

# THE SIDE EFFECTS OF COMMON PSYCHIATRIC DRUGS



A REPORT BY THE CITIZENS COMMISSION ON HUMAN RIGHTS® INTERNATIONAL

## MISSION STATEMENT

The Citizens Commission on Human Rights is a mental health watchdog that investigates and exposes psychiatric violations of human rights. It works shoulder-to-shoulder with like-minded groups and individuals who share a common purpose to clean up the field of mental health. It shall continue to do so until psychiatry's abusive and coercive practices cease and human rights and dignity are returned to all.

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**Report any adverse psychiatric drug effects to the FDA's MedWatch program at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm> or log onto <http://cchrint.org/>. Keep up on latest news at <http://twitter.com/cchrint>.**

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## PRELUDE

This report is an overview of the side effects of common psychiatric drugs and includes information on drug regulatory agency warnings, studies and other reports that may not appear in the packaging information for the drugs. For further information consult the *Physicians' Desk Reference* which can be found at <http://www.pdrhealth.com>.

It could be dangerous to immediately cease taking psychiatric drugs because of potential significant *withdrawal* side effects. No one should stop taking any psychiatric drug without the advice and assistance of a competent, medical doctor.

CCHR does not offer medical advice or referrals. The information in this publication is offered as a public service. Some of the brand names of drugs included relate to countries outside of the United States.

# PSYCHOSTIMULANTS

## BRAND NAMES (GENERIC NAMES):

Adderall (amphetamine and dextroamphetamine)	Dexedrine (dextroamphetamine sulfate)
Benzedrine (amphetamine sulfate)	Dextrostat (dextroamphetamine)
Concerta (methylphenidate)	Equasym (methylphenidate)
Cylert (pemoline - removed from the market)	Focalin (dexmethylphenidate)
Daytrana (methylphenidate - skin patch)	Metadate (methylphenidate)
Desoxyn (methamphetamine hydrochloride)	Methylin (methylphenidate hydrochloride)
	Provigil (modafinil)
	Ritalin (methylphenidate)
	Vyvanse (lisdexamphetamine)

## SIDE EFFECTS:

Abdominal pain	Headaches	Stomach pain
Aggressive or hostile behavior	Heart attack	Stroke
Agitation	Hives	Stuffed or runny nose
Angina (sudden acute pain)	Hypersensitivity	Stunted growth
Anorexia	Impotence	Sudden death
Blisters or rash	Increased irritability	Suicidal thoughts
Blood pressure and pulse changes	Insomnia	Swelling inside the nose
Changes in sex drive or ability	Involuntary tics and twitching	Swelling of the eyes, face, tongue, or throat
Changes in vision or blurred vision	Itching	Tourette's Syndrome*
Chest pain	Liver problems	Toxic psychosis
Depression	Loss of appetite	Unusual bleeding or bruising
Diarrhea	Mania	Unusual sadness or crying
Difficulty falling asleep or staying asleep	Mental/mood changes	Unusual weakness or tiredness
Dizziness or faintness	Muscle or joint tightness	Violent behavior
Drowsiness	Nausea	Vomiting
Dry mouth	Nervousness	Weakness or numbness of an arm or leg
Fast, pounding, or irregular heartbeat	Painful menstruation	Weight loss
Fever	Psychosis	"Zombie" demeanor <sup>1</sup>
Hallucinations	Purple blotches under the skin	
	Restlessness	
	Seizures	
	Slow or difficult speech	
	Sore throat	

\***Tourette's Syndrome:** a neurological disorder characterized by recurrent involuntary movements, including multiple neck jerks and sometimes vocal tics, as grunts, barks, or words, esp. obscenities.

Suicide is a major complication of withdrawal from Ritalin and similar amphetamine-like drugs.<sup>2</sup>

**Note:** The U.S. Drug Enforcement Administration (DEA) classifies **methylphenidate**, the generic name for Ritalin, Concerta, Metadate and Methylin, as a Schedule II narcotic in the same abuse category as morphine, opium and cocaine.<sup>3</sup>

**Methylphenidate** is amphetamine-like because it is very similar in chemical structure to amphetamine and how it affects the body. The DEA says that it is structurally and pharmacologically similar to cocaine. An amphetamine's chemical structure resembles natural stimulants in the body, like adrenaline. However, as a drug, it alters the natural system and can reduce appetite and fatigue and "speed" you up. A stimulant (psychostimulant) 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. Stimulants are most often prescribed to children for the so-called condition Attention Deficit Hyperactivity Disorder (ADHD). In children, however, stimulants appear to act as suppressants, but psychiatrists and doctors have no idea why. A 1999 study published in *Science Journal*, determined: "The mechanism by which psychostimulants act as calming agents...is currently unknown."<sup>4</sup>

#### **NON-STIMULANT "ADHD" DRUGS:**

**Celexa** (citalopram), **Strattera** (atomoxetine) and **Wellbutrin** (bupropion HCL) are all antidepressants prescribed to treat "ADHD" and are covered in the section on new antidepressants (page 8). Strattera is the only one the FDA has approved for treating ADHD and carries serious warnings (page 15).

