

Three, as you know, is 60 percent of 5. And 300 is 60 percent of 500. And there is a difference of several hundred there. And in general this does explain why I was not alarmed by what I read. I was somewhat alarmed, however, that the PMA and others began quoting from and basing testimony on what I considered to be quite insubstantial grounds. And I think that any critical reader of the speech or anyone knowledgeable in the area would realize that you really cannot say too much definitive on the basis of this.

For example, it is stated that we do not inspect 100 percent of drug firms every 2 years. And of course we do not. We cannot. There is no way we can.

Senator NELSON. But you do 100 percent in 2½ years?

Dr. SCHMIDT. Well, we do do that. We do 100 percent of inspections of those firms that manufacture 95 percent, at least of prescription drugs. We do many more inspections of those drug firms in which we know there are problems. So that the main question I have in regard to what Mr. Feinberg says is, what relationship does all that he says bear to the quality of drugs.

You mentioned early on his making the point of their standards exceeding compendial standards. Well, fine. My question is, what relationship do the standards they set, exceeding compendial standards have to do with the quality of the drug. And from what I have seen of their standards, they either do not relate to the quality of the drug at all or they may relate to packaging or some legitimate need of the military.

I did send a team to visit the establishment and Mr. Feinberg was generally cordial and helpful to our team in reviewing what he does and how he does it. And I think perhaps, was a little embarrassed after he had information provided to us that there were inaccuracies in his speech. He still did not change the speech. He apparently had some secretarial problems that prevented the speech from being retyped.

The inspections, the big point about GMP's, I think, failed to find evidence to support his charges, and he has failed to provide us with evidence that support the charges in his speech that his inspections demonstrate our failure to maintain quality. The number of analyses of drugs done there is very small, and the principal analyses are done, not on production runs of drugs, but on special runs of drugs done by a new company wishing to make the drug, in many instances a company that has never made it before. And his 45-percent rejection rate is of a relative handful of drugs on a nonproduction run by companies, some of which have never made it before and have never sold drugs to DOD before.

Mr. GORDON. Dr. Schmidt, may I interrupt for a moment?

Here is the kind of statement the public has been hearing—I am going to quote from his speech:

The rejection rate on DOD plant inspections is 45 percent, and the rejection rate on precontract award samples inspections is 42 percent.

It does not say percentage of what or anything. Now, when a lay reader sees this, he is going to be alarmed, do you not think, when he sees this?