

Psychiatric drugs induced violence

A call for a study of its increasing threat for safety in society



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Foundation Nederlands Comité voor de Rechten van de Mens

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Summary

Throughout the years scientific evidence has been building up linking psychiatric medication and (severely) violent behavior due to these drugs.

An interesting publication in this field was from December 2010, when the *Public Library of Science* published a study entitled, "Prescription Drugs Associated with Reports of Violence Towards Others,"

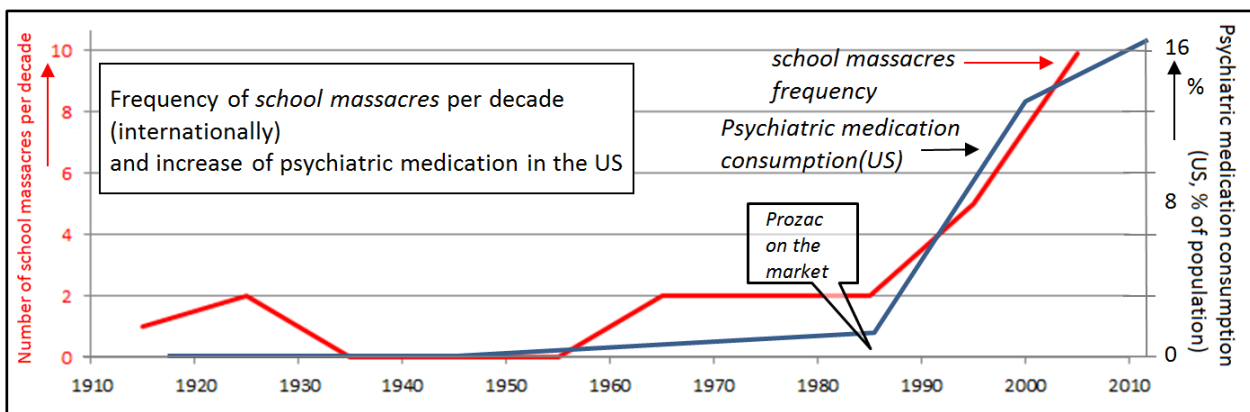
The authors took the U.S. Food and Drug Administration's Adverse Event Reporting System data, and extracted all "serious adverse events" received from 2004 through to September 2009. They identified 484 drugs that accounted for 780,169 serious adverse event reports of all kinds, including 1,937 cases meeting their violence criteria.

Of the 484 drugs identified, 31 drugs were disproportionately associated with violence. These drugs, accounting for 79% of all the cases of violence, included 11 antidepressants, 6 sedative/hypnotics and 3 drugs for attention deficit hyperactivity disorder. Also included was Varenicline -also known as Chantix, a "smoking cessation" drug which affects a certain type of neurotransmitter receptor in the brain.

It is very clear that psychiatric medication may cause severe violence. With the large scale and continuously increasing usage of such medications this should be viewed as a source of increasing threat to general safety in our society.

Information on the relationship between violence and psychiatric medication are being collected by several websites, partly driven by individuals and non-governmental organizations.

This report recommends collecting data internationally and having an open exchange of data on this subject. This would be done in order to get a clearer view on the actual threat of (extreme) violence due to the use of psychiatric drugs.



Coincidence of increasing psychiatric medication (US) and school massacres. This graphic does not prove a causal relation. It should, however, stimulate discussion about the possible relation between psychiatric medication and extreme violence.

Introduction

Every now and then the international community is shocked by acts of severe violence like shootings in malls and schools. Such acts are most of the time attributed to the psychological state of the perpetrator and to the availability of weapons.

One subject consistently gets too little attention: the influence of psychiatric medication. Scarcity of data may play a role in the lack of attention for this subject by legislators and Members of Parliaments, causing a sort of *Catch-22* situation. This report is a short introduction in the subject, presenting data and a call for measures to get a better understanding and to get quantitative data about these effects of psychiatric drugs.



After a shooting at the US army base Fort Hood, the base commander acknowledged that the gunman used psychiatric medication. This was one of the scarce events where a coincidence of, or causal relation between psychiatric drugs and acts of violence was openly admitted.

(April 2014, Fort Hood Texas, US)¹

This is a revised version of March 2014.

By O.G. Kruijt, foundation NCRM. We are CCHR research staff grateful for presented data.

The most recent version can be found at <http://www.ncrm.nl/NCRM-rapporten.htm>



Foundation Nederlands Comité voor de Rechten van de Mens (NCRM) is part of the international CCHR network, with a focus on violation of human rights in psychiatry. CCHR (<https://secure.cchr.org/>) is founded by Scientology Church and the late dr. Thomas Szasz, emeritus professor in psychiatry.

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¹ <http://www.cchrint.org/2014/04/03/army-admits-fort-hood-shooter-was-on-psychiatric-drugs/>

Prescription drugs associated with reports of violence towards others.

December 2010, the *Public Library of Science* published a study entitled, "Prescription Drugs Associated with Reports of Violence Towards Others," by Thomas J. Moore, senior scientist, drug safety and policy at Institute for Safe Medication Practice, Joseph Glenmullen, M.D., and Curt D. Furberg, M.D., Ph.D.²

The authors took the Food and Drug Administration's Adverse Event Reporting System data, and extracted all "serious adverse event" reports for drugs with 200 or more cases received from 2004 through to September 2009. They identified 484 drugs that accounted for 780,169 serious adverse event reports of all kinds, including 1,937 cases meeting their violence criteria.

Of the 484 drugs identified, 31 drugs were disproportionately associated with violence. These drugs, accounting for 79% of all the violence cases, included varenicline (also known as Chantix, a "smoking cessation" drug)³, 11 antidepressants, 6 sedative/hypnotics and 3 drugs for attention deficit hyperactivity disorder.

The specific violence cases included:

- 387 reports of homicide
- 404 physical assaults
- 27 cases indicating physical abuse
- 896 homicidal ideation reports
- 223 cases described as violence-related symptoms

Taking into consideration that an estimated 1-10% of side effects are reported to the FDA these numbers could be a factor of ten to hundred higher.

The type of drugs which had produced the most violent cases, were mostly those that increased the availability of serotonin or dopamine in the brain. The authors concluded, "These data provide new evidence that acts of violence towards others are a genuine and serious adverse drug event that is associated with a relatively small group of drugs."

Varenicline had 408 reported violence cases, the highest proportion of violence cases of any of the other drugs. Varenicline has not been officially labeled a "psychiatric drug", but does affect the brain by increasing the availability of dopamine through blocking certain brain receptors.

In addition, antidepressant drugs showed a consistently elevated risk of violence.

² <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0015337>

Note: Furberg was a member of the FDA's Drug Safety and Risk Management Advisory Committee, but had been removed from the FDA's 2004 advisory panel meeting on Vioxx and other arthritis drugs because he had said publicly that based on an analysis he did, he believed the Pfizer drug Bextra was as bad as Vioxx or worse when it comes to cardiovascular risk. So he was removed for an "intellectual conflict of interest."

(Marc Kaufman, "FDA Bars Critic From Meeting" *The Washington Post*, Nov. 13, 2004)

³ According to Shane Ellison, Chantix (varenicline) targets a certain type of neurotransmitter receptor, "which are located within the brain and it is therefore a psychiatric drug." Though the package inserts the FDA and NIH strictly call it a "smoking cessation" drug and do not class it under a psychiatric drug.

Some background information on the rise of psychiatric drug-related violence and crime.

This report is an overview of the side effects of common psychiatric drugs known to cause violent and suicidal behavior. In fact, Harvard University's Dr. Joseph Glenmullen warns that antidepressants could explain the rash of school shootings and mass suicides over the last decade. People taking them "feel like jumping out of their skin. The irritability and impulsivity can make people suicidal or homicidal."⁴

A study of 950 acts of violence committed by people taking antidepressants found 362 murders, 13 school shootings, 5 bomb threats or bombings, 24 acts of arson, 21 robberies, 3 pilots who crashed their planes and more than 350 suicides and suicide attempts.⁵ Medical studies show that patients with no history of violence, develop "violent urges to assault" while under the effects of psychiatric drugs.

As medical writer Robert Whitaker reports, "Little could the public have suspected that the madman of its nightmares, who kills without warning and for no apparent reason, was not always driven by an evil within but rather by a popular medication."⁶

Courts of law also now recognize the link between acts of violence and psychotropic drugs.⁷

What causes violence in people who take psychiatric drugs?

One reason may be a common side effect called akathisia commonly found in people taking antipsychotic drugs and antidepressants. Akathisia is a terrible feeling of anxiety, an inability to sit still, a feeling that one wants to crawl out of his or her skin. Behind much of the extreme violence to self or others we see in those taking psychiatric drugs is akathisia.

As early as 1975, studies described patients experiencing "violent urges to assault anyone near" them while taking psychotropic drugs. A 1990 study determined that 50% of all fights in a psychiatric ward could be tied to akathisia.⁸ Patients described "violent urges to assault anyone near" them.⁹

Though psychiatrists are aware that extreme violence is a documented side effect both of taking psychiatric drugs and withdrawing from them, the tendency is to blame it on the patient's "sickness" or his failure to continue his or her medication.

However, government drug regulatory agencies around the world have made the connection between psychiatric drugs and violence, warning that Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants such as Prozac, Zoloft and Paxil/Seroxat cause agitation, irritability, hostility, impulsivity, akathisia and mania.¹⁰

4 Elizabeth Showgren, "FDA reviews labels on antidepressants," *The Seattle Times*, 21 Mar. 2004.

5 Counted over an 18 year period, from International Coalition for Drug Awareness, *ssrstories.com* database compilation, Jan. 1988-Sept 2006.

6 Robert Whitaker, *Mad in America: Bad Science, Bad Medicine, and the Enduring Mistreatment of the Mentally Ill* (Perseus Publishing, New York, 2002), p 189.

7 Jim Rosack, "SSRIs Called on Carpet Over Violence Claims," *Psychiatric News*, Vol. 36, No. 19, 5 Oct. 2001.

8 Robert Whitaker, *Mad in America: Bad Science, Bad Medicine, and the Enduring Mistreatment of the Mentally Ill* (Perseus Publishing, New York, 2002), p 188.

9 "Worsening Depression and Suicidality in Patients Being Treated with Antidepressant Medications," *US Food and Drug Administration Public Health Advisory*, 22 Mar. 2004.

10 Theodore A. Henderson, MD, Ph.D., *Matrix ADHD Diagnostic Clinic*; Keith Hartman, MD, "Aggression, Mania, and Hypomania Induction Associated with Atomoxetine," *Pediatrics*, Vol. 114, No. 3, Sept. 2004.

