PREVENTING ANOTHER OPIOID CRISIS

HOW CONSUMERS OF PRESCRIPTION DRUGS CAN BE PROTECTED FROM SIDE EFFECTS THAT CAUSE DEATH, DISABILITY AND DYSFUNCTION

David Carmichael, Executive Director

VANESSA’S LAW
CANADIANS FOR VANESSA’S LAW
OPIOIDS

• Have caused hundreds of thousands of deaths worldwide.

• Purdue Pharma considered a catalyst in the opioid crisis with the introduction of OxyContin in 1995.

• Purdue Pharma and three executives fined $634.5 million in the United States in 2007 for concealing data about the risk of addiction and potential for abuse.
“We have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.’

- Massachusetts Attorney General Lawsuit
OPIOID CRISIS

TIP OF THE ICEBERG

DEATH, DISABILITY AND DYSFUNCTION

<table>
<thead>
<tr>
<th>PHARMACEUTICAL COMPANY</th>
<th>TOTAL FINANCIAL PENALTIES</th>
<th>PERCENT OF TOTAL ($35.7 BILLION)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. GlaxoSmithKline</td>
<td>$7.88 billion</td>
<td>22.0%</td>
</tr>
<tr>
<td>2. Pfizer</td>
<td>$3.94 billion</td>
<td>11.0%</td>
</tr>
<tr>
<td>3. Johnson &amp; Johnson</td>
<td>$2.82 billion</td>
<td>7.9%</td>
</tr>
<tr>
<td>4. Merck</td>
<td>$1.91 billion</td>
<td>5.4%</td>
</tr>
<tr>
<td>5. Abbott</td>
<td>$1.84 billion</td>
<td>5.1%</td>
</tr>
<tr>
<td>6. Eli Lilly</td>
<td>$1.74 billion</td>
<td>4.9%</td>
</tr>
<tr>
<td>7. Teva</td>
<td>$1.47 billion</td>
<td>4.1%</td>
</tr>
<tr>
<td>8. Schering-Plough</td>
<td>$1.34 billion</td>
<td>3.7%</td>
</tr>
<tr>
<td>9. Novartis</td>
<td>$1.25 billion</td>
<td>3.5%</td>
</tr>
<tr>
<td>10. AstraZeneca</td>
<td>$1.02 billion</td>
<td>2.9%</td>
</tr>
<tr>
<td>11. Amgen</td>
<td>$901 million</td>
<td>2.5%</td>
</tr>
<tr>
<td>12. TAP</td>
<td>$875 million</td>
<td>2.4%</td>
</tr>
<tr>
<td>13. Bristol-Myers Squibb</td>
<td>$795 million</td>
<td>2.2%</td>
</tr>
<tr>
<td>14. Mylan</td>
<td>$715 million</td>
<td>2.0%</td>
</tr>
<tr>
<td>15. Serono</td>
<td>$704 million</td>
<td>2.0%</td>
</tr>
<tr>
<td>16. Purdue Pharma</td>
<td>$646 million</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

Source: False Claims Act, Public Citizen Health Research Group
Illegal marketing of the antidepressants Wellbutrin and Paxil (Paroxetine) and the fraudulent concealment of negative clinical trial data for Paxil are major reasons why GlaxoSmithKline (GSK) was the most penalized pharmaceutical company in the US between 1991 and 2015, and paid the largest penalty of $3 billion in a 2012 settlement with the federal government.
“GSK sales force bribed physicians to prescribe GSK products using every form of high priced entertainment from Hawaiian vacations to paying doctors millions of dollars to go on speaking tours.”

Carmen Ortiz, US Attorney, Massachusetts News conference about $3 billion penalty The United States Department of Justice July 2, 2012, Washington, D.C.
$275,000 PAYMENT TO DR. DREW
Out-of-Pocket Expenses, March and April 1999
• Clinical trial data about suicidal side effects was not presented in a 2001 article published in the Journal of the American Academy of Child and Adolescent Psychiatry.

• Journal article was written by a professional writer hired by GSK (ghostwriter).

• Paxil was marketed as being effective and safe for treating adolescent major depression (off-label).

• 22 medical researchers from the United States and Canada signed the article as co-authors without reviewing the data from the 8-week clinical trial.
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 KOPElewicz, 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 PAPATHEODOROU, 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.
Senator Stan Kutcher - Professor Emeritus of Psychiatry at Dalhousie University, Canada; has been involved in mental health work for children and adolescents in more than 20 countries. Pyramid in Mental Health & High School Curriculum Guide: Understanding Mental Health and Mental Illness. Updated edition/version (2015). Developed the original version (2010), which promotes the theory that depression is caused by a chemical imbalance in the brain, in collaboration with the Canadian Mental Health Association (National Office).
“Clinical depression is believed to be caused by a chemical imbalance in the brain.” New Zealand

“It’s a chemical imbalance in your brain that needs to be treated.” United States

“Medications help the brain to restore its usual chemical balance.” Australia

“Brain chemicals (neurotransmitters) play a mediating role in the development of depression.” South Africa

“Antidepressant drugs affect and increase the activity of the neurotransmitters to restore balance.” Sweden

“Chemicals in your brain called neurotransmitters may be out of balance.” Canada

“We know that depression is associated with abnormal levels of neurotransmitters.

The most important neurotransmitters associated with depression are serotonin, noepinephrine, and dopamine. They are also the target of nearly every antidepressant medication.” (2019)

Dr. Diane McIntosh - B.Pharm, MD, Psychiatrist. General Manager, Copeman Healthcare Centres, Canada. Chief Neuroscience Officer, TELUS Health.

“I work as a consultant and speaker with the pharmaceutical industry.”

"Scientifically speaking, there never was a network of validated hypothesis capable of sustaining a full-blown chemical imbalance theory of mental illness. Moreover – and here we come back to Myth 2 – psychiatry as a profession and medical specialty has never endorsed such a bogus “theory,” when judged by its professional organizations, its peer reviewed publications, its standard textbooks, or its official announcements.

The SSRIs were accorded a rock-star status as effective antidepressants they did not deserve. Most troubling from the standpoint of misleading the general public, pharmaceutical companies heavily promoted the “chemical imbalance” trope in their direct-to-consumer advertising.”

Dr. Ronald Pies – Professor of Psychiatry, SUNY Upstate Medical University, US. Editor in Chief Emeritus, Psychiatric Times, 2007 to 2010.
“Chemical Imbalance” was a Big Pharma scam to push drugs on normal people experiencing the expectable sadness/anxiety of everyday life.”

Allen Frances, MD, Tweet, January 8, 2018

Interview with Allen Frances – October 25, 2017

“The drug companies have convinced the world that major depressive disorder is one entity, that it’s always a chemical imbalance, and that it always requires a chemical solution in the form of a pill.”

We’re turning the everyday distress of life - filled with anxiety, with sadness, with loss, with disappointment - into mental disorders.

“When it comes to most psychiatric problems, they get better in a week, two weeks, three weeks on their own.”

Dr. Allen Frances - Psychiatrist. Professor and Chairman Emeritus of the Department of Psychiatry and Behavioral Sciences at Duke University School of Medicine, US. Chair of the Task Force that produced the Fourth Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV).
“I spent 13 years at NIMH really pushing on the neuroscience and genetics of mental disorders, and when I look back on that I realize that while I think I succeeded at getting lots of really cool papers published by cool scientists at fairly large costs - I think $20 billion - I don’t think we moved the needle in reducing suicide.”

Source: Interview with WIRED. Star Neuroscientist Tom Insel Leaves the Google-Spawned Verily for ... a Startup? May 11, 2017.
Source: Screening + Drug Treatment = Increase in Veteran Suicides
ANTIDEPRESSANT USEAGE AND SUICIDE RATE AMONG YOUNG AUSTRALIANS

Antidepressant Useage: Under 28

<table>
<thead>
<tr>
<th>Year</th>
<th>2009</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Useage</td>
<td>2.9%</td>
<td>4.8%</td>
</tr>
</tbody>
</table>

Number of Suicides: Under 25

<table>
<thead>
<tr>
<th>Year</th>
<th>2009</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suicides</td>
<td>279</td>
<td>458</td>
</tr>
</tbody>
</table>

CORRELATION does not imply CAUSATION
CAUSAL RELATIONSHIPS can be determined by analyzing individual patient level data from clinical trials.
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

Joanna Le Noury, research psychologist¹, John M Nardo, retired clinical assistant professor², David Healy, professor¹, Jon Jureidini, clinical professor³, Melissa Raven, postdoctoral fellow³, Catalin Tufanaru, research associate⁴, Ella Abi-Jaoude, staff psychiatrist⁵
REPORTED RESULTS/CONCLUSIONS

**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

Study329.org
To: All Sales Representatives Selling
Paxil

From: Zachary Hawkins
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

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.
“By 2005, brand-name companies were spending over $1 billion a year to reach seventy thousand doctors in Canada.

Almost all doctors deny the influence and control the drug companies exert. The medical profession in Canada insists that it remains independent, even as it goes to industry-sponsored ‘educational’ events, dinners, trips, and training sessions, take freebie samples from drug reps, and prescribes the medicines recommended by drug reps.

