FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 3973882

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 15-Jun-2005 Mfr Rcvd Date: 03-Jun-2005 Mfr Control #: US-GLAXOSMITHKLINE-A0383979A

Patient Information:

Age: 16 YR Sex: Male Weight: 88.2 KG

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral		PSYCHOLOGICAL DISORDER NOS	08-Feb-2001	Jul-2001
2	RISPERDAL						

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL	43 Day		U				GLAXOSMITHKLINE
2	RISPERDAL			U				

Event Information:

Preferred Term (MedDRA® Version: 17.0)	ReC
Aggression	
Anger	
Delusion	
Disinhibition	
Drug withdrawal syndrome	
Feeling abnormal	
Headache	
Homicide	U
Insomnia	
Mental impairment	

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 3973882

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** N **Country:** USA **Outcomes:** OT **(A)NDA/BLA:** 020031 /

FDA Rcvd Date: 15-Jun-2005 **Mfr Rcvd Date:** 03-Jun-2005 **Mfr Control #:** US-GLAXOSMITHKLINE-A0363979A

Patient Information:

Age: 16 YR **Sex:** Male **Weight:** 68.2 KG

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral		PSYCHOLOGICAL DISORDER NOS	06-Feb-2001	Jul-2001
2	RISPERDAL						

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL	43 Day		U				GLAXOSMITHKLINE
2	RISPERDAL			U				

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Aggression	
Anger	
Delusion	
Disinhibition	
Drug withdrawal syndrome	
Feeling abnormal	
Headache	
Homicide	U
Insomnia	
Mental impairment	

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 3973882

Negativism

Event/Problem Narrative:

Report number A0363979A, describes a homicide by a male, aged 16 years, prescribed paroxetine (Paxil) for "psychological problems", and because the patient's parents and friends were insensitive to the patient's [redacted] This report was initially received from a lawyer and a television news report. Follow-up information was received from a variety of media broadcasts. This report has been verified by a physician's and pharmacologist's testimony at trial. Six months prior to the event the patient [redacted] Reportedly, the patient was taking risperidone (Risperdal) concurrently with Paxil. On 06-Feb-2001, the patient allegedly started Paxil 20mg/day. It was reported, the dose of Paxil was increased to 40mg/day on 26-Feb-2001, approximately [redacted] weeks before the homicide. In [redacted], patient's [redacted] The decedent's [redacted] and friend was charged with homicide days later and was in custody by [redacted] Paxil was discontinued at that time, and he experienced discontinuation symptoms (NOS). Paxil was restarted by a physician, and he was weaned off Paxil in July 2001. The patient told police that he and the [redacted] Reportedly, that is when the patient hit him in the [redacted] According to the defense, allegedly sometime after starting Paxil the patient reportedly experienced becoming intoxicated with the antidepressant. The defense was citing temporary insanity due to "involuntary intoxication". A defense attorney claimed, the patient was "under the influence of Paxil" when he beat the victim to death [redacted] The defense said, Paxil, the antidepressant he was taking, [redacted] It was alleged, Paxil played a role in the patient's inability to know right from wrong. It was reported, the patient was unable to appreciate the wrongfullness of his conduct or could not conform his conduct to the requirements of the law. Allegedly, this caused him to murder a [redacted] A news report revealed, the defense lawyer was trying to say his client had been taking Paxil and Risperdal, which may have affected his mental status. The patient was standing trial [redacted] for first degree murder, and his trial was started in late [redacted] The report revealed, the defense pleaded temporary insanity due to involuntary intoxication with antidepressant Paxil. During the trial the patient's mother alleged her son became more defiant and aggressive after taking Paxil. The patient's psychiatrist also testified the same, saying he treated the patient after the murder and had to lower his dosage. Reportedly, he had to the take the patient off Paxil because it made him violent and delusional. It was reported, a pharmacologist was asked on cross examination by the prosecution, was there any scientific evidence Paxil could make one homicidal, to which he answered no. It was reported, the patient did not deny killing the victim. He was saying he was temporarily insane. The patient claimed the victim

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 3973882

and himself [redacted] and the jury found him guilty of murder. The panel deliberated approximately [redacted] years in prison. The patient's mother reported that Paxil was prescribed for a diagnosis of depression and that the patient had never [redacted]

Drug Quality Reporting System (DQRS) Number: 2003-02081

The following information was provided by the medical records. On 26 February 2001 the patient was seen by his physician for depression with psychotic features. Patient reported that Paxil had helped. Paxil 20 mg daily was continued. On [redacted] physician noted that the patient had been charged with murder. The patient's parents had felt the patient had improved with Paxil. He learned by reading the police report that the patient had also experienced delusions during Paxil therapy. Review of the medical record indicated that during a phone conversation between a mental health professional and the patient's father, he reported that his son (the patient) was [redacted]. The patient reported to his father that he had been having [redacted]. The father also reported that he planned to take his son to another mental health therapist that he had seen previously. On 12 December 2001, the therapist [redacted]

The mental health professional also stated that the difficulties that the patient was having in High School regarding social and behavioral "episodes" had caused his condition to worsen. It was noted that the patient would have less difficulty in recovering as long as he was also under the stress of dealing with the reactions, pressures and expectations of his current peer group at school. Documentation was not provided to indicate if and when the patient [redacted] prior to the onset of the events. A psychiatrist who treated the patient after the murder noted that the patient "had an adverse reaction of manic disinhibition. In that Paxil-induced state he was devoid of his usual appreciation of consequences, and murdered another [redacted]." A letter from a clinical psychologist dated 22 March 2002 reported an interview with the patient after the crime. His letter reported that the patient started Paxil on 06 February 2001 and became "[redacted]." His mood was lifted and he no longer felt suicidal. On 26 February 2001 the dose of Paxil was increased to 40 mg daily. The patient then became emotionally reactive and less inhibited and began to engage in risky behaviors such as [redacted] without thinking about the consequences. His behavior changed and he was defiant with his parents and skipped school. He stopped caring for any other people except for a few friends. He also felt little need for sleep. The patient was in turmoil. [redacted] weeks after Paxil dose was increased the patient had an idea that he could [redacted]. He did not think about consequences but it was "in his mind as a conclusion." The patient invited his [redacted]

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[redacted] and acted normally the next days. He denied knowing where the victim was when the victim's mother and police questioned him. The patient was arrested [redacted] days later. Paroxetine was stopped abruptly in prison and the patient experienced withdrawal side effects or headache, in a daze and could not think "and was unable to sleep. Paroxetine was restarted at 20 mg after a few weeks and slowly tapered off. The patient's withdrawal symptoms resolved after two weeks. The clinical psychologist reported that the [redacted] behavior involved in this murder was not in character for the [patient], but was instead a product of the actions of Paxil." He believed "the event would never had occurred had it not been for his ingestion of Paxil." He felt that Paxil suspended his regard for consequences and removed his inhibitions that enable a person to conform his actions to his values." A different psychologist examined the patient and his letter dated March 2002 reported that the patient did not indicate at any time that he was "[redacted] or experiencing any other state of mind that would suggest he was impaired." He stated that the patient's was troubled, conflicted, confused and angry with many psychological problems. But his actions clearly revealed he was aware of the illegal nature of his actions and he made a conscious effort to avoid calling the attention of the victim to his intentions until he was in a postions to carry out the act. He believed the patient was of "sound mind and should be legally responsible for his actions."

Relevant Medical History:

[redacted]. Urine tested positive for marijuana on [redacted]. Hospitalized for "[redacted]" in 1988. Patient's psychological problems started around [redacted] grade when he became depressed and suicidal. This was mainly from his struggles with [redacted]. On 06 November 2000, the patient's father shared his concerns regarding his son (the patient) with a mental health professional. He was concerned with his son's history of depression and angry outbursts. His son was confused about [redacted]. The patient had made accusations of [redacted]. The patient was also experiencing nightmares where he was being attacked by others. Patient abused all varieties of alcohol, marijuana daily, Xanax, LSD, cigarettes. He admitted to heavily abusing cocaine prior to his criminal offense. In 1999, prior to taking Paroxetine, the patient acted on his suicidal thoughts by snorting an overdose of cocaine. He suffered no [redacted]-effects.

Disease/Surgical Procedure	Start Date	End Date	Continuing?
SUICIDAL IDEATION	1999		UNKNOWN
AGGRESSION			UNKNOWN
COCAINE ABUSE			UNKNOWN
DEPENDENCE ON MARIJUANA			UNKNOWN
DEPRESSION			UNKNOWN
[redacted]			UNKNOWN

FDA - Adverse Event Reporting System (FAERS)

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Case ID: 3973882

HALLUCINATION	UNKNOWN
[redacted]	UNKNOWN
OPPOSITIONAL	UNKNOWN
OVERDOSE	UNKNOWN
POLYSUBSTANCE ABUSE	UNKNOWN
SELF ESTEEM DECREASED	UNKNOWN
SUICIDE ATTEMPT	UNKNOWN

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No Sender Organization: GLAXOSMITHKLINE

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 4118456

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020938

FDA Rcvd Date: 02-Apr-2004 Mfr Rcvd Date: 29-Mar-2004 Mfr Control #: US-GLAXOSMITHKLINE-A0504909A

Patient Information:

Age: Sex: Female Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL CR		Oral				

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL CR			U				GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA Version: 17.0)

	ReC
Amnesia	
Homicide	U

Event/Problem Narrative:

This case was reported by a physician and described the occurrence of homicide in an adult female patient who received Paroxetine hydrochloride (Paxil) tablet-controlled release tablets. The patient's past medical history included [redacted]. Concurrent medications included Ribavirin, Interferon and Nytol. On an unknown date, the patient started Paroxetine hydrochloride (oral) at 25 mg. On [redacted], the patient killed her husband during the night, but she did not recall committing the homicide. This case was assessed as medically serious by GSK. The outcome of the event is unknown. The patient is on trial for killing her husband. Patient's husband had [redacted]. The patient is on trial for killing her husband.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 4136744

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 07-May-2004 Mfr Rcvd Date: 04-May-2004 Mfr Control #: US-GLAXOSMITHKLINE-A0509770A

Patient Information:

Age: 27 YR Sex: Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL				PRODUCT USED FOR UNKNOWN INDICATION		
2	ZYPREXA				PRODUCT USED FOR UNKNOWN INDICATION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE
2	ZYPREXA			U				

Event Information:

Preferred Term (MedDRA® Version: 17.0)	ReC
Homicide	U

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 4136744

Event/Problem Narrative:

This case was reported by a consumer via a newspaper article and described the occurrence of homicide committed by a 27-year-old patient who received Paroxetine hydrochloride (Paxil) for unknown indication. A physician or other health care professional has not verified this report. Co-suspect medication included Zyprexa.

On an unknown date, the patient started Paroxetine hydrochloride. At an unknown time after starting Paroxetine hydrochloride, the patient committed a homicidal act by killing his mother with [redacted]. The patient was sentenced indefinitely to the [redacted]. The patient's father [redacted] No other information was provided regarding treatment with Zyprexa. This case was assessed as medically serious by GSK. The outcome of the event is unknown.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No Sender Organization: GLAXOSMITHKLINE

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 4136744

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 4184936

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: HO,LT,OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 06-Feb-2006 Mfr Rcvd Date: 26-Jan-2006 Mfr Control #: US-GLAXOSMITHKLINE-A0371852A

Patient Information:

Age: 26 YR Sex: Male Weight: 86.4 KG

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral	20MG Per day	DEPRESSION	13-Mar-2002	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA® Version: 17.0)	ReC
Anger	
Dissociation	
Hallucination, auditory	
Homicidal ideation	
Homicide	U
Injury	
Insomnia	
Intentional overdose	
Psychiatric symptom	
Restlessness	
Suicidal ideation	
Suicide attempt	

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 4184936

Preferred Term (MedDRA Version: 18 0 ReC

Event/Problem Narrative:

Report number A0371852A describes the occurrence of attempted suicide in an adult male taking Paroxetine (Paxil) for an unspecified indication. This report was received via newspaper articles via interviews with the patient's [redacted]. Concurrent medical conditions, allergies and concurrent medications were not provided. Medical history included "deep emotional problems." The patient had been severely abused and sexually molested as a child. The patient's [redacted] stated that the childhood abuse caused the patient to [redacted]. The patient's [redacted] stated that the patient [redacted]. On an unknown date, the patient began treatment with Paxil (dose and frequency unspecified). In [redacted], the patient attempted suicide by taking an intentional overdose of Paxil (dose unspecified). The patient's [redacted] stated that she and her [redacted] found the patient [redacted]. The patient's [redacted] stated [redacted]. She reported that the patient would not [redacted]. The patient's wife persuaded him to go to the emergency room (ER) the following day. The [redacted] reported that the ER doctor told the patient that he had bipolar disorder. The patient was checked into the county mental hospital that night. The [redacted] reported that the doctors there told the patient that [redacted] and sent him home to be treated as an outpatient. She further stated that the patient "seemed to get better in the days that followed." She reported that he was "on his meds" (NOS) and "he was doing fine, so everybody thought." It was not specified what medication the patient was taking following his suicide attempt. It is unknown if Paxil therapy was continued. The most recent information received on 17-June-2002 reported the outcome of the events as resolved. A lawyer reported via litigation proceedings that the patient started Paroxetine hydrochloride on 13 March 2002 and experienced restlessness and insomnia. On [redacted] the patient experienced homicidal thoughts described as [redacted]. The patient pled guilty to murder and is serving [redacted]. The following information was provided by medical records. Past history of sexual and physical abuse as a child, hearing voices, drug abuse, suicide attempt in 2000. Concurrent medical condition included bipolar disorder. The patient had recent history of suicidal thoughts and thoughts of injuring others in [redacted], while taking Prozac. On [redacted] he took an overdose of sleeping pills and was hospitalized for one day. Patient was discharged the next day because he told the physician

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 4184936

he was safe to go for outpatient treatment. however he told his therapist he still had thoughts of harming himself or others. Medical notes dated [redacted], noted that the patient was having passive thoughts of wanting to harm [redacted]", and [redacted]." The patient stated that "I always push these thoughts away." Patient also declined to participate in family therapy while in the psychiatric hospital. A therapist noted in the medical record that the patient s wife was instructed to remove a gun from the home. The medical record indicated that the patient reported that even as a child [redacted], but was never treated for it. He feels [redacted]

The patient started Paroxetine hydrochloride 20 mg daily while he was in the hospital on [redacted]. The patient shared with his [redacted] that he had murderous thoughts towards people, and he thought that he would never harm himself, or anyone else, but just recently the thought [redacted] The medical record indicated that the patient tried to commit suicide two years ago, when he was separated from his wife, but stated "I was doing drugs then." The medical record indicated that on 16 April 2002, the patient reported to a mental health worker, that he was being seen privately and on medication and to close his case with the county mental health department. Review of the medical record indicated that the patient started seeing a mental health counselor privately after his suicide attempt and subsequent hospitalization in [redacted]. The patient reported to a police officer during an interview after the assault, that he had told his therapist that he had been having strong feelings and thoughts of killing his wife. Police interview notes further indicated that the patient had shared with his [redacted]

He stated that he [redacted] Review of the medical record indicated that the suicide attempt by the patient in [redacted] was actually with over the counter sleeping pills, and not with Paroxetine as previously reported. The patient reported to a police officer during an interview after the assault that he originally planned on killing his [redacted]. On [redacted]

[redacted]. He left the home to go to his [redacted] home, and then decided that he did not want to wake him up. The patient drove to the police station and at four am reported to the police that he had killed his wife, or she was dying at home in bed.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

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He further reported that he knew that what he did was wrong and he was trying to get his wife some medical attention. The patient's wife was taken to the hospital with diagnoses of

The wife died on secondary to increased and loss of blood flow. An autopsy was performed which recorded the cause of death as Secondary diagnoses were A State of Death certificate indicated that the patient's wife died on , and the cause of death was A bottle of Paroxetine 20 mg with the patients name on the label was obtained from the home, and taken as evidence by the police investigating the crime scene. The patient was charged with assault with a deadly weapon inflicted serious injury, and first degree homicide. The patient was convicted of first degree murder, and is serving Follow up medical records received on 05 August 2005, indicated that a psychological evaluation was performed on the patient to ascertain the characteristics of his psychological functioning at the time that he assaulted his wife. A detailed report was completed on 23 July 2003. The results of a psychological evaluation by a psychologist indicated that the patient suffers from severe psychopathology. There is no diagnosis or combination of diagnoses that can adequately characterize the quality and severity of his symptoms and behaviors. Diagnostic impressions were posttraumatic stress disorder, chronic major depressive disorder-recurrent, severe with psychotic features and avoidant personality disorder with

