



FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 6179785

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Outcomes:** DE, **(A)NDA/BLA:** 018936 /
FDA Rcvd Date: 09-Oct-2014 **Mfr Rcvd Date:** 08-Oct-2014 **Mfr Control #:** GB-ELI_LILLY_AND_COMPANY-US89103610A

Patient Information:

Age: 47 YR **Sex:** Male **Weight:**

Suspect Products:

| # | Product Name | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date |
|---|--------------|--------------------|-------|----------------|----------------|-------------|-------------|
| 1 | PROZAC | 20 MG/ | Oral | 20 mg, unknown | Depression | 10-Aug-1989 | 11-Sep-1989 |

| # | Product Name | Interval 1st Dose to Event | DeC | ReC | Lot# | Exp Date | NDC # | MFR/Labeler |
|---|--------------|-------------------------------|-----|-----|------|----------|-------|------------------|
| 1 | PROZAC | 36 Day | | A | | | | ELI LILLY AND CO |

Event Information:

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

- Aggression
- Agitation
- Fatigue
- Homicide
- Insomnia
- Suicide attempt
- Tangentiality



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Event/Problem Narrative:

PATIENT ENTERED HIS (b) (6) AND SHOT (b) (6) BEFORE SHOOTING HIMSELF. (b) (6) PRIOR TO THE SHOOTINGS, THE PATIENT HAD BEEN SEEN BY HIS PSYCHIATRIST AND EXHIBITED "TANGENTIAL THOUGHTS" AND "INCREASED LEVEL OF AGITATION AND ANGER." PATIENT **CONT FROM SEC 7* (b) (6) PZ REPORTEDLY WAS D/C 3 DAYS PRIOR TO SHOOTING.PT PREVIOUSLY TAKEN PZ IN 1988 BUT STOPPED TX DUE TO FATIGUE. COPY OF 102089 AND102689 NEWSPAPER ARTICLES ATTACHED. (b) (6) CORONER(DR. (b) (6) (b) (6))PROVIDED ADDT'L INFO IN PHONE CONVERSATION 103089. NEWSPAPER ARTICLE MENTIONED POSSIBLE PZ ASS'N. 1030 CONVERSATION W CORONER PROVIDED REPORTED BLOOD LEVELS. F/U 111689: COPY OF HOSP SUMMARY FROM THE CORONER'S ATTACHED. IF FURTHER INFO RETOX OR AUTOPSY DATA BECOMES AVAILABLE, WE WILL FORWARD. **CONT'D FROM SEC. 23** 2 PREVIOUS HOSPITALIZATIONS THAT HE MIGHT LIKE TO (b) (6) PREVIOUS DX,IN ADDT'N TO MANIC DEPRESSIVE, INC BORDERLINE PERSONALITY W PARANOID FEATURES, DYSTHYMIC DISORDER W PARANOID TYPE PERSONALITY. F/U 121589: AUTOPSY REPORT ATTACHED. F/U 1/9/90: PER DR. (b) (6) , CORONER:PT'S TIME OF DEATH LISTED @ APPROX. 8:40AM, HIS AUTOPSY STARTED AT 5:10 PM. BLOOD LEVELS DRAWN @ 5:20 PM.SITE FROM WHICHSAMPLE WAS COLLECTED WAS FROM THE HEART. F/U 7/26/90: MORE THAN A YEAR BEFORE THIS ASSAULT, PT HAD BROUGHT (b) (6) THIS REPORT WAS FOUND TO HAVE A DUPLICATE, US94061414A, WHICH WILL BE DELETED. F/U 23NOV94: PATIENT EXPERIENCED INSOMNIA WHILE ON PROZAC.

THIS IS FOUR OF FOUR CASES ALSO DESCRIBED IN THE ARTICLE: HAND J, TOBIN D. PROZAC DEFENSE MAY DEBUT IN CNY. THE POST-STANDARD. SUNDAY, NOVEMBER 17, 2002. SEE US_021089209, US_010157233 AND US95011864A.

THIS CASE WAS ALSO DESCRIBED IN THE FOLLOWING ARTICLE: LENZER J. FDA TO REVIEW "MISSING" DRUG COMPANY DOCUMENTS. BRITISH MEDICAL JOURNAL. 01JAN2005. THE FOLLOWING ARTICLES REPORTED ON THE ABOVE BMJ PUBLICATION THAT DESCRIBED THIS CASE:

(b) (6)

(b) (6)



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(b) (6)

EDIT 04-DEC-2002: ADDITIONAL INFORMATION RECEIVED IN THE LITERATURE (NEWSPAPER) ON 25-NOV-2002. ADDED NON HEALTH CARE PROVIDER REPORTER AND LOCAL ID OF "LIT." ADDED LITERATURE CITATION TO NARRATIVE PAGE. ON SUSPECT DRUG PAGE ENTERED DRUG TYPE AND ANSWERED EXPOSURE CONDITIONS OF HEPATIC AND RENAL IMPAIRED.

EDIT 10JAN05: UPDATED NARRATIVE PAGE TO ADD EIGHT LITERATURE CITATIONS.

UPDATE 30-NOV-2006: IT WAS NOTED ON 21-NOV-2006, IN THE ARTICLE, BY HEALY, D, HERXHEIMER, A, MENKES, D, THAT THIS CASE WAS DISCUSSED. NO NEW MEDICALLY SIGNIFICANT INFORMATION WAS PROVIDED. THE SOURCE OF THE CASE WAS CHANGED FROM SPONTANEOUS TO LITERATURE. LITERATURE CITATION WAS ADDED. SEE ALSO, CASES DISCUSSED IN THE ARTICLE; GB200611000347 AND US96112359A.

THIS CASE WAS DESCRIBED IN THE ARTICLES: HEALY, D, HERXHEIMER, A, MENKES, D. ANTIDEPRESSANTS AND VIOLENCE: PROBLEMS AT THE INTERFACE OF MEDICINE AND LAW. PLOS MEDICINE. 2006;3(9), 1478-1487, AND HEALY, D, HERXHEIMER, A, MENKES, D. ANTIDEPRESSANTS AND VIOLENCE: PROBLEMS AT THE INTERFACE OF MEDICINE AND LAW. INTERNATIONAL JOURNAL OF RISK AND SAFETY IN MEDICINE. 2007; 19: 17-33. Rokuro Hama. Harmful effects of medicines; Harmful effects of selective serotonin reuptake inhibitor (SSRI). Check up your medicine. 51. 20-28. Not Reported. Medication-Induced violence towards others. Prescrire International. 23 (150) (pp 153-155), 2014. Not Reported. IRS antidepressants and violence. Rev Prescrire, 2008; 28(296):431-431.

UPDATE 05-DEC-2006: UPON REVIEW OF CASE NOTED THAT LISTEDNESS WAS SHOWING AS "UNKNOWN" FOR MOST OF THE EVENTS AND THERE WAS NO PSUR COMMENT. LISTEDNESS ADDED FOR EVENTS AND PSUR COMMENT ADDED.

UPDATE 25JAN2008: DUPLICATE ARTICLE BY THE SAME AUTHORS IN A DIFFERENT JOURNAL RECEIVED ON 22JAN2008. ADDED REPORTER AND CITATION INFORMATION. UPDATED NARRATIVE.

Update 23Jan2014: A new citation was received on 21Jan2014. Added citation to narrative and added author; no new clinical information was added to the case.



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Edit 30JAN2014: Edit performed to amend E2B Company number to reflect country of case. No other changes.

Edit 31Jan2014: Upon internal review, for submission purposes added suspect drug action taken, added the as reported descriptions for the coded events of agitation and insomnia.

Edit 03Feb2014: Upon internal review, removed onset date for event of fatigue as med sig edit.

Update 16Sep2014. A new citation was received on 15Sep2014; no new clinical information was added

Update 08Oct2014: Additional citation received on 08Oct2014 via a literature search from another article; no new clinical information added.

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 |
|---|--------------|--------------------|-------|--------------|----------------|------------|----------|-------------------------------|
| 1 | LITHIUM | TID | | UNK, 3/D | | | | |
| 2 | TEMAZEPAM | | | UNK, unknown | | | | |
| 3 | TRAZODONE | | | UNK, other | | | | |



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Reporter Source:

Study Report?: No

Sender Organization: ELI LILLY AND CO

Literature Text: Healy, D, Herxheimer, A, Menkes, D..Antidepressants and Violence: Problems at the Interface of Medicine and Law..PLoS Medicine. 2006;3(9):1478-1487.