

the case may be. Certainly, it would be a good idea and I understand that Dr. Edwards expressed the opinion that FDA should eventually get into the position where they can give this kind of assurance to everybody in the country for any drugs which do not reach the marketplace.

I think certainly, as you indicated, this is a good objective for the Federal Government to strive to.

Senator NELSON. So, for example, here you have sample failure, but you say that the central procurement is using USP or NF standards.

If there is a sample failure and that supplier is rejected on the grounds that the product did not meet USP or NF standards, then would it not be critically important that the Defense Department notify the FDA forthwith? Otherwise those drugs are going into the marketplace not meeting USP and NF standards and nobody knows it.

Mr. AHART. I think this would be valuable information to the FDA and if it is in the Government's hands I think it should be made available. I understand there is no routine mechanism to make all inspection data available now. As to whether there is provision for exception reporting where the case seems to be particularly bad, I think we would have to check on that and see what has been done.

Senator NELSON. I think you were at the top of page 18 or bottom of page 17.

Mr. STAATS. Bottom of page 17. Let me reread that one sentence, Mr. Chairman. The VA inspects each contractor plant with regard to its entire product line. This is done prior to the contractor being awarded any contracts so that the Veterans' Administration can be assured that the supplier is suitable for any of the products it may offer to the Government. These initial contractor plant inspections represent about 60 percent of all inspections.

The remaining inspections are reinspections on a cycle basis. All inspections evaluate such areas of contractor operations as the adequacy of quality control, test facilities, and sanitation.

All plant inspections are made by two Veterans' Administration pharmacists.

During fiscal year 1970, the two pharmacists performed 134 inspections at 122 contractors' plants. The inspections resulted in 37 disapprovals, the most common reason being the lack of following adequate quality control procedures. Veterans' Administration does not utilize military inspections of domestic plants except as a supplement to its own inspection. Veterans' Administration does rely upon Department of Defense inspections of foreign plants.

The Food and Drug Administration performs testing of selected drug samples for the Veterans' Administration. Brand-name drug items which are centrally stocked are tested on a sample basis once a year. Each order of generic drug items which are centrally managed is tested.

Drug items under Federal Supply Schedule contracts administered by the Veterans' Administration are rarely tested except that the products of any new contractor under schedule contracts are tested.

A compilation of testing reports received by the Veterans' Admin-