#### **GENERAL WARNINGS AND STUDIES ON PSYCHOSTIMULANTS:**

**June 28, 2005:** The Food and Drug Administration (FDA) identified possible safety concerns with methylphenidate (Ritalin, Adderall, Concerta, etc.) drug products. Specifically noted were psychiatric adverse effects when prescribed to treat "ADHD," such as visual hallucinations, suicidal ideation, psychotic behavior, aggression and violent behavior.<sup>5</sup>

**September 13, 2005:** The Oregon Health & Science University, Evidence-Based Practice Center published the findings of its review of 2,287 studies—virtually every study ever conducted on ADHD drugs—and found that no trials had shown the effectiveness of these drugs and that there was a lack of evidence that they could affect "academic performance, risky behaviors, social achievements, etc." Further, "We found no evidence on long-term safety of drugs used to treat ADHD in young children" or "adolescents."<sup>6</sup>

**January 5, 2006:** The FDA said it had received reports of sudden deaths, strokes, heart attacks and hypertension (high blood pressure) in both children and adults taking ADHD

drugs and asked its Drug Safety and Risk Management advisory committee to examine the potential of cardiovascular (heart) risks of the drugs.<sup>7</sup>

**February 4, 2006:** A University of Texas study published in *Pediatric Neurology* reported cardiovascular problems in children taking stimulants.<sup>8</sup>

**February 9, 2006:** The FDA's Drug Safety and Risk Management Advisory Committee urged that the FDA's strongest "black box" warning be issued for stimulants because they may cause heart attacks, strokes and sudden death.<sup>9</sup>

**March 22-23, 2006:** Two FDA advisory panels held hearings into the risk of stimulants and another new ADHD drug called Sparlon (Provigil). Between January 2000 and June 30, 2005, the FDA had received almost 1,000 reports of kids experiencing psychosis or mania while taking the drugs. The first panel recommended stronger warnings against stimulants, emphasizing these should appear on special handouts called "Med Guides" (Medication Guides) that doctors must give to patients with *each* prescription. The second committee recommended against approval of Sparlon.<sup>10</sup>

**March 28, 2006:** The Australian Therapeutic Goods Administration reported 400 adverse reactions to stimulants in children taking them, including strokes, heart attacks and hallucinations.<sup>11</sup>

**December 2007:** A study in the journal *Pediatrics* concluded: "[S]timulants were associated with an increase in cardiac emergency department visits."<sup>12</sup>

**February 2008:** A study in *Arthritis & Rheumatism*, entitled, "Association between treatment with central nervous system [CNS] stimulants and Raynaud's Syndrome [RS\*] in children: a retrospective case-control study of rheumatology [disorder of the muscles, tendons, joints, bones, or nerves, characterized by discomfort and disability] patients," concluded: "[T]here is a significant association between development of RS and therapy with CNS stimulants used for the treatment of ADHD."<sup>13</sup> [\*RS: Discoloration of the fingers and/or toes after changes in temperature or emotional events due to abnormal spasms of the blood vessels resulting in lost blood supply to the area.]

## **ABUSE OF STIMULANTS:**

The FDA requires stimulants such as Ritalin and Adderall to carry a boxed warning that states the drug is "a federally controlled substance because it can be abused or lead to dependence. Keep RITALIN [Adderall] in a safe place to prevent misuse and abuse."

**August 2001:** A study published in the *Journal of the American Medical Association* concluded that methylphenidate is chemically similar to cocaine.<sup>14</sup> Children who took stimulants were more likely to start smoking or use cocaine and continue these habits into adulthood.<sup>15</sup>

**April 2005:** Partnership for a Drug-Free America released the findings of its survey, which determined that 10% (2.3 million) of teens had abused Ritalin and Adderall.<sup>16</sup>

**February 25, 2006:** A study in the journal *Drug and Alcohol Dependence* revealed that seven million Americans were estimated to have abused stimulant drugs and a substantial amount of teenagers and young adults appeared to show signs of addiction.<sup>17</sup>

## **WARNINGS AND STUDIES ON SPECIFIC PSYCHOSTIMULANTS:**

### **ADDERALL (amphetamine and dextroamphetamine):**

Adderall is an amphetamine mixture that has been linked to violent behavior when, in 1999, a North Dakota judge acquitted 24-year-old Ray Ehlis of murdering his 5-week-old daughter after two independent psychiatrists testified he was suffering a severe psychosis induced by Adderall.<sup>18</sup>

**June 2004:** The FDA ordered that the packaging for Adderall include a warning about sudden cardiovascular deaths, especially in children with underlying heart disease.<sup>19</sup>

**February 9, 2005:** Health Canada, the Canadian counterpart of the FDA, suspended marketing of Adderall XR (Extended Release, given once a day) due to reports of 20 sudden unexplained deaths (14 in children) and 12 strokes (2 in children) in patients taking Adderall or Adderall XR. However, in August 2005, Health Canada agreed to reinstate the marketing authorization with a number of revisions to the labeling to warn against the use of Adderall XR in patients with structural heart abnormalities and advised about the dangers of misusing amphetamines.<sup>20</sup> The FDA warned that as Adderall is an amphetamine, it has a “high potential for abuse. Taking amphetamines for long periods of time may lead to drug addiction.” Further, Adderall should never be taken in conjunction with antidepressants in the (MAOI) Monoamine Oxidase Inhibitor class.<sup>21</sup> (See page 17)

### **CYLERT (pemoline):**

**September 1997:** Britain removed Cylert from the market after reports of death related to liver toxicity in people taking it. Cylert posed a threat of serious liver complications, including liver failure resulting in death or liver transplantation.<sup>22</sup>