Relevant Medical History:

Patient had history of taking Prozac and had thoughts of injuring himself with a gun or threats of injuring others. In March 2002 before taking Paroxetine. Patient attempted suicide by taking an overdose of sleeping pills on and was hospitalized. While hospitalized, the patient indicated that he had been Prozac was discontinued because of complaints of some "vague" twitching. The patient gave mixed messages while in hospital by telling the therapist he still had thoughts of injuring himself or others. The patient told the doctor he was safe to go to outpatient. Patient was discharged from the psychiatric hospital. Has a history of violence and assault when he hit a fellow He was medically discharged from the for ankle problems in 1998. Patient reported to a therapist that he but he never received mental health treatment or evaluation. The patient tortured and killed numerous times during his childhood. He reported that he use to kill History also included frequent fantasies of killing people since childhood, frequent headaches, migraines in adolescence, head injury, concussion at age eight, multiple suicide attempts including at age and at age 23 by ingesting alcohol and sleeping pills. His biological mother has been married over times, and has a history of alcohol and drug abuse. Patient has not had any contact with his mother in the past three years. When he was years old, his biological mother turned over legal custody to his , who raised him in a strict family. Patient has never had any contact with his biological

Disease/Surgical Procedure	Start Date	End Date	Continuing?
DRUG ABUSE	1999		UNKNOWN
			UNKNOWN
CHILD ABUSE			UNKNOWN

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DETACHMENT EMOTIONAL	UNKNOWN
DIFFICULTY SLEEPING	UNKNOWN
DRUG ABUSE	UNKNOWN
HALLUCINATION AUDITORY	UNKNOWN
HEAD INJURY	UNKNOWN
HEADACHE	UNKNOWN
HOMICIDAL IDEATION	UNKNOWN
MARITAL PROBLEM	UNKNOWN
PERSONALITY DISORDER	UNKNOWN
PHYSICAL ABUSE	UNKNOWN
SELF ESTEEM DECREASED	UNKNOWN
SEXUAL ABUSE	UNKNOWN
SUICIDAL IDEATION	UNKNOWN
SUICIDE ATTEMPT	UNKNOWN

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	PROZAC						13-Mar-2002	

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 4184936

Reporter Source:

Study Report?: No **Sender Organization:** GLAXOSMITHKLINE

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 4204324

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: DE (A)NDA/BLA: 020031 /

FDA Rcvd Date: 07-Sep-2004 Mfr Rcvd Date: 26-Aug-2004 Mfr Control #: US-GLAXOSMITHKLINE-A0523522A

Patient Information:

Age: 37 YR Sex: Female Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral		POSTPARTUM DEPRESSION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA Version: 18.0)

	ReC
Completed suicide	
Homicide	U
Intentional overdose	

Event/Problem Narrative:

This case was reported in a newspaper article and described the occurrence of murder and suicide in a 37-year-old female patient who received Paroxetine hydrochloride (Paxil) for postpartum depression. Concurrent conditions included postpartum depression. Concurrent medications included Darvocet. On an unknown date, the patient started Paroxetine hydrochloride (oral). On [redacted], the patient commited suicide. She was found [redacted] with a [redacted]. The patient had also murdered her [redacted] daughter, who was found [redacted]. Large amounts of Paroxetine hydrochloride and Darvocet were found in the patient s system after she died by the medical examiner. It was reported that the drug levels suggested that [redacted]. The patient died on [redacted] from asphyxiation. An autopsy was performed.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 4206453

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 09-Sep-2004 Mfr Rcvd Date: 30-Aug-2004 Mfr Control #: US-GLAXOSMITHKLINE-A0523725A

Patient Information:

Age: Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral		PRODUCT USED FOR UNKNOWN INDICATION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Homicide	U
Memory impairment	

Event/Problem Narrative:

This case was reported in a newspaper article and described the occurrence of murder by a male patient who received Paroxetine hydrochloride (Paxil) for drug use for unknown indication. On an unknown date, the patient started Paroxetine hydrochloride (oral). On [redacted], an unknown time after starting Paroxetine hydrochloride, the patient committed murder. The patient shot at [redacted]. The patient reported that he did not remember what he was doing. This case was assessed as medically serious by GSK. The outcome of the event is unknown.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 4208287

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 13-Sep-2004 Mfr Rcvd Date: 07-Sep-2004 Mfr Control #: US-GLAXOSMITHKLINE-A0524768A

Patient Information:

Age: Sex: Female Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Unknown		ILL-DEFINED DISORDER		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Homicide	U

Event/Problem Narrative:

This case was reported by a lawyer and described the occurrence of murder committed by an adult patient who received Paroxetine hydrochloride (Paxil) for unknown drug indication. A physician or other health care professional has not verified this report. On an unknown date, the patient started Paroxetine hydrochloride (unknown) unknown dosing. At an unknown time after starting Paroxetine hydrochloride, the patient committed murder. The attorney reported that Paxil usage was implicated as the cause of a murder. This case was assessed as medically serious by GSK. The outcome of the event is unknown.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 4220083

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 04-Oct-2004 Mfr Rcvd Date: 01-Oct-2004 Mfr Control #: US-GLAXOSMITHKLINE-A0527382A

Patient Information:

Age: 49 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral		ANXIETY		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA® Version: 17.0)	ReC
Amnesia	
Anger	
Gun shot wound	
Homicide	U
Intentional self-injury	

U.S. Department of Health and Human Services

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Form Approved: OMB No. 0910-0291 Expires: 03/31/05
See OMB statement on reverse.

Individual Safety Report

VOLUNTARY reporting of adverse events and product problems

Submission Page 1

4485302-5-00-01

FDA USE ONLY

Triage unit 220309

1. Patient Identifier	2. Age at time of Event: 41 years or Date of Birth:	3. Sex	4. Weight
[redacted]		☑ Female ☐ Male	135 lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defect/malfunction)

2. Outcome Attributed to Adverse Event (Check all that apply)
☑ Death [redacted] (mm/dd/yyyy)
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Disability
☐ Congenital Anomaly
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Other: _____

3. Date of Event (mm/dd/yyyy): 05/03/2003

4. Date of This Report (mm/dd/yyyy): 10/21/2004

5. Describe Event or Problem

My [redacted] on the drug Paxil. It had a horrible effect on her. I saw the effects on her, and reported it to her therapist to no avail. Because of problems with withdrawl, she committed a homicide. The victim was our elderly mother who was also on Paxil for OCD. Neither of these women had ever been violent in their entire lives. But got into a physical conflict, when my mother slapped my sister, for some unknown reason. My [redacted] has no memory of the events.

RECEIVED

OCT 22 2004

MEDWATCH CTU

6. Relevant Tests/Laboratory Data, Including Dates

None

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

My [redacted] also got cancer of her breast. Paxil has been found to increase possibility of this type of cancer by 7 times for a woman. There is no history of any kind of female cancer in either side of our family.

C. SUSPECT MEDICATION(S)

1. Name (Give strength & manufacturer, if known)
#1 Paxil 10 mg. Glaxo-Smith-Kline
-fluoxetine-
#2

2. Dose, Frequency & Route Used
#1 1 daily Oral
#2

3. Therapy Dates (if unknown, give duration)
#1 07/20/2001 05/03/2003
#2

4. Diagnosis for Use (Indication)
#1 Severe Major Depression
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot # (if known)
#1
#2

7. Exp. Date (if known)
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# (For product problems only)

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
Under care of psychiatrist from 2001-was put on Paxil while in a Rehab Center-until our mother's untimely death May 3, 2003.

