designed to see that the drugs the military buys meet whatever standards they choose to set up.

Now, one of the things they do is say to a manufacturer if you want us to buy your drug, submit us a sample of what you can make. And the manufacturer may never have made it before. He may not be marketing that drug. And those are the ones they apparently, as far as we can tell, put most of their laboratory investment into testing. And therefore, they are dealing with a different population of drugs than we are dealing with. That is why they get defect rates orders of magnitude different than we see. Their testing is done for a different purpose.

Senator NELSON. I take it from your comment, Dr. Schmidt, on page 14 then, that you agree with Dr. Edwards' statement made on February 1st before the Health Subcommittee: "Nevertheless, based upon present knowledge, I believe that with very few exceptions any drug prescribed in this country will give the same therapeutic results as any other chemically equivalent product. . . . we regard this issue as limited, well recognized, and manageable."

Do you agree with that?

Dr. SCHMIDT. Yes, sir. I do.

Senator NELSON. Then you stated on February 1st yourself, you estimated that there may be "10, 12 or 14 drugs" which may have bioavailability problems.

Is that correct?

Dr. SCHMIDT. Yes, sir.

Senator NELSON. Can you give us the number of drugs which in the opinion of the FDA present bioavailability problems at this time?

Do you have them along? If not, can you submit their names?

Dr. SCHMIDT. Yes, sir. My comments were based on a comprehensive analysis of list of drugs that have been mentioned in articles, drugs that are in our own files, and so on, that are purported to have bioavailability problems.

I need to take a moment to define carefully this list, because the proper assessment of the bioavailability problem includes answering the questions about precisely what drug one is talking about.

We ask the question in how many cases have two or more drugs which contain the same active ingredient, the same chemical, which would include the same salt which is in the same dosage form, that is, in pills as opposed to one pill and one capsule, in the same amount—that is, the same amount of the ingredient—in which dosage form meets all official compendium standards.

Now, I think it is only fair to say that there are bioavailability problems with a drug when one can say that he is dealing with two things that are the same salt, in the same amount, and the same dosage form, both of which meet compendium standards.

When we analyze then the drugs that there have been shown bioequivalency problems with that meet those requirements, we come up with a list of 12 or 13, which include—would you like me to read the list?

Senator NELSON. Sure.