

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Mr. report #
US_980809092

Individual Safety Report



3138497-X-00-01

A. Patient information

1. Patient Identifier [REDACTED]	2. Age at time of event: 39 yrs	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 130 lbs or 59 kgs
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B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

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

<input checked="" type="checkbox"/> death 07/05/98	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input checked="" type="checkbox"/> other: MI

3. Date of event (month/year): 05/JUL/1998

4. Date of this report (month/year): 30/SEP/1998

5. Describe event or problem

THIS CASE, REPORTED BY A PSYCHIATRIST, CONCERNS A 39-YEAR OLD CAUCASIAN FEMALE WHO DIED; CAUSE OF DEATH PER CORONER WAS "TOXIC EFFECTS OF FLUOXETINE AND PROPOXYPHENE". THE PATIENT WAS RECEIVING FLUOXETINE (PROZAC) 80 MG DAILY FOR CHRONIC DEPRESSION. THE PATIENT, WHO HAD A HISTORY OF ALCOHOLISM TREATED WITH DISULFIRAM AND SCHIZOPHRENIA, HAD BEEN RECEIVING RISPERIDONE (RISPERDAL) 3 MG TWICE DAILY FOR A LONG PERIOD OF TIME, TRIHEXYPHENIDYL AND BENZONATATE.

APPROXIMATELY SEVEN MONTHS AFTER FLUOXETINE INITIATION (06JUL98), THE PATIENT, WHO WAS CHRONICALLY PSYCHOTIC, WAS FOUND DEAD IN HER APARTMENT; APPROXIMATE TIME OF DEATH WAS STATED TO BE 9:00 P.M. ON 05JUL98. SHE WAS FOUND SITTING AT A TABLE IN A *

6. Relevant tests/laboratory data including dates

Lab data:

Lab test or Procedure / Result Units / Date and Time / Reference to normal range

1) FLUOXETINE/2.0 MICROGRAM/MILLILITER/07-JUL-1998/ABOVE *

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

Relevant history / Concurrent conditions:

CHRONIC PSYCHOSIS (PSYCHOSIS NOS)
RHEUMATIC FEVER (RHEUMATIC FEVER W/O HEART INVOLVE)
SUICIDE ATTEMPTS (SUICIDE, SELF-INFLICTED INJURY) *

C. Suspect

1. Name (give labeled strength & ml/tablet, if known)

#1 PROZAC (FLUOXETINE HYDROCHLORIDE)

#2 PROPOXYPHENE NAPSYLATE-WITH ACETAMINOPHEN

2. Dose, frequency & route used

#1 80 mg/DAY

#2 UNK

3. Therapy dates (if unknown, give duration)

#1 ??-DEC-97 to 05-JUL-98

#2 NI to 05-JUL-98

4. Diagnosis for use (indication)

#1 CHRONIC DEPRESSION

#2 NI

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 NI

7. Exp. date (if known)

#1 NI

#2 NI

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 product and therapy dates (exclude treatment of event)

1) RISPERDAL (RISPERIDONE)
Dose: 6 mg/DAY, Dates: NI to 05-JUL-1998, Route: PO2)

2) TRIHEXYPHENIDYL
Dose: UNK, Dates: NI to 05-JUL-1998, Route: PO3)

G. All manufacturers

1. Contact office - name/address (if mailing site for devices)

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

2. Phone number

NI

3. Report source (check all that apply)

foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other:

4. Date received by manufacturer (month/year)

21AUG98

(F/N: 21SEP98)

5. (A)NDA # 18-936

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 # 2

8. Adverse event term(s)

ACCIDENTAL OVERDOSE
ECCHYMOSIS
HEMORRHAGE *

9. Mr. report number

US_980809092

E. Initial reporter

1. Name, address & phone #

Dr. [REDACTED]
[REDACTED] STREET
[REDACTED]
[REDACTED] US

2. Health professional?

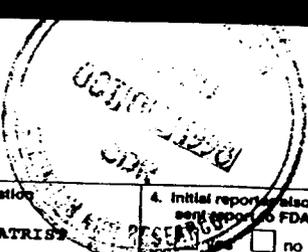
yes no

3. Occupation

PSYCHIATRIST

4. Initial report also sent report to FDA

no unk



FDA

Domestic Facsimile of
FDA Form 3500A

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.