In a 2016 survey, 46 percent of physicians said that they had been retained by a pharmaceutical company in some capacity at some point in their career.” (2017)

2007 SUICIDE, SARA CARLIN

Jury Verdict (June 28)

- Cause of death of 18-year Sara Carlin on May 6, 2007 in Oakville was “hanging by ligature while affected by depression, cocaine and ethanol.”
- Sara had been taking the SSRI antidepressant Paxil for about 14.5 months.
- Deputy Chief Coroner acknowledged that Sara might have been without Paxil for 3-4 days before consuming 120 milligrams within 36 hours of her suicide.
PAROXETINE (PAXIL)

2007
Usual adult dosage range
10-60mg daily

2013
Usual adult dosage range
10-40mg daily
MECHANISMS FOR SSRI ANTIDEPRESSANTS CAUSING VIOLENCE AND SUICIDE:

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

Dr. David Healy - Psychiatrist, Psychopharmacologist and Scientist. Author of several books including *Pharmageddon* (2012), *Mania* (2010), *Psychiatric Drugs Explained* (2008), and *Let Them Eat Prozac* (2004). Professor at McMaster University, Canada. Former Secretary of the British Association for Psychopharmacology. Expert witness in homicide and suicide trials involving psychotropic drugs. CEO and principal founder of Data Based Medicine Americas Limited, which operates RxISK.org and SSRIstories.org.

# PRESCRIPTION DRUGS ASSOCIATED WITH VIOLENCE

1. **Chantix**/Champix
2. **Prozac**/Sarafem
3. **Paxil**/Seroxat/Aropax
4. **Amphetamines (Adderall)**
5. **Lariam**
6. **Strattera**
7. **Halcion**
8. **Luvox**
9. **Effexor**
10. **Pristiq**
11. **Singulair**
12. **Zoloft**
13. **Ambien**
14. **Cipralex/Lexapro**
15. **Xyrem**
16. **Celexa**
17. **Abilify**
18. **OxyContin/Roxicodone**
19. **Wellbutrin/Zyban**
20. **Geodon**
21. **Ritalin**
22. **Remeron**
23. **Neurontin**
24. **Keppra/Elepsia/Spritam**
25. **Valium**
26. **Xanax**
27. **Cymbalta**
28. **Klonopin**
29. **Roferon**
30. **Risperdal**
31. **Seroquel**

In 2019, the FDA Adverse Event Reporting System (FAERS) received 2,191,808 reports of adverse drug reactions (ADRs) from pharmaceutical companies (submitted 95% of the reports), healthcare professionals and the public. 173,875 of the reports FAERS received were for deaths caused by ADRs.
Globally, no more than 10% of serious ADRs are reported to government regulators of the pharmaceutical industry.
DRUG SAFETY ISSUES CAN BE IDENTIFIED if hospitals, doctors and consumers (parents, guardians or caregivers) report serious ADRs to government regulators of the pharmaceutical industry.
HOSPITALS

- Examined databases from 1966 to 1996 from 39 hospitals in the United States;
- 2,216,000 hospitalized patients (6.7%) had serious ADRs in 1994;
- 106,000 hospitalized patients (0.32%) in 1994 died from ADRs;
- ADRs estimated to be the fourth to sixth leading cause of death in American hospitals in 1994.
Top causes of death in Canadian hospitals

(Source: CIHI, 2017)
Protecting Canadians from Unsafe Drugs Act became a federal law on November 6, 2014 after being passed unanimously in the House of Commons and Senate.

On December 16, 2019, a regulation went into effect making it mandatory for hospitals to report serious ADRs to Health Canada within 30 days of the incident being documented.

“Less than five percent are being reported” according to researchers at Simon Fraser University and the University of British Columbia.

DOCTORS
Barriers to Reporting ADRs

Some doctors:

• Fear that the acknowledgement of adverse reactions may reflect negatively on their competence or put them at risk of litigation.

• Might be reluctant to report adverse reactions because of doubts regarding the causal role of the drug.
“Medical error” includes mistakes involving prescription drugs.

FAERS received 116,815 reports of ADR deaths in 2013; 97% of all 1,074,538 ADR reports received that year were from the pharmaceutical industry through mandated reporting.
CONSUMERS
“Prescription drugs are the third leading cause of death behind heart disease and cancer.

The main reason we take so many drugs is that drug companies don’t sell drugs, they sell lies about drugs. Virtually everything we know about drugs is what the companies have chosen to tell us and our doctors.

The patients don’t realise that, although doctors may know a lot about diseases and human physiology and psychology, they know very, very little about drugs that hasn’t been carefully concocted and dressed up by the drug industry.

If such a hugely lethal epidemic had been caused by a bacterium or a virus, or even one-hundredth of it, we would have done everything we could to get it under control.”

The reporting of suspected ADRs to government regulators of the pharmaceutical industry by consumers (parents, guardians or caregivers) is key to identifying drug safety issues and improving prescription drug safety.

RxISK Reports determine how likely it is that an adverse reaction was caused by a drug side effect.
IT COULD BE A MATTER OF LIFE AND DEATH

Adverse drug reactions are a leading cause of death

Get involved with this Global Awareness Campaign

KnowYourDrugs.org