

KNOW YOUR DRUGS

**If your government approved it,
your doctor prescribed it, and
your pharmacist dispensed it,
then it must be safe.**

Right?

WRONG

Possibly deadly wrong.

Adverse drug reactions are a leading cause of death;



Largely because pharmaceutical companies hide the truth about potentially deadly side effects.



The pharmaceutical industry is guilty of more violations of government regulations than any other industry based on penalties it has paid to governments in the United States.

Between 1991 and 2015, pharmaceutical companies paid \$35.7 billion in criminal and civil penalties to federal and state governments in the United States.

Sammy Almashat, Sidney M. Wolfe and Michael Carome

Twenty-Five Years of Pharmaceutical Industry Criminal
and Civil Penalties: 1991 Through 2015

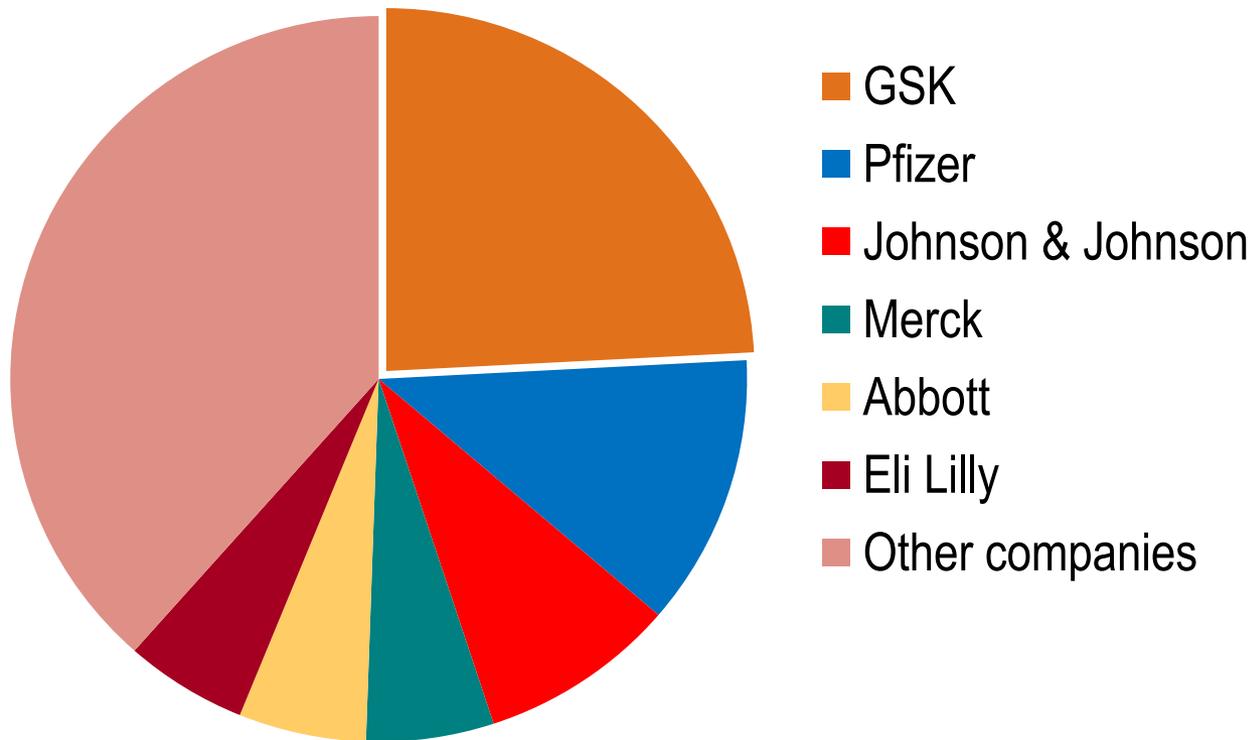
Public Citizen, March 31, 2016

The pharmaceutical company that paid most of the penalties and the largest penalty is GlaxoSmithKline (GSK).