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Seroquel Inn

2. Type of Device

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other
Serial #	Other #	

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor:

DSS

10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on OCT 22 2004 (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. REPORTER (See confidentiality section on back)

1. Name and Address	Phone #
[redacted]	[redacted]

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health Professional	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FDA Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to 1-800-FDA-0178

FORM FDA 3500 (9/03) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5670532

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020938

FDA Rcvd Date: 18-Oct-2004 Mfr Rcvd Date: 14-Oct-2004 Mfr Control #: US-GLAXOSMITHKLINE-A0529935A

Patient Information:

Age: 35 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL CR		Oral	12.5MG Per day	DEPRESSION	02-Oct-2003	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL CR	17 Day		U				GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Homicide	U

Event/Problem Narrative:

This case was reported by a lawyer and described the occurrence of murder committed by a 35-year-old male patient who received Paroxetine hydrochloride (Paxil) tablet-controlled release over a period of 17 Days for depression. A physician or other health care professional has not verified this report. Patient had a previous history of assault and aggressive behavior with prior convictions. No concurrent medication. On 2 October 2003 the patient started Paroxetine hydrochloride (oral) at 12.5 mg daily. Approximately later, on , the patient committed murder. This case was assessed as medically serious by GSK. Treatment with Paroxetine hydrochloride was discontinued. The outcome of the event is unknown. The patient claims . Patient was given two boxes of Paxil CR 12.5 mg samples and three boxes of Paxil CR 25 mg samples by his physician.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5676743

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: DE (A)NDA/BLA: 020031 /

FDA Rcvd Date: 22-Sep-2006 Mfr Rcvd Date: 20-Sep-2006 Mfr Control #: US-GLAXOSMITHKLINE-A0321142A

Patient Information:

Age: 60 YR Sex: Male Weight: 83.9 KG

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral	20MG Per day	ANXIETY	11-Feb-1998	Feb-1998

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				SMITHKLINE BEECHAM

Event Information:

Preferred Term (MedDRA® Version: 17.0)	ReC
Akathisia	
Completed suicide	
Homicide	U
Psychotic disorder	

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5679392

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 22-Nov-2004 Mfr Rcvd Date: 16-Nov-2004 Mfr Control #: US-GLAXOSMITHKLINE-A0534172A

Patient Information:

Age: 31 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral		PRODUCT USED FOR UNKNOWN INDICATION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Homicide	U
Overdose	

Event/Problem Narrative:

This case was reported in a newspaper article and described the allegation of murder by a 31-year-old male patient who received Paroxetine hydrochloride (Paxil formulation unknown) for drug use for unknown indication. Concurrent medical conditions included diabetic blindness, high blood pressure and a heart condition. On an unknown date, the patient started Paroxetine hydrochloride (oral) at unknown, unknown dosing. On [redacted], the patient allegedly murdered his ex-girlfriend by shooting her numerous times. The patient was being held under police guard after ingesting a large amount of Paxil (dose unknown). The police ruled out a suicide attempt since the patient had the gun; it was believed that he had the means to take his own life if he wanted to. This case was assessed as medically serious by GSK. The outcome of the events was unknown.

Individual Safety Report

4631029-8-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Lilly and Company

US_0503114723

Page 1 of 2

A. Patient Information

1. Patient identifier (b) (6) — in confidence
2. Age at time of event — or — Date of birth:
3. Sex: ☐ female ☒ male
4. Weight: NI lbs — or — kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defect/malfunction)
2. Outcome attributed to adverse event (check all that apply)
   - ☐ death
   - ☐ life-threatening
   - ☐ hospitalization - initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☒ other: NI
3. Date of event: 21/MAR/2005
4. Date of this report: 30/MAR/2005
5. Describe event or problem:

THIS CASE, REPORTED BY A COMPANY REPRESENTATIVE VIA TRANSCRIPTS FROM LOCAL TELEVISION STATION, CONCERNS A MALE PATIENT.

THE PATIENT'S MEDICAL HISTORY AND CONCOMITANT MEDICATIONS WERE NOT REPORTED.

THE PATIENT BEGAN ORAL OLANZAPINE (ZYPREXA) ON AN UNSPECIFIED DATE. THE DOSAGE, WAS NOT PROVIDED, BUT HE WAS RECEIVING A DOSE EACH NIGHT. THE DURATION AND INDICATION FOR USE WAS NOT PROVIDED. THE LAST TWO WEEKS (APPROXIMATED 7-MAR-2005 THROUGH 21-MAR-2005. THE PATIENT EXPERIENCED BAD REACTION TO THE OLANZAPINE. ON [redacted] THE PATIENT (b) (6) AND KILLED HIS MOTHER. THE PATIENT WAS CHARGED WITH FIRST DEGREE MURDER. THE PATIENT DID NOT REMEMBER THE

6. Relevant tests/laboratory data, including dates

RECEIVED

APR 0 6 2005

CDR / CDER

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer if known)
   - #1 ZYPREXA-ORAL (OLANZAPINE)(OLANZAPINE)
   - #2
2. Dose, frequency & route used
   - #1 QHS
   - #2
3. Therapy dates (if unknown, give duration)
   - #1 NI, unknown
   - #2
4. Diagnosis for use (indication)
   - #1 NI
   - #2
5. Event abated after use stopped or dose reduced
   - #1 ☐ yes ☐ no ☒ doesn't apply
   - #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   - #1 NI
   - #2
7. Exp. date (if known)
   - #1 NI
   - #2
8. Event reappeared after reintroduction
   - #1 ☐ yes ☐ no ☐ doesn't apply
   - #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # for product problems only (if known)
   - #1
   - #2
10. Concomitant medical products and therapy dates (exclude treatment of event)

11 Unknown

G. All manufacturers

1. Contact office - name/address (& mfr'ing site for devices)

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

2. Phone number: 317-276-7588

3. Report source (check all that apply)
   - ☐ foreign
   - ☐ study
   - ☐ literature
   - ☐ consumer
   - ☐ health professional
   - ☐ user facility
   - ☒ company representative
   - ☐ distributor
   - ☐ other

4. Date received by manufacturer: 22/MAR/2005

5. (A)NDA #: 20-592
   - IND #:
   - PLA #:
   - pre-1938: ☐ yes
   - OTC product: ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
   - ☐ 5-day ☒ 15-day
   - ☐ 10-day ☐ periodic
   - ☒ initial ☐ follow-up #

8. Adverse event term(s)

MURDER

UNEVALUABLE EVENT

9. Mfr report number: US_0503114723

E. Initial reporter

1. Name, address & phone #: (b) (6)

2. Health professional? ☐ yes ☒ no

3. Occupation: *

4. Initial reporter also sent report to FDA: ☐ yes ☐ no ☐ unk

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Item completed on continuation pages

DSS

APR 0 6 2005

APR 0 7 2005

Eli Lilly and Company

Individual Safety Report

4522496-7-00-01

USA041184424	Page 2 of 2

B.5 Describe event or problem

[continuation:] ACT, THE PATIENT'S SON HAD BEEN GETTING TEASED AT SCHOOL. DETAILS REGARDING THE MANNER, IN WHICH THE ACT WAS COMITTED, WERE NOT PROVIDED. THE PATIENT REMAINED ON OLANZAPINE, RECOVRED FROM HIS SUICIDAL IDEATION AFTER AN UNSPECIFIED AMOUNT OF TIME AND WAS SENT TO JAIL. AT THE TIME OF THIS REPORT HE WAS REPORTEDLY DOING FINE ADDITIONAL INFORMATION WILL BE REQUESTED.

THE REPORTING PSYCHIATRIST FELT THAT THE HOMICIDAL ACT WAS DUE TO THE PATIENT'S ILLNESS. HE DID NOT PROVIDE AN ASSESSMENT OF RELATEDNESS REGARDING THE SUICIDAL THOUGHTS.

THE SALES REPRESENTATIVE ATTEMPTED TO OBTAIN THE CONTROL/ LOT NUMBER, HOWEVER, THE INFORMATION WAS NOT KNOWN.

DSS

DEC 0 8 2004

DEC - 7 2004

Individual Safety Report

4631029-8-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Lilly and Company

US_0503114723

Page 1 of 2

A. Patient Information

1. Patient identifier (b) (6) — in confidence
2. Age at time of event — or — Date of birth:
3. Sex: ☐ female ☒ male
4. Weight: NI lbs — or — kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defect/malfunction)
2. Outcome attributed to adverse event (check all that apply)
   - ☐ death
   - ☐ life-threatening
   - ☐ hospitalization - initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☒ other: NI
3. Date of event: 21/MAR/2005
4. Date of this report: 30/MAR/2005
5. Describe event or problem:

THIS CASE, REPORTED BY A COMPANY REPRESENTATIVE VIA TRANSCRIPTS FROM LOCAL TELEVISION STATION, CONCERNS A MALE PATIENT.