**September 1999:** Canada removed Cylert from the market after reports of death related to liver toxicity in people taking it.<sup>23</sup>

**October 24, 2005:** The FDA finally withdrew Cylert from the market because of its “overall risk of liver toxicity” and liver failure.<sup>24</sup>

### **METADATE CD (methylphenidate):**

Metadate is a reformulation of Ritalin for extended delivery over several hours and carries the same warnings as Ritalin and potential for abuse. Metadate should not be taken if: “You have significant anxiety, tension, or agitation since METADATE CD may make these conditions worse...you have glaucoma, an eye disease, you have tics or Tourette’s Syndrome (condition manifesting in involuntary physical and vocal tics.)”<sup>11</sup>

### **PROVIGIL (modafinil):**

Provigil was approved to treat daytime sedation as a means to keep people awake. Its manufacturer, Cephalon, unsuccessfully attempted to get FDA approval for the drug’s use in treatment of ADHD under the trade name Sparlon. However, this does not mean that psychiatrists or physicians will not prescribe Provigil for ADHD, even though it is not FDA approved for this use or for any pediatric use.

**September 2007:** Cephalon sent a letter to health care professionals informing them of new warnings: “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.”<sup>25</sup>

### **RITALIN (methylphenidate):**

The *Physicians’ Desk Reference (PDR)* warns, “psychotic episodes can occur” with abuse. Suicide is the major complication of withdrawal from Ritalin and similar drugs.<sup>26</sup>

The DEA says Ritalin could lead to addiction and that “psychotic episodes, violent behavior and bizarre mannerisms have been reported” with its use.<sup>27</sup>

**October 17, 2007:** In Japan, the Health, Labor and Welfare Ministry panel (similar to the FDA) removed Ritalin from its list of approved medicines to treat depression. It was considered that it could exacerbate the already significant amount of Ritalin abuse in the country.<sup>28</sup>

**2008:** The current FDA Medication Guide warns of heart-related problems with Ritalin and other stimulants, including, “sudden death in patients who have heart problems or heart defects; stroke and heart attack in adults; increased blood pressure and heart rate.” Further, for all patients, “new or worse behavior and thought problems...new or worse aggressive behavior or hostility” and in children and teens, “new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms.”<sup>29</sup>

# NEWER ANTIDEPRESSANTS

(Including Selective Serotonin Reuptake Inhibitors or SSRIs; Selective or Serotonin/Norepinephrine Reuptake Inhibitors or SNRIs)

## BRAND NAMES (GENERIC NAMES):

### SSRIs (SELECTIVE SEROTONIN REUPTAKE INHIBITORS\*)

Akarin (citalopram)	Lovan (fluoxetine)
Apo-Sertral (sertraline)	Lustral (sertraline)
Aropax (paroxetine)	Luvox (fluvoxamine)
Asentra (sertraline)	Paroxat (paroxetine)
Celexa (citalopram)	Paxil (paroxetine)
Cipralext (escitalopram)	Pexeva (paroxetine)
Cipram (citalopram)	Prisdal (citalopram)
Cipramil (citalopram)	Prozac (fluoxetine hydrochloride)
Citopam (citalopram)	Psiquial (fluoxetine)
Deroxat (paroxetine)	Sarafem (fluoxetine hydrochloride)
Dumyroxt (fluvoxamine)	Sercerin (sertraline)
Eufor (fluoxetine)	Serlift (sertraline)
Faverin (fluvoxamine)	Seroplex (escitalopram)
Floxyfral (fluvoxamine)	Seroplexa (escitalopram)
Fluctine (fluoxetine)	Seropram (paroxetine)
Fluocim (fluoxetine)	Seroxtat (paroxetine)
Fluox (fluoxetine)	Sipralexta (escitalopram)
Fluvox (fluvoxamine)	Tolrest (sertraline)
Gladem (sertraline)	Veritina (fluoxetine)
Ladose (fluoxetine)	Zoloft (sertraline hydrochloride)
Lexapro (escitalopram oxalate)	Xydep (sertraline)

### SNRIs (SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS\*)

Ariclaim (duloxetine)	Effexor (venlafaxine)
Cymbalta (duloxetine)	Ixel (milnacipran)
Dalcipran (milnacipran)	Pristiq (desvenlafaxine)
Dobupal (venlafaxine)	Yentreve (duloxetine)
Efectin (venlafaxine)	

### SNRIs (SELECTIVE NOREPINEPHRINE REUPTAKE INHIBITORS\*)

Edronax (reboxetine)	Serzone (nefazodone)
Outonin (nefazodone)	Strattera (atomoxetine)
Merital (nomifensine)	Vestra (reboxetine)
Norebox (reboxetine)	

### NDRIs (NOREPINEPHRINE-DOPAMINE REUPTAKE INHIBITORS\*)

Odranal (bupropion)	Zyban (bupropion)
Wellbutrin (bupropion)	

### OTHER

Desyrel (trazodone)	Serzone (nefazodone)
Dutonin (nefazodone)	Symbyax (fluoxetine and olanzapine – antidepressant/antipsychotic mix)
Ludiomil (maprotiline hydrochloride)	
Nedafar (nefazodone)	

