



Making medicines safer for all of us

Enter a drug name (e.g., Paxil)

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All prescription drugs have benefits and side effects.

BENEFIT

ANTI-ANXIETY MEDS

SIDE EFFECT



GOOD
BAD



REDUCES PARANOIA

DROWSINESS

Find the right balance. RxISK is the drug safety website to research and report side effects.

No one knows a drug's side effects like the person taking it. Use this website to inform yourself on the drugs you are being prescribed. Take the next step and [report any side effects](#) you are experiencing to...

Get a Free RxISK Report

Share your experiences with the prescription drugs you are taking and receive a free report to take to your doctor or pharmacist.



You've been handed a megaphone to help change drug safety. Make your voice heard!

Report a drug side effect

The RxISK Team





Thalidomide

**Randomized
Controlled
Trials**

**Efficacy
&
Safety**



**Louis
Lasagna**

Dancing with Pythons



Modern version of Hippocratic Oath

A widely used modern version of the traditional oath was penned in 1964 by Dr. Louis Lasagna, former Principal of the Sackler School of Graduate Biomedical Sciences and Academic Dean of the School of Medicine at Tufts University

I swear to fulfil, to the best of my ability and judgment, this covenant:

I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow.

I will apply, for the benefit of the sick, all measures [that] are required, avoiding those twin traps of overtreatment and therapeutic nihilism.

I will remember that there is art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug.

I will not be ashamed to say "I know not", nor will I fail to call in my colleagues when the skills of another are needed for a patient's recovery.

I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know. Most especially must I tread with care in matters of life and death. If it is given to me to save a life, all thanks. But it may also be within my power to take a life; this awesome responsibility must be faced with great humbleness and awareness of my own frailty. Above all, I must not play at God.

I will remember that I do not treat a fever chart, a cancerous growth, but a sick human being, whose illness may affect the person's family and economic stability. My responsibility includes these related problems, if I am to care adequately for the sick.

I will prevent disease whenever I can, for prevention is preferable to cure.

I will remember that I remain a member of society with special obligations to all my fellow human beings, those sound of mind and body as well as the infirm.

If I do not violate this oath, may I enjoy life and art, be respected while I live and remembered with affection thereafter. May I always act so as to preserve the finest traditions of my calling and may I long experience the joy of healing those who seek my help.



DANCE with PYTHONS



AERS v ASRS





**Regulators &
Companies
Say**

**Thalidomide
Prevents
Spontaneous
Miscarriages**

**Doesn't
Cause
Phocomelia**



Matt Miller
13

Zoloft
7 days



Matt Miller
13

Zoloft

Auto Erotic
Asphyxiation

May 31 2001 American Woman to GSK

My name is.... I was diagnosed with panic disorder 4 years ago. Since then I've been taking Paxil, which is truly a miracle drug. I've been panic-free and able to go on with a normal life.

I was married in October 2000. My husband and I found we were pregnant at Christmas. I was so excited. I love children. I carried the baby to six months and then had to have a termination.

The doctors diagnosed my son with Truncus Arteriosus. They said 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.)

I was absolutely distraught. I thought this was something that I did, was because I stayed on the Paxil for selfish reasons.

May 31 2001 Continued

I want to know if you could direct me to any information you have of any woman that has taken Paxil and still had healthy babies.

My husband and I are ready to get pregnant in the next month or two. I am so nervous. I don't want to stop taking my miracle pill. But, if there is a chance 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 this drug has done for me. 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 always wanted.

Please don't forget about me,

Thursday May 31st GSK to AW

We are attaching a copy of our product information for Paxil.

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 treatment to their physician... because your physician knows your condition he is best suited to answer your questions.

Our drug information department is available to answer any questions your physician may have

Friday, June 1, 2001,

This is in regards to an e-mail I sent you ... asking if you have any clinical trials for women who are on Paxil and pregnant. I wanted to find out how many women were on Paxil during pregnancy - if they were able to have healthy babies.

I am in no way insinuating your product did this to my child. I love the product, and I don't think I could have gotten through my panic attacks without the wonderful help of this miracle drug. I just want 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 this information, where is this information held? Does anyone do studies like this? Any information you may give me would be great.

Thanks again for your help.

GSK has Many Phone Numbers.

A Medical Information No – rarely listed.

DTC Ads No - But don't connect to GSK.

Journal Ads No - But don't reach GSK directly.

DTC Ads offer medical information through a call center – but this is not a medical information center, nor the GSK Customer Response Center call center.

Paxil CR's toll free no. now reaches Neevo Plus - a different Co.
Paxil's DTC numbers just ring.

If AW left a voice message, it is almost certain that no one called her back as she had not reached GSK.
Hence her email pleas for a response?

Companies now refer you to FDA's Medwatch & "Talk to your Doctor".

Companies have to follow up on adverse event reports.
Communication from patients could change their warnings.

Medwatch does not follow up on adverse events.
Reports to Medwatch makes action on adverse events less likely

Diverting reports to the regulator saves money, reduces legal liability and relegates them to the status of anecdotes

"Because patient care is individualized, we encourage patients to direct questions about their treatment to their physician."

"Talk to your doctor" instead of call our Medical Information Center stops reporting of adverse events to the company.



GlaxoSmithKline

June 13, 2001
PRX 2001014040-1
2001014040-2

GlaxoSmithKline
1250 South Collegeville Road
PO Box 5089
Collegeville, PA
19426-0989

Tel. 610 917 7000
Fax. 610 917 7707
www.gsk.com

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 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-3410, in the mailing address.

Sincerely,

LIST_NM	ABBREV	CRTDT	CRTUSR	MODDT	MODUSR	ABBREV_DESCR	SHORT_DESCR
LOC_CAUSALTY	1	30-Apr-08	N	30-Apr-08	OCEANS_ADMIN	Unrelated	Unrelated
LOC_CAUSALTY	2	30-Apr-08	N	30-Apr-08	OCEANS_ADMIN	Unlikely	Unlikely
LOC_CAUSALTY	3	30-Apr-08	N	30-Apr-08	OCEANS_ADMIN	Possible	Possible
LOC_CAUSALTY	4	30-Apr-08	N	30-Apr-08	OCEANS_ADMIN	Probable	Probable
LOC_CAUSALTY	5	30-Apr-08	N	30-Apr-08	OCEANS_ADMIN	Almost certain	Almost certain
LOC_CAUSALTY	N	30-Apr-08	N	30-Apr-08	OCEANS_ADMIN	No	No
LOC_CAUSALTY	U	30-Apr-08	N	30-Apr-08	OCEANS_ADMIN	Unknown	Unknown
LOC_CAUSALTY	W	30-Apr-08	N	30-Apr-08	OCEANS_ADMIN	Not Assessable	Not Assessable

OR	ABBREV_DESCR	SHORT_DESCR
IN	Unrelated	Unrelated
IN	Unlikely	Unlikely
IN	Possible	Possible
IN	Probable	Probable
IN	Almost certain	Almost certain
IN	No	No
IN	Unknown	Unknown
IN	Not Assessable	Not Assessable



Jane Niemann

JUN 3 2009

9:58:09AM



No. 09-1156

IN THE
Supreme Court of the United States

MATRIX INITIATIVES, *et al.*,
Petitioners,
v.

JAMES SIRACUSANO AND
NECA-IBEW PENSION FUND,
Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF FOR THE PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA AND THE
BIOTECHNOLOGY INDUSTRY ORGANIZATION
AS AMICI CURIAE SUPPORTING PETITIONERS





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Liver disorder (153 reported)

Graphic | [Table](#)

Side effects:



Based on 153 reports where Paroxetine was the suspect drug associated with Liver disorder, of which 54 do not specify



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**Randomized
Controlled
Trials**

**Efficacy
&
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(Copyright © 1960 by The C. V. Mosby Company)



THALIDOMIDE—A NEW NONBARBITURASLEEP-INDUCING DRUG

LOUIS LASAGNA, M.D.
BALTIMORE, MD.

From the Departments of Medicine (Division of Clinical Pharmacology), Pharmacology, and Experimental Therapeutics, Johns Hopkins University School of Medicine

(Received for publication Dec. 9, 1959)

THALIDOMIDE* is the generic name for N-phthalyl-glutamic acid imide, a compound which has been employed in Europe for several years as a sedative-hypnotic. It is chemically related to glutethimide (Doriden), another sedative-hypnotic, and to bemegride (Megimide), a convulsant analeptic.