Warnings have also been issued about the antidepressant Strattera, prescribed to children for so-called attention-deficit hyperactivity disorder (ADHD), stating it could cause extreme irritability, aggression and mania.¹¹

In the last few years, drug regulatory agencies have cracked down on psychiatric drug labeling, such as a requirement to indicate in package inserts that stimulants such as Ritalin may cause “psychotic behavior, as well as aggression or violent behavior.”¹²

Studies also show that, “From agitation and hostility to impulsivity and mania, antidepressant-induced behaviors are identical to that of PCP (hallucinogenic drugs such as angel dust), methamphetamine and cocaine—drugs known to cause aggression and violence.”¹³ Withdrawal from antidepressants can cause extreme violence too. Research shows that in just a few days, a person can unknowingly go into severe withdrawal and not even know why he or she is feeling so violent or suicidal.

Dr. Richard Kapit, a former US Food and Drug Administration (FDA) researcher who investigated Prozac, Paxil and Zoloft before the drugs were allowed on the US market, testified in a murder case linked to SSRIs that he always suspected in some patients the drugs could cause mania that can lead to violence. “In the psychiatric profession, antidepressants have always been thought to cause manic episodes,” Kapit said.¹⁴

Between 1990 and 2005, there was a more than 380% increase in the pediatric use of stimulants in the US of which the FDA warned in 2005 could cause psychosis, mania and aggression.¹⁵

In September 2006, Dr. David Healy, director of the North Wales Department of Psychological Medicine, and colleagues released the findings of their study published in the journal *Public Library of Science Medicine (PloS)* that determined GlaxoSmithKline’s Paxil raises the risk of severe violence in people taking them. “We’ve got good evidence that the drugs can make people violent and you’d have to reason from that that there may be more episodes of violence,” Dr. Healy stated. The findings are based in part on clinical trial data GSK submitted to the UK’s Committee on Safety of Medicines Expert Working Group. “I have no reason to think all of the drugs in the group don’t pose just as much risk,” he said. Adds Dr. Healy, “What is very, very clear is that people do become hostile on the drugs.”¹⁶

11 Peter R. Breggin, MD, “Recent Regulatory Changes in Antidepressant Labels: Implications of Activation (Stimulation) for Clinical Practice,” *Primary Psychiatry*, Jan. 2006; 13(1): p 58.

12 “TeenScreen—Prescription Drug Pusher in Schools,” *Scoop Independent News*, 24 July 2006.

13 FDA’s Safety Information and Adverse Event Reporting Program, *Effexor XR*, Nov. 2005.

14 Jason Cato, “As trial nears, defense team in Pittman case grows by three,” *The Herald (Rock Hill, SC)*, 12 Oct. 2004.

15 FDA Statement on Concerta and Methylphenidate, 28 June 2005.

16 <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0030372>

Coincidence of school massacres and psychiatric medication.

Nationally and internationally critical experts noted the possible link between shootings in schools and shopping malls and psychiatric medication. An insightful graphical representation of a coincidence of psychiatric drugs and violence, however, did not exist.

News about cases of lethal senseless violence with multiple victims reached the international media, but their frequency in smaller (European) countries is so low that statistics is problematic. In addition, in a high percentage of such violent incidents the medical records of the offender has not been revealed, which is an additional handicap to encourage policymakers to get this phenomenon investigated.

A graphic presentation may help informing about such possibly unknown effects of psychiatric drugs on the brain.

Here we used the following approach. As a measure for the increase of psychiatric medications we used data on psychiatric medication in the U.S.¹⁷ Although data for the US cannot not one-to-one be used for other areas, we present those data as a global picture, a trend, valid in many western countries. Another reason for choosing the U.S. is that it is a large geographical area, flattening out local peaks.¹⁸

For the counting of violent crimes we chose the list of international school massacres on the English Wikipedia (see the footnote for further explanation).

¹⁷ It may be illustrative for the scarcity of data on this subject that data points for the curves for medication as well as for school massacres, were laboriously collected from various sources.

<http://online.wsj.com/article/SB10001424052970203503204577040431792673066.html>

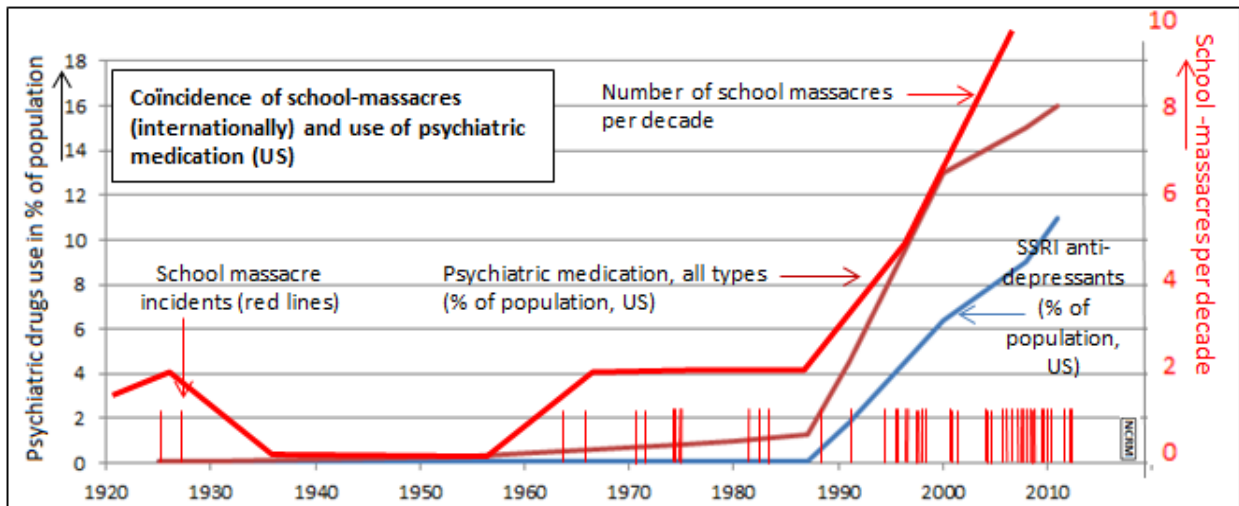
http://en.wikipedia.org/wiki/Demographics_of_the_United_States#Age_structure

<http://www.thestreetspirit.org/August2005/interview.htm>

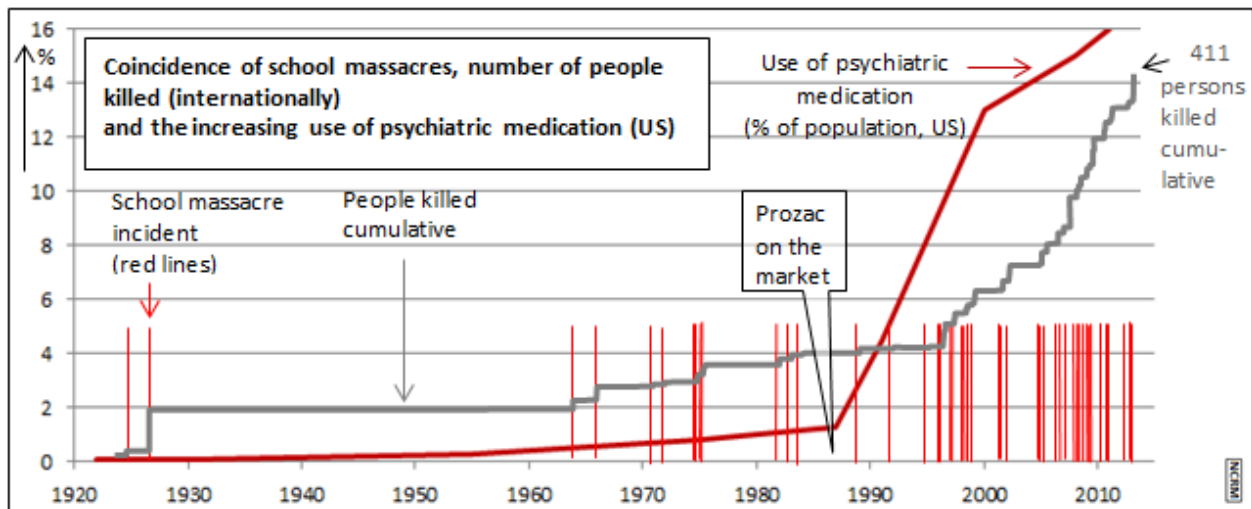
<http://www.cdc.gov/nchs/data/hus/hus10.pdf>, table 95. And as a starting point: 1987, Prozac appears on the market.

http://en.wikipedia.org/wiki/List_of_rampage_killers:_School_massacres. We realize that reliability of information on Wikipedia is dependent on the activity of volunteers. However, and especially in the English wiki, there are many checks by fellow users. Moreover, also from other sources no high frequency of school shootings in the period before 1950 were found. There is a striking lack of data available by bodies which might be considered responsible for the subject.

¹⁸ Criticism of choice for the U.S. is possible because in the U.S. relatively many shootings take place, which influences statistics. We would encourage that discussion, which we would then give in hands of neutral and objective scientists; a study of this topic has too long been deprived of resources.



Psychiatric medication and frequency of killings in school massacres.



A cumulative count of people killed in incidents of senseless violence in schools (internationally), together with increasing psychiatric medication (US data). The steep rise in victims of school massacres may be influenced by other causes than drugs, e.g. the availability of automatic firearms. This is, however, no reason to neglect the effects of psychiatric drugs on the minds of perpetrators who were possibly already instable.

Again we emphasize that the above graphics are no prove of a causal relation between the curves. We think, however, that this coincidence should stimulate attention for the subject. Also, we invite to compare the graphics with the aforementioned chapter on aggression-inducing effects of mind-altering drugs.¹⁹

¹⁹ <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0015337>

A few examples of severe violence where psychiatric drugs were involved

At least 11 recent school shootings in the US were committed by teens that had been taking prescribed psychotropic drugs known to cause violent and suicidal behavior.

Following are some examples of violent incidents where psychiatric drugs were involved:

- Teenager Kip Kinkel was taking Prozac when he murdered his parents and then proceeded to school where he opened fire on students in the cafeteria, killing 2 and wounding 22 (1998).
- At Columbine High School, on April 20, 1999, teens Eric Harris and Dylan Klebold shot dead 12 students and a teacher and wounded 23 others before shooting and killing themselves. Harris was taking Luvox, an antidepressant known to cause mania and violence.
- 15-year-old T. J. Solomon was being treated with Ritalin when he opened fire on and wounded 6 of his classmates (1999).
- Andreas B., of Germany, aged 15, shot and killed his private teacher while taking prescribed psychotropic drugs (Feb. 2004).
- Teenager Ryan Furlough of Maryland was convicted of the first-degree murder of a school friend, committed while taking a prescribed antidepressant (17 May 2004).
- In Japan, two boys, aged 15 and 16, stabbed a 16-year-old high-school student, while taking a sedative (sleeping pill) because, they said, it made them feel “invincible.”
- In Minnesota, 16-year-old Jeff Weise killed his grandfather and 8 others before taking his own life. He was taking Prozac (March 2005).
- Pekka-Eric Auvinen had been taking a prescribed antidepressant prior to killing 8 people and then killed himself at his school in Jokela, Finland (7 November 2007)
- Elizabeth Bush, 14 years old, was taking Prozac when she shot at fellow students, wounding one (2001).