## SIDE EFFECTS:

Abnormal bleeding or bruising	Gas or bloating	Rash
Abnormal thoughts	Hallucinations	Restlessness
Agitation	Headache	Ringing in the ears
Akathisia (severe restlessness)	Heart attacks	Runny nose
Anxiety	Heartburn	Seizures
Black and tarry stools	Hives	Sensitivity to light
Blisters	Hoarseness	Sexual dysfunction
Blood in stools	Hostility	Slow or difficult speech
Bloody vomit	Hot flashes or flushing	Small purple spots on the skin
Blurred or changes in vision	Hypomania (abnormal excitement)	Sneezing
Burning or tingling in the hands, arms, feet, or legs	Impotence	Sore throat, fever, chills, and other signs of infection
Burping	Increased appetite	Stomach pain
Changes in ability to taste food	Increased sweating	Sudden muscle twitching or jerking that can't be controlled
Changes in sexual desire or ability	Indigestion	Sudden upset stomach
Chest pain	Insomnia	Suicidal thoughts or behavior
Coma	Itching	Swelling of the eyes, face, lips, tongue, throat, hands, arms, feet, ankles, or lower legs
Confusion	Joint pain	Swelling, itching, burning, or infection in the vagina
Constipation	Loss of appetite	Tightness in hands and feet
Cough	Lump or tightness in throat	Twitching
Dark colored urine	Mania	Uncontrollable shaking of a part of the body
Delusions	Memory lapses	Violent behavior
Diarrhea	Mood swings	Vomiting
Difficult, frequent, or painful urination	Muscle weakness or tightness	Vomiting material that looks like coffee grounds
Difficulty breathing or swallowing	Nausea	Weakness or numbness of an arm or leg
Difficulty concentrating	Nervousness	Weakness or tiredness
Dizziness or faintness	Neuroleptic Malignant Syndrome*	Weight gain
Drowsiness	Nightmares	Weight loss
Dry mouth	Numbness in your hands, feet, arms, or legs	Withdrawal symptoms include deeper depression
Emotional numbing	Pain in the back, muscles, joints, or anywhere in the body	Yellowing of the skin or eyes <sup>30</sup>
Enlarged pupils (black circles in the middle of the eyes)	Pain in the upper right part of the stomach	
Eye pain or redness	Painful erection that lasts for hours	
Fast, pounding, or irregular heartbeat	Painful or irregular menstruation	
Fever	Panic attacks	
Flu-like symptoms	Paranoia	
Flushing	Problems with coordination	
Forgetfulness	Problems with teeth	
	Psychotic episodes	

\**Neuroleptic malignant syndrome*: A potentially fatal toxic reaction where patients break into fevers and become confused, agitated and extremely rigid. An estimated 100,000 Americans have died from it after taking the older antipsychotics.<sup>88</sup>

## EXPLANATORY NOTE:

The newer antidepressants, Selective Serotonin Reuptake Inhibitors (SSRIs) emerged in the late 1980s/1990s, marketed as being capable of selectively targeting a chemical—serotonin—in the brain that was theorized to influence depression. This has remained a theory only. **Serotonin** (of which about only 5% is found in the brain) is one of the chemicals by which brain cells signal each other. SSRIs prevent serotonin from being naturally reabsorbed and thus create continued stimulation of cells. **Norepinephrine** is a hormone secreted by the adrenal gland that increases blood pressure and rate and depth of breathing, raises the level of blood sugar, and decreases the activity of the intestines. Norepinephrine is very similar to its cousin, adrenaline. **Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)** boost levels of norepinephrine in addition to serotonin. There is another SNRI, which is called **Selective Norepinephrine Reuptake Inhibitors**, and is largely prescribed for “ADHD” but carries the same suicide warning as SSRIs and other antidepressants. **Norepinephrine-Dopamine Reuptake Inhibitors (NDRIs)** are said to influence norepinephrine and dopamine, another chemical messenger that is similar to adrenaline. There are no physical tests or scientific evidence to substantiate the theory that a chemical imbalance in the brain causes depression or any mental disorder.

**Wellbutrin** is a short-acting antidepressant and amphetamine-like drug similar to Ritalin and Dexedrine.

**Strattera** (atomoxetine) increases norepinephrine and dopamine in the frontal part of the brain and is a Selective NRI. The precise mechanism by which atomoxetine produces its effects on so-called ADHD is unknown.

## GENERAL WARNINGS AND STUDIES ON NEWER ANTIDEPRESSANTS:

**1997:** Candace B. Pert, Research Professor at Georgetown University Medical Center in Washington, D.C., and credited as one of the researchers that helped develop Prozac, wrote that SSRIs “may also cause cardiovascular problems in some susceptible people after long-term use, which has become common practice despite the lack of safety studies.” In 2002, she added, “They are supposed to help but they actually cause violence. There’s scientific literature that supports that.”<sup>31</sup>

**March 22, 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].”<sup>32</sup>

**August 20, 2004:** A Columbia University review of the pediatric clinical trials of Zoloft, Celexa, Effexor, Paxil, Prozac and another older antidepressant, found that young people who took them could experience suicidal thoughts or actions.<sup>33</sup>

**2004:** The British Healthcare Products Regulatory Authority (MHRA, similar to the FDA) issued guidelines that children should not be given most SSRIs because clinical trial data showed an increased rate of harmful outcomes, including hostility.<sup>34</sup>

**October 15, 2004:** The FDA ordered pharmaceutical companies to add a “black box” warning to all antidepressants because the drugs could cause suicidal thoughts and actions in children and teenagers. The agency also directed the manufacturers to print and distribute medication guides with every antidepressant prescription and to inform patients of the risks.<sup>35</sup>

