

the Nation's drug supply, and you cannot be claiming that we make high-quality drugs. And on the other hand, say there is someone else who makes bad drugs. Well, who are they, and what percent? They have to fall within that 5 percent, or less than 5 percent, and we want to know who they are. We do not believe it, frankly, Mr. Chairman.

Dr. FELDMANN. Mr. Chairman, I would like to add a little bit to what Dr. Apple has said here. I think it goes beyond simply the brand name versus generic name aspect that they are attempting to muddy the waters with. I think that they have attempted, in a type of psychological warfare, almost, to create a climate of distrust, so that the individual practitioner—and this is especially true of the practitioner who might have an opportunity to choose between different company's products—would be fearful of making his own decision.

In other words, you could have three or four brand name articles, but they do not even want the pharmacist to be able to select among those. So they have created an atmosphere of fear, of concern, so that the guy is afraid to make a choice, because he thinks he is taking a chance. So I think this really is at the heart of the matter.

Incidentally, in Dr. Apple's response a minute ago—I believe he meant to say that some people have said there is a *potentiality* that there might be 70 drugs involved in this matter, and he inadvertently said *probability*; this is just to correct that record.

Mr. GORDON. Where did you get that number, 70?

Dr. FELDMANN. I believe Dr. Cavallito mentioned it in his testimony before Senator Kennedy, and you will recall that we tried to emphasize, following his testimony, that in each case, he did qualify his statements by saying, *potential* bioequivalence problems, *potential* inequivalency.

Now, there is a great deal of difference between "potential" problems and actual problems, and I think that that is a distinction that all of us, and particularly your committee, Mr. Chairman, must not overlook. What has, in fact, been the record; what has, in fact, been the number of therapeutic failures; how many drugs, actually, will present a problem; and once a problem has been identified, continue to represent a problem? And that has not been adequately corrected, and is not just ancient history now?

Senator NELSON. I think the testimony was yesterday on the question of bioavailability, that there were perhaps 12 or 13 cases of such problems. As a general proposition, the same compound, the same salt, and the same dosage form will produce the same result therapeutically, with limited exceptions which have been discovered. I suppose there will be some in future dates. But it is a limited, manageable problem.

Would that be a correct statement of the issue?

Dr. FELDMANN. I think that that would represent our assessment of it, Mr. Chairman; yes, sir.

Mr. GORDON. You mentioned that the Pharmaceutical Manufacturers Association's members manufacture 95 percent of the drugs.