let alone the clinical quality of their products, is too longstanding to brush aside. And the possibility of that situation soon or ever changing is extremely remote." Frankly, that is about as strong a charge as anybody could come before this committee and make. And then you come up here—and I was waiting for these 211 examples of doctors' reports—I don't know whether you have read them, but, when you are asked any questions about them, frankly you cannot answer them—do they meet U.S.P. standards.

I would think you would come up here and have fairly accurate and detailed knowledge about these 211 cases, or at least be able to say of the 211 half of them did this or that. But it just seems like you are throwing 211 things that you want everybody to read, and you know nobody is going to read.

Dr. SLESSER. Mr. Grossman——

Senator NELSON. I have to answer another rollcall. You may continue with your questions.

Dr. SLESSER. Mr. Grossman, I would simply like to repeat a comment that I made earlier, and I think certainly it is one that is factual. And that is no matter what tests you may have in the U.S.P. or N.F., you have many marginal and incapable manufacturers of pharmaceuticals in this country today. And irrespective of the legal requirements—after a product has failed to do a job it is supposed to do and there is a casualty as a result of the—in tolbutamide, it was easily recognized after the tablet passed through the GI tract without dissolving it did not meet standards. The fact of the matter was it was on the market, available, prescribed and taken. The same thing, I am sure, happens many times. The fact that I personally do not know about them is simply an indication of the fact that this kind of a thing is not the kind of a thing you are apt to see in the scientific literature.

Mr. GROSSMAN. I am assuming none of these firms are members of PMA that you are talking about. Is that safe to say?

Dr. SLESSER. They may be. I do not say being a member of PMA means one is perfect. I think PMA members make mistakes, too. But I think their batting average is far better than those who are much more poorly qualified.

Mr. GROSSMAN. It just seems to me—and again I waited to see what evidence you would present—that—and Mr. Cutler, as a lawyer—when you come into court or a committee, that if you have 211 cases, that they are just not thrown at us and say "Here are 211 cases." I would like to know what they all mean. When you were asked whether they were below U.S.P. standards and so on—there was no answer.

Dr. SLESSER. Mr. Grossman, I said there were 211 papers that dealt with the subject of biopharmaceutics, which indicated the vast and profound effects that can occur in drug products depending on particle size of the drug, depending on the crystalline form of the drug, depending on certain additives that are present, pH, and so forth.

Mr. GROSSMAN. Have you yourself made efforts to study the various 211 articles, whatever they are, to decide how many say this and how many say that, and whether they refer to the same items, are they duplicative.

Dr. SLESSER. They are not duplicative pieces of work. Some of them—more than one may involve a certain drug. But I would say some different aspect.