**October 21, 2004:** The New Zealand Medicines Adverse Reactions Committee recommended that old and new antidepressants not be administered to patients less than 18 years of age because of the potential risk of suicide.<sup>36</sup>

**December 2004:** The Australian Therapeutic Goods Administration said children and adolescents prescribed SSRI antidepressants should be carefully monitored for the emergence of suicidal ideation. In a study involving Prozac, it said, there was an increase in adverse psychiatric events (acts and thoughts of suicide, self-harm, aggression and violence).<sup>37</sup>

**December 9, 2004:** The European Medicines Agency’s Committee for Medicinal Products for Human Use, representing 25 European countries, recommended that product information should be changed for antidepressants (including SSRIs, SNRIs) to warn of the risk of suicide-related behavior in children and adolescents and of withdrawal reactions when stopping treatment. This was reaffirmed in April 2005, warning that the drugs increased suicide-related behavior and hostility in young people.<sup>38</sup>

**February 18, 2005:** A study published in the *British Medical Journal* determined that adults taking SSRI antidepressants were more than twice as likely to attempt suicide as patients given placebo (a substance with no real effect; it contains no active ingredients and is given to a patient in a clinical trial to assess and compare the performance of a new drug).<sup>39</sup>

**July 16, 2005:** The *British Medical Journal* published a study, “Efficacy of antidepressants in adults,” by Joanna Moncrieff, senior lecturer in psychiatry at University College London who found that antidepressants, especially SSRIs, were no more effective than placebo and did not reduce depression. In a media interview Dr. Moncrieff stated, “**The bottom line is that we really don’t have any good evidence that these drugs work.**”<sup>40</sup>

**August 2005:** The Australian Therapeutic Goods Administration found a relationship between SSRIs and suicidality, akathisia (severe restlessness), agitation, nervousness and anxiety in adults. It also determined that similar symptoms could occur during withdrawal from the drugs.<sup>41</sup>

**August 19, 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.<sup>42</sup>

**August 22, 2005:** Norwegian researchers determined that patients taking SSRI antidepressants were seven times more likely to experience suicide than those taking placebo.<sup>43</sup>

**May 1, 2006:** An *American Journal of Psychiatry* study revealed that elderly people prescribed SSRI antidepressants such as Prozac, Paxil and Zoloft are almost five times more likely to commit suicide during the first month on the drugs than those given other classes of antidepressants.<sup>44</sup>

**July 19, 2006:** The FDA warned that migraine sufferers should not take SSRI or SNRI antidepressants while taking migraine drugs known as triptans as it could result in a life-threatening condition called serotonin syndrome. Serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhea. Serotonin syndrome may be more likely to occur when starting or increasing the dose of a triptan, SSRI or SNRI, according to the FDA.<sup>45</sup>

**May 2, 2007:** The FDA officially extended the age group for the black box warning about antidepressants inducing suicide from 18 to 24.<sup>46</sup>

**January 2008:** The Pharmacovigilance Working Party (advises on the safety and adverse reactions of medicinal products authorized for use in the European Union) recommended an update to product labeling and all antidepressant patient information leaflets to warn about the increased risk of suicide in children and young adults taking them.<sup>47</sup>

**January 22, 2008:** *The Annals of Pharmacotherapy* published a study on the risk of cerebrovascular (of or relating to the brain and the blood vessels that supply it) events (CVE) associated with antidepressant use and found that a "24% increased risk of a CVE was noted in patients with current exposure to selective serotonin-reuptake inhibitors... 34% increased risk for current exposure to tricyclic antidepressants (older form of antidepressant)... and 43% increased risk for current exposure to other antidepressants."<sup>48</sup>

**February 5, 2008:** Britain's Medicines and Healthcare Products Regulatory Agency advised that antidepressant manufacturers would be required to update warnings about suicidal thoughts and behavior to align with EU agreements, as noted above in January 2008.<sup>49</sup>

**February 26, 2008:** *Public Library of Science* (PLOS) published an antidepressant efficacy

study, which found that at moderate levels of depression there was virtually no difference between antidepressants and placebo. Further, there was only a relatively small difference for patients with very severe depression. The study concluded: “increased benefit for extremely depressed patients seems attributable to a decrease in responsiveness to placebo, rather than an increase in responsiveness to medication.”<sup>50</sup>

**March 2008:** Researchers conducted a study monitoring the daily news for accurate scientific data regarding the theory that depression is caused by a chemical imbalance and found there was no evidence to support it. Jeffrey Lacasse, a Florida State University doctoral candidate and visiting lecturer in the College of Social Work, and Jonathan Leo, a neuroanatomy professor at Lincoln Memorial University in Tennessee, found that reporters were unable to cite or provide any evidence to substantiate that a chemical imbalance or lack of serotonin caused depression, requiring antidepressants. Further, “[T]here are few scientists who will rise to its defense, and some prominent psychiatrists publicly acknowledge that the serotonin hypothesis is more metaphor than fact.” As such, SSRIs cannot correct an imbalance that does not exist. The researchers said the popularity of the theory was in large part based on the presumed efficacy of the SSRIs, but that several large studies now cast doubt on this efficacy.<sup>51</sup>

**January 2009:** The FDA issued a letter requiring the manufacturers of Paxil, to update their drug safety label to include information on Serotonin Syndrome or Neuroleptic Malignant Syndrome -like reactions associated with selective serotonin reuptake inhibitors and serotonin norepinephrine reuptake inhibitors.

