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RELEASED

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JUN 6 1975

The Honorable Robert W. Kastenmeier, Chairman
Subcommittee on Courts, Civil Liberties,
and the Administration of Justice
Committee on the Judiciary
House of Representatives

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H-2553

Dear Mr. Chairman:

Your October 24, 1974, letter requested that we study the use of certain potentially dangerous drugs being administered at the Medical Center for Federal Prisoners in Springfield, Missouri. The facility is operated by the Bureau of Prisons, Department of Justice.

In discussions with your office we agreed to determine the cost of the drugs--Thorazine, Stelazine, Prolixin (Enanthate), Mellaril, and Permitil--purchased; the quantities prescribed; and the officially stated reasons for using them. We agreed to restrict our review to patients currently assigned to the Medical Center and not examine records before January 1972.

A recent GAO report, "Controls On Use of Psychotherapeutic Drugs and Improved Psychiatrist Staffing Are Needed in Veterans Administration Hospitals" (MWD-75-47), issued April 18, 1975, provides definitions and additional background on the use of psychotherapeutic drugs which should be helpful in using this report.

BACKGROUND

Federal prisoners are transferred to the Medical Center for medical, surgical, and/or psychiatric treatment. In addition, the courts assign suspected psychotics to the Medical Center for pretrial evaluation of competency and for posttrial observation.

When we began our review in November 1974, there were 589 patients at the Medical Center--275 assigned to psychiatric wards and 314 to medical-surgical wards.

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The drugs of interest are antipsychotic agents, derived from the phenothiazine chemical compounds which modify psychotic symptoms. Repeated studies have demonstrated their effectiveness in treating acute and chronic schizophrenic patients by helping to substantially decrease combative, destructive, or antisocial and withdrawn behavior. These drugs are sometimes used to suppress symptoms of anxiety, tension, and emotional disturbances in neurotic patients. Some have also been used in nonpsychiatric situations, such as adjuncts to anesthesia and to control nausea, vomiting, or severe chronic pain.

Medical authorities agree that benefits may be obtained from these drugs but caution that their prolonged or improper use may be detrimental to the patient's health.

The frequency with which these drugs were prescribed at the Medical Center varied by type of drug and by patient. Prolixin was administered by injection at intervals usually ranging from 1 to 2 weeks. The other drugs were generally administered orally from one to four times daily. In some cases the drugs were prescribed on an "as-needed" basis.

We scheduled drug purchases since 1972 and prepared drug profiles including information on dosage, frequency of administration, and length of time the drugs were prescribed for treatment of the 589 patients. Where prescribed "as needed," we obtained the actual amounts administered. We converted dosage and frequency to determine daily dosage prescribed (biweekly for Prolixin).

DRUG PURCHASES

The Medical Center purchased about \$26,000 worth of the five drugs from January 1972 through December 1974. Purchases, by drug type and by year, are summarized in enclosure I.

The number of doses purchased could not be established because the drugs were administered in varying amounts and frequencies. For example, Prolixin was purchased in 5 cc bottles of 25 milligrams per cc strength and administered in 0.5 cc to 5 cc doses. Thus each bottle contained from 1 to 10 doses.

NUMBER OF PATIENTS TREATED

One or more of the drugs were administered to 183 of the 275 patients assigned to the psychiatric wards and to

31 of the 314 patients assigned to the medical-surgical wards. The drug profiles showed that 84 patients were treated with only 1 drug; 20 were treated with 2 or more drugs, but not more than 1 at a time; and 110 were treated with 2 or more drugs simultaneously. A detailed breakdown, by drug type, is shown in enclosure II.

Thorazine was the most widely used of the drugs. It was administered to 150 patients--either separately or in combination with the other drugs. Prolixin was administered to 119 patients, Stelazine to 81, Mellaril to 55, and Permittil to 9.

PATIENTS RECEIVING DRUGS IN EXCESS
OF RECOMMENDED MAXIMUM DOSAGE

Optimum amounts of the drugs and frequency of administration must be determined for each patient because dosage requirements vary with clinical circumstances as well as individual responses. The Physicians Desk Reference to Pharmaceutical Specialties and Biologicals 1/ specifies the quantity of phenothiazine drugs which usually provide optimum responses and therapeutic gains. For example, the reference states that, although most patients show optimum response on 15 or 20 milligrams of Stelazine a day, a few patients may require 40 milligrams a day or more. The reference also states that, although gradual increases of Thorazine to 2,000 milligrams a day or more may be necessary, usually little therapeutic gain is achieved by exceeding 1,000 milligrams a day for extended periods. In some cases the reference also specifies maximum dosage. For example, Mellaril dosage should not exceed 800 milligrams a day.

