Case ID: 7979016

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** CAN **Outcomes:** OT, **(A)NDA/BLA:** 018936 /

FDA Rcvd Date: 22-Jan-2013 **Mfr Rcvd Date:** 14-Jan-2013 **Mfr Control #:** CA-ELI_LILLY_AND_COMPANY-CA201105008333

Patient Information:

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

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PROZAC			UNK UNK, unknown	Depression	24-Jun-2009	
2	PROZAC			UNK, unknown		2009	2009
3	PROZAC			UNK, unknown		Jun-2009	2009

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PROZAC			A				ELI LILLY AND CO
2	PROZAC			A				ELI LILLY AND CO
3	PROZAC			A				ELI LILLY AND CO

Event Information:

Preferred Term (MedDRA® Version: 18.0)	ReC
Agitation	
Anger	
Condition aggravated	
Feeling abnormal	
Homicide	
Mania	
Mental impairment	
Off label use	

Case ID: 7979016

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

Self injurious behaviour

Suicide attempt

Event/Problem Narrative:

This spontaneous case, reported by a consumer, from the newspaper articles containing two psychiatrists published on (b) (6), with additional information from another consumer from the newspaper articles by (b) (6) with additional information from previous consumer reporters, and additional information from another consumer reporter from the (b) (6), concerns a 16-year-old male patient of unknown origin.

Medical history included depression and drug and alcohol abuse. It was reported that he went from a (b) (6) Concomitant medications were not provided.

The patient received fluoxetine hydrochloride (Prozac) tablets for treatment of depression starting on 24Jun2009; dosage regimen and route of administration were not provided. Starting on an unspecified date, he seemed to be getting worse (no details provided) while taking fluoxetine (time to onset not provided). On an unspecified date, after starting fluoxetine, he began to act out violently and even tried to harm himself on several occasions. On approximately (b) (6), (b) (6) after starting the fluoxetine, he took an overdose of an unspecified medication that belonged to his (b) (6) in an apparent suicide attempt. This prompted his doctor to increase the fluoxetine dosage (no details provided) despite indications his mental state was worsening/mental deterioration (conflicting start date of Jun2009 provided for increased dose). On a (b) (6) in (b) (6), (b) (6) months after beginning fluoxetine, a friend of the patient went to the home of the patient and (b) (6) He then stabbed the victim. The victim died after suffering a (b) (6) stab (b) (6) The psychiatrist reporter in the article stated: (b) (6) The psychiatrist reported (b) (6) Health Canada rules stated fluoxetine was not for use by anyone younger than 18 (off label use). An attorney indicated the homicide was (b) (6) he cold-bloodedly stabbed his friend who (b) (6). The patient pleaded guilty to second-degree murder and was sentenced as a youth to (b) (6) years of custody and conditional supervision. The

Case ID: 7979016

homicide, tried to harm himself, suicide attempt, agitation with manic symptoms and mental state worsening/mental deterioration were considered serious by the company for their medical significance. He was weaned off of fluoxetine at his own request (dates not provided). Further information regarding the events, corrective treatment, and event outcomes was not provided.

The reporting psychiatrist assessed the homicide, self-injurious behavior, manic symptoms, and worsening of his condition as related to fluoxetine, it drove him over the edge and it contributed to his actions. He did not provide an opinion for the other events.

Update 21Sep2011: Additional information was received 17Sep2011 via a newspaper article containing HCP reporters; added 2 consumer reporters serious event of self harm. Upon review on 21Sep2011 it was determined that CA201106000890 is follow up to this case; therefore CA201106000890 will be deleted from the database. All information from CA201106000890 is contained in this case. Added fluoxetine indication for use and start date; entered serious events of suicide attempt, severe agitation and manic; non-serious events of feeling bad and off label use. Updated narrative and PSUR.

Update 13Oct2011: Additional information was received from previous consumer reporters from newspaper articles on 06Oct2011. Added medical history (depressed). Added address of patient. Added two fluoxetine dose tabs with start and stop dates. Added serious event of mental state worsening / mental deterioration. Added onset date for some events and stop date for off label use. Updated narrative. Regenerated PSUR comment.

Update 17Jan2013: Additional information was received on 14Jan2013 from a consumer via a company representative. Added consumer and company representative reporters. Updated health care professional reporter types. Updated patient demographics. Added suspect drug start date and event onset date for serious event of homicide. Narrative updated with additional information.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Alcohol abuse			
Depression			
Drug abuse			

Case ID: 7979016

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:** ELI LILLY AND CO

Literature Text: