ADVERSE EXPERIENCE (AE) COVER SHEET

CASE CLOSED TO CENTRAL 08/15/01 [Patient's initials]

MAINTENANCE DATA CLOSED TO CENTRAL [Date/Initials]

ADVERSE EXPERIENCE(S) REPORTED (FOR US CASES: NOTE PRIMARY AE, NOTE AE CLASSIFICATION AND GROUPING):

S/D [Signature/Date]

See previous sheet.

REDACTED

PRODUCT CODE/MRL/PRN:
PRX001014040-2

DATE OF REPORT AT SB (PHILA): 08/15/01

FOLLOW-UP ACTIVITY

PHONE CALL BY MEDICAL MONITORING:

SITE VISIT BY MEDICAL MONITORING:

LETTER - CLINICAL SAFETY:

AWAITING RECEIPT OF REASONABLE REQUESTED INFORMATION:

US PI REPORT CLASSIFICATION:

EXPEDE:

PERIOD:

NDS REPORT CLASSIFICATION:

DISTRIBUTION DECISION:

SIGNATURE:

DATE:

CORRECTIONS FROM PHYSICIAN CLIN: D.J. CLINICAL SAFETY PHARMACEUTICAL PERSONNEL

X: Letter unclaimed

FOLLOWUP INFORMATION TO BE REQUESTED BY CLINICAL SAFETY

SOURCE TO BE CONTACTED

INFORMATION TO BE REQUESTED

DATE OF FOLLOW-UP LETTER:

FOLLOW-UP TELEPHONE CALLS:

COPY TO PRODUCT INFORMATION SERVICES DEPT. FOR PROCESSING OF ADDITIONAL INFORMATION

COPY TO QUALITY ASSURANCE - COMPLAINT NO.

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER -
PRODUCED BY GSK IN CROOKS VS. SMITHKLINE BEECHAM (NO. 07 L 002934, COOK COUNTY, IL)
June 13, 2001

Dear Ms. [Redacted],

This is to acknowledge your e-mail to GlaxoSmithKline in which you reported that you were treated with Paxil® while pregnant. The pregnancy had to be terminated because the fetus developed Truncus arteriosus. We responded to your initial e-mail on June 6, 2001. This information has been forwarded to me.

In order to follow-up on your report, it is necessary that we have the details of your clinical course as it relates to your report. To obtain this, we need the name and address of your OB/GYN. For your convenience, I have enclosed an authorization form for you to sign and return to me.

We appreciate your cooperation. In the reply, please refer to our files numbered: 2001014040-1 and 2001014040-2, and use my mail code, UP-9410, in the mailing address.

Sincerely,

[Signature]

Deborah Pollak, R.N.
Assistant Clinical Safety Scientist

Enclosure

®SmithKline Beecham Pharmaceuticals
Authorization for Release of Records

I, ___________________________ hereby authorize the following persons and/or institutions to provide to SmithKline Beecham Corporation a copy of my medical records and/or other information regarding my medical status. I understand that any information provided may be forwarded to the FDA (Food & Drug Administration).

Physician:

Name ___________________________

Address ___________________________

Nurse, Pharmacist, or other Health Professional:

Name ___________________________

Address ___________________________

Hospital:

Name ___________________________

Address ___________________________

Date: ___________________________ Signed: ___________________________

(patient or legal guardian)

Relationship (if legal guardian): ___________________________

Please Return To:

SmithKline Beecham Pharmaceuticals

U.S. Clinical Safety
Mailcode: UP-3420
1250 S. Collegeville Road
P.O. Box 5989
Collegeville, PA 19426-0989

PAR060290281
June 13, 2001
PRX 2001014040-1
2001014040-2

Redacted

Dear Ms. Redacted

This is to acknowledge your e-mail to GlaxoSmithKline in which you reported that you were treated with Paxil® while pregnant. The pregnancy had to be terminated because the fetus developed Truncus arteriosus. We responded to your initial e-mail on June 8, 2001. This information has been forwarded to me.

In order to follow-up on your report, it is necessary that we have the details of your clinical course as it relates to your report. To obtain this, we need the name and address of your OB/GYN. For your convenience, I have enclosed an authorization form for you to sign and return to me.

We appreciate your cooperation. In the reply, please refer to our files numbered: 2001014040-1 and 2001014040-2, and use my mail code, UP-3410, in the mailing address.

Sincerely,

Deborah Pollak, R.N.
Assistant Clinical Safety Scientist

Enclosure

®GlaxoSmithKline Beecham Pharmaceuticals
Redacted
To:               <ww.clinical.safety-org>
cc:               
Subject:         FW: Paxil Use During Pregnancy GM

> --------Original Message------
> From: US CRC Web Response Group Mailbox
> Sent: Wednesday, June 06, 2001 11:32 AM
> To: safety-org@ghrd.com
> Subject: FW: Paxil Use During Pregnancy GM
> Here's the newest reply from the customer. We have not responded to this email.
> > --------Original Message------
> > From: <Redacted>
> > Sent: Friday, June 01, 2001 10:04 PM
> > To: US CRC Web Response Group Mailbox
> > Subject: Re: Paxil Use During Pregnancy GM
> > This response is in regards to an email that I had sent you previously.
> I
> I was asking to see if you have any, or are in the process of any clinical trials for women who are currently on Paxil and pregnant. I wanted to find out information to see how many women were on Paxil during pregnancy and if they were able to successfully have healthy babies.
> I am in no way insinuating that your product did this to my child. I love the product and I don't think that I could have gotten through my panic attacks without the wonderful help of this miracle drug. I just want to start to try and get pregnant again soon. I DO NOT want to put my unborn child through anything that would hurt him/her. Please, if you do not have information where is this information held? Does anyone do studies like this? Please any information that you may give me would be great.
> Thank you again for your help-
> <Redacted>
To:  ww.clinical.safety-srg
CC:
Subject:  FW: Paxil Use During Pregnancy GM

-----Original Message-----
From: US CRC Web Response Group Mailbox
Sent: Wednesday, June 06, 2001 11:32 AM
To: safety-srg@sphrd.com
Subject: FW: Paxil Use During Pregnancy GM

Here's the newest reply from the customer. We have not responded to this
email.

> -----Original Message-----
> From: 
> Sent: Friday, June 01, 2001 10:04 PM
> To: 
> Subject: Re: Paxil Use During Pregnancy GM
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> This response is in regards to an email that I had sent you previously.
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> was asking to see if you have any, or are in the process of any clinical
> trials for women who are currently on Paxil and pregnant. I wanted to
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> I am in no way insinuating that your product did this to my child. I
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> the product and I don't think that I could have gotten through my panic
> attacks without the wonderful help of this miracle drug.
> I just want to start to try and get pregnant again soon, I DO NOT want
> to
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> my unborn child through anything that would hurt him/her.
> Please, if you do not have information where is this information held?
> Does
> anyone do studies like this?
> Please any information that you may give me would be great.
> Thank you again for your help--
To:      waller@clinical-safety.org

cc:      

Subject: FW: Paxil Use During Pregnancy GM


Original Message-----
From:      US CRC Web Response Group Mailbox
Sent:      Thursday, May 31, 2001 12:55 PM
To:      waller@clinical-safety.org
Subject: Paxil Use During Pregnancy GM
Dear Ms. Redacted

Thank you for your inquiry.

We are attaching a copy of our current product information for Paxil® (paroxetine HCL). Please review the section on USE DURING PREGNANCY.

Further questions about your treatment should be directed to the physician, pharmacist, or healthcare provider who has the most complete information about your medical condition. Because patient care is individualized, we encourage patients to direct questions about their medical condition and treatment to their physician.
We believe that because your physician knows your medical history, he or she is best suited to answer your questions. Our Drug Information department is available to answer any questions your physician or pharmacist may have about our products. Your health care professional can call our Drug Information department at 1-888-825-5249.

Again, thank you for your inquiry to GlaxoSmithKline. If you should have any further questions concerning our company or our products, please feel free to contact our Customer Response Center at 1-888-825-5249 during our normal business hours, Monday through Friday, 8:00 am to 8:00 pm Eastern Standard Time.

