

Administration and the Defense Department, with their own inspectors and so forth?

Mr. AHART. Well, I think if the intent of our recommendation is carried through, it will mean that the quality assurance function will rest solely with the Food and Drug Administration.

Senator NELSON. Well, does it appear that they are proceeding to implement a policy of that kind?

Mr. AHART. Every indication that we have is that they are moving in that direction and are trying to reach the agreements necessary and move toward the consolidation of that function. Yes, Mr. Chairman.

Senator NELSON. The GAO has no doubt that the FDA has the capacity to guarantee or the capacity to carry out an effective quality assurance program?

Mr. AHART. Well, I think certainly if they are not now in a position to meet the requirements of the Department of Defense and VA—

Senator NELSON. If they are what?

Mr. AHART. If they are not now in a position to do all of the things that DOD and VA feel are necessary to meet their requirements, I feel certain that the potential is there for them to acquire that capacity and to carry it out.

Senator NELSON. What does that mean?

Are you suggesting that the VA and the Department of Defense carry on a quality assurance program that is somehow superior to what FDA now does?

Mr. AHART. No. What I am suggesting, Mr. Chairman, is that the Department of Defense does have quite a number of specific requirements that go beyond the requirements for drugs which are now available to the general public in terms of—

Senator NELSON. Well, what kind of requirements?

Mr. AHART. In terms of color tolerances, indication of deterioration of the drug, packaging requirements—these types of things that will have to be built into the FDA program if they are going to meet the specific requirements of the Department of Defense.

Senator NELSON. Well, I guess we will be going into that later; but do those requirements have anything to do with the effectiveness of the drug?

Mr. AHART. Well, I think we are talking here about meeting the specific military requirements which are above and beyond what would be suitable for the general public.

Senator NELSON. I cannot quite understand what you mean above and beyond. Every witness we have had from the medical and science fields have stated that if you are meeting USP standards, that is as high a quality—as high as there is.

What quality would they have specified that is super-duper?

Mr. AHART. Mr. Crowther has some examples to illustrate what I am talking about, Mr. Chairman, that might help clarify the situation.

Mr. CROWTHER. Mr. Chairman, in a couple of cases, particularly one that the military brought to our attention—it was called co-