

Senator NELSON. I could not draw much of a conclusion from the phrase "inadequate capacity or sample failure". Sample failure—does that refer to a sample off the line?

Mr. CROWTHER. Yes, sir; off a particular drug line.

Senator NELSON. And now, what was the sample failure, based on a USP or NF standard or some standard that the military has?

Mr. AHART. This would be the failure of the product, the preaward sample, to meet the standards which have been established in the specifications which as I mentioned are largely drawn from the USP or NF, using the testing protocols which the Defense Department has established in their specification or in the purchase description.

Senator NELSON. When you say inadequate capacity, are you referring to inadequate capacity or inability to make this particular kind of a drug as well as amount?

Mr. AHART. I am not sure we are in a position to give all the circumstances which might give rise to an inadequate capacity determination but I am sure that one of them would be the manufacturer's inability to provide the particular drug in the quantities which the procuring agency requires. It might go to some of the other things which Mr. Crowther mentioned, such as the ability to produce this particular product on the lines which they have available in the plant. It could be either one of those.

I think we would be happy to submit for the record in as much detail as we can, the various kinds of things which come under this category as well as the other reasons for disqualification of these plants.

(The subsequent information was received and follows:)

DEFENSE PREAWARD SURVEYS OF DOMESTIC DRUG MANUFACTURERS CLASSIFIED AS LARGE OR SMALL BUSINESS,
FISCAL YEAR 1969

	Preaward surveys		
	Large	Small	Total
Manufacturers surveyed	26	62	88
Results of survey:			
Qualified	34	43	77
Disqualified	25	47	72
Total	59	90	149
Reasons by survey applicable to—			
Disqualification by survey	Large	Small	Total
Quality control	2	7	9
Quality control and housekeeping	6	27	33
Quality control, and product sample		1	1
Quality control, housekeeping, and capacity	1	2	3
Quality control, housekeeping, and subcontractor		1	1
Quality control, subcontractor, and capacity		1	1
Product sample	3		3
Product sample and subcontractor	3		3
Product sample and capacity	1		1
Subcontractor	2	5	7
Capacity	7	3	10
	25	47	72