about 50 widely employed drugs.

Mr. GORDON. You say in all these cases you have controlled clinical studies showing the lack of therapeutic equivalency?

Dr. GODDARD. It is my understanding that controlled clinical studies have been carried out in a number of instances demonstrating lack of therapeutic equivalency.

Mr. GORDON. How many such cases are there altogether?

Dr. GODDARD. Well, we were talking about this in preparation for the hearings. The best figure we could come up with was approximately two dozen such instances have occurred where lack of therapeutic equivalency has been demonstrated.

Mr. GORDON. Do you know what they are? Can you name the 12 of them?

Dr. GODDARD. Dr. Banes, perhaps, who has been involved in this field—you see, even one of these is significant and we then have to try to ferret out the reason. Some of these are the sugar-coated tetracycline, chloromycetin, and diphenylhydantoin.

Mr. GORDON. So far you have named antibiotics.

Dr. GODDARD. Diphenylhydantoin. Prednisone is one.

Senator NELSON. One what?

Dr. GODDARD. That there has been demonstrated lack of therapeutic equivalence.

Senator NELSON. When was that case?

Dr. BANES. There have been reports in the literature, isolated reports from physicians, stating that one brand of prednisone would maintain a patient satisfactorily, but when the brand is switched, the new medicaments will not maintain that patient.

On the other hand, going back to the first product, the patient responded satisfactorily. We have recently received a letter from a physician from the Mayo Clinic to the same purport.

These situations, of course, require investigation and we have looked into the possible differences in these medications. It turns out that chemically they appear to be the same, but that pharmacologically on testing in animals, there are some differences apparent.

Senator NELSON. It might be valuable, then, if you would be willing to look at the Medical Letter showing the results of their tests on 22 prednisone products. They found no clinical evidence to indicate a lack of equivalency among these drugs. They go on to say, "We therefore recommend that at least to the impecunious patients, you ought to prescribe generically."

Would you look at the Medical Letter and see whether or not any one of these drugs you are mentioning is included in the Medical Letter? It would be interesting to find that out.

Dr. GODDARD. I would be happy to do so.

I might also add that in the potency survey we did there were two prednisone products that were below potency.

So there may be no reason for there being substance to the complaints of these individual physicians.