### **WARNINGS AGAINST NEWER ANTIDEPRESSANTS TAKEN DURING PREGNANCY:**

**February 5, 2005:** An analysis of World Health Organization medical records found that infants whose mothers took SSRI antidepressants while pregnant could suffer withdrawal effects.<sup>53</sup>

**September 7, 2005:** The Australian Therapeutic Goods Administration warned that SSRI antidepressant use during pregnancy could cause “withdrawal effects that can be severe or life-threatening.”<sup>54</sup>

**September 27, 2005:** The FDA warned that Paxil and other SSRI antidepressants taken during the first trimester of pregnancy could cause increased risk of major birth defects, including heart malformations in newborn infants.<sup>55</sup>

**February 6, 2006:** A study published in the *Archives of Pediatrics and Adolescent Medicine* determined that nearly one-third of newborn infants whose mothers took SSRI antidepressants during pregnancy experienced withdrawal symptoms that included high-pitched crying, tremors and disturbed sleep.<sup>56</sup>

**March 10, 2006:** Health Canada issued a warning that pregnant women taking SSRIs and other newer antidepressants placed newborns at risk of developing a rare lung and heart condition.<sup>57</sup>

**October 2007:** A study released at the 54th Annual Meeting of the American Academy of Child & Adolescent Psychiatry showed that babies born to mothers who took antidepressants during pregnancy had high levels of cortisol (hormone that helps manage blood pressure) in umbilical cord-blood at birth and that the mothers were more likely to experience delivery complications. When examined at two weeks of age, these infants were more excitable than those born to women who did not take antidepressants.<sup>58</sup>

**May 6, 2008:** The results of a study of 200 pregnant women, was presented at the annual meeting of the American Psychiatric Association. About half of the women were diagnosed with depression, and half of these took SSRIs throughout pregnancy. About 23% of those who took SSRIs gave birth to pre-term babies at a rate that was nearly four times that experienced by women (6%) who did not take antidepressants or *did not* have depression.<sup>59</sup>

## **WARNINGS ON SPECIFIC NEWER ANTIDEPRESSANTS:**

### **CYMBALTA (duloxetine, SNRI):**

**June 30, 2005:** The FDA warned that Cymbalta could increase suicidal thinking or behavior in pediatric patients taking it.<sup>60</sup>

**October 17, 2005:** The FDA ordered Eli Lilly & Co. to add a warning to the packaging of Cymbalta that it could cause liver damage.<sup>61</sup>

**October 2, 2007:** The FDA faxed Eli Lilly & Co. about its professional mailer for Cymbalta, stating that it was “false or misleading in that it overstates the efficacy of Cymbalta and omits some of the most serious and important risk information associated with its use.”<sup>62</sup>

### **PAXIL (paroxetine, SSRI):**

**September 27, 2005:** The FDA warned that Paxil taken by pregnant women in their first trimester might cause birth defects, including heart malformations.<sup>63</sup>

**May 12, 2006:** GlaxoSmithKline, the manufacturer of Paxil, wrote to doctors warning that Paxil increased the risk of suicide in *adults*.<sup>64</sup>

**January 29, 2008:** *The Canadian Medical Association Journal* published a study on the effectiveness of Paxil that involved data from 40 trials and “showed an absence of a positive effect of paroxetine [Paxil].”<sup>65</sup>

### **STRATTERA (atomoxetine, SNRI):**

*Often prescribed to treat ADHD as well as depression.*

**December 17, 2004:** The FDA required that Strattera packaging carry a new warning advising, “Severe liver injury may progress to liver failure resulting in death or the need for a liver transplant in a small percentage of patients.”<sup>66</sup> The drug should be discontinued in patients who develop jaundice (condition that causes yellowness of the skin, eyes and body fluids) or liver injury. The FDA also noted, “The labeling warns that severe liver injury may progress to liver failure resulting in death or the need for a liver transplant in a small percentage of patients.”<sup>67</sup> Signs of the possible liver problems included jaundice, dark urine, unexplained flu-like symptoms, upper right-side abdominal tenderness and a form of itchy skin known as pruritus (caused by irritation of the sensory nerve endings).<sup>68</sup> Other common side effects were headache, abdominal pain, nausea and vomiting, anorexia (eating “disorder”) and weight loss, nervousness, somnolence (drowsiness).<sup>69</sup>

**September 29, 2005:** The FDA directed Eli Lilly & Co. to revise Strattera labeling to include a boxed warning about the increased risk of suicidal thinking in children and adolescents taking it.<sup>70</sup>

**July 2008:** Health Canada published an article entitled “Atomoxetine [Strattera] and suicidal behavior: update” in its *Canadian Adverse Reaction Newsletter*, stating that as of December 2007, 1989 adverse reactions had been reported. Of these, 55 were classified as suicide attempt with about 75% of those being children. They stressed that health care providers needed to remind patients and family members to monitor moods, behaviors, thoughts and feelings when ADHD medication was used.<sup>71</sup>

**March 2009:** The 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.<sup>72</sup>

### **WELLBUTRIN (bupropion):**

The FDA approved Wellbutrin as an antidepressant in 1985 but because of the significant incidence of seizures at the originally recommended dose (400-600 mg), the drug was withdrawn in 1986. It was reintroduced in 1989 with a maximum dose of 450 mg per day. In 1996, the FDA approved a sustained release (taken twice daily) for treatment of depression. The same drug is marketed in slow-release form as Zyban for people trying to quit smoking.<sup>73</sup> While Wellbutrin is not FDA-approved to treat ADHD, doctors still prescribe it for this.

It can cause seizures and at rates of four times that of other antidepressants.<sup>74</sup> Fatal heart attacks in those with a history of heart-rhythm disturbances have occurred.<sup>75</sup> Other side effects include agitation, insomnia, increased restlessness, anxiety, delusions, hallucinations, psychotic episodes, confusion, weight loss and paranoia.<sup>76</sup> Teens have abused the drug by crushing and snorting it, causing seizures.<sup>77</sup>

# OLDER ANTIDEPRESSANTS

(Including Tricyclics, Tetracyclics and MAOIs)

## BRAND NAMES (GENERIC NAMES):

### TRICYCLICS

Adapin (doxepin)	Saroten (amitriptyline)
Anafranil (clomipramine)	Sinequan (doxepin hydrochloride)
Asendin (amoxapine)	SK-Pramine Oral (imipramine)
Aventyl (nortriptyline)	Surmontil (trimipramine maleate)
Elavil (amitriptyline)	Tofranil (imipramine hydrochloride)
Endep (amitriptyline)	Triavil (amitriptyline hydrochloride and perphenazine)
Etrafon (amitriptyline and perphenazine)	Triptazine (amitriptyline)
Janimine (imipramine)	Triptil (protriptyline)
Maneon (amitriptyline)	Tryptizol (amitriptyline)
Norpramin (desipramine hydrochloride)	Tryptanol (amitriptyline)
Nortilen (nortriptyline)	Vivactil (protriptyline hydrochloride)
Pamelor (nortriptyline)	
Pertofrane (norpramin)	

### TETRACYCLICS

Avanza (mirtazapine)	Remeron (mirtazapine)
Ludiomil (maprotiline hydrochloride)	Tolvon (mianserin hydrochloride)
Remergil (mirtazapine)	Zispin (mirtazapine)

### MAOIS

Aurorix (moclobemide)	Marplan (isocarboxazid)
Emsam (selegiline - skin patch)	Nardil (phenelzine sulfate)
Manerix (moclobemide)	Parnate (tranylecypamine sulfate)

## SIDE EFFECTS:

Anxiousness	concentration	Extreme restlessness
Black tongue	Delirium	Eye pain
Blurred vision	Delusions	Eyes more sensitive to light than usual
Breast enlargement in men and women	Depression	Fainting
Changes in appetite or weight	Diarrhea	Fast, irregular, or pounding heartbeat
Changes in sex drive or ability	Difficulty breathing or swallowing	Flu-like symptoms, fever, chills, sore throat, or other signs of infection
Cold, clammy skin	Difficulty falling asleep or staying asleep	Flushing
Coma	Difficulty thinking	Forgetfulness
Confusion	Dizziness	Frequent, painful, or difficult urination
Constipation	Drowsiness	Gas
Crushing chest pain	Dry mouth	
Decreased memory or	Excessive sweating	
	Excitement or anxiety	

Hair loss	Numbness, burning, or tingling	Tightness in the chest or throat
Hallucinations	Panic feelings	Tiredness
Heartburn	Rash or blisters	Uncontrollable shaking of any part of the body
Hives	Ringing in the ears	Unsteadiness
Hyperactivity	Sedation	Unusual bleeding or bruising
Itching	Seizures	Unusual movements that are difficult to control
Jaw, neck, and back muscle spasms	Severe headache	Unusual taste in the mouth
Lethargy	Severe muscle stiffness	Unusual tiredness or weakness
Lightheadedness	Shakiness	Weakness or tiredness
Liver problems	Shuffling walk	Widened pupils (black circles in the middle of the eyes)
Lowered white blood cell count (with risks of infection)	Slow or difficult speech	Yellowing of the skin or eyes <sup>78</sup>
Manic reactions	Stomach pain or cramps	
Muscle pain or weakness	Stroke	
Muscle twitching or jerking	Stuffy nose	
Nausea	Sudden, severe nausea and vomiting	
Neck stiffness or soreness	Sweating	
Nervousness	Swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs	
Nightmares		

### EXPLANATORY NOTE:

**Tricyclics:** (TCAs) were introduced in the late 1950s/early 60s and the name refers to the three rings in the chemical structure of the drugs.

**Tetracyclics:** The name derives from the drug’s molecular structure that consists of four-ring-like structures in a T-shape.

**MAOIs:** Monoamine Oxidase Inhibitors (MAOIs). Monoamine Oxidase is an enzyme that has the function of getting rid of *used* neurotransmitters found in the gap between nerve cells. It was theorized (not proved) that too low concentrations of neurotransmitters may cause depression and MAOIs blocked the activity of this enzyme, resulting in higher levels of neurotransmitters (serotonin, norepinephrine and dopamine, which are all “monoamines” meaning they have a single amino acid – a compound used to form proteins that are essential for function and structure of cells in the body.)