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A.2. Date of birth(mo/day/yr)

39 years 32 weeks 4 days

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B.5. Describe event or problem

[continuation:] STRAIGHT-BACKED CHAIR WITH HER HEAD AND NECK BACK. THE APARTMENT WAS LOCKED FROM THE INSIDE; THERE WAS NO SIGN OF FOUL PLAY. THE PATIENT, WHO HAD A HISTORY OF SEVERAL "SPECTACULAR" SUICIDE ATTEMPTS INCLUDING ONE IN WHICH SHE CUT HER NECK AND WRISTS, HAD BEEN ISSUED A MEDICATION MONITORING SYSTEM. THE PATIENT'S PSYCHIATRIST STATED THAT THE PATIENT'S WEEKLY MEDICATION BOX WAS FOUND WITH THE APPROPRIATE NUMBER OF DOSES REMAINING. ACCORDING TO THE CORONER'S REPORT, NO MEDICATIONS WERE PRESENT IN THE ROOM; HOWEVER, PRESCRIPTION MEDICATION CONTAINERS WERE FOUND IN HER BEDROOM, THOSE FOR TRIHEXYPHENIDYL BEING EMPTY, BENZONATATE CONTAINING FORTY CAPSULES (60 CAPSULES PRESCRIBED) AND THAT FOR FLUOXETINE 20 MG CONTAINING SEVENTEEN CAPSULES (90 CAPSULES PRESCRIBED AND PRESCRIPTION ISSUED ON JANUARY 10, 1998). NO OTHER MEDICATIONS WERE FOUND ALTHOUGH IT WAS KNOWN THAT SHE WAS BEING TREATED WITH DISULFIRAM AND IT WAS REPORTED THAT HER MEDICATIONS WERE CURRENTLY BEING ISSUED IN LIMITED QUANTITIES.

THE TOXICOLOGY REPORT REVEALED THE FOLLOWING BLOOD LEVELS: FLUOXETINE 2.0 MCG/ML (THERAPEUTIC 0.09-0.4), NORFLUOXETINE 0.67 MCG/ML (THERAPEUTIC 0.072-0.258), PROPOXYPHENE 3.6 MCG/ML (THERAPEUTIC 0.13-1.07), NORPROPOXYPHENE 9.1 MCG/ML (THERAPEUTIC 0.80-2.64), ACETAMINOPHEN 111 MCG/ML (THERAPEUTIC 10-20), DIAZEPAM 0.01 MCG/ML (THERAPEUTIC 0.02-2.00), AND NORDIAZEPAM 0.05 MCG/ML (THERAPEUTIC 0.02-1.8). CARDIAC BLOOD DRAWN AT 11:00 A.M. ON 07JUL98 WAS USED FOR THE TOXICOLOGY SCREEN. TO THE KNOWLEDGE OF THE REPORTER, THE PATIENT DID NOT HAVE AN ACTIVE PRESCRIPTION FOR PROPOXYPHENE/ACETAMINOPHEN; THE PATIENT'S BOYFRIEND DID HAVE A PRESCRIPTION FOR THIS MEDICATION. NO ETHANOL WAS FOUND IN HER BLOOD, ALTHOUGH IT WAS KNOWN THAT THE PATIENT DID DRINK AT TIMES, AFTER DISCONTINUING HER DISULFIRAM. A VITREOUS SAMPLE REVEALED AN ALCOHOL LEVEL OF 0.01%. CARBON MONOXIDE LEVELS WERE WITHIN NORMAL RANGE.

THE PATIENT HAD A HISTORY OF CHILDHOOD RHEUMATIC FEVER BUT DID NOT HAVE ANY RESULTING CARDIAC SYMPTOMS AND DID NOT REQUIRE CARDIAC CARE. MICROSCOPIC EXAMINATION AT AUTOPSY REVEALED ACUTE PASSIVE CONGESTION OF THE HEART WITH OCCASIONAL SMALL FOCI OF FRESH INTRAMYOCARDIAL HEMORRHAGE AND ACUTE PASSIVE LIVER CONGESTION. MICROSCOPIC EXAMINATION OF THE LUNGS REVEALED ACUTE PASSIVE CONGESTION AND AREAS OF FRESH INTIA-ALVEOLAR HEMORRHAGE, SUBPLEURAL FIBROSIS, CHRONIC INFLAMMATION, SCATTERED DEPOSITS OF PARTICULATE MATTER IN THE PULMONARY INTERSTITIUM AND MORE EXTENSIVE DEPOSITS OF SIMILAR MATERIAL WITHIN THE PLEURA. SECTIONS SHOWED THE DEPOSIT MATERIAL TO BE BROWN TO GREY IN COLOR; SCATTERED SMALL SLENDER CRYSTALS WERE PRESENT AMONG THE DEPOSITS. FINAL DIAGNOSES FROM THE AUTOPSY REPORT CONSISTED OF CONTUSIONS ON THE LEFT THIGH AND BUTTOCK, VISCERAL CONGESTION, PULMONARY EDEMA, SLIGHT HYDROCEPHALUS AND MODERATE OBESITY. THE CORONER DETERMINED THE MANNER OF DEATH TO BE AN ACCIDENTAL OVERDOSE AND STATED THAT THE DEATH WAS POSSIBLY RELATED TO FLUOXETINE. THE REPORTING PSYCHIATRIST DOES NOT BELIEVE THAT THE PATIENT OVERDOSED AND DID NOT RELATE THE EVENT TO FLUOXETINE.