The website <http://ssristories.com/> contains thousands of incidents where antidepressants are involved. The website was a personal initiative of 2 women (VS)²⁰.

If these violent incidents indeed were (partly) caused by psychiatric medication, this would mean a potentially destabilizing factor in society.

²⁰ The last added item is from November 2012 because the person maintaining the site tragically passed away. This may illustrate the scarcity of data on this subject at international level. The website now refers to website <https://www.rxisk.org/Default.aspx>, initiated by Dr. D. Healy (professor in Psychological Medicine at Cardiff University School of Medicine, Wales) and colleagues.

Antidepressants

Although antidepressants were once reserved for the mentally disturbed, today it is difficult to find someone who has not taken one. In fact, these drugs have become such a part of life for many people that "life without them" is simply unimaginable.

Prescribed for everything from learning and behavioral problems, bedwetting, juvenile delinquency, aggression, criminality, drug addiction and smoking, to handling the fears and problems of our elderly, antidepressants are among the most widely prescribed drugs on Earth, with fifty-four million worldwide currently on them.

But for many, taking antidepressants comes at a severe cost.

Eleven-year-old Candace was on the swimming team, played soccer and basketball, and loved to trampoline. What made her nervous, though, were exams, and for this she was prescribed an antidepressant. On January 10, 2004, Candace hanged herself in her bedroom at the age of 12. Nine months later, the US Food and Drug Administration (FDA) ordered its strongest "black box" warning to alert parents that antidepressants can cause suicidal thoughts and feelings in children under 18.

But children are not the only ones experiencing these thoughts while on antidepressants.

A 2005 Norwegian study determined that patients of all ages taking a type of antidepressant known as an SSRI were seven times more likely to commit suicide than those taking sugar pills.²¹

Most shockingly, these drugs have also proven to be ineffective.



*Still from a video registration of an FDA hearing (US) held as early as 1991.*²²

The person from the picture declares how his wife killed her children before killing herself, after taking Prozac for a few weeks.

²¹ Ivar Aursnews, et al, "Suicide attempts in clinical trials with paroxetine randomized against placebo," *BMC Medicine*, Aug. 22, 2005.

²² The video was seen Feb. 2013 at <http://www.youtube.com/watch?v=FxJomeak4V4>

Antidepressants and the placebo effect

A study published in the prestigious British Medical Journal found that antidepressants are no more effective than a sugar pill and do not reduce depression.²³ “The bottom line,” its lead author stated, “is that we really don’t have any good evidence that these drugs work.”²⁴

Unlike medical drugs, which commonly may prevent or cure disease or improve health, psychiatric drugs are only designed to suppress symptoms that return once the drug wears off. Meanwhile, physical illnesses that may be causing the symptoms go unrecognized and may get worse.

Dr. Darshak Sanghavi, clinical fellow at Harvard Medical School, is among many medical experts publicly debunking the psychiatric “chemical imbalance” theory. “Despite pseudoscientific terms like ‘chemical imbalance,’ nobody really knows what causes mental illness. There’s no blood test or brain scan for major depression. No geneticist can diagnose schizophrenia,” he said.²⁵

Like illicit drugs, these drugs provide no more than a temporary escape from problems, unwanted behavior or unpleasant emotions. The user may experience a “rebound effect” where the original mental symptoms come back even when starting withdrawing. Medical experts point out that this is the drug effect, not the “mental illness.”

Drug regulatory agency warnings on antidepressants

March 2004: The FDA warned that SSRIs could cause “anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia (severe restlessness), hypomania [abnormal excitement] and mania (psychosis characterized by exalted feelings, delusions of grandeur).”

October 2004: The FDA ordered pharmaceutical companies to add a “black box” warning that antidepressants could cause suicidal thoughts and actions in those under 18 years of age. This was later extended to age 24. Drug regulatory agencies in Australia, New Zealand and Japan have issued similar warnings.

August 2005: The European Medicines Agency’s Committee for Medicinal Products for Human Use issued its strongest warning against child SSRI antidepressant use, stating that the drugs caused suicide attempts and thoughts, aggression, hostility, oppositional behavior and anger.

January 2009: The FDA issued a letter requiring the manufacturers of Paxil to update its drug safety label to include information on serotonin syndrome or neuroleptic malignant syndrome-like reactions associated with SSRIs and SNRIs. These are potentially fatal, which manifest in high fever, muscle rigidity, loss of muscle control, racing pulse, change in blood pressure and more.

See the appendix for more official warnings on psychiatric drugs causing aggression, hostility, violence, mania, psychosis, homicidal thoughts/actions, etc.

²³ Joanna Moncrieff, MD, and Irving Kirsch, “Efficacy of antidepressants in adults,” *The British Medical Journal*, Vol. 331, pp 155-9, 16 July 2005.

²⁴ Salynn Boyles, “Battle Brews Over Antidepressant Use,” *Fox News channel*, 15 July, 2005.

²⁵ Dr. Darshak Sanghavi, “Health Care System Leaves Mentally Ill Children Behind,” [3] *The Boston Globe*[4], 27 Apr. 2004.