THE PATIENT'S MEDICAL HISTORY AND CONCOMITANT MEDICATIONS WERE NOT REPORTED.

THE PATIENT BEGAN ORAL OLANZAPINE (ZYPREXA) ON AN UNSPECIFIED DATE. THE DOSAGE, WAS NOT PROVIDED, BUT HE WAS RECEIVING A DOSE EACH NIGHT. THE DURATION AND INDICATION FOR USE WAS NOT PROVIDED. THE LAST TWO WEEKS (APPROXIMATED 7-MAR-2005 THROUGH 21-MAR-2005. THE PATIENT EXPERIENCED BAD REACTION TO THE OLANZAPINE. ON [redacted] THE PATIENT (b) (6) AND KILLED HIS MOTHER. THE PATIENT WAS CHARGED WITH FIRST DEGREE MURDER. THE PATIENT DID NOT REMEMBER THE

6. Relevant tests/laboratory data, including dates

RECEIVED

APR 0 6 2005

CDR / CDER

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer if known)
   - #1 ZYPREXA-ORAL (OLANZAPINE)(OLANZAPINE)
   - #2
2. Dose, frequency & route used
   - #1 QHS
   - #2
3. Therapy dates (if unknown, give duration)
   - #1 NI, unknown
   - #2
4. Diagnosis for use (indication)
   - #1 NI
   - #2
5. Event abated after use stopped or dose reduced
   - #1 ☐ yes ☐ no ☒ doesn't apply
   - #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   - #1 NI
   - #2
7. Exp. date (if known)
   - #1 NI
   - #2
8. Event reappeared after reintroduction
   - #1 ☐ yes ☐ no ☐ doesn't apply
   - #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # for product problems only (if known)
   - #1
   - #2
10. Concomitant medical products and therapy dates (exclude treatment of event)

11 Unknown

G. All manufacturers

1. Contact office - name/address (& mfr'ing site for devices)

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

2. Phone number: 317-276-7588

3. Report source (check all that apply)
   - ☐ foreign
   - ☐ study
   - ☐ literature
   - ☐ consumer
   - ☐ health professional
   - ☐ user facility
   - ☒ company representative
   - ☐ distributor
   - ☐ other

4. Date received by manufacturer: 22/MAR/2005

5. (A)NDA #: 20-592
   - IND #:
   - PLA #:
   - pre-1938: ☐ yes
   - OTC product: ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
   - ☐ 5-day ☒ 15-day
   - ☐ 10-day ☐ periodic
   - ☒ initial ☐ follow-up #

8. Adverse event term(s)

MURDER

UNEVALUABLE EVENT

9. Mfr report number: US_0503114723

E. Initial reporter

1. Name, address & phone #: (b) (6)

2. Health professional? ☐ yes ☒ no

3. Occupation: *

4. Initial reporter also sent report to FDA: ☐ yes ☐ no ☐ unk

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Item completed on continuation pages

DSS

APR 0 6 2005

APR 0 7 2005

Individual Safety Report

4031029-6-00-02

Eli Lilly and Company

MED WATCH

US_0503214723

B.5 Describe event or problem

[continuation:] EVENT AND CLAIMED HE HAD A BAD REACTION TO OLANZAPINE. THE STATUS OF THE OLANZAPINE THERAPY WAS NOT PROVIDED.

B.6 Occupation

SALES REPRESENTATIVE

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5790200

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 12-May-2005 Mfr Rcvd Date: 11-May-2005 Mfr Control #: US-GLAXOSMITHKLINE-A0555879A

Patient Information:

Age: 35 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Unknown		PRODUCT USED FOR UNKNOWN INDICATION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Aggression	
Homicide	
Injury	U

Event/Problem Narrative:

This case was reported in a newspaper article and described the occurrence of violence in a 35-year-old male patient who received Paroxetine hydrochloride (Paxil) for drug use for unknown indication. On an unknown date, the patient started Paroxetine hydrochloride (unknown). On [redacted], the patient stabbed and killed [redacted]. He was indicted for assault and murder. This case was assessed as medically serious by GSK. The outcome of the events is unknown. It was reported that the patient was taking Paroxetine hydrochloride when the assaults occurred. A family member subsequently reported that the patient's attorney was considering a 'Paxil Defense."

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5790200

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 12-May-2005 Mfr Rcvd Date: 11-May-2005 Mfr Control #: US-GLAXOSMITHKLINE-A0555879A

Patient Information:

Age: 35 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Unknown		PRODUCT USED FOR UNKNOWN INDICATION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Aggression	
Homicide	
Injury	U

Event/Problem Narrative:

This case was reported in a newspaper article and described the occurrence of violence in a 35-year-old male patient who received Paroxetine hydrochloride (Paxil) for drug use for unknown indication. On an unknown date, the patient started Paroxetine hydrochloride (unknown). On [redacted], the patient stabbed and killed [redacted]. He was indicted for assault and murder. This case was assessed as medically serious by GSK. The outcome of the events is unknown. It was reported that the patient was taking Paroxetine hydrochloride when the assaults occurred. A family member subsequently reported that the patient's attorney was considering a 'Paxil Defense."

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5790200

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No

Sender Organization: GLAXOSMITHKLINE

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5798213

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: DE,HO (A)NDA/BLA: 020031 /

FDA Rcvd Date: 18-May-2005 Mfr Rcvd Date: 12-May-2005 Mfr Control #: US-GLAXOSMITHKLINE-A0558578A

Patient Information:

Age: 41 YR Sex: Female Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Unknown		ANTIDEPRESSANT THERAPY		
2	METFORMIN HYDROCHLORIDE		Unknown		MEDICAL DIET		
3	TRAZODONE HYDROCHLORIDE		Unknown		PRODUCT USED FOR UNKNOWN INDICATION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE
2	METFORMIN HYDROCHLORIDE			U				
3	TRAZODONE HYDROCHLORIDE			U				

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Completed suicide	U
Homicidal ideation	
Homicide	
Suicidal ideation	

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5798213

Event/Problem Narrative:

This case was reported in a newspaper article and described the occurrence of murder/suicide in a 41-year-old female patient who received Paroxetine hydrochloride (Paxil) over a period of Unknown for antidepressant therapy. A physician or other health care professional has not verified this report. Co-suspect medication included Trazodone and Metformin. On an unknown date, the patient started Paroxetine hydrochloride (unknown), unknown dosing. On an unknown date, the patient had been hospitalized. She had told a friend that she intended to kill her children. On [redacted] the patient was [redacted] after telling the doctor [redacted] On [redacted], the patient shot her [redacted] and committed suicide.

Relevant Medical History:

Disease/ Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No Sender Organization: GLAXOSMITHKLINE

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5798213

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5801931

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: HO,OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 06-Jan-2006 Mfr Rcvd Date: 03-Jan-2006 Mfr Control #: US-GLAXOSMITHKLINE-A0559419A

Patient Information:

Age: 8 YR Sex: Female Weight: 38.2 KG

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral		ANXIETY	04-Aug-2003	29-Aug-2003
2	RISPERDAL		Unknown		ANXIETY	2003	2003
3	ZOLOFT		Oral	25MG Unknown	ANXIETY	2003	2003

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE
2	RISPERDAL			U				
3	ZOLOFT			U				

Event Information:

Preferred Term (MedDRA® Version: 17.0) ReC

Aggression
Agitation
Anxiety
Homicide
Insomnia
Personality change
Psychomotor hyperactivity
School refusal

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5801931

Suicidal ideation U

Event/Problem Narrative:

