Dr. SCHMIDT. Well, an uncritical reader may very well be misled by those statements.

Mr. GORDON. Here is another statement:

> Based on my experience of drug plants, it is my firm conviction that the primary problem lies in the fact that many producers in the business today are in gross violation of FDA's good manufacturing practices regulations. Those same firms are manufacturing drugs on a daily basis.

Here is another quote:

> We have seen totally unacceptable housekeeping conditions involving dirt, filth and rodents. We have reviewed production records that showed noncompliance with the company's own standards. We have found instances where ingredients in finished products are not adequately tested.

If a person reads or hears this, I would think he would be alarmed. I certainly would.

We asked the DOD for evidence to support these statements. We submitted the information to you.

And what do you have to say about it?

Dr. SCHMIDT. Well, many, many of the inspections that they have done, I think principally the inspections that he is quoting from there, were not done when the company was in full production. I really do not know on what basis the author of those statements is convinced. He would have to speak for himself in those matters.

I think it is true, I could go into the kitchen of the home of every individual in this room and shut it down for being unsanitary. I made a specialty of that when I was in the service, and I think that as the GAO found out I could probably go into drug firms today and find some violation of GMP in some plant at some time.

If we find major and serious GMP violations we take corrective actions immediately on these.

Part of his statement, and I think part of what he was able to put together with other things to convince him, was the statement in the GAO report that in some instances we have not taken action when a "critical" GMP violation was discovered. We had a problem with the GAO and the definition of the word "critical." We supplied the GAO with proper definition of the word "critical" which did not mean in that report what it sounded like, that we were ignoring critically important GMP violations.

It is true that we make informed judgments and wise judgments, hopefully, from time to time not to shut down a plant for any GMP violation. We could readily shut down every pharmaceutical plant in the United States if we went in, as I would in your kitchen if I wanted to find dirt. So that, you know, there is an element of truth in some of these statements. But again, the relationship of these statements to the quality of drugs is inapparent to me, and many of the statements are unsupported totally by any evidence, either in the paper or by any evidence that he has provided to us.

I mention the sampling; the program includes, as you know, drug sampling and inspections, and the numbers of these both are small, and when these are done raises a question, because some of the inspections are not done when the plant is in operation, and therefore would have no meaning to the quality of the drug produced.