have to be so much different that you end up with sole suppliers, while, at the same time, there are other manufacturers in the marketplace.

Mr. AHART. If I may comment, Mr. Chairman, I think I can clarify this a little bit. I think basically, what the Defense Department is doing is establishing the specifications, is adopting the standards which are in the USP.

Senator NELSON. They are what?

Mr. AHART. They are adopting the standards in the USP or NF, but they are adding to that the testing protocols which they are going to use in satisfying themselves that the manufacturer, whether he be a brand name manufacturer or generic name manufacturer, is actually meeting these standards in the production of the drug.

So, as Mr. Crowther pointed out, it is basically the technique which they are using to assure themselves that regardless of the plant from which they get the drug—whether it is a brand-name, big company, small company or whatever—the drug in fact, by following these testing protocols, does meet the standards which have been established.

Now, most of these standards will be the USP or NF standards for drugs which are listed in those two compendiums but it is the testing protocols, the quality control tests which they are going to require to make sure they are getting the product to meet those standards for which they are paying. I do not think it is a question of developing independent standards in most cases, but setting up the regimens, protocols that make sure that the product they get meets these standards.

Senator NELSON. Well, I do not think anybody would object to inspection of plants. In fact, there ought to be much more of it and the FDA ought to have more inspectors to insure quality control so that they are in the position of being able to guarantee to the profession and the public that whatever goes into the marketplace meets appropriate standards as only careful inspection and supervision can guarantee.

And so, if the objective—I assume it is—of the military is to be sure everybody is meeting the standard, that is fine. But I am a little concerned that some artificial barriers may be getting into the specifications so that you end up, as you do here, with 96 percent negotiated and no real assurance that the end product is on the average any better than the product being purchased by New York City or a good general hospital that has a good pharmacy department. The situation, as I see it, is that we have mostly sole source negotiated purchasing. Government financed purchases are rising rapidly, and although we have a statute that permits examination of costs to see whether or not the profit is reasonable, the GAO has never been asked to use it.

That kind of a situation, I would think, raises a very serious problem, besides having within it the seeds of eliminating competition and denying economic opportunities to perfectly qualified producers if abused. I do not say that it is being abused because I do not know anything about it. It could be abused unconsciously. It would eliminate competition and end up with lots of high prices, especially when you do not use the statutes and we do not check