

How SSRI Antidepressants Cause Suicide, Violence and Homicide

David Carmichael

KNOW YOUR DRUGS

WHY PEOPLE MIGHT NOT KNOW THE RISKS

Pharmaceutical companies have fraudulently concealed negative data from clinical trials for decades to get prescription drugs approved by government regulators, and deny causal relationships when adverse drug reactions are reported based on postmarketing experiences.





Approval of SSRIs

- 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

2001 - Study 329

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

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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.

08/16/01

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

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

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.



2002 - The Secrets of Seroxat

Discussed results from Study 329 and other GlaxoSmithKline (GSK) clinical trials, which concluded that Seroxat (Paxil) can cause healthy people to become suicidal, violent and homicidal.



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.



Oct 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."

2015 - Restoring Study 329

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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)

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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



2017 - Drug label for Paroxetine (Paxil)

Homicidal ideation was added as an adverse reaction based on reports from postmarketing experiences.

Mechanisms for SSRI antidepressants causing suicide, violence and homicide

Dr. David Healy

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



2017 – GSK Statement to BBC

“Mr. Carmichael’s case is clearly a tragedy, but medicines like paroxetine have helped many people.

Patient safety is our priority, and there is no scientific evidence that paroxetine causes homicidal, psychotic, or violent behaviour.”