I would like to make one comment, however, in relation to Dr. Cherkasky's concepts of who is testing all of the generic drugs in mass programs all over the country. I think that there should be certainly a good deal of this kind of testing, and that testing is being done. But to extend it to every single generic preparation simply to do it, to speak when one can perhaps satisfy many of these questions by chemical analysis alone may be overwhelming. It may not be necessary.

Senator NELSON. I don't know that he was suggesting that. I had asked him whether it would be feasible to take the most often prescribed drugs and start a program of clinical testing. I think it is correct that if there are 40 or 50 versions of a particular drug, 40 or 50 manufactured by that many different companies, that you would have to select a few of this number for clinical and chemical testing, and then probably conclude that if the rest of them come within the range of those that have passed the tests, until proven otherwise, it is likely that they are equivalent.

Dr. KUNIN. That is quite reasonable, sir.

Mr. GORDON. Are you assuming, Doctor, that if certain drugs are chemically the same, they will have about the same therapeutic effect?

Dr. KUNIN. This would be correct, assuming that the formulations that are used in the mixers are the same. There is the classical story with the tetracyclines which I alluded to in my text, in the story of the gilded antibiotics. Here different corporations used different methods of manufacturing these drugs. It turned out that the excipients that were used; that is, the materials to make up the capsules actually were inhibitory to the final product, so that although they all contained tetracycline, the presence of calcium and magnesium salts was detrimental. Actually this whole story even became worse when it was found that one company, which had done quite a good job of putting in a good excipient to enhance absorption of their product and it later turned out that this particular excipient in the presence of moisture and heat turned the product into a toxic substance which then was quite dangerous.

So that one cannot ignore, you might say, the pharmacist's art here in terms of how the drug is compounded and one cannot use potency alone.

On the other hand, it is quite easy to state what type of excipient should be used, and this could be characterized very nicely, so I see no major problem here.

Senator NELSON. Dr. Miller of the USP testified here. I don't have the exact quotation but the impression he left with me was that if all products listed in the U.S. Pharmacopeia meet USP standards for dissolution time, potency, purity, et cetera, they are clinically equivalent and for any drug included in the USP there is no evidence to the contrary.

Is that your judgment?

Dr. KUNIN. Yes, that is right.

One learns of many of these things retrospectively. For example, the companies that work with the tetracyclines did this in all good faith. It was only in retrospect that one learned that certain problems were encountered, so that one can only go in good faith and on the basis of his best information. I believe that under those conditions I would agree completely.