Analysis of the drug profiles showed that:

- Stelazine was administered in excess of 20 milligrams a day to 27 patients; 8 of these received over 40 milligrams a day.
- Thorazine was administered in excess of 1,000 milligrams a day to nine patients, but none received as much as 2,000 milligrams a day.
- Prolixin was administered in excess of the maximum specified dosage to one patient; Mellaril was administered to two patients in excess of the maximum.

1/ The most widely accepted of the many medical references.

The 39 instances of excess dosage noted above involved 36 patients. Three received two drugs in excess of the reference-specified dosage but not simultaneously except in one case for a period of 2 days. Permitil was not administered in excess doses. A schedule of dosages and lengths of administration is presented in enclosure III.

LENGTH OF CONFINEMENT VERSUS
LENGTH OF TREATMENT

Comparison of length of confinement at the Medical Center to length of drug treatment showed that 34 patients were treated less than 25 percent of the time, 56 less than 50 percent of the time, and 86 less than 75 percent of the time. One hundred and twenty-eight patients were treated 75 percent or more of the time confined. Of these, 25 received the drugs during the full length of their confinement, including 3 patients confined for over 1 year and 2 patients confined for over 2 years. Details are shown in enclosure IV.

COMPARING MEDICATION TO DIAGNOSIS

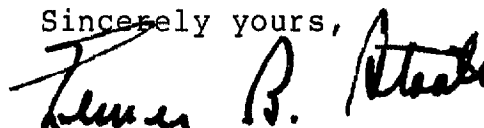
Schizophrenia and personality disorders, attributed to 169 of the 214 patients treated, were the most common diagnoses associated with phenothiazine drug use.

The drugs were administered to six patients during psychiatric evaluation. The remaining patients receiving the drugs were treated for agitation, anxiety and depression, organic brain syndrome, psychosis, and for other undetermined reasons. A schedule of drugs used to treat the diagnosed conditions is in enclosure V.

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As your office requested, we did not obtain formal agency comments; however, we discussed the scope of our review with Medical Center officials. We plan no further distribution of this report unless you agree or publicly announce its contents.

Sincerely yours,



Comptroller General
of the United States

COST OF DRUGS PURCHASED

<u>Drug</u>	<u>1972</u>	<u>1973</u>	<u>1974</u>	<u>Total</u>
Thorazine	\$1,100	\$ 2,000	\$3,200	\$ 6,300
Stelazine	2,600	6,200	1,200	10,000
Prolixin	200	2,700	3,300	6,200
Mellaril	1,000	200	1,300	2,500
Permitil	<u>400</u>	<u>400</u>	<u>-</u>	<u>800</u>
Total	<u>\$5,300</u>	<u>\$11,500</u>	<u>\$9,000</u>	<u>\$25,800</u>

NUMBER AND TYPE OF
PHENOTHIAZINE DRUGS ADMINISTERED

<u>Patient ward- type of drugs</u>	<u>One drug only</u>	<u>Number of patients receiving two or more drugs</u>			<u>Total</u>
		<u>One at a time</u>	<u>Two at a time</u>	<u>Three at a time</u>	
Psychiatric:					
Thorazine	25				25
Prolixin	23				23
Stelazine	8				8
Mellaril	4				4
Permitil	1				1
Prolixin					
Thorazine		3	32		35
Stelazine					
Thorazine		1	11		12
Mellaril					
Thorazine		3	5		8
Prolixin					
Stelazine		3	3		6
Mellaril					
Stelazine		2	2		4
Mellaril					
Prolixin		-	2		2
Prolixin					
Stelazine					
Thorazine		2	21	6	29
Mellaril					
Prolixin					
Thorazine		-	5	-	5
Mellaril					
Prolixin					
Stelazine		-	3	-	3
Mellaril					
Stelazine					
Thorazine		1	1	-	2
Permitil					
Prolixin					
Thorazine		-	2	-	2
Permitil					
Prolixin					
Mellaril		-	1	-	1
Mellaril					
Prolixin					
Stelazine					
Thorazine		-	6	2	8