FOLLOW-UP RECEIVED 11SEP98: REPORTER PROVIDED INFORMATION FROM AUTOPSY REPORT. CHANGED EVENT "DEATH" TO "ACCIDENTAL OVERDOSE"; ADDED EVENT "ECCHYMOSIS". MOVED DARVOCET FROM CONCOMITANT MEDICATION TO SUSPECT MEDICATION FIELD. UPDATED LABS, CONCOMITANT MEDS, HISTORY, CAUSE AND DATE OF DEATH, AND TEXT.

FOLLOW-UP RECEIVED 21SEP98: AUTOPSY REPORT RECEIVED. ADDED REPORTER; UPDATED PATIENT, SUSPECT MEDICATION AND CONCOMITANT MEDICATION FIELDS; ADDED LAB VALUES; UPDATED TEXT. ADDED EVENTS "HEMORRHAGE", "CARDIOVASCULAR DISORDER", "LIVER DAMAGE", "LUNG EDEMA", "LUNG HEMORRHAGE", "LUNG FIBROSIS", "LUNG DISORDER", "HYDROCEPHALUS".

Cause of Death: TOXIC EFFECTS OF FLUOXETINE AND PROPOXYPHENE/ACETAMINOPHEN PER CORONER

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B.6. Relevant tests/laboratory data (including dates)

- [continuation:] 2) NORFLUOXETINE/0.67 MICROGRAM/MILLILITER/07-JUL-1998/ABOVE
 3) PROPOXYPHENE/3.6 MICROGRAM/MILLILITER/07-JUL-1998/ABOVE
 4) ACETAMINOPHEN/111 MICROGRAM/MILLILITER/07-JUL-1998/ABOVE
 5) NORPROPOXYPHENE/9.1 MICROGRAM/MILLILITER/07-JUL-1998/ABOVE
 6) DIAZEPAM/0.01 MICROGRAM/MILLILITER/07-JUL-1998/BELOW
 7) NORDIAZEPAM/0.05 MICROGRAM/MILLILITER/07-JUL-1998/WITHIN
 8) ALCOHOL LEVEL/0.01 PERCENT/07-JUL-1998/ABOVE

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

[continuation:] SCHIZOPHRENIA (DISORDERS, SCHIZOPHRENIC)
 ALCOHOLISM (SYNDROME, ALCOHOL DEPENDENCE)

HISTORY SCHIZOPHRENIA, CHRONIC PSYCHOSIS, ALCOHOLISM TREATED WITH DISULFIRAM. HISTORY OF SEVERAL "SPECTACULAR" SUICIDE ATTEMPTS INCLUDING ONE IN WHICH SHE CUT HER NECK AND WRISTS. HISTORY OF RHEUMATIC FEVER AS A CHILD; NO RESULTING CARDIAC SYMPTOMS OR CARDIAC CARE REQUIREMENTS.

Origin: CAUCASIAN

C.10. Concomitant medical product and therapy dates (exclude treatment of event)

[continuation:] BENZONATATE

Dose: UNK, Dates: NI to 05-JUL-1998, Route: PO4) DISULFIRAM

Dose: UNK, Dates: NI to 05-JUL-1998, Route: PO Indication: ALCOHOLISM

G.8. Adverse event term(s)

[continuation:]
 CARDIOVASCULAR DISORDER

LIVER DAMAGE

LUNG EDEMA

LUNG HEMORRHAGE

LUNG FIBROSIS

LUNG DISORDER

HYDROCEPHALUS

OCT 06 1998