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Psychiatric Drugs & Violence—The Facts

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Psychiatric Drugs—Regulatory Warnings on Violence, Mania, Psychosis, Homicide

Fact: Despite 22 international drug regulatory warnings on psychiatric drugsciting effects of mania, hostility, violence and even homicidal ideation, and dozens of high profile shootings/killings tied to psychiatric drug use, there has yet to be a federal investigation on the link between psychiatric drugs and acts of senseless violence.

Fact: At least 34 school shootings and/or school-related acts of violence have been committed by those taking or withdrawing from psychiatric drugs resulting in 166 wounded and 78 killed (in other school shootings, information about their drug use was never made public—neither confirming or refuting if they were under the influence of prescribed drugs).

Fact: Between 2004 and 2012, there have been 14,773 reports to the U.S. FDA's MedWatch system on psychiatric drugs causing violent side effects including: 1,531 cases of homicidal ideation/homicide, 3,287 cases of mania & 8,219 cases of aggression. Note: The FDA estimates that less than 1% of all serious events are ever reported to it, so the actual number of side effects occurring are most certainly higher**.**

School-related acts of violence aren't the only cases commonly found to be under the influence of psychiatric drugs. There are 18 other recent acts of senseless violence committed by individuals taking or withdrawing from psychiatric drugs resulting in an additional 76 dead and 61 wounded.

To read all drug regulatory agency warnings & studies on psychiatric drugs, visit CCHR's Psychiatric Drug Side Effects Search Engine.

The Drug Regulatory Agency Warnings on Psychiatric drugs and violence:

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

Source: "Detailed View: Safety Labeling Changes Approved By FDA Center for Drug Evaluation and Research (CDER) — November 2005," FDA MedWatch, November 2005.

United States, March 22, 2004: The FDA Public Health Advisory was issued, on **antidepressants** stating: "**Anxiety**, **agitation**, panic attacks, insomnia,**irritability**, **hostility**, impulsivity, **akathisia [severe restlessness]**,**hypomania [abnormal excitement, mild mania]** and **mania** [psychosis characterized by exalted feelings, delusions of grandeur and overproduction of ideas], have been reported in adult and pediatric patients being treated with antidepressants."

Source: "WORSENING DEPRESSION AND SUICIDALITY IN PATIENTS BEING TREATED WITH ANTIDEPRESSANT MEDICATIONS," FDA Public Health Advisory, 22 Mar. 2004.

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United States, 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 abuse.
Source: "Methylphenidate," U.S. Drug Enforcement Administration (DEA), October 1995.

United States, 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**." The FDA announced its intention to also investigate possible cardiac concerns with these drugs.
Source: "Statement on Concerta and Methylphenidate for the June 30 PAC", Food and Drug Administration (FDA), June 2005.

Canada, 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**.
Source: Kate Jaimet, "'I've learned a lesson in the worst way possible': What drove a loving father to kill his son?," Ottawa Citizen, 27 Aug. 2006.

Canada, June 03, 2004: Health Canada issued an advisory to the public that stated that stronger warnings have been placed on **antidepressants**. 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**."
Source: Jirina Vlk, "Health Canada advises Canadians of stronger warnings for SSRIs and other newer anti-depressants," Health Canada, 2004-31, June 3, 2004.

Japan, May 2009: 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 newer antidepressants stating, "There are cases where we cannot rule out a causal relationship [of **hostility**, **anxiety**, and **sudden acts of violence**] with the medication."
Source: "Japan Revises SSRI Warnings–Hostility, Violence," Medical News Today, May 28, 2009.

European Union, 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

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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.
Source: Commission of the European Communities Commission Decision concerning the placement on the market, under Article 21 of the Directive 2001/83/EC of the European Parliament and of the Council, Brussels 19-VIII-2005, C (2205) 3256.

Australia, February 2009: The Australian Therapeutic Goods Administration reported that a boxed warning (the strongest warning) was placed onto the ADHD psychostimulant drug methylphenidate (**Concerta and Ritalin**) for drug dependence. It warns that chronic abuse of methylphenidate can lead to a marked tolerance and psychological dependence with varying degrees of**abnormal behavior** and **frank psychotic episodes** can also occur.
Source: "Boxed Warning, Contraindications and strengthened Precautions for Methylphenidate," Janssen-Cilag, February 2009.

Australia, December 2004: The Australian Therapeutic Goods Administration published an Adverse Drug Reactions Bulletin recommending that any use of SSRI **antidepressants** 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**.
Source: "Use of antidepressants in children and adolescents," The Australian Therapeutic Goods Administration (TGA) published an Adverse Drug Reactions Bulletin, Vol 23, No. 6, Dec. 2004, p. 22.