Patient ward- type of drugs	One drug only	Number of patients receiving two or more drugs			Total
		One at a time	Two at a time	Three at a time	
Permitil					
Prolixin					
Stelazine					
Thorazine		-	1	2	3
Mellaril					
Permitil					
Stelazine					
Thorazine		-	-	1	1
Mellaril					
Permitil					
Prolixin					
Stelazine					
Thorazine		-	1	-	1
<u> </u>	<u> </u>	<u>-</u>	<u>1</u>	<u>-</u>	<u>1</u>
Total	<u>61</u>	<u>15</u>	<u>96</u>	<u>11</u>	<u>183</u>
Number receiving no phenothiazine medication					<u>92</u>
Total psychiatric patients					<u>275</u>
Medical-surgical:					
Thorazine	13				13
Mellaril	9				9
Stelazine	1				1
Mellaril					
Thorazine		3	1		4
Mellaril					
Prolixin		-	1		1
Mellaril					
Stelazine		1	-		1
Stelazine					
Thorazine		1	-		1
Mellaril					
Stelazine					
Thorazine		-	1	-	1
<u> </u>	<u> </u>	<u>-</u>	<u>1</u>	<u>-</u>	<u>1</u>
Total	<u>23</u>	<u>5</u>	<u>3</u>	<u>-</u>	<u>31</u>
Number receiving no phenothiazine medication					<u>283</u>
Total medical-surgical patients					<u>314</u>

PATIENTS RECEIVING DOSAGE
IN EXCESS OF
PHYSICIANS DESK REFERENCE
RECOMMENDED MAXIMUM DOSAGE

Drug-highest dosage (note a)	Total continuous days receiving		Total days confinement
	Highest dosage (note b)	Excess dosage (note b)	
Thorazine:			
1,800	182 (256)	209 (299)	1,057
1,400 (note c)	2	2	8
1,300	3	5	1,057
1,300	1	3	11
1,250	3 (10)	28	261
1,200	174	174	513
1,200	44	44	456
1,200 (note d)	32	32	367
1,200	1	1	101
Prolixin:			
125 (note d)	82	82	1,057
Stelazine:			
120 (note c)	4	4	8
80	27	55	231
60	63	217	974
60	128	156 (181)	573
60	85	106	531
60	19	77 (102)	477
60	110	110 (112)	271
60	63	77	495
40 (note d)	331	331	1,057
40	31	31	855
40	62 (72)	62 (72)	616
40	4	4	614
40	35	35	547
40	43	43	525
40	4	138	367
40	79	79	337
40	32 (131)	99 (131)	248
40	8	8	170

Drug-highest dosage (note a)	Total continuous days receiving		<u>Total days confinement</u>
	<u>Highest dosage (note b)</u>	<u>Excess dosage (note b)</u>	
Stelazine:			
30	32	32	958
30	94	94	867
30	7	7	560
30	5	5	425
30 (note d)	86	86	367
30	303	303	304
30	18	18	297
30	114	114	231
30	13	13	139
Mellaril:			
1,600	94	246 (289)	501
1,000	2	2	644

a/Dosage is shown in milligrams per day--except Prolixin is shown in total milligram dosage.

b/Numbers in parentheses show total days that patients received drugs exceeding Physicians Desk Reference recommended dosage. In other cases continuous and total days treated were the same.

c/Patient received excess dosage of two drugs--simultaneously.

d/Patient received excess dosage of two drugs--not simultaneously.

