PID 329.001.00065 (94011450-1)

Primary Adverse Experience: **WORSENING DEPRESSION, HOSTILITY**

Demography: Age: 14 YEARS Date of Birth: 08-FEB-80 Sex: Male
Height: 65.0 in Weight: 125.6 lbs Race: Caucasian

Country: **United States**

Medical History: **Dizziness (when changing position), hand tremors, headaches, nausea, Osgood-Schlatter Disease**

Study Diagnosis: **Depression/Affective Disorders**

Study Drug: **Paroxetine**

Start: 17-Nov-94 **End: 30-Nov-94**

AE Remarks:
This 14 year old Caucasian male patient was a participant in study 29060/329 for depression/affective disorders. On 17-Nov-94, the patient received his first dose of study medication.

On 30-Nov-94, the patient became very angry. He punched pictures, broke glass, and sustained lacerations that required six sutures. His anger subsided, but he expressed hopelessness and possible suicide thoughts. The patient was hospitalized due to his severe anger outburst and a worsening of his depression. The investigator broke the study blind and determined that the patient was on paroxetine. Study medication was discontinued on this day.

In the opinion of the investigator, the worsening of depression was possibly related to the study medication and the anger outburst was probably unrelated to study medication.

Concomitant Drugs:	**Start**	**End**
TYLENOL (ACETAMINOPHEN)	01-FEB-89	Unknown

PID 329.001.00065 (94011450-1)

Medical History Remarks:
History of major depressive disorder since 1992.

Reporter Attribution for Primary AE:	POSSIBLY RELATED/ SUSPECTED
Reason for Seriousness:	HOSPITALIZATION REQUIRED

PID 329.002.00106 (95010303-1)

Primary Adverse Experience: **HOSTILITY**

Demography: Age: 15 YEARS Date of Birth: 25-APR-80 Sex: Female
Height: 68 in Weight: 147.6 lbs Race: Caucasian

Country: **United States**

Study Diagnosis: **Depression/Affective Disorders**

Study Drug: **Paroxetine**

Start: 27-Jun-95 **End: 12-Sep-95**

AE Remarks:
This 15 year old Caucasian female patient, weight 147.6 lbs, height 68.0 in, was a participant in study 29060/329, for depression/affective disorders. On 27-Jun-95, the patient received her first dose of study medication.

On 15-Sep-95, the patient had to be hospitalized after an argument. She had become combative with her mother and had threatened suicide. She was prescribed Zoloft. Several days before her hospitalization, she had not taken her study medication. At the time of discharge, the patient was experiencing some depressive symptoms.

In the opinion of the investigator, the event was probably not related to the study medication but to the parent's primary condition and family problems.

Treatment Drugs:	**Start**	**End**
ZOLOFT	Unknown	Unknown

Lab Remarks:
Labs were all normal at week 4 visit.

Medical History Remarks:
Concomitant medications: none. Relevant medical history: none.

PID 329.002.00106 (95010303-1)

Reporter Attribution for Primary AE:	PROBABLY UNRELATED/ UNLIKELY
Reason for Seriousness:	HOSPITALIZATION REQUIRED

PID 329.006.00038 (95003398-1)

Primary Adverse Experience: **EMOTIONAL LABILITY (ATTEMPTED SUICIDE, INTENTIONAL OVERDOSE)**

Other Adverse Experience: **HEADACHE, CONSTIPATION, MYALGIA, MYASTHENIA, DIZZINESS**

Demography: Age: 15 YEARS Date of Birth:28-MAR-79 Sex: Female
Height: 67.0 in Weight: 170.7 lbs Race: Caucasian

Country: **United States**

Medical History: **Asthma**

Study Diagnosis: **Depression/Affective Disorders**

Study Drug: **Paroxetine**

Start: 15-Feb-95 **End: 12-Apr-95**

AE Remarks:
This 16 year old Caucasian female patient, weight 170.7 lbs, height 67.0 in, was a participant in study 29060/329, for depression/affective disorders. On 15-Feb-95, the patient received her first dose of study medication. She completed the week 7 visit of the acute phase on 05-Apr-97.

Following a disagreement with her mother, on 12-Apr-95, the patient intentionally overdosed. She consumed 12 tablets of study drug (level 4), 23 Advil, 12 Ibuprofen 400's, 23 Ibuprofen 600's, 29 "long skinny white pills", 4 Tylenol's and 10 fiorinal tablets. The patient reported headache, constipation, myalgia, myasthenia, and dizziness. The patient was withdrawn from the study on 12-Apr-95, prior to completion of the final study visit.