This case was reported by a lawyer via the litigation process, and described the occurrence of suicidality in an eight year old female patient who received Paroxetine hydrochloride (Paxil) over an unknown period of time for treatment of anxiety. Concurrent medical conditions included anxiety disorder, esotropia, family history of depression and wears glasses full time. Co-suspect medications included Zoloft and Risperdal. In 2003 the patient started Paroxetine hydrochloride (Unknown route) at an unknown dosing. At an unknown time after starting Paroxetine hydrochloride, the patient experienced suicidality, homicidal act, exacerbation of anxiety, suicidal threats, violent behavior, school refusal, hyperactive, anxiety and apprehension. The patient was hospitalized. Treatment with Paroxetine hydrochloride was discontinued in 2003. Review of the medical record indicated that the patient was examined in the emergency room on [redacted] for complaints of "anxiety." The patient was experiencing anxiety about [redacted]. The patient's mother informed a physician that the patient had started Zoloft 25 mg on 29 August 2003, and became hyperactive and the medication was discontinued approximately three days ago. The physician noted in the record that the patient had "agitation due to medication side effects." He advised her to "discontinue SSRI." The patient's mother also reported that the patient had previously taken Paxil and also had problems with that medication. No additional information provided regarding the patient taking Paroxetine. The parent's refused inpatient hospitalization for the patient at this time, and the patient was discharged home with her parents after contracting for safety with a psychiatrist. On [redacted], the patient became combative and violent with her mother. She was hitting her mother with her [redacted]. The patient took a knife [redacted]. The patient was taken to the emergency room for evaluation. The mother reported to a physician that the patient was on Risperdal and selective serotonin reuptake inhibitors (SSRI), but the SSRI's made her more agitated. She stated that they attempted to taper them and substitute Risperdal. The mother stated that the patient was off all medication now. A physician noted in the record during the emergency room visit, that the patient's anxiety started three months ago and the patient was started on Paxil. The patient's behavior became worse, and she was placed on Zoloft. The mother reported that the Zoloft made her hyperactive, and was also eventually discontinued. The patient was hospitalized for four days. While in the hospital, the patient was prescribed Ativan. The patient was discharged from the hospital on [redacted], and was not prescribed any medication. The outcome of the events is unknown. Records from the licensed social worker reported that the patient recieved Paxil tablets from 04 August 2003 to 29 August 2003 for anxiety and panic disorder. The patient's anxiety had increased when it was time to return to school and for her mother to return to work. The patient's behavior became worse when she was on Paxil. Paxil was discontinued and Zoloft started on 29 August 2003. Patient's behavior became [redacted] and she had increased energy to [redacted]. Patient was admitted to the

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5801931

psychiatric hospital on [redacted] and through [redacted] and Zoloft was discontiued. Notes dated 02 October 2003 reported that the patient had improved. Notes dated 03 February 2004 reported that the patient was happy at school and home. She was "functioning at age appropriate level in all areas."

Relevant Medical History:

The patient's mother has a history of depression, and has been treated with Zoloft unsuccessfully. Family history of depression in [redacted] and [redacted]. The patient developed anxiety approximately two years ago. (NOS). The patient's mother reported that during the previous school year the patient was fearful of a school employee.

Disease/Surgical Procedure	Start Date	End Date	Continuing?
ANXIETY DISORDER			UNKNOWN
ESOTROPIA			UNKNOWN
EYEGLASSES WEARER			UNKNOWN
FAMILIAL RISK FACTOR			UNKNOWN

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5801931

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No

Sender Organization: GLAXOSMITHKLINE

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5855053

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 09-Aug-2005 Mfr Rcvd Date: 05-Aug-2005 Mfr Control #: US-GLAXOSMITHKLINE-A0589020A

Patient Information:

Age: 60 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral				
2	WELLBUTRIN						

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE
2	WELLBUTRIN			U				GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA® Version: 17.0)	ReC
Homicide	U

Event/Problem Narrative:

This case was reported in a newspaper article and described the occurrence of homicide by a 60-year-old male patient who received Paroxetine hydrochloride (Paxil). On an unknown date, the patient started Paroxetine hydrochloride (oral). At an unknown time after starting Paroxetine hydrochloride, the patient [redacted] The victim died from multiple gunshot wounds [redacted] The patient claimed that the victim [redacted] The newspaper article stated that the patient was [redacted] This case was assessed as medically serious by GSK. The outcome of the event is unknown.

[redacted]

e4745031-7-00-01e

For use by user facilities, importers and manufacturers for MANDATORY reporting Watson Laboratories, Inc

FDA Form e Approva 11-JUN-1998

MFR report # 2005 02789

FDA Use Only

A. Patient information

1 Patient identifier [redacted] in confidence

2 Age at time of event UNK

Date of birth UNK

3 Sex ☐ female ☒ male

4 Weight UNK lbs or UNK kgs

B. Adverse event or product problem

1 ☒ Adverse event and/or ☐ Product problem (e.g. defect/malfunction)

2 Outcomes attributed to adverse event (check all that apply)

☐ death
☐ life threatening
☐ hospitalization - initial or prolonged
☒ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☒ other overdose, med sig

3 Date of event UNK

4 Date of this report 08/10/2005

5 Describe event or problem

murder of [redacted] [Murder]
chronic addiction to medications [Drug dependence]
withdrawal reaction [Drug withdrawal syndrome]
psychological injuries [Mental disorder]
unconsciousness [Loss of consciousness]
physical injuries [Injury]

Case Description:
Date of initial report: 29-JUL-2005
A legal case was received describing a male patient (Patient Initials: [redacted]) who was incarcerated for the murder of [redacted] and claimed he experienced chronic addiction to prescribed medications, withdrawal reactions, physical injuries, psychological injuries, and unconsciousness after receiving Hydrocodone and Paxil.

Comment:
continued in additional info section...

6 Relevant tests/laboratory data, including dates
NI

7 Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
NI

C. Suspect medication(s)

1 Name (give labeled strength & manufacturer, if known)
#1 Hydrocodone (continued)
#2 PAXIL(PAROXETINE (continued)

2 Dose, frequency & route used
#1 500 mg, 8 (continued)
#2 40 mg, daily, UNK

3 Therapy dates (if unknown, give duration)
#1 duration 730 days
#2 duration 730 days

4 Diagnosis for use (indication)
#1 unspecified indication
#2 unspecified indication

5 Lot # (if known)
#1 unknown
#2 unknown

7 Exp. date (if known)
#1 UNK
#2 UNK

8 NDC # - for product problems only (if known)

6 Event abated after use (stopped or dose reduced)
#1 ☐ yes ☐ no ☐ doesn't apply UNK
#2 ☐ yes ☐ no ☐ doesn't apply UNK

9 Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply UNK
#2 ☐ yes ☐ no ☐ doesn't apply UNK

10 Concomitant medical products and therapy dates (exclude treatment of event)
NI

G. All Manufacturers

1 Contact office - name/address (& mfrng site for devices)
Watson Laboratories, Inc.

311 Bonnie Circle
Corona, CA 92880 UNITED STATES

2 Phone number 9512701400

3 Report source (check all that apply)
☐ foreign
☐ study
☐ literature
☒ consumer
☐ health professional
☐ user facility
☐ company representative
☐ distributor
☐ other

4 Date received by manufacturer 07/29/2005

5 (A)NDA # 089-883
IND #
PLA #
pre 1938 ☐ yes
OTC product ☐ yes

6 If IND, protocol #

7 Type of report (check all that apply)
☐ 5-day ☒ 15-day
☐ 10-day ☐ periodic
☒ initial ☐ follow-up #

8 Adverse event term(s)
Murder, Drug dependence, Drug withdrawal syndrome, Mental disorder, Loss of consciousness, Injury

9 MFR report number 2005-02789

E. Initial reporter

1 Name & address [redacted] phone # UNK

2 Health professional? ☐ yes ☒ no

3 Occupation Not Applicable

4 Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk

FDA Form / Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

DSS
AUG 15 2005

AUG 11 2005

15 Aug 2005 10:17:05

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5867561

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 26-Aug-2005 Mfr Rcvd Date: 22-Aug-2005 Mfr Control #: US-GLAXOSMITHKLINE-A0571285A

Patient Information:

Age: 30 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral		MAJOR DEPRESSION	2003	
2	HEROIN		Unknown		PRODUCT USED FOR UNKNOWN INDICATION		
3	METHAMPHETAMINE HYDROCHLORIDE		Unknown		PRODUCT USED FOR UNKNOWN INDICATION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE
2	HEROIN			U				
3	METHAMPHETAMINE HYDROCHLORIDE			U				

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Homicide	U
Mental disorder	

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5872820

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Y Country: USA Outcomes: DE (A)NDA/BLA: 021346 /

FDA Rcvd Date: 06-Sep-2005 Mfr Rcvd Date: 26-Aug-2005 Mfr Control #: US-JNJFOC-20050806707

Patient Information:

Age: Sex: Female Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	RISPERDAL CONSTA		Intramuscular		PRODUCT USED FOR UNKNOWN INDICATION		
2	RISPERIDONE				PRODUCT USED FOR UNKNOWN INDICATION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	RISPERDAL CONSTA			N				
2	RISPERIDONE			N				

Event Information:

Preferred Term (MedDRA® Version: 17.0)	ReC
Completed suicide	N
Homicide	N

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5872820

Event/Problem Narrative:

Spontaneous report received from a physician via a company representative. 1-159101492. A woman (age, weight, and history unknown), received risperidone (microspheres, intra-muscular), dosage unknown, initiated in Aug-05, for an unknown indication. Additional company suspect drug: risperidone (unspecified), dosage unknown, initiated in Aug-05, for an unknown indication. No concomitant medications were reported. Two to three days after receiving an initial injection of risperidone, the patient killed her son and then herself (exact cause of death not provided). This report is serious (death).