Psychostimulant drugs

Psychostimulants are commonly prescribed for so-called ADHD, “behavioral” or study problems. Psychostimulants, also called stimulants, mainly consist of amphetamines (Dexedrine) and methylphenidates (Ritalin, Concerta, Metadate etc.), which are very similar in chemical structure to amphetamines.

A stimulant refers to any mind-altering chemical or substance that affects the central nervous system by speeding up the body’s functions, including the heart and breathing rates.

In children, however, stimulants appear to act as suppressants, but psychiatrists and doctors state they have no idea why.²⁶

Methylphenidate, the generic name for Ritalin, is classified as a narcotic in the same abuse category as morphine, opium and cocaine. It is also classified by the International Convention on Psychotropic Substances in the same abuse category as amphetamine, PCP (hallucinogenic drugs such as angel dust) and methamphetamine.

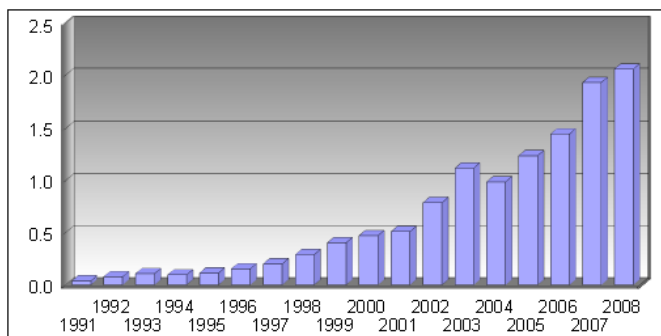
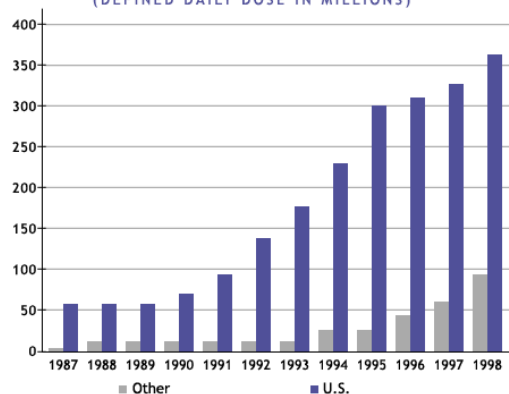
Psychiatrists claim that psychostimulants can improve a child’s academic performance by helping him to focus.

This is not totally true. Findings of a large research project over more than a decade suggested in first instance best results with medication, or medication with therapy. After 3 years those effects were gone and after 8 years there was no prove of benefits for study- or behavioral problems.²⁷

The US National Institutes of Health (NIH) ADHD Consensus Statement found that “there is little improvement in academic achievement or social skills” in children taking stimulants.²⁸

Celexa, Strattera and Wellbutrin are antidepressants prescribed to treat ADHD.

UNITED NATIONS DATA METHYLPHENIDATE CONSUMPTION
(DEFINED DAILY DOSE IN MILLIONS)



Left:: World methylphenidate consumption from the 80-ies²⁹. Right picture: Increase of methylphenidate ADHD drug use in Europe in DDD per 1000 inhabitants. (DDDs or Defined daily doses are a World Health Organisation (WHO) statistical unit of drug consumption. DDDs are used to standardize the comparative usage of various drugs between themselves or between different healthcare areas. For methylphenidate (Ritalin, Rilatine, Concerta, etc.) the DDD has been set to 30 mg per 70 kg of body weight by the WHO.)

26 Raul R. Gainetdinov; William C. Wetsel; Edward D. Sara R. Levin Jones; Mohamed Jaber; Marc G. Caron, “Role of Serotonin in the Paradoxical Calming Effect of Psychostimulants on Hyperactivity,” [28]Science,[29] 15 Jan. 1999; Brian Vastag, “Pay Attention Ritalin Acts Much Like Cocaine,” [30]Journal of the American Medical Association,[31] 22/29 Aug. 2001, Vol. 286, No. 8, p. 905.

27 Multimodal Treatment Study of Children With ADHD (MTA). Also see Shankar Vedantam, Washington Post Staff Writer in The Washington Post, Debate Over Drugs For ADHD Reignites - Long-Term Benefit For Children at Issue, 27 March 2009.

28 National Institutes of Health Consensus Statement:[33] “Diagnosis and Treatment of Attention Deficit Hyperactivity Disorder (ADHD),” Volume 16, Number 2, 16–18 Nov. 1998.

29 <http://www.dea.gov/pubs/cngrtest/ct051600.htm>

Psychostimulant drugs adverse effects and drug regulatory agency warnings

The long list of psychostimulant drugs' adverse effects include nervousness, psychosis, violent behavior, "zombie" appearance and suicidal thoughts.

These drugs are now widely abused as street drugs. About 10% (2.3 million) of American teens abuse Adderall and/or Ritalin.

In 2005, the FDA announced labeling changes for ADHD stimulants to warn that they can cause "visual hallucinations, suicidal ideation [thoughts], psychotic behavior, aggression or violent behavior."

January 2009: The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) said information packaging for methylphenidate-containing medicines must include a statement that they could cause or worsen "depression, suicidal thoughts, hostility, psychosis and mania."

See the appendix for more warnings on psychiatric drugs causing aggression, hostility, violence, mania, psychosis, homicidal thoughts/actions, etc.

The lack of effectiveness of psychiatric drugs; alternative therapies

The World Psychiatric Association and the US National Institute of Mental Health admit that psychiatrists do not know the causes or cures for any mental disorder or what their "treatments" (usually drugs) specifically do to the patient.