GSK paid 22% of the \$35.7 billion

Twice the percentage of any other company

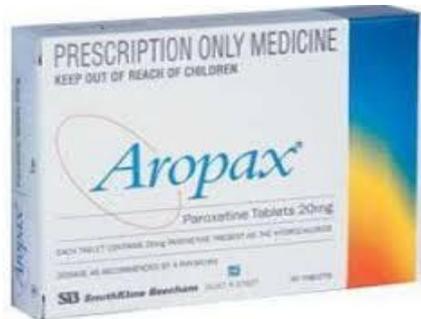


GSK also paid the largest penalty of \$3 billion in a 2012 settlement with the federal government.



The \$3 billion settlement included a penalty for concealing negative clinical trial data from study 329 about the antidepressant paroxetine and claiming that it was safe and effective for adolescents.

The brand names for paroxetine include Paxil, Seroxat and Aropax.



Negative clinical trial data from study 329 about the increased risk of suicidality among adolescents was not presented in a 2001 psychiatric journal article.

The journal article was written by a professional writer hired by GSK.

22 medical researchers from the United States and Canada signed the article as co-authors without reviewing the clinical trial data.

Journal of the American Academy of

CHILD & ADOLESCENT PSYCHIATRY

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[July 2001](#) Volume 40, Issue 7, Pages 762–772

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Efficacy of Paroxetine in the Treatment of Adolescent Major Depression: A Randomized, Controlled Trial

[MARTIN B. KELLER](#), M.D., , [NEAL D. RYAN](#), M.D., [MICHAEL STROBER](#), PH.D., [RACHEL G. KLEIN](#), PH.D., [STAN P. KUTCHER](#), M.D., [BORIS BIRMAHER](#), M.D., [OWEN R. HAGINO](#), M.D., [HAROLD KOPLEWICZ](#), M.D., [GABRIELLE A. CARLSON](#), M.D., [GREGORY N. CLARKE](#), PH.D., [GRAHAM J. EMSLIE](#), M.D., [DAVID FEINBERG](#), M.D., [BARBARA GELLER](#), M.D., [VIVEK KUSUMAKAR](#), M.D., [GEORGE PAPTAEODOROU](#), M.D., [WILLIAM H. SACK](#), M.D., [MICHAEL SWEENEY](#), PH.D., [KAREN DINEEN WAGNER](#), M.D., PH.D., [ELIZABETH B. WELLER](#), M.D., [NANCY C. WINTERS](#), M.D., [ROSEMARY OAKES](#), M.S., [JAMES P. MCCAFFERTY](#), B.S.

A group of 7 medical researchers from Wales, United States, Australia and Canada examined the clinical trial data from study 329, came up with different conclusions and published the results in a 2015 journal article.

Research**Restoring Study 329: efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence**

BMJ 2015 ; 351 doi: <https://doi.org/10.1136/bmj.h4320> (Published 16 September 2015)

Cite this as: *BMJ* 2015;351:h4320

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*Joanna Le Noury, research psychologist*¹, *John M Nardo, retired clinical assistant professor*², *David Healy, professor*¹, *Jon Jureidini, clinical professor*³, *Melissa Raven, postdoctoral fellow*³, *Catalin Tufanaru, research associate*⁴, *Elie Abi-Jaoude, staff psychiatrist*⁵

Reported Results/Conclusions

Study 329 (2001)

Paroxetine is generally well tolerated and effective for treating major depression in adolescents.

Restoring Study 329 (2015)

Paroxetine is not effective for treating major depression in adolescents and there is an increased risk of harm including suicidal ideation and behaviour.

The 2001 journal article about study 329 was used by GSK sales representatives in the United States to convince doctors to prescribe Paxil to adolescents even though it has never been approved for use with this age group.



08/16/01

To: All Sales Representatives Selling **cc:** RVPs
Paxil TSMs

From: Zachary Hawkins *Paxil* DSMs
RMSs
Paxil Product Management

Study Title "Efficacy of Paroxetine in the Treatment of Adolescent Major Depression: A Randomized, Controlled Trial"

Author(s) Martin B. Keller, M.D.

Journal *J. AM.ACAD. CHILD ADOLESC. PSYCHIATRY* 2001

Date Vol Pages 2001, July, Vol. 40:7: 762-772

Significance of article This "cutting-edge," landmark study is the first to compare efficacy of an SSRI and a TCA with placebo in the treatment of major depression in adolescents. *Paxil* demonstrates **REMARKABLE** Efficacy and Safety in the treatment of adolescent depression.

"GSK sales force bribed physicians to prescribe GSK products using every imaginable form of high priced entertainment from Hawaiian vacations to paying doctors millions of dollars to go on speaking tours."

Carmen Ortiz, U.S. Attorney, Massachusetts

News conference about \$3 billion penalty

The United States Department of Justice

July 2, 2012, Washington, D.C.

"If you really want the companies to behave in an ethical and legal manner, people need to go to jail. \$3 billion is not a lot of money to them. They had it set aside ready to pay as soon as they had to."

Blair Hamrick, GSK whistleblower, \$3 billion settlement
Presentation, Celebrating Vanessa's Law panel discussion
Hosted by People's Right to Integrative Medicine
October 16, 2014, Toronto, Canada

Total sales for GSK in 2016 \$36 billion (American dollars)

(Total penalties between 1991 and 2015 was \$7.9 billion)

59 GSK Annual Report 2016

Strategic report

Governance and remuneration

Financial statements

Investor information

Group turnover

Turnover (£bn)

£27.9bn



Group turnover for the year increased 17% at actual rates and 6% CER to £27,889 million, with Pharmaceuticals up 3%, Vaccines up 14% and Consumer Healthcare up 9%, the growth in all three businesses still reflecting the impact of the Novartis transaction which completed on 2 March 2015. On a pro-forma basis, Group turnover was up 5%, with Pharmaceuticals up 4%, Vaccines up 12% and Consumer Healthcare up 5%. Sales of New Pharmaceutical and Vaccine products were £4,453 million, a Sterling increase of £2,465 million.

The hiding of clinical trial data about suicidality among adolescents in study 329 by GSK is just one example of fraud in the pharmaceutical industry.

Financial penalties alone are not likely to prevent pharmaceutical companies from hiding the truth about potentially deadly side effects.

To protect people from unsafe drugs, countries need to have laws in place and enforced that can send pharmaceutical company executives responsible for criminal activities to prison.



Vanessa's Law (Protecting Canadians from Unsafe Drugs Act) is an example of a federal government law that can help prevent criminal activities by pharmaceutical companies.



Vanessa's Law became a federal law on November 6, 2014 after it was passed unanimously in the House of Commons of Canada and by the Senate of Canada.

**KNOW YOUR
DRUGS DAY
November 6**

With Vanessa's Law

The penalty for pharmaceutical companies that market unsafe drugs has gone from \$5,000 to \$5 million a day for not complying with Health Canada requests and possible jail time for those responsible.

We need government laws to help protect us from unsafe drugs, but we also need to be knowledgeable about drug side effects.