LENGTH OF CONFINEMENT COMPARED
TO LENGTH OF TREATMENT
WITH PHENOTHIAZINE DRUGS

Hospital ward and number of days confined	Number of patients (By percent of days treated to days confined)						Total patients	
	0%	1-24%	25-49%	50-74%	75-99%	100%	Con- fined	Treated
Psychiatric:								
1- 90	64	7	4	5	21	9	110	46
91-180	14	3	4	7	23	4	55	41
181-365	7	1	-	4	28	6	46	39
366-730	4	6	2	7	21	3	41	39
Over 730	<u>3</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>8</u>	<u>1</u>	<u>23</u>	<u>18</u>
	<u>92</u>	<u>19</u>	<u>13</u>	<u>27</u>	<u>101</u>	<u>23</u>	<u>275</u>	<u>183</u>
Medical- surgical:								
1- 90	141	5	2	-	-	1	149	8
91-180	58	1	2	1	1	-	63	5
181-365	55	5	3	-	1	-	64	9
366-730	21	4	2	2	-	-	29	8
Over 730	<u>8</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>1</u>	<u>9</u>	<u>1</u>
	<u>283</u>	<u>15</u>	<u>9</u>	<u>3</u>	<u>2</u>	<u>2</u>	<u>314</u>	<u>31</u>
Combined:								
1- 90	205	12	6	5	21	10	259	54
91-180	72	4	6	8	24	4	118	46
181-365	62	6	3	4	29	6	110	48
366-730	25	10	4	9	21	3	70	47
Over 730	<u>11</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>8</u>	<u>2</u>	<u>32</u>	<u>19</u>
Total	<u>375</u>	<u>34</u>	<u>22</u>	<u>30</u>	<u>103</u>	<u>25</u>	<u>589</u>	<u>214</u>

COMPARISON OF MEDICATION TO DIAGNOSISPatients assigned to psychiatric wards

Drugs administered	Person-ality disorder	Observa-tion and evaluation	Diagnosis				Total
			Schizo-phrenia	Organic brain syn-drome	Psy-choctic	Other	
Thorazine	11	-	12	2	-	-	25
Prolixin	2	3	17	-	1	-	23
Stelazine	3	-	5	-	-	-	8
Mellaril	1	1	-	1	-	1	4
Permitil	-	-	1	-	-	-	1
Prolixin							
Thorazine	1	1	31	-	1	1	35
Stelazine							
Thorazine	1	-	10	-	1	-	12
Mellaril							
Thorazine	6	-	1	1	-	-	8
Prolixin							
Stelazine	-	-	6	-	-	-	6
Mellaril							
Stelazine	-	-	4	-	-	-	4
Mellaril							
Prolixin	-	-	2	-	-	-	2
Prolixin							
Stelazine							
Thorazine	1	-	24	1	2	1	29
Mellaril							
Prolixin							
Thorazine	-	-	5	-	-	-	5
Mellaril							
Prolixin							
Stelazine	-	-	2	-	1	-	3
Mellaril							
Stelazine							
Thorazine	2	-	-	-	-	-	2
Permitil							
Prolixin							
Thorazine	-	1	1	-	-	-	2
Permitil							
Prolixin							
Mellaril	-	-	1	-	-	-	1
Mellaril							
Prolixin							
Stelazine							
Thorazine	3	-	4	-	1	-	8

Drugs administered	Diagnosis						Total
	Person-ality disorder	Observa-tion and evaluation	Schizo-phrenia	Organic brain syn-drome	Psy-chotic	Other	
Permitil							
Prolixin							
Stelazine							
Thorazine	-	-	3	-	-	-	3
Mellaril							
Permitil							
Stelazine							
Thorazine	-	-	1	-	-	-	1
Mellaril							
Permitil							
Prolixin							
Stelazine							
Thorazine	-	-	1	-	-	-	1
Total	<u>31</u>	<u>6</u>	<u>131</u>	<u>5</u>	<u>7</u>	<u>3</u>	<u>183</u>

Patients assigned to medical-surgical wards

Drugs administered	Diagnosis						Total
	Agita-tion	Person-ality disorder	Anxiety and de-pression	Organic brain syndrome	Schizo-phrenia	Other	
Thorazine	10	1	-	-	-	2	13
Mellaril	2	1	4	1	-	1	9
Stelazine	-	-	1	-	-	-	1
Mellaril							
Thorazine	1	1	2	-	-	-	4
Mellaril							
Prolixin	-	-	-	-	1	-	1
Mellaril							
Stelazine	-	-	-	-	1	-	1
Stelazine							
Thorazine	-	-	-	-	1	-	1
Mellaril							
Stelazine							
Thorazine	-	1	-	-	-	-	1
Total	<u>13</u>	<u>4</u>	<u>7</u>	<u>1</u>	<u>3</u>	<u>3</u>	<u>31</u>