The positive effect of antidepressants is hardly better than the effect of a placebo pill.³⁰

Courts have determined that informed consent for people who receive prescriptions for psychotropic (mood-altering) drugs must include the doctor providing information about possible side effects and benefits, ways to treat side effects, and risks of other conditions as well as, information about alternative treatments. Yet psychiatrists generally tend to ignore these requirements.

There is a large number of alternative therapies available, these are, however, outside the context of this report.

³⁰ E.g. see <http://www.dailymail.co.uk/health/article-1299791/Why-antidepressants-simply-confidence-trick-A-leading-psychologist-claims-taking-sugar-pills-work-just-well.html?ito=feeds-newsxml>

Recommendations

The following measures should be prepared for European law to get a better view on the threat of psychiatric drug use and (extreme) violence as this may be a potential threat for a large proportion of our society.

- In every case of (severe) violence, including traffic- and industrial accidents, a forensic and/or medical investigation should be done in order to check for psychiatric medication. The outcome of each investigation must be made public and be added to a central international data base.
- Until an international system is operational, registration of psychiatric drugs related incidents should be collected at a national level.
- These data centers for data collection should be controlled by an independent party. The information should be available for everyone.
- The European Commission should fund such a center. All drugs packaging leaflets should contain a web link to the data collection center.
- Withholding information on the subject of psychiatric drug induced violence must be discouraged in the strongest possible way.

Appendix

Warnings of Psychiatric Drug Causing Aggression, Hostility, Violence, Mania, Psychosis, Homicidal Thoughts/Actions, etc.

Across 5 countries (US, UK, Canada, Australia, and Japan) and Europe, there have been 24 drug regulatory and pharmaceutical company warnings about psychiatric drugs causing violence and aggression.

These warnings are as follows:

1995:

October 1995: The U.S. Drug Enforcement Administration (DEA) said Ritalin use could lead to addiction and that “**psychotic episodes, violent behavior** and bizarre mannerisms had been reported” with its use.ⁱ

2003:

July 2003: Health Canada’s Health Products and Food Branch warned health care professionals, “Until further information is available, Paxil should not be used in...pediatric patients...**due to a possible increased risk of suicide-related adverse events in this patient population.**” Further, incidents of suicidal thoughts and self-harm were nearly twice as high on Paxil as on placebo (5.3% vs. 2.8%).ⁱⁱ

August 22 2003: Wyeth Pharmaceuticals, the makers of SSRI antidepressant Effexor, issued a warning to U.S. doctors that use of the drug could cause **hostility, suicidal ideation and self-harm** in patients under the age of 18. In September, a similar alert was sent to Canadian doctors telling them Effexor had been linked with a possible increase in suicidal thinking in children.ⁱⁱⁱ

2004:

March 22 2004: The FDA Public Health Advisory was issued, stating: “**Anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia [severe restlessness], hypomania [abnormal excitement, mild mania] and mania [psychosis]** have been reported in adult and pediatric patients being treated with [Paxil-like] antidepressants...both psychiatric and non-psychiatric.”^{iv}

April 22, 2004: The European Agency for the Evaluation of Medicinal Products issued a press release to the press and public. In this press release, they report that, according to clinical trials, Paroxetine (**Paxil**) **containing medicines can cause suicidal behavior and hostility in children.** It recommends that Paroxetine not be used in children and recommends that young adults be observed carefully for signs and symptoms of suicidal behavior or hostility. Paroxetine is

shown to have little effectiveness in children according to clinical trials. The committee also recommends strengthened warnings on the withdrawal symptoms of paroxetine, which are common.^v

June 3, 2004: Health Canada issued an Advisory to the public. Stronger warnings have been placed on SSRIs and other newer anti-depressants. These warnings indicate that people taking these drugs at any age are at greater risk of behavioral or emotional changes including self-harm or harm to others. The advisory said, "A small number of patients taking drugs of this type may feel worse instead of better.... 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.**" The drugs mentioned in this Advisory are Welbutrin, Zyban, Celexa, Prozac, Luvox, Remeron, Paxil, Zoloft and Effexor.^{vi}

September 21 2004: The British Healthcare Products Regulatory Authority advised that it had issued guidelines that children should not be given most SSRI antidepressants because of clinical trial data showing an increased rate of harmful outcomes, **including hostility.**^{vii}

December 2004: The Australian Therapeutic Goods Administration published an Adverse Drug Reactions Bulletin recommending that any use of SSRIs in children and adolescents should be carefully monitored for the emergence of suicidal ideation. In a recent study involving Prozac, it said, there was an increase in adverse psychiatric events of **suicide, self-harm, aggression and violence.**^{viii}

2005:

April 25 2005: The European Medicines Agency's scientific committee, the Committee for Medicinal Products for Human Use (CHMP) concluded that Prozac-type SSRIs and SNRIs antidepressants were associated with increased **suicide-related behavior and hostility** in young people. The London-based watchdog said it was recommending the inclusion of strong warnings across the whole of the European Union to doctors and parents about these risks and that the drugs should not be used in children and adolescents in off label situations.^{ix}

June 28 2005: The FDA announced its intention to make labeling changes for Concerta and other methylphenidate (Ritalin) products (stimulants) to include, "psychiatric events such as **visual hallucinations, suicidal ideation, psychotic behavior, as well as aggression or violent behavior.**"^x The FDA announced its intention to also investigate possible cardiac concerns with these drugs.^{xi}

August 19 2005: The Commission of the European Communities, representing 25 European countries, endorsed and issued the strongest warning yet against child antidepressant use as recommended by Europe's Committee for Medicinal Products for Human Use (CHMP). Clinical trials had shown that the drugs caused suicidal behavior including suicide attempts and suicidal ideation, **aggression, hostility (predominantly aggression, oppositional behavior and anger) and/or related behavior.**^{xii}

November 2005: The FDA's Safety Information and Adverse Event Reporting Program reported "**homicidal ideation**" as an adverse event of Effexor ER (extended release).^{xiii}

2006:

February 2006: Health Canada approved a new warning label for Paxil that read, in part: "A small number of patients taking drugs of this type may feel worse instead of better. For example, they may experience unusual feelings of **agitation, hostility or anxiety, or have impulsive or disturbing thoughts, such as thoughts of self-harm or harm to others.**" Health Canada required Paxil's product information to detail a list of "rare" side effects, affecting fewer than one in 1,000 patients. These include **delusions, hostility, psychosis, and psychotic depression.** That's 1,000 cases in a million who could all potentially kill one or more people.^{xiv}

August 21, 2006: FDA said "ADHD" stimulant manufacturers have to strengthen their warning labels to warn that the drugs can cause suppression of growth, **psychosis**, bipolar illness, **aggression**, and 'serious' cardiovascular side effects. GlaxoSmithKline and Shire Company posted a letter to doctors about the revised prescribing information.^{xv}

October 18, 2006: The Australian Therapeutic Goods Administration ordered manufacturers of "ADHD" drugs, Ritalin, Strattera and dexamphetamine to add stronger warnings to their information packaging after receiving 200 complaints about the drugs. The TGA had received 123 reports of adverse reactions involving Ritalin, including complaints that it caused headache, nausea, anorexia, somnolence and depression; **23 reports about atomoxetine (Strattera), including aggression**, and 60 reports about dexamphetamine, including seven of agitation, five of tachycardia (rapid heartbeat) and four reports each of hypertonia (abnormally tight muscles), hyperkinesia (muscle spasm) and insomnia.^{xvi}

2007:

February 21, 2007: The FDA directed ADHD drug manufacturers to distribute "patient friendly" guides to consumers warning about serious psychiatric and cardiovascular problems, including stroke, heart attack, sudden death and **psychotic reactions** caused by ADHD drugs.^{xvii}

2008:

November 20, 2008: ELI LILLY STRATTERA WARNING: Eli Lilly including in their Strattera label in Europe to include warnings that Strattera causes "hallucinations, delusional thinking, **mania or agitation in children and adolescents without a prior history of psychotic illness or mania...**"^{xviii} Strattera is an antidepressant prescribed as a "non stimulant" drug to treat ADHD.

2009:

February 2009: AUSTRALIAN METHYLPHENIDATE WARNING: **A Boxed Warning (the strongest warning) was placed onto the ADHD drug Methylphenidate (Concerta and Ritalin)** by the Australian Therapeutic Goods Administration **for drug dependence**. It warns that chronic abuse of Methylphenidates can lead to a marked tolerance and psychological dependence with varying degrees of abnormal behaviour and **frank psychotic episodes can also occur**.^{xxix}

March 2009: UK STRATTERA WARNING: Medicines and Healthcare products Regulatory Agency (UK) published in their *Drug Safety Update* newsletter new information about Atomoxetine (Strattera, a non-stimulant ADHD drug). They warned that Atomoxetine is associated with **treatment-emergent psychotic or manic symptoms in children without a history of such disorders**.^{xxx}

May 2009: JAPANESE SSRI WARNING. The Japanese Ministry of Health, Labor and Welfare investigated news reports of antidepressant users "who developed increased feelings of hostility or anxiety, and have even committed sudden acts of violence against others." After its investigation, the Ministry decided to revise the label warnings on SSRI antidepressant stating, **"There are cases where we cannot rule out a causal relationship [of hostility, anxiety, and sudden acts of violence] with the medication."**^{xxxi}

July 2009: US WELLBUTRIN WARNING UPDATE: The FDA updated the warning label for the antidepressant Wellbutrin (bupropion) to include Boxed Warnings that patients being treated with it for smoking cessation should be observed for neuropsychiatric symptoms and **changes in behavior such as hostility agitation**, suicidal ideation as well as attempted suicide. They also updated the patient medication guide.^{xxii}

July 2009: US ZYBAN WARNING: The FDA updated the warning label for Zyban (an antidepressant used for smoking cessation) to include that all patients being treated with Zyban should be **observed for neuropsychiatric symptoms including changes in behavior, hostility, agitation**, depressed mood, and suicide-related events, including ideation, behavior, and attempted suicide. Completed suicides have been reported in some patients attempting to quit smoking while on Zyban. The label was also updated to include precautions and a medication guide.^{xxiii}

July 1, 2009: US BENZO/ANTIDEPRESSANT WARNING: The FDA has required the manufacturers of the smoking cessation aids varenicline (Chantix) and bupropion (Zyban, aka Wellbutrin) to add new Boxed Warnings and develop patient Medication Guides highlighting the **risk of serious neuropsychiatric symptoms** in patients using these products. **These symptoms include changes in behavior, hostility, agitation**, depressed mood, suicidal thoughts and behavior, and attempted suicide.^{xxiv}

2010:

October 2010: US WAKEFULNESS PROMOTING AGENT WARNING: The FDA added data to Provigil’s package insert, which now includes the Psychiatric Symptom “**aggression**” in the Warnings section.^{xxv}

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