Customer Response Center
1-888-825-5249

JUN-7 2001


To:       ww.clinical.safety-srg
CC:       
Subject:  FW: Paxil Potential Adverse Event GM

-----Original Message-----
From:     US CRC Web Response Group Mailbox
Sent:     Wednesday, June 06, 2001 11:50 AM
To:       safety-srg@sbsphrd.com
Subject:  FW: Paxil Potential Adverse Event GM
Importance: High

We are resending an email that came in last week, followed by our
response,
and then a new email reply from this same person.

-----Original Message-----
From:     US CRC Web Response Group Mailbox
Sent:     Thursday, May 31, 2001 12:57 PM
To:       safety-srg@sbsphrd.com
Subject:  Paxil Potential Adverse Event GM

This e-mail was received by one of our external websites.

Glenna/CRC

Contact Name:  [Redacted]
Email Address:  [Redacted]
Questions/Comments: Please someone respond to me!!

My name is [Redacted] I was diagnosed with Panic Disorder about 4 1/2 years
ago. Since that time I have been taking Paxil (which is truly a miracle
drug). I have been Panic free with this drug and have been able to go
on
with a normal life.
I was married in October of 2000. My husband and I found out that we
were
pregnant at Christmas time. I was so excited. I love children. The
only
problem is that I carried the baby to 6 months gestation and that had to
have a termination. The doctor's diagnosed my son with Truncous
arteriosis. They said that he would not lead a normal childhood and
would
most likely not make it through the open heart surgery that he would
need.
As soon as he was delivered (if he was able to make it to that time)
To say the least, I was absolutely distraught with this news. I thought
that it was something that I did. Was it because I stayed on the Paxil
for selfish reasons?? I wanted to know if you could direct me to any
information that you might have of any woman that have taken Paxil and
still had healthy babies. My husband and I are ready to try again to
get
pregnant in the next month or two. I am so nervous. I don't want to
stop
taking my miracle pill, but then again if there is a chance that this
might hurt or affect the baby I want to know upfront and I will somehow stop taking it for the time being. Please contact me as soon as possible.

I love everything that this drug has done for me and I am so thankful that your company had this available for me. I just want to continue to have a normal life, and have the child that I have always wanted. Please contact me as soon as possible.

Please don't forget about me...
Thank you in advance for your time.

Redacted
### Adverse Experiences

<table>
<thead>
<tr>
<th>Term</th>
<th>Code</th>
<th>IB</th>
<th>MDS</th>
<th>EMEA Loc</th>
<th>Onset</th>
<th>Clear</th>
<th>r</th>
<th>c</th>
<th>Ord</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRUNCUS ARTERIOSIS</td>
<td>UNC</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**FRM-40400:** Transaction complete -- 3 records posted and committed.
Count: *1

<OSC><DBG><List><Replace>
**MEDWATCH**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

---

### A. Patient Information

1. **Patient Identifier**
   - [ ] Age at time of event
   - [ ] Sex
   - [ ] Weight
   - [ ] Date of birth
   - [ ] Race
   - [ ] ID

---

### B. Adverse Event or Product Problem

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

2. **Outcomes**
   - [ ] disability
   - [ ] death
   - [ ] congenital anomaly
   - [ ] life-threatening
   - [ ] hospitalization - initial or prolonged

3. **Date of event**
   - [ ] Date of this report
   - [ ] Date of event

---

### C. Suspect Medication(s)

1. **Name** (give brand strength & manufacturer, if known)
   - [ ] Name: PAXIL
   - [ ] Manufacturer: SMITHKLINE BEECHAM

2. **Dose, frequency & route used**
   - [ ] Dose:
   - [ ] Frequency:
   - [ ] Route:

3. **Therapy dates**
   - [ ] Start date:
   - [ ] End date:

4. **Diagnosis for use**
   - [ ] Indication:

5. **Event abated after use stopped or dose reduced**
   - [ ] Yes
   - [ ] No
   - [ ] Does not apply

6. **Lot # (if known)**
   - [ ] Lot:

7. **Exp. Date (if known)**
   - [ ] Exp. Date:

8. **NDC # - for product problems only (if known)**
   - [ ] NDC:

---

### D. Additional Information

Report 2001014040-2 describes the occurrence of Truncus Arteriosus in a fetus whose mother was treated with paroxetine (Paxil) for panic disorder. This report was received from the mother and has not been confirmed by a physician or other healthcare professional.