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No Sender Organization: JOHNSON AND JOHNSON

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5872820

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5882305

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Y Country: USA Outcomes: DE,OT (A)NDA/BLA: 020639

FDA Rcvd Date: 14-Oct-2005 Mfr Rcvd Date: 06-Oct-2005 Mfr Control #: 2005UW13792

Patient Information:

Age: 28 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	SEROQUEL		Oral	AN UNKNOWN QUANTITY CRUSHED AND PUT INTO BEER		28-Aug-2005	28-Aug-2005
2	UNSPECIFIED INGREDIENT		Oral	DRANK 2 BEERS		28-Aug-2005	28-Aug-2005

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	SEROQUEL	1 Day						ZENECA
2	UNSPECIFIED INGREDIENT	1 Day						

Event Information:

Preferred Term (MedDRA Version: 18.0 ReC

Dizziness
Loss of consciousness
Overdose
Toxicity to various agents
Victim of crime

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5882305

Preferred Term (MedDRA Version: 17.0 ReC

Event/Problem Narrative:

{POLYSUBSTANCE INTOXICATION, DRUG OVERDOSE, PASSED OUT, DIZZY, VICTIM OF CRIME} A report was received from a physician via a pharmaceutical sales specialist and an article posted in the on and concerning a 28-year-old male victim. The male victim received an unknown dose of SEROQUEL (quetiapine fumarate) orally that had been prescribed to a female patient for her (unspecified) mental illness. On the male victim died after receiving a drug overdose when a woman who he met at . It was reported in an article in the that a woman

The article went on to say that after he passed out, the

The victim's body was on the floor . The victim's assessed as pulseless, and began to administer cardiopulmonary resuscitation. It was noted that when rescuers arrived, the police stopped them at the door indicating that the victim was already dead. Per the newspaper article, an autopsy was performed which detected a toxic amount of Seroquel in the victim's system and indicated a drug overdose as the likely cause of his death. In a follow-up article posted in the , it was noted that toxicology tests showed that the victim's bloodstream

The pathologist who performed the autopsy on the victim's body noted that there was no other evidence that would explain the man's death. The pathologist classified the victim's cause of death as . Per the pathologist

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5882305

[redacted] The company physician considered the events of toxic drug overdose, polysubstance intoxication, passed out, dizzy and victim of crime to be serious due to the criteria of death and medically important. Corrected report. Information from this case (the victim's case) was also entered into the perpetrator's case (case 2005UW14509). The event terms amended from Homicide, Drug Overdose, Drug Overdose, Passed Out, Dizzy, and Intentional Misuse to Drug Overdose, Drug Toxicity, Passed Out, Dizzy, and Victim of Crime. Summary of follow-up information received by AstraZeneca on 06-OCT-2005 amended the event terms from Drug Overdose, Drug Toxicity, Passed Out, Dizzy, and Victim of Crime to Polysubstance Intoxication, Drug Overdose, Passed Out, Dizzy, and Victim of Crime. In addition, laboratory results regarding toxicology studies and blood alcohol levels were obtained and details surrounding the victim's death and cause of death (due to polysubstance intoxication) were received.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Blood alcohol	0.122	%	<0.08		

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No Sender Organization: ASTRAZENECA

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5882305

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5888893

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: USA Outcomes: OT (A)NDA/BLA: 020639 /

FDA Rcvd Date: 30-Sep-2005 Mfr Rcvd Date: 15-Sep-2005 Mfr Control #: 2005UW14509

Patient Information:

Age: Sex: Female Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	SEROQUEL		Oral		MENTAL DISORDER		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	SEROQUEL							ZENECA

Event Information:

Preferred Term (MedDRA® Version: 17.0) ReC

Homicide

Intentional product misuse

Legal problem

Theft

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5888893

Preferred Term (MedDRA Version: 18 0 ReC

Event/Problem Narrative:

{HOMICIDE, INTENTIONAL MISUSE, STEALING, LEGAL ISSUE} A report was received from a physician via a pharmaceutical sales specialist and an article posted in the [redacted] on [redacted] concerning a female patient. The female patient was under treatment with SEROQUEL (quetiapine fumarate) for an unspecified mental illness. On [redacted], the patient [redacted] It was reported in an article in the [redacted] Per the newspaper article, an autopsy detected a toxic amount of Seroquel in the victim s system and indicated a drug overdose as the likely cause of his death. Per the [redacted] article posted in the [redacted] The company physician considered the events of homicide, intentional misuse, stealing and legal issues to be serious and medically important. This information was initially reported as one case 2005UW13792. The case has since been split into two cases (case 2005UW13792 and 2005UW14509).

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5888893

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No

Sender Organization: ASTRAZENECA

Literature Text:

Case ID: 5890599

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: CAN Outcomes: HO (A)NDA/BLA: 020031 /

FDA Rcvd Date: 01-Nov-2011 Mfr Rcvd Date: 28-Oct-2011 Mfr Control #: CA-GLAXOSMITHKLINE-A0578480A

Patient Information:

Age: 47 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL	60 MG/	Oral	60MG Per day	MAJOR DEPRESSION	Jul-2003	2004

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL							GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA Version: 17.0) ReC

Agitation
Akathisia
Delusion
Depression
Drug ineffective
Homicide
Hyperhidrosis
Insomnia
Major depression
Mania
Mental disorder
Obsessive thoughts
Personality change

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 5935626

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020031 /

FDA Rcvd Date: 05-Dec-2005 Mfr Rcvd Date: 29-Nov-2005 Mfr Control #: US-GLAXOSMITHKLINE-A0243563A

Patient Information:

Age: 16 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral		DEPRESSION	18-Sep-1995	
2	ALCOHOL						

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				SMITHKLINE BEECHAM
2	ALCOHOL			U				

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Feeling abnormal	
Feeling jittery	
Homicide	U
Psychotic disorder	

Individual Safety Report

5074682-8-00-01

Adverse Event Reporting Program

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting to FDA. Eli Lilly and Company

US2006[illegible]

A. PATIENT INFORMATION

1. Patient Identifier: [redacted] In confidence
2. Age at Time of Event: 45 Years — or Date of Birth: UNK
3. Sex: ☐ Female ☒ Male
Weight: UNK kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

☒ Adverse Event ☐ Product Problem (e.g. defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death ☐ Disability
☐ Life-threatening ☐ Congenital Anomaly
☐ Hospitalization - initial or prolonged ☐ Required Intervention to Prevent Permanent Impairment/Damage
☒ Other: mad sign

3. Date of Event (mo/day/year): 01/--/2006
4. Date of This Report (mo/day/year): 07/31/2006

5. Describe Event or Problem
Event Verbatim (PREFERRED TERM) (Related symptoms if any separated by commas)
[redacted][Homicide]
constant suicidal thought[Suicidal ideation]
psychotic depression[Major depression]
bipolar illness[Bipolar disorder]
delusions, allowed him enough energy to acte on the delusions
caused by mental illness[Delusion]

Case Description:
[redacted]

6. Relevant Tests/Laboratory Data, Including Dates
NI

7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
#1 01/20/2006 to UNK Historical AR, (continued)
#2 UNK, Historical Drug, PAXIL (continued)
#3 UNK, Medical Condition, Depression (continued)
#4 [illegible]1995 to UNK Medical Condition, (continued)
continued in additional info section...