KNOW YOUR DRUGS

**AS A CONSUMER, PARENT,
GUARDIAN OR CAREGIVER**

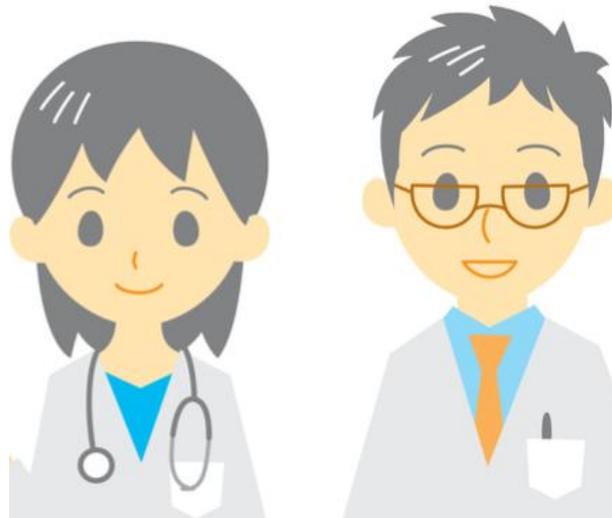


As a **CONSUMER**, be informed and share your knowledge with a buddy; Someone who can watch for drug side effects.



As a **PARENT, GUARDIAN** or **CAREGIVER**, be informed so you can watch for and report any unusual changes in behaviour when a drug is started, changed in dosage or stopped.

One way to become more knowledgeable about drugs is to ask your doctor and pharmacist **QUESTIONS.**





Answers to these 12 questions could save your life:

1. How does this drug work, how much improvement can I expect, and how soon?
2. If I don't take this drug now, and instead wait for a while, what will happen?
3. Are there any lifestyle changes (e.g., diet) or non drug treatments that will help?
4. What are the most likely side effects?
5. Are there any rare serious side effects or any permanent problems this drug can cause?

6. If this is a new drug, why can't I take an older drug?
7. Why are you recommending this particular dose?
8. What date will we review my use/dose of this drug?
9. Are there problems stopping the drug or any special considerations on stopping or changing dose that I should watch for?
10. Are there any potential interactions with food, my other medical conditions, or my current medications?
11. Might this drug affect my weight/sleep/hair/skin/nails/mood/sex life and/or relationships, and if so, how?
12. Do I need to stop this drug before I get pregnant?

RxISK.org

RESEARCH the safety and effectiveness of your drugs.

REPORT adverse drug reactions to your doctor, pharmacist, government, and drug safety organizations.

KnowYourDrugs.org provides links to government and independent drug safety websites that can help you **RESEARCH** your drugs and **REPORT** adverse drug reactions.

One of the drug safety websites listed is **RxISK.org**.



No one knows a prescription drug's side effects like the person taking it.

Make your voice heard.

RxISK is a free, independent drug safety website to help you weigh the benefits of any medication against its potential dangers.

Could it be my meds?

All drugs have side effects, but people often don't link the effect they are experiencing to starting, stopping, or changing the dose of a drug. RxISK provides free access to information and tools to help you assess the connection between a drug and a side effect.



Drug search



Lifesaving checklist



Interaction checker



SSRI sexual dysfunction



Complex withdrawal



Too many drugs?



Guides & papers



Search by side effect

Are you experiencing a drug side effect?

Get your free RxISK Report to find out

The RxISK Report takes 10 minutes to complete and provides you with a RxISK Score indicating how likely it is that your problem is caused by starting or stopping a prescription drug.

Get your FREE RxISK Report now



RxISK Polypharmacy Index



Could you be on too many drugs?

Answer the following 10 questions to assess the risk of your taking a mixture of drugs that is of more harm than benefit to you. We will email you a record of your answers along with your RxISK Polypharmacy Index.

The higher the number, the more important it is that you have a conversation with your doctor.

Experiencing a Drug Side Effect?

Get your free RxISK Report to find out

All prescription drugs can cause side effects, but it can often be difficult to engage with your doctor when your treatment might be causing a problem.



SUMMARY

- Adverse drug reactions are a leading cause of death;
- Pharmaceutical companies hide the truth about potentially deadly side effects;
- The pharmaceutical industry is guilty of more violations of government regulations than any other industry based on penalties it has paid to federal and state governments in the United States;
- Government laws can help protect people from unsafe drugs if the laws are enforced;
- Consumers, parents, guardians, and caregivers need to be knowledgeable about drug side effects.

KNOW YOUR DRUGS

**QUESTION, RESEARCH
AND REPORT**

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November 6**

KnowYourDrugs.org