United States, July 01, 2009: The FDA has required the manufacturers of the smoking cessation aids varenicline (Chantix) and bupropion (Zyban, aka the antidepressant **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**.
Source: "Information for Healthcare Professionals: Varenicline (marketed as Chantix) and Bupropion (marketed as Zyban, Wellbutrin, and generics)," FDA, July 1, 2009.

United Kingdom, March 2009: 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.
Source: Medicines and Healthcare products Regulatory Agency, Drug Safety Update newsletter, Vol. 2, March 8, 2009.

Australia, December 2008: The Australian Adverse Drug Reactions Bulletin published an article about the psychostimulant **Modafinil**. The bulletin advised that this drug has

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been reported to cause serious adverse skin and psychiatric reactions including **anxiety, hallucination, aggression**, and **mania**.
Source: Adverse Drug Reactions Advisory Committee, Australian Adverse Drug Reactions Bulletin, Vol. 27, No. 6, December 2008.

European Union, November 20, 2008: Eli Lilly included in their Strattera label in Europe warnings that **Strattera** causes "hallucinations, delusional thinking, **mania** or **agitation** in children and adolescents without a prior history of psychotic illness or mania…" Strattera is an antidepressant prescribed as a "non stimulant" drug to treat ADHD.
Source: "Official warnings issued: The ADHD drug Strattera CAUSES psychosis, hallucinations, mania and agitation" TransWorldNews, November 20, 2008.

United States, September 2007: The Vice President of Medical Services at the drug company Cephalon sent out a letter to health care professionals informing them of new warnings for the company's psychostimulant **Provigil**. "Updated Safety Information: Warnings regarding serious rash, including Stevens Johnson Syndrome [a life-threatening condition affecting the skin] and hypersensitivity reactions, and psychiatric symptoms (including **anxiety**, **mania**,hallucinations, and suicidal ideation). 1. Provigil can cause life-threatening skin and other serious hypersensitivity reactions… 2. Provigil is not approved for use in pediatric patients for any indication. 3. Provigil can cause psychiatric symptoms."
Source: Jeffrey M. Dayno, M.D., "Dear Healthcare Professional," Cephalon, September 2007.

United States, 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. The psychiatric adverse events included hearing voices, becoming suspicious for no reason, or**becoming manic**, even in patients who did not have previous psychiatric problems.
Source: "FDA Directs ADHD Drug Manufacturers to Notify Patients about Cardiovascular Adverse Events and Psychiatric Adverse Events," FDA News, February 21, 2007.

United States, August 21, 2006: The FDA said that **ADHD drug**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, including misuse possibly leading to sudden death from heart attacks and strokes. Psychostimulant drug companies GlaxoSmithKline and Shire posted a letter to doctors about the revised prescribing information.
Source: "UPDATE 2-US FDA calls for new warnings on ADHD drugs", Reuters, August 21, 2006.

European Union, April 25, 2005: The European Medicines Agency's scientific committee, the Committee for Medicinal Products for Human Use, concluded

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that **Prozac-type antidepressants** were associated with**increased suicide-related behavior** and **hostility** in young people. The London-based watchdog said it recommended 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.
Source: "EU calls for tougher warnings on antidepressants for kids" News-Medical.net April 25, 2005.

United Kingdom, 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 increase rate of harmful outcomes, including **hostility**.
Source: "Antidepressant aggression concern," BBC News, 21 Sept. 2004.

European Union, 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 reported that, according to clinical trials, **Paroxetine** (**Paxil** in the U.S.) containing medicines could cause **suicidal behavior** and **hostility** in children. It recommended that Paroxetine not be used in children and recommended that young adults be observed carefully for signs and symptoms of **suicidal behavior** or **hostility**. Paroxetine was shown to have little effectiveness in children according to clinical trials. The committee also recommended strengthened warnings on the withdrawal symptoms of paroxetine, which are common.
Source: "European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products 20-22 April 2004″ EMEA, The European Agency for the Evaluation of Medicinal Products, Press Release April 2004.

Canada, August 22, 2003: Wyeth Pharmaceuticals, the makers of the antidepressant **Effexor**, issued a warning to U.S. and Canadian doctors that use of this drug could cause **hostility**, **suicidal ideation** and **self-harm** in patients under the age of 18.
Source: Wyeth Pharmaceuticals, "Dear Health Care Professional…" Health Canada, Health Products and Food Branch, August 22, 2003.

United States, May 2007: The FDA's MedWatch system published a warning on the psychostimulant **Desoxyn** which is used for ADHD stating that the drug could cause: sudden death with pre-existing structural cardiac abnormalities or other serious heart problems, psychiatric adverse avents including **aggression**and the **emergence of new psychotic or manic symptoms**, long-term suppression of growth, seizures, visual disturbance, as well as serious cardiovascular adverse event.
Source: Food and Drug Administration (FDA), "Detailed View: Safety Labeling Changes Approved By FDA Center for Drug Evaluation and Research (CDER)", MedWatch, May 2007.