The mother's concurrent medications and medical conditions were not specified. Four and a half years ago, the mother started Paxil (close unknown). The mother discovered she was pregnant in December 2000 while being treated with Paxil. However, she reported that at six months gestation, the pregnancy had been terminated because the fetus was diagnosed as having Truncus Arteriosus. The mother was told by the physician that the child would not lead a normal childhood and was most likely not make it through the open heart surgery that he would need as soon as he was delivered (if he was able to make it to that time). The mother noted, "I am in no way insinuating that this product [Paxil] did this to my child".

Additional information has been requested.

See report 2001014040-1 for information regarding the mother.

---

### E. Initial Reporter

1. **Name, address & phone #**
   - [ ] Name:
   - [ ] Address:
   - [ ] Phone:

2. **Health Professional**
   - [ ] Yes
   - [ ] No

3. **Occupation**
   - [ ] Yes
   - [ ] No

4. **Initial reporter also sent report to FDA**
   - [ ] Yes
   - [ ] No
15-DAY ALERT REPORTS

JUN 13 2001

NDA 20-031 (Paxil®)

FDA, Central Document Room
12229 Wilkins Avenue
Rockville, MD 20852

Dear Sir/Madam:

Enclosed please find two copies of an initial 15-day alert report concerning a fetus whose mother had been treated with Paxil® therapy during pregnancy.

Patient 2001080140402 - Truncus arteriosis:
FDA Form 3500A.

Thank you for your attention to this matter.

Sincerely,

[Signature]
Patricia Kaufman, M.D.
Associate Director
Global Clinical Safety and Pharmacovigilance

PK:dp
Enclosure
SMITHKLINE BEECHAM PHAR
1250 SOUTH COLLEGEVILLE ROAD
PO BOX 9266
COLLEGEVILLE PA 19426-0926 US
1-800-877-7074

Page 1 of 1

A: Patient Information
1. Patient identifier [in confidence]
2. Age at time of event
3. Sex: [ ] male [ ] female
4. Weight: lbs
5. Date of birth: [ ]

B: Adverse event or product problem
1. [ ] Adverse event 
   [ ] Product problem (e.g. defect/malfunction)
   [ ]
2. Outcomes attributed to adverse event
   [ ] death
   [ ] disability
   [ ] congenital anomaly
   [ ] other
3. Date of event
4. Date of this report
5. Describes event or problem
   Report 2001014040-2 describes the occurrence of Truncus arteriosus in a fetus whose mother was treated with paroxetine (Paxil) for panic disorder.
   This report was received from the mother and has not been confirmed by a physician or other healthcare professional.
   The mother's concurrent medications and medical conditions were not specified. Four and a half years ago, the mother started Paxil (dose unknown). The mother discovered she was pregnant in December 2000 while being treated with Paxil. Since the baby was at six gestation, the pregnancy had to be terminated because the fetus was diagnosed as having Truncus arteriosus. The mother was told by the physician that the child "would not lead a normal childhood and would most likely not make it through open heart surgery that he would need as soon as he was delivered (if he was able to make it to that time)." The mother noted, "I am in no way insinuating that this product [Paxil] did this to my child.

Additional information has been requested.

See report 2001014040-1 for information regarding the mother.

4. Relevant tests/laboratory data including dates

5. Other relevant history, including pre-existing medical conditions
   (e.g. allergies, high risk, pregnancy, smoking and alcohol use, neurological dysfunction, etc.)

   The mother's concurrent medications and medical conditions were not specified.

C: Suspect Medication(s)
1. Name: [ ]
   [ ] unknown
   [ ]
   [ ]
   [ ]
   [ ]

2. Dose, frequency & route used
   [ ]

3. Therapy dates & duration
   [ ]

4. Diagnosis for use
   [ ]

5. Event started after use
   [ ]

6. Lot # & Exp. Date
   [ ]

7. Adverse event term(s)
   [ ]

8. Mfr. report number
   [ ]

9. Initial Reporter
   [ ]

JUN 13 2001

Redacted