			Case Group	Death Outcomes	Sole
Case Count			68	0	39
Reaction Count	Blood and lymphatic system disorders	Neutropenia	1	0	0
		Blood and lymphatic system disorders	1	0	0
	Cardiac disorders	Tachycardia	5	0	1
		Palpitations	2	0	1
		Cardiomyopathy	1	0	1
		Cardiac disorders	8	0	3
	Congenital, familial and genetic disorders	Multiple congenital abnormalities	1	0	1
		Congenital, familial and genetic disorders	1	0	1
	Ear and labyrinth disorders	Hearing impaired	1	0	1
		Tinnitus	1	0	1
		Ear and labyrinth disorders	2	0	2
	Eye disorders	Mydriasis	2	0	0
		Photophobia	1	0	1
		Retinal pigmentation	1	0	0
		Vision blurred	1	0	1
		Eye disorders	5	0	2
	Gastrointestinal disorders	Abdominal pain	2	0	2
		Vomiting	1	0	0
		Cheilitis	1	0	1
		Stomatitis	1	0	1
		Dry mouth	2	0	2
		Gastrointestinal disorders	7	0	6
	General disorders and administration site conditions	Asthenia	2	0	0
		Fatigue	1	0	1
		Abasia	1	0	1
		Irritability	1	0	1
		Face oedema	1	0	1
		Chills	3	0	1
		Drug effect decreased	1	0	1
		Drug ineffective	1	0	0
		Paradoxical drug reaction	1	0	0
		Therapeutic response decreased	1	0	0

7 Outcome Description

(Causality possible, Causality probable, Causality certain)

Suspect Type

Y Suspect Code

T Case Group

₮ <u>GM</u>

			Case Group	Death Outcomes	Sole
Reaction Count	General disorders and administration site conditions	General disorders and administration site conditions	13	0	6
	Investigations	Electroencephalogram abnormal	1	0	0
		Weight decreased	1	0	1
		Investigations	2	0	1
	Metabolism and nutrition disorders	Anorexia	1	0	1
		Hyponatraemia	1	0	0
		Hypoglycaemia	1	0	0
		Metabolism and nutrition disorders	3	0	1
	Musculoskeletal and connective tissue	Myalgia	1	0	0
	disorders	Muscle spasms	1	0	0
		Muscle twitching	4	0	3
		Muscle rigidity	1	0	0
		Musculoskeletal and connective tissue disorders	7	0	3
	Nervous system disorders	Subarachnoid haemorrhage	1	0	1
		Headache	1	0	1
		Disturbance in attention	2	0	2
		Judgement impaired	1	0	1
		Dyskinesia	2	0	1
		Hyperkinesia	4	0	0
		Dystonia	2	0	0
		Tremor	4	0	3
		Hyperreflexia	2	0	0
		Hyporeflexia	1	0	0
		Nystagmus	1	0	0
		Loss of consciousness	1	0	0
		Clonus	1	0	0
		Dizziness	1	0	1
		Myoclonus	1	0	0
		Crying	1	0	1
		Burning sensation mucosal	1	0	1
		Paraesthesia	1	0	1
		Neuralgia	1	0	0

7 Outcome Description

(Causality possible, Causality probable, Causality certain)

Suspect Type

Y Suspect Code

T Case Group

₮ <u>GM</u>

			Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	Dysarthria	1	0	1
		Speech disorder	1	0	0
		Hypertonia	3	0	0
		Hypotonia	1	0	0
		Serotonin syndrome	1	0	0
		Muscle contractions involuntary	1	0	0
		Convulsion	2	0	0
		Nervous system disorders	39	0	14
	Pregnancy, puerperium and perinatal	Neonatal disorder	1	0	1
	conditions	Pregnancy, puerperium and perinatal conditions	1	0	1
	Psychiatric disorders	Agitation	5	0	2
		Anxiety	3	0	0
		Nervousness	3	0	1
		Neurosis	1	0	0
		Obsessive-compulsive disorder	2	0	0
		Restlessness	1	0	1
		Confusional state	2	0	1
		Disorientation	1	0	1
		Depression	1	0	1
		Depressed mood	1	0	1
		Delusion	3	0	3
		Hallucination	2	0	0
		Hallucination, auditory	2	0	2
		Hallucination, visual	1	0	1
		Thinking abnormal	1	0	1
		Anger	1	0	1
		Mood swings	2	0	2
		Apathy	1	0	1
		Aggression	4	0	4
		Homicidal ideation	1	0	1
		Paranoia	1	0	1
		Abnormal behaviour	2	0	2

7 Outcome Description

(Causality possible, Causality probable, Causality certain)

Suspect Type

Y Suspect Code

T Case Group

			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Neglect of personal appearance	1	0	1
		Alcohol abuse	1	0	0
		Drug abuse	1	0	0
		Psychotic disorder	2	0	1
		Insomnia	4	0	4
		Suicidal ideation	2	0	2
		Psychiatric disorders	52	0	35
	Renal and urinary disorders	Renal pain	1	0	1
		Renal and urinary disorders	1	0	1
	Reproductive system and breast disorders	Testicular disorder	1	0	0
		Reproductive system and breast disorders	1	0	0
	Respiratory, thoracic and mediastinal disorders	Bronchospasm	1	0	1
		Dyspnoea	1	0	1
		Hyperventilation	1	0	0
		Respiratory, thoracic and mediastinal disorders	3	0	2
	Skin and subcutaneous tissue disorders	Periorbital oedema	1	0	1
		Urticaria	1	0	1
		Erythema	1	0	1
		Rash erythematous	2	0	1
		Pruritus	3	0	3
		Rash	2	0	2
		Skin ulcer	1	0	1
		Alopecia	1	0	0
		Hyperhidrosis	2	0	0
		Nail discolouration	1	0	1
		Purpura	1	0	1
		Skin and subcutaneous tissue disorders	16	0	12
	Social circumstances	Sexual abuse	1	0	0
		Social circumstances	1	0	0
	Surgical and medical procedures	Therapy regimen changed	1	0	0
		Surgical and medical procedures	1	0	0
	Vascular disorders	Peripheral ischaemia	1	0	1

7 Outcome Description

(Causality possible, Causality probable, Causality certain)

Suspect Type

Y Suspect Code

T Case Group

₮ <u>GM</u>

			Case Group	Death Outcomes	Sole
Reaction	Vascular disorders	Orthostatic hypotension	1	0	1
Count		Vascular disorders	2	0	2
	Reaction		166	0	92

Nows are suppressed based on zeros and empty cells for Case Group

- **7** Outcome Description
- (Causality possible, Causality probable, Causality certain)
- Suspect Type
- Suspect Code
- **T** Case Group
- **₹** <u>GM</u>
- **7** Dexamphetamine Sulphate