DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**
Center for Drug Evaluation and Research
Office of Training and Communication
Freedom of Information Staff HFD-205
5600 Fishers Lane 12 B 05
Rockville, Maryland 20857

July 14, 1999

In Response Refer to File : F99-15489

Peter Breggin, MD
4628 Chestnut Street
Bethesda, MD 20814

Dear Dr. Breggin:

This is in response to your request of 7/7/99, in which you requested adverse events associated with the use of Fluvoxamine. Your request was received in the Center for Drug Evaluation and Research on 7/14/99.

Charges of $4.50 (Search $1.75, Review $1.75, Reproduction $1.00, Computer time $0) will be included in a monthly invoice. **DO NOT SEND ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE.**

If there are any problems with this response, please notify us in writing of your specific problem(s). Please reference the above file number.
Enclosed are copies of the adverse event cases. In order to help reduce processing time and costs, certain material has been deleted from the record(s) furnished to you because a preliminary review of the records indicated that the deleted material is not required to be publicly disclosed. If, however, you do desire to review the deleted material, please make an additional request to the following address:

Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane
Rockville, Maryland 20857

Should the Agency then deny this information, you would have the right to appeal such a denial. Any letter of denial will explain how to make this appeal.

This concludes the response for the Center for Drug Evaluation and Research.

Sincerely,

Hal Stepper

Hal Stepper
Freedom of Information Technician
Office of Training and Communications
Freedom of Information Staff, HFD-205

Individual Safety Report

<3263621-8-00-01>

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Solvay Pharmaceuticals

Page 1 of 2

Optional Facsimile — Approved by FDA on 3/22/94

Mfr report #: FLUV00299000121

LP/Dist report #:

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] in confidence	18 yrs or Date of birth: NI	☐ female ☒ male	UNK lbs or UNK kgs

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)
- ☒ death 04/20/99 (mo/day/yr)
- ☒ life-threatening
- ☐ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/day/yr): 04/20/99

4. Date of this report (mo/day/yr): 05/14/99

5. Describe event or problem

THE INITIAL CASE WAS REPORTED IN THE MEDIA: ON APRIL 20, 1999 TWO MALE STUDENTS ([redacted] AND [redacted]) ENTERED THEIR HIGH SCHOOL EQUIPPED WITH MANY DIFFERENT TYPES OF GUNS AND EXPLOSIVES. THEY BEGAN SHOOTING STUDENTS AND TEACHERS. IN THE AFTERMATH, 13 INDIVIDUALS WERE KILLED AND MANY SERIOUSLY INJURED. IN ADDITION, BOTH STUDENTS DIED AS A RESULT OF ASSUMED SELF-INFLICTED GUNSHOT WOUNDS TO THE HEAD AND MOUTH. ON MAY 3, 1999, THE ALLEGATION WAS REPORTED THAT "FURTHER TESTS REVEALED THE PRESENCE OF THE ANTIDEPRESSANT LUVOX IN [redacted] SYSTEM."

ON MAY 4, 1999 A SOLVAY REPRESENTATIVE CONTACTED THE CHIEF DEPUTY OFFICER OF THE [redacted] COUNTY CORONER'S OFFICE. THE CHIEF DEPUTY CONFIRMED THE PRESENCE OF A *

6. Relevant tests/laboratory data, including dates

LUVOX BLOOD LEVEL AT AUTOPSY [illegible] THERAPEUTIC

MAY 18 1999

ADVERSE EVENT REPORTING SYSTEM

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

NONE SIGNIFICANT

Race: CAUCASIAN

RECEIVED MAY 17 1999

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 LUVOX
- #2

2. Dose, frequency & route used
- #1 unk UNK PO
- #2

3. Therapy dates (if unknown, give duration) (mo/da/yr or best estimate)
- #1 UNK to UNK
- #2

4. Diagnosis for use (indication)
- #1 UNK
- #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 NI
- #2

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

NI

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

Solvay Pharmaceuticals
901 Sawyer Road
Marietta, Georgia 30062

2. Phone number: (770) 578-9000

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

4. Date received by manufacturer (mo/day/yr): 05/04/99

5. (A)NDA # 20-263
- 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)

INTENTIONAL INJURY
SUICIDE ATTEMPT

9. Mfr. report number

FLUV00299000121

E. Initial reporter

1. Name, address & phone #

Mr. [redacted]
[redacted]
Phone: [redacted]

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.

Optional Facsimile of FDA Form 3500A

ED WATCH	A.1. Patient identifier [redacted]	G.9. Mfr. report number FLUV00299000121	Page 2 of 2

B.5. Describe event or problem

[continuation:] "THERAPEUTIC BLOOD LEVEL" OF LUVOX FOR STUDENT [redacted] THE REQUEST FOR THE SPECIFIC BLOOD LEVEL WAS DENIED AND NO ADDITIONAL INFORMATION WAS GIVEN SINCE THIS CASE IS UNDER CRIMINAL INVESTIGATION. THIS CASE HAS BEEN REFERRED TO THE LEGAL DEPARTMENT FOR ADDITIONAL INFORMATION SUCH AS THERAPY DATES, DOSAGE, AND INDICATION.

E.3. Occupation

CHIEF DEPUTY OFFICER