caine penicillin C for aqueous injection, 300,000 units. The original technical requirements were the FDA and USP monographs. There was a field complaint that arose in DOD that involved the syringeability problem. It was reported the material could not be aspirated from the bottle or could not be injected from the syringe. Additionally, there were some vials that were overfilled.

In order to avoid this they had to have a higher degree of consistency. For example, they added a standard that when the drug was reconstituted, each milliliter of the resulting suspension would contain not less than 280,000, not more than 380,000 USP penicillin units, and when reconstituted and shaken for 30 seconds it should flow freely without binding with the contents of the final containers or aspirated through a 22 gage hypodermic needle using a suitable syringe.

They found a particular problem with the drug in their use. Now, whether this had to do with the specific locations, temperatures, many other things, it is not obvious. But nonetheless, in their field use they did identify these kinds of problems that required a higher degree of consistency and more specific tolerances.

Senator NELSON. So you are not talking about the question of the quality of the drug. You are talking about problems that may arise from being shipped to different parts of the world, or shelved in a tropical climate versus a moderate one, or subjected to much rougher handling.

Is that the kind of thing that we are talking about?

Mr. CROWTHER. Generally that is the kind of specific requirements that they would have to include rather than ones dealing with effectiveness.

Mr. GORDON. Mr. Chairman, may I ask a question at this point?

Senator NELSON. Yes.

Mr. GORDON. In your report of March 29, 1973, you stated that, "FDA has not always enforced aggressively compliance with good manufacturing practices by many drug producers."

In fact, an employee of the Department of Defense, Mr. Max Feinberg and also Mr. Stetler of the Pharmaceutical Manufacturers Association, have used quotations from your report to show that the FDA cannot be depended on to insure that only high quality drugs are produced.

In this connection, then, can you tell us if the recommendations in your March 29, 1973, report have been accepted and are being followed by the Food and Drug Administration?

Mr. AHART. To our knowledge, Mr. Gordon, all six of the recommendations we included in that report have been accepted by the Food and Drug Administration, and action has been taken to implement those recommendations.

So I think the Food and Drug Administration is in full agreement with the need for improvement in those specific areas.

Mr. GORDON. And they are doing something about it?

Mr. AHART. They have implemented all six of the recommendations. I think there is one that, just because of the timing of it, will not be in full implementation until about April; and that is the