000277

Theo was patient Donner told Rose about

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

01-FEB-89

Unknown

(ACETAMINOPHEN)