or has been implied, that because there are 18 or 20 known instances of so-called generic equivalent products, those which meet specifications by USP or NF which are not therapeutically equivalent, that that number is the full total that is known about—and that for this reason we are talking about a small percentage of the total drugs in use.

I disagree with that wholeheartedly.

I think the fact that there are 211 references, that are related to factors, which, can affect the therapeutic effectiveness and safety of products scientifically, shows that there are many more than 18. The only reason the 18 have been acknowledged is in retrospect, because they were so dramatically obvious that it was unmistakable to overlook them. I think this whole problem is more like an iceberg, where nine-tenths of it is below the surface. And I think we have only scratched the surface. To the extent that we study this problem in more detail, more in depth, I think we will find there will be a lot more than 18.

Mr. GORDON. Dr. Slesser, I would like to ask you a couple of questions. With regard to your 211 references of published literature on the effect of drug formulation on therapeutic activity—one, how many are duplicate studies, two, do they cover 211 different drugs? And, three, over how long a period of time were the studies published?

Dr. SLESSER. They do not cover 211 different drugs.

Mr. GORDON. How many drugs are actually discussed?

Dr. SLESSER. I do not know exactly how many are discussed. I am going to make this available to the committee, a copy of these references, if it has not already been available to the committee. But the interesting thing about it, Mr. Gordon, is that one cannot help but be impressed by the effect on the activity, therapeutic activity of a product by differences which are rather subtle—particle size, crystalline structure, PH, additive materials of various kinds, and so forth. And I would like to use this as an example.

You very often hear a negative statement made. "We have not in our experience found that there was any difference between a series of, let's say, generically equivalent products when we have used them."

Here is a hypothetical situation which I think—I think anyone familiar with medicine knows that there are patients who do not respond to certain drugs. The body builds up a tolerance, or there is a certain idiosyncrasy, and they fail to respond.

Let's create a situation here.

We have a patient who is seriously ill, and he needs a certain medication. That medication is supplied to him. The patient dies.

Now, I think without question the verdict would be—even though the death may be due to a failure in the quality of that product, its inability to perform as it should—I think more than likely the verdict would be the patient failed to respond to the drug.

Here is a case where it would not even be recognized for what it is. And I am sure the fact that this can happen, that we have seen dramatic instances where it has happened, certainly is good inference that it is very likely to happen and will continue to happen.

Mr. GORDON. I do not think my question has been answered.

Dr. SLESSER. If you repeat it, I will be glad to answer it, sir.