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT MEDICATION(S)

1. Name (Give strength & manufacturer, if known)
#1 PAROXETINE HYDROCHLORIDE UNKNOWN (continued)
#2

2. Dose, Frequency & Route Used
#1. UNK, UNK, Oral
#2.

3. Therapy Dates (if unknown, give duration)
#1. 01/06/2006, duration UNK
#2

4. Diagnosis for Use (Indication)
#1. Depression
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply UNK
#2. ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot # (if known)
#1. UNK
#2.

7. Exp. Date (if known)
#1. UNK
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply UNK
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# (For product problems only)

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
ESZOPICLONE (ESZOPICLONE) UNK to UNK
PAXIL (PAROXETINE HYDROCHLORIDE) 01/06/2006 to
continued in additional info section...

G. ALL MANUFACTURERS

1. Contact Office - Name, Address and Phone Number (for Devices)
Eli Lilly and Company

Lilly Corporate Center
Indianapolis, IN 46285 UNITED STATES

2. Phone Number

3. Report Source (Check all that apply)
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☒ Other: D&A

4. Date Received by Manufacturer (mo/day/yr)
07/28/2006

5. (A) NDA # 18-936
IND #
PLA #
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5 day ☒ 15 day
☐ 10 day ☐ Periodic
☐ Initial ☒ Follow-up # 1

8. Adverse Event Term(s)
Homicide, Suicidal ideation, Major depression, Bipolar disorder, Delusion

9. Manufacturer Report Number
US200604002470

E. INITIAL REPORTER

1. Name and Address
[redacted]

Phone #
[redacted]

2. Health Professional?
☐ Yes ☒ No

3. Occupation
Consumer

4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No ☒ Unk

DSS

AUG 04 2006

AUG 03 2006

Case ID: 6077845

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: OT (A)NDA/BLA: 020031

FDA Rcvd Date: 21-Feb-2007 Mfr Rcvd Date: 14-Feb-2007 Mfr Control #: US-GLAXOSMITHKLINE-A0611010A

Patient Information:

Age: 45 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Oral		DEPRESSION		Jan-2006
2	PROZAC		Oral		DEPRESSION	Jan-2006	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE
2	PROZAC			U				

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Bipolar disorder	
Delusion	
Homicidal ideation	
Homicide	U
Major depression	
Psychotic disorder	
Thinking abnormal	
Weight increased	

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 6167713

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** Y **Country:** USA **Outcomes:** OT **(A)NDA/BLA:** 019908 /

FDA Rcvd Date: 20-Jun-2008 **Mfr Rcvd Date:** 18-Jun-2008 **Mfr Control #:** US-SANOFI-SYNTHELABO-A03200808398

Patient Information:

Age: 32 YR **Sex:** Male **Weight:** 81.6 KG

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	AMBIEN	5 MG/	Oral		INSOMNIA	2003	06-Oct-2006
2	AMBIEN	10 MG/	Oral				Oct-2006

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	AMBIEN	3 Year						
2	AMBIEN	3 Year						

Event Information:

Preferred Term (MedDRA® Version: 17.0) **ReC**

Abnormal behaviour
Aggression
Amnesia
Confusional state
Drug withdrawal convulsions
Fatigue
Fear
Homicide
Hyperhidrosis
Intentional overdose

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 6181156

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: N Country: USA Outcomes: DE (A)NDA/BLA: 020031 /

FDA Rcvd Date: 07-Dec-2006 Mfr Rcvd Date: 06-Dec-2006 Mfr Control #: US-GLAXOSMITHKLINE-A0630818A

Patient Information:

Age: 39 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PAXIL		Unknown		DEPRESSION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PAXIL			U				GLAXOSMITHKLINE

Event Information:

Preferred Term (MedDRA® Version: 17.0)	ReC
Completed suicide	U
Hallucination, auditory	
Homicide	
Thinking abnormal	

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 9241120

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: JPN Outcomes: LT,OT (A)NDA/BLA: 021323 /

FDA Rcvd Date: 17-May-2013 Mfr Rcvd Date: 10-May-2013 Mfr Control #: JP-FRI-1000044481

Patient Information:

Age: 80 YR Sex: Male Weight: 70 KG

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	LEXAPRO	10 MG QD	Oral	10 mg	Depression	28-Mar-2013	30-Mar-2013

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	LEXAPRO	3 Day		A				FOREST

Event Information:

Preferred Term (MedDRA Version: 17.0) ReC

Homicide

Suicide attempt

Event/Problem Narrative:

Mochida reference number: A20130592

Case reference number DKLU1090235, is a spontaneous case received from a health professional in Japan.

This case concerns a 80 year old Male administered Lexapro film-coated tablets (generic name: escitalopram), 10 mg daily, from 28/Mar/2013 to 30/Mar/2013 for depression.

Behaviours that harm to others (verbal abuse or violent actions etc) in the past: None. Suicidal ideations or attempts in the past: None.

On an unknown date in Feb/2013, the patient's wife was diagnosed with dementia.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 9241120

On an unknown date in Mar/2013, the patient was suffering for his wife whose dementia became noticeable.

On 28/Mar/2013, the patient had his son with psychiatric disorders due to an injury at his youth besides his wife with dementia and the reporting physician had multiple consultations with the patient whose chief complaints were anxiety and feeling irritated for the future. The reporting physician prescribed escitalopram to energize him after observing his facial expression of being worn out and his attitude of being depressed.

On 30/Mar/2013, the last day of escitalopram administration.

On an unknown date, compliance with escitalopram was unknown, although the patient visited the reporting clinic every day after initiation of escitalopram. It did not seem that there was a big change in three days up to the incident, although regarding the patient's mental condition, he was depressed and anxious throughout the course from escitalopram initiation to homicide and suicide attempt.

On [redacted] at around 10:00 the patient strangled his wife to death and then he attempted a suicide with a [redacted]. He was found unconscious. It seemed that the patient committed a family suicide.

On an unknown date, it was said that the patient was emergently transported and became alert after admitted to a hospital.

The patient s medical history comprised Hyperlipidaemia, Hypertension, Sleep loss, Gastritis, Pain, and Common cold.

Concomitant medication included:
Mevan (Pravastatin sodium), unknown form, oral, 10 mg daily dose, from 03/Mar/2009 to 30/Mar/2013 for hyperlipidaemia.
Amlodipine OD (Amlodipine besilate), unknown form, oral, 5 mg daily dose, from 21/May/2012 to 30/Mar/2013 for hypertension.
Depas (etizolam), unknown form, 0.5 mg daily from 13/Sep/2011 to 30/Mar/2013 for sleep loss.
Rebamipide (Rebamipide), unknown form, oral, 300 mg daily from 21/Dec/2010 to 30/Mar/2013 for gastritis.
Neurotropin (An extract obtained from inflammatory rabbit skin inoculated by vaccinia virus), unknown form, oral, 12 UT, from 21/Dec/2010 to 30/Mar/2013 for pain.
Ringereaze (Loxoprofen sodium hydrate), unknown form, oral, 180 mg daily, from 15/Feb/2011 to 30/Mar/2013 for pain.
PA (Non-pyrine cold preparation), unknown form, oral, 6 DF, from 21/Mar/2013 to 30/Mar/2013 for common cold.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 9241120

LATEST FOLLOW-UP INFORMATION RECEIVED ON 10/May/2013
The case has been updated with the following information
- Narrative

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Gastritis			
Hyperlipidaemia			
Hypertension			
Insomnia			
Nasopharyngitis			
Pain			

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 9241120

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	AMLODIPINE OD	5 MG/QD	Oral	5 mg	Hypertension	21-May-2012	30-Mar-2013	
2	DEPAS	5 MG/QD	Oral	0.5 mg	Insomnia	13-Sep-2011	30-Mar-2013	
3	MEVAN	10 MG/QD	Oral	10 mg	Hyperlipidaemia	03-Mar-2009	30-Mar-2013	
4	NEUROTROPIN	TID	Oral	12 UT	Pain	21-Dec-2010	30-Mar-2013	
5	PA	2 DF/TID	Oral	2 DF	Nasopharyngitis	21-Mar-2013	30-Mar-2013	
6	REBAMIPIDE	100 MG/TID	Oral	300 mg	Gastritis	21-Dec-2010	30-Mar-2013	
7	RINGEREAZE	60 MG/TID	Oral	60 mg	Pain	15-Feb-2011	30-Mar-2013	

Reporter Source:

Study Report?: No **Sender Organization:** FOREST

Literature Text: