

11778 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Mr. McKENZIE. The total quality assurance function.

The CHAIRMAN. So that includes your determination of the quality of the drugs once they are received by DOD, is that correct?

Mr. McKENZIE. Yes, Mr. Chairman.

I could provide for the record a detailed break-out of that data.

[The information referred to follows:]

QUALITY ASSURANCE FUNCTION

The following data represents the number of Department of Defense personnel engaged in drug quality assurance by position, series, grade and percentage of time devoted to drugs. The personnel reflected under the heading Defense Contract Administration Services (DCAS) perform drug plant inspections. The Defense Personnel Support Center (DPSC) is engaged in determining contract provisions, evaluating test and inspection results and conducting product tests.

<u>Position</u>	<u>Series/Grade</u>	<u>100%</u>	<u>50%</u>	<u>20%</u>	<u>5%</u>	<u>Total</u>
<u>DCAS</u>						
Chemist	GS-1320-12		3	4		7
Chemist	GS-1320-11	5	28	7	1	41
Chemist	GS-1320-9		2	1		3
Chemist	GS-1320-7		1	1		2
Quality Assurance Representative	GS-1910-12			4	1	5
Quality Assurance Representative	GS-1910-11	<u>1</u>		<u>10</u>	<u>1</u>	<u>12</u>
Sub-Total		6	34	27	3	70
<u>DPSC</u>						
Supervisor Chemist	GS-1320-13	1			1	2
Pharmacist	GS-660-12	1				1
Microbiologist	GS-403-12		1			1
Chemist	GS-1320-12		1			1
Chemist	GS-1320-11	1				1
Chemist	GS-1320-9	1				1
Chemist	GS-1320-7	<u>1</u>				<u>1</u>
Sub-Total		<u>5</u>	<u>2</u>	<u>0</u>	<u>1</u>	<u>8</u>
Grand Total		11	36	27	4	78

The CHAIRMAN. And whatever date is agreed on, whether it is July 1, or at a different date, is it the intention then that all quality assurance functions would be turned over to FDA, or will DOD reserve some function to itself?

Mr. McKENZIE. Well, this, of course, is a matter still under consideration and discussion. We do anticipate that there may be some residual functions which would remain with DOD.

The CHAIRMAN. Does DOD generally agree with the GAO and the OMB recommendations?

Mr. McKENZIE. Yes, Mr. Chairman. We are in general agreement.

Mr. GORDON. How does the DOD plan to involve the VA and the FDA in the specification development process?