

How SSRI Antidepressants Cause Suicide, Violence and Homicide



David Carmichael

KNOW YOUR DRUGS

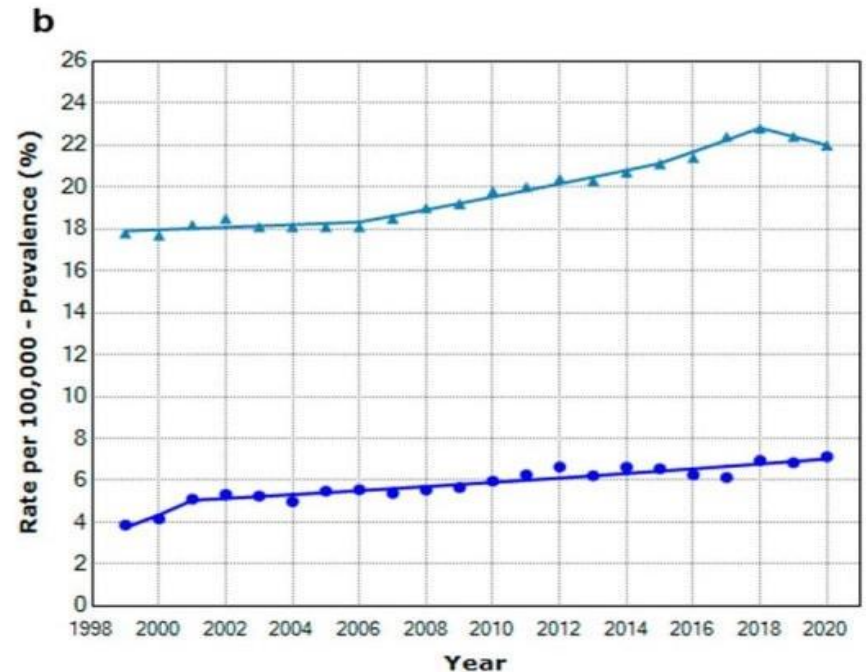
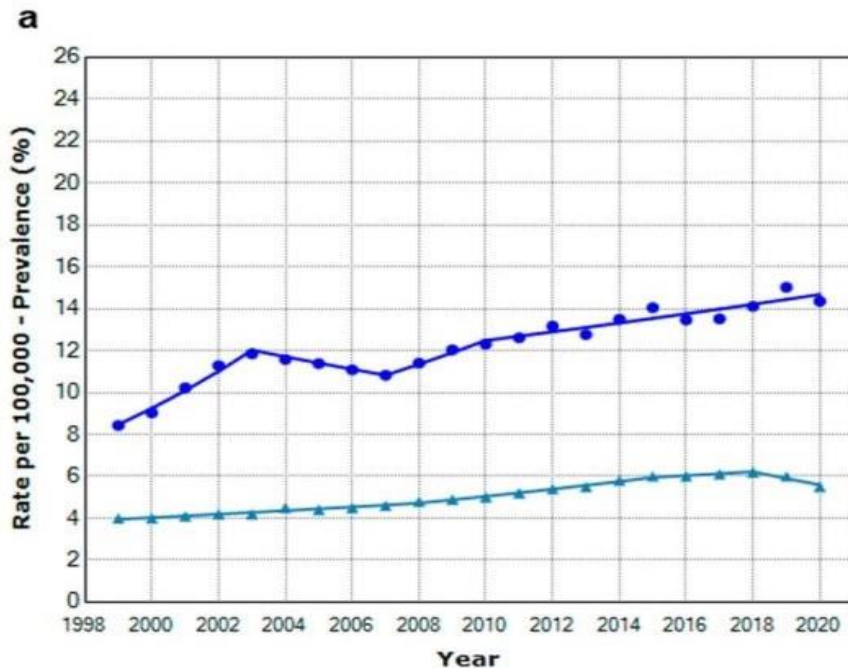


SSRIs (selective serotonin reuptake inhibitors)

- 1987 - Prozac (fluoxetine) Eli Lilly
- 1991 - Zoloft (sertraline) Pfizer
- 1992 - Paxil (paroxetine) GlaxoSmithKline
- 1994 - Luvox (fluvoxamine) Abbott Laboratories
- 1998 - Celexa (citalopram) Forest Laboratories
- 2002 - Lexapro (escitalopram) AbbVie
- 2011 - Viibryd (vilazodone) AbbVie

Correlation between antidepressant use and suicide rates in the United States - 1999 to 2020

a) Female b) Male Antidepressant use ● Suicide rate ▲



Source: Simone Amedola, Martin Ploderl, Michael Nengartner. Suicide Rates and Prescription of Antidepressants. *The Journal of Crisis Intervention and Suicide Prevention*. February 14, 2024.





Pharmaceutical companies mislead the public about the safety and efficacy of prescription drugs by fraudulently concealing negative clinical trial data and illegally promoting drugs for off-label uses

2001 - Study 329

Eight-week, placebo-controlled, double-blind, randomized control trial - Ghostwritten article

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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

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Study 329 - Results/Conclusions

Five percent taking paroxetine (5/93) and one percent on a placebo (1/87) experienced “emotional lability”

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

2015 - Restoring Study 329

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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

Article

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

Clinical Trial Conclusions/Results

Study 329 (2001)

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

5% taking paroxetine (5/93) and 1% on a placebo (1/87) experienced “emotional lability”

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.

12% taking paroxetine (11/93) and 1% on a placebo (1/87) became suicidal



2001 Staff Memorandum

08/16/01

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

**Staff memorandum part of evidence in
\$3 billion U.S. federal government False
Claims Act settlement in 2012 against
GSK based on whistleblower complaints**

"Once you realize what you're doing could cause more harm than good, you say to yourself, this is wrong."

Blair Hamrick

Illegal Off-Label Promotion

- Doctors are allowed to prescribe a drug for off-label use (not approved by government regulator to treat that health condition).
- It is against the law for pharmaceutical companies to market prescription drugs for off-label uses.
- Pharmaceutical companies promote drugs for off-label uses based on pseudoscience, which puts lives at risk for a commercial motive.
- Pharmaceutical sales representatives illegally influence doctors to prescribe and promote drugs for off-label uses with things such as financial kickbacks, free lunches and dinners, all-expense paid trips to retreats, and paid speaking opportunities.
- Doctors also take large sums of money under the guise of educational grants to push drugs for off-label uses, and receive honoraria to promote products in unlicensed areas, which results in immense profits for pharmaceutical companies.



\$275,000 Payment to Dr. Drew

Out-of-pocket expenses, March and April 1999



COONEY WATERS		
INVOICE		
PO # 0031908		
Client: Glaxo Wellcome, Inc. 5 Moore Drive, P.O. Box 13398 Research Triangle Park, NC 27709	Date: March 31, 1999	
Attn: Holly Russell	Invoice No.: 3-120	
<u>Services for Wellbutrin for the Month of March 1999</u>		
<u>HONORARIA</u>		
<u>Out-of-Pocket Expenses</u>		
Honoraria-Dr. Drew Pinsky/ 1st Installment	100,000.00	100,000.00
Total Out-of-Pocket Expenses		
Total Invoice for the Month of March 1999		\$108,000.00
Date: 3-120.XLS (5/15/2006) yr		
Cooney/Waters Group 141 Fifth Avenue, 9th Floor New York, NY 10010 p.212-886-2200 f.212.886.2288 www.cooneywaters.com		

COONEY WATERS		
INVOICE		
PO # 0031908		
Client: Glaxo Wellcome, Inc. 5 Moore Drive, P.O. Box 13398 Research Triangle Park, NC 27709	Date: April 30, 1999	
Attn: Holly Russell	Invoice No.: 4-113	
<u>Services for Wellbutrin for the Month of April 1999</u>		
<u>HONORARIA</u>		
<u>Out-of-Pocket Expenses</u>		
Dr. Drew Pinsky/ 2nd Installment	175,000.00	175,000.00
Total Out-of-Pocket Expenses		
Total Invoice for the Month of April 1999		\$175,000.00
Date: 4-113.XLS (5/15/2006) yr		
Cooney/Waters Group 141 Fifth Avenue, 9th Floor New York, NY 10010 p.212-886-2200 f.212.886.2288 www.cooneywaters.com		

Doctors promote the chemical imbalance theory of depression, prescribe SSRIs for normal mental health challenges and rarely obtain informed consent before prescribing an SSRI

“Chemical Imbalance” was a
Big Pharma scam to push
drugs on normal people
experiencing the expectable
sadness/anxiety of everyday life.”

Dr. Allen Frances

Tweet: January 18, 2018

Prescribing of SSRIs for normal mental health challenges starts at a young age

“My family doctor wanted to prescribe Prozac to my 5-year-old son because he got really nervous before batting in Tee Ball”

Mother

Sacramento, California, May 2024



It is a legal requirement for doctors to obtain informed consent:

1. Nature of procedure or intervention;
2. Risks and benefits of procedure or intervention;
3. Reasonable alternatives;
4. Risks and benefits of alternatives.

MEDICATION CONSENT FORM			
PATIENT INFORMATION			
PATIENT NAME	DATE OF BIRTH		
ADDRESS	PHONE NUMBER		
ALLERGIES			
MEDICATION INFORMATION			
NAME OF MEDICATION	DOSAGE	ROUTE	FREQUENCY
INDICATION			
CONSENT			
<p>I, the undersigned, understand that the decision to use this medication is based on the professional judgment of the prescribing healthcare provider. I acknowledge that no guarantees or assurances have been made to me regarding the outcomes or effects of this medication.</p> <p>I have been provided with information regarding the potential risks, benefits, and alternatives to this medication. I have had the opportunity to ask questions and have received satisfactory answers.</p> <p>By signing this form, I hereby give my informed consent to receive the medication as prescribed above.</p>			
PATIENT SIGNATURE	DATE		
GUARDIAN/REPRESENTATIVE SIGNATURE <i>(if applicable)</i>	RELATIONSHIP TO PATIENT	DATE	
PRESCRIBER INFORMATION			
PHYSICIAN/PREScriBER NAME	LICENSE NUMBER		
PHYSICIAN/PREScriBER SIGNATURE	DATE		
PROVIDER NAME	CONTACT INFORMATION		SAVE PRINT Page 1 of 1

Mechanisms for SSRIs causing suicide, violence and homicide

Dr. David Healy

1. Akathisia
2. Emotional blunting
3. Delirium - Psychosis

Delirium - Psychosis

Delirium

Delirium is a state of mental confusion that starts suddenly. It is also called an 'acute confusional state'.

Medical problems, surgery and medications can all cause delirium. It usually lifts when the condition causing it gets better. It can be frightening - not only for the person who is unwell, but also for those around him or her.

Source: Royal College of Psychiatrists, United Kingdom

Psychosis

Psychosis refers to a collection of symptoms that affect the mind, where there has been some loss of contact with reality. During a psychotic episode, a person's thoughts and perceptions are disrupted and they may have difficulty recognizing what is real and what is not.

People with psychosis experience delusions (fixed-false beliefs) and/or hallucinations (seeing or hearing things that others do not).

Source: National Institute of Mental Health, United States

2001 legal precedent against for fraudulent concealment



- A Wyoming jury awarded \$6.4 million to the family of Donald Schell, who, in 1998 at 60 years of age, fatally shot his wife, their daughter, and 9-month-old granddaughter after taking two pills of Paxil the day after he received a prescription.
- The jury was shown hidden data from GlaxoSmithKline (GSK) clinical trials supporting the argument that Paxil can cause healthy adults to become suicidal, violent and homicidal.

Plaintiff's Lawyers: James Fitzgerald from Cheyenne, Wyoming and Andy Vickery from Houston, Texas



Health
Canada

June 2004

Health Canada is advising Canadians that Selective Serotonin Re-uptake Inhibitors (SSRIs) and other newer anti-depressants, now carry stronger warnings. These new warnings indicate that patients of all ages taking these drugs may experience behavioural and/or emotional changes that may put them at increased risk of self-harm or harm to others.

Patients, their families and caregivers should note that a small number of patients taking drugs of this type may feel worse instead of better, particularly within the first few weeks of treatment or when doses are adjusted. For example, they may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts that could involve self-harm or harm to others.



October 2004

Black box warning about SSRIs was issued:

"Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior."

2023 legal precedent against IDAHO DEPARTMENT OF **HEALTH & WELFARE** for medical malpractice for not obtaining informed consent for prescribing Prozac

- In 2023, the Supreme Court of the State of Idaho vacated the summary judgment of the District Court for further proceedings for medical malpractice against the Idaho Department of Health & Welfare and a physician's assistant for outpatient mental health services.
- In 2018, Terri Mattson was diagnosed with major depressive disorder and prescribed Prozac by a physician's assistant without receiving any information about side effects after signing a general "Informed Consent for Treatment" form.
- Two months later, the day of a follow-up appointment, she bought a bottle of vodka, drank the entire bottle while driving to her appointment and attempted suicide by shooting herself in the head in the Department's parking lot.
- The lawsuit against the Idaho Department of Health & Welfare and the physician's assistant was settled out of court in 2024.

Plaintiff's Lawyers: John Layman from Spokane, Washington and Andy Vickery from Houston, Texas





2018 Statement The Dr. Oz Show

Mr. Carmichael's case is clearly a tragedy but medicines like this are an important option for treating depression.

Patient safety is our priority and there is no scientific evidence that this medication causes homicidal, psychotic or violent behavior.

Scientific evidence is based only on results from clinical trials, which could be fraudulent.

Postmarketing reports of adverse drug reactions (side effects) are considered anecdotal and defended as correlation not causation.

Drug Label for Paroxetine (Paxil)

In 2017, homicidal ideation was added as a possible side effect based on postmarketing reports of adverse drug reactions.

Postmarketing Reporting of Adverse Drug Reactions

- Government regulators (e.g., FDA, Health Canada) are responsible for collecting postmarketing reports of adverse drug reactions (ADRs).
- Pharmaceutical companies are mandated to report ADRs to government regulators.
- Healthcare providers (e.g., doctors) voluntarily report ADRs to government regulators and pharmaceutical companies.
- Consumers (parents, guardians or caregivers) voluntarily report ADRs to healthcare providers, government regulators and pharmaceutical companies.
- In the United States, it is estimated that only 1 to 10% of ADRs are reported.

Source: Sylvia Lucas, Jessica Ailani, Timothy R. Smith, Ahmad Abdrabboh, Fei Xue and Marco S. Navetta. Pharmacovigilance: reporting requirements throughout a product's lifecycle. *Therapeutic Advances in Drug Safety*. Vol. 16 (2022). Pages 1-16.

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