But when it comes to whether or not the law has been violated and the law says that drugs must be manufactured under current good manufacturing practice, and the courts have held that this current good manufacturing practice is articulated in the regulations under part 133 in the Code of Federal Regulations, title 21, what we call GMP regulations.

If there is—I hate to use these adjectives, because they get us in trouble—but if there is a significant deviation from GMP, if a reasonable man who knows something about drug manufacturing would be led to believe or would believe that something is going on in that firm might cause that drug to become adulterated, FDA has an obligation, a duty to act and act now. Our position is that we do.

The allegation of Mr. Feinberg's speeches—and it is throughout many of his speeches, throughout the years—that many drug firms in the United States operate under gross violation of FDA's GMP's is his own private, personal opinion. He believes this. I have had conversations with him that convinced me he believes this deep in his soul.

I do not agree with him, nor do our people in our Washington headquarters or in the field.

There is a situation which DPSC follows—I have no quarrel with it—the military sets its own rules. We do not interfere with them—in which for some reason a firm that wants to bid and is not on a bidders list must pass a pre-award survey inspection. The preaward survey inspection requires absolute perfection. I do not understand this, but I do not quarrel with it.

For some reason, again that I do not understand, once a firm has a contract to manufacture drugs, the rules change and the absolute perfection parameters disappear. Proof of this is the fact that samples that they analyze—what do they call them, first production —or samples that they analyze of drugs when a—first article samples—when a production just starts under contract are 20 percent defective. These are their own figures.

I do not know how they could be 20 percent defective while they are under inspection by the Department of Defense—they call it DCAS inspector—if they have absolute perfection. It does not make sense.

Again, I do not want to, and the Commissioner has tried very hard not to deprecate the requirements of as much perfection as you can possibly get. This is what we are working for. We are not trying to pooh-pooh good housekeeping. We want good housekeeping in drug firms.

Senator NELSON. But if I understand your testimony and that of the Commissioner: One, that you have considered their criticisms on good manufacturing practices in the main to be insubstantial; two, that if there was any violations of good manufacturing practices that affected the quality of the drug, you would consider that a major, important matter, and if they did not affect the quality of the drug, you may require them to correct it, but that you do not consider it a substantial matter.