Mr. GORDON. That was a big company, too, was it not?

Dr. GODDARD. That involved a large company, yes. So, yes, they are making the claim, but their making the claim does not make the fact so, is my point.

Mr. GORDON. But it is not so. Is that right?

Dr. GODDARD. Our job literally is to assure the physician: "Doctor, you can prescribe any drugs in the marketplace with the assurance that it will do the job that you had in mind when you selected it." Once that is done, we will have taken a great step.

Mr. GORDON. I have no further questions.

Senator NELSON. We had testimony at an earlier date from a pharmacologist. It was on the question that you have just commented on that I did not intend to raise at this hearing with you. It was on the question of whether, if a drug meets USP standards, the presumption can be made that all drugs which meet that standard are equivalent. The testimony that we have in the record is that there are only about a dozen cases where this did not turn out to be true. The testimony was that for almost all of the thousands of drugs on the market, if they met USP standards, they are equivalent in their therapeutic value and effectiveness.

Do you agree with that position?

Dr. GODDARD. I think that is a fair statement.

Senator NELSON. This was the statement of Dr. Miller of USP.

Dr. GODDARD. I think Dr. Miller's point is well taken. However, I say there is enough concern at the present time about the question of therapeutic equivalency that we are undertaking the testing of about 40 or 50 of the most frequently prescribed drugs that are available as both generic and brand-name drugs to determine biological availability, if you will, blood levels, which indicate that the drug has been absorbed. You can get some direct measurement in humans.

Now, if we find that after 20, 30, 40 of these drugs have been tested that equivalency is present, I think we have reason to feel reassured that this is true across the board.

Now, you see, there are also exceptions, in these systems. A man working on a given piece of equipment in any firm can fail to provide the proper maintenance or can make a slight change; for example, the tab letting pressure could be changed. This could influence the availability of a drug when ingested.

Senator NELSON. Well, it probably would not meet USP standards. It would not dissolve at the proper rate.

Dr. GODDARD. Right. But you see, there would not be any knowledge of that. This means a feedback into the production in terms of the quality program may have to be made. But generally, I agree with Dr. Miller.

Senator NELSON. We are talking about the heart of a persistent argument that goes on in the industry and the medical profession.

Dr. GODDARD. This is why, Senator, I have said, show me your evidence. The large companies that make this claim consistently, and I would like to see their evidence. They have not produced it yet, other than these 12 isolated episodes that you have been talking about.

Senator NELSON. This is the problem about which there is so much confusion. It seems to me that what the industry is really arguing is that the exceptions that we find once in a thousand times prove