In the opinion of the investigator, the event was considered unrelated to the study medication.

Concomitant Drugs:	**Start**	**End**
ADVIL (IBUPROFEN)	12-APR-95	12-APR-95
IBUPROFEN 400	12-APR-95	12-APR-95
TYLENOL (ACETAMINOPHEN)	12-APR-95	12-APR-95

PID 329.006.00038 (95003398-1)

FIORINAL (ASPIRIN, CAFFEINE, BUTALBITAL)	12-APR-95	12-APR-95
IBUPROFEN 600	12-APR-95	12-APR-95

Medical History Remarks:
The patient's parents are divorced and there is a history of sexual abuse at the hands of a stepfather. There is also a history of significant disagreements with the mother over the patient's activity.

Reporter Attribution for Primary AE: UNRELATED/NOT RELATED

Reason for Seriousness: OVERDOSE

PID 329.009.00201 (96004543-1)

Primary Adverse Experience: **AGITATION, HOSTILITY, PARANOID REACTION**

Demography: Age: 14 YEARS Date of Birth: 11-NOV-81 Sex: Male
Height: 67.0 in Weight: 151.6 lbs Race: Caucasian

Country: **United States**

Medical History: **Fever, headache, strep throat, tonsillitis**

Study Diagnosis: **Depression/Affective Disorders**

Study Drug:

Start: 06-Feb-96 **End: 04-Apr-96**

AE Remarks:
This 14 year old Caucasian male patient, weight 151.6 lb, height 67.0 in, was a participant in study 29060/329, for depression/affective disorders. On 06-Feb-96, the patient received his first dose of study medication.

On 31-Mar-96, the patient had an episode of extreme anger and agitation that lasted two to three hours. On 03-Apr-96, the patient again became very angry and agitated. He got into a physical fight with his brother. He was later admitted to a psychiatric unit. The patient also had a weight gain at week 8 of 13 lbs from baseline. On 04-Apr-96, his medication was discontinued.

In the opinion of the investigator, the events could be associated with the patient's primary condition and is possibly related to the study medication.

PID 329.009.00201 (96004543-1)

Concomitant Drugs:	**Start**	**End**
AUGMENTIN (AMOXICILLIN/ CLAVULANATE POTASSIUM)	01-APR-96	Unknown
AUGMENTIN (AMOXICILLIN/ CLAVULANATE POTASSIUM)	28-JAN-96	Unknown
CODIMAL DH	01-APR-96	Unknown
PROZAC (FLUOXETINE)	12-APR-96	Unknown
TRAZADONE	12-APR-96	Unknown
ENTEX LA (PHENYLPROPAN-OLAMINE HYDROCHLORIDE)	07-APR-96	Unknown
TYLENOL (ACETAMINOPHEN)	28-JAN-96	Unknown

Treatment Drugs:	**Start**	**End**
DROPERIDOL	08-APR-96	08-APR-96
LOXITANE (LOXAPINE SUCCINATE)	08-APR-96	08-APR-96

Medical History Remarks:
Concomitant medication: Augmentin 250 mg tid for tonsilitis and Codimal DH one teaspoon four to five times daily. Tylenol 650 mg prn for fever.

Reporter Attribution for Primary AE: POSSIBLY RELATED/ SUSPECTED

Reason for Seriousness: HOSPITALIZATION REQUIRED

PID 329.002.00321 (96007756-1)

Primary Adverse Experience: **HOSTILITY**

Demography: Age: 14 YEARS Date of Birth: 03-JUL-81 Sex: Male
Height: 65.0 in Weight: 113.7 lbs Race - Caucasian

Country: **United States**

Medical History: **Conduct Disorder**

Study Diagnosis: **Depression/Affective Disorders**

Study Drug: **Imipramine**

Start: 23-May-96 **End: 03-Jun-96**

AE Remarks:
This 14 year old Caucasian male patient, weight 113.7 lbs., height 65 in., was a participant in study 29060/329 for depression/affective disorders. On 23-May-96, the patient received his first dose of study medication.

On 02-Jun-96, the patient was hospitalized for a conduct disorder. He had a violent outburst and punched his mother's boyfriend. The patient has a history of a conduct disorder for several years and the investigator felt that this contributed to the violent outburst. The patient was withdrawn from the study at this time so that more intensive family treatment could be obtained.

In the opinion of the investigator, this event was unrelated to the study medication.

Medical History Remarks:
The patient was previously hospitalized for depression and instances of aggression.

Reporter Attribution for Primary AE: UNRELATED/NOT RELATED

Reason for Seriousness: HOSPITALIZATION REQUIRED