## GENERAL WARNINGS AND STUDIES ON OLDER ANTIDEPRESSANTS:

**October 15, 2004:** The FDA ordered pharmaceutical companies to add a “black box” warning to *all antidepressants*, saying the drugs could cause suicidal thoughts and actions in children and teenagers.<sup>79</sup>

**October 21, 2004:** The New Zealand Medicines Adverse Reactions Committee recommended that old and new antidepressants not be administered to patients less than 18 years of age because of the potential risk of suicide.<sup>80</sup>

**September 26, 2005:** *The Italian Gazette* (official news agency of the Italian government) published a resolution of the Agenzia Italiana del Farmaco (Italian Drug Agency, equivalent to the FDA) ordering a warning label for older antidepressants stating that the drugs should not be prescribed for under 18 year olds. They also determined that they were associated with heart attacks in people of any age.<sup>81</sup>

**September 28, 2005:** The British National Health Service’s Institute for Health and Clinical Excellence warned that “all antidepressant drugs have significant risks when given to children and young people.”<sup>82</sup>

**May 2, 2007:** The FDA told makers of all antidepressants to update the existing black box warning on their products’ labeling to include warnings about increased risks of suicidal thinking and behavior, known as suicidality, in young adults ages 18 to 24 during initial treatment.<sup>83</sup>

**October 2007:** A study released at the 54th Annual Meeting of the American Academy of Child & Adolescent Psychiatry found that babies born to mothers who take antidepressant medication during pregnancy have high levels of cortisol (a hormone that helps regulate blood pressure) in umbilical cord-blood at birth, and their mothers are more likely to experience delivery complications. When examined at 2 weeks of age, the infants of women taking antidepressants were more excitable than infants born to women not taking antidepressants.<sup>84</sup>

**February 28, 2009:** Pharmacotherapy published a study on “Antidepressant drug use and risk of venous thromboembolism [blockage of a blood vessel due to a clot],” which concluded, “Current exposure to amitriptyline [antidepressant], particularly at high doses, was associated with an increased risk of idiopathic [of unknown cause] venous thromboembolism.”

# ANTIPSYCHOTICS

(Called Major Tranquilizers or Neuroleptics)

## BRAND NAMES (GENERIC NAMES):

### OLDER ANTIPSYCHOTICS

Compazine (prochlorperazine)	Proketazine (carphenazine)
Haldol (haloperidol)	Prolixin (fluphenazine hydrochloride)
Largactil (chlorpromazine)	Repoise (butaperazine Maleate)
Lidone (molindone)	Serentil (mesoridazine besylate)
Loxitane (loxapine)	Sparine (promazine)
Mellaril (thioridazine hydrochloride)	Stelazine (trifluoperazine)
Moban (molindone hydrochloride)	Stemetil (prochlorperazine)
Navane (thiorixene)	Taractan (chlorprothixene)
Novo-Trifluzine (trifluoperazine)	Thorazine (chlorpromazine)
Nozinan (methotrimeprazine)	Tindal (acetophenazine)
Orap (pimozide)	Trancopal (chlormezanone)
Permitil (fluphenazine)	Trilafon (perphenazine)
Phenergam (promethazie)	Vesprin (triflupromazine)

### NEWER ATYPICAL ANTIPSYCHOTICS

Abilify (aripiprazole)	Serlect (sertindole)
Clozaril (clozapine)	Seroquel (quetiapine)
Geodon (ziprasidone hydrochloride)	Symbyax (fluoxetine and olanzapine – antidepressant/antipsychotic mix)
Invega (paliperidone)	Zeldox (ziprasidone)
Leponex (clozapine)	Zyprexa (olanzapine)
Risperdal (risperidone)	

### SIDE EFFECTS:

Abnormal gait (manner of walking)	Constipation	Dizziness
Agitation	Death from liver failure	Dreaming more than usual
Akathisia*	Decreased sexual interest or ability	Drowsiness
Anxiety	Depression	Dry mouth
Birth defects	Diabetes	Dry or discolored skin
Blood disorders	Diarrhea	Excess sweating
Blood-sugar abnormalities	Difficulty breathing, swallowing or fast breathing	Excessive weight gain
Blurred vision	Difficulty falling asleep or staying asleep	Extreme inner anxiety
Breastmilk production	Difficulty urinating or loss of bladder control	Eye pain or discoloration
Cardiac arrest		Fainting
Changes in behavior		Fast, irregular, or pounding heartbeat
Chest pain		Fatal blood clots
Confusion		Fever

Fine worm-like tongue movements	Light-headedness	Shakiness
Flu-like symptoms	Loss of appetite	Shaking hands that you cannot control
Headache	Manic reaction	Sleepiness
Heart arrhythmia	Mood changes	Slow or difficult speech
Heart failure	Muscle or joint stiffness, pain, or weakness	Slow, jerky movements
Heart palpitation	Muscle twitching	Sore throat
Heartburn	Nausea	Spasms
Heat stroke	Nervousness	Suicidal thoughts
Hemorrhage	Neuroleptic Malignant Syndrome*	Swelling of the arms, hands, feet, ankles, or lower legs
High fever	Nightmares	Swollen and leaking breasts
Hives	Pacing	Tachycardia (heart irregularity)
Hostility	Pain in arms, legs, back, or joints	Tardive Dyskinesia*
Hyperglycemia (abnormally high blood sugar)	Pain in the upper right part of the stomach	Tremors
Hypoglycemia (abnormally low blood sugar)	Painful erection that lasts for hours	Unusual behavior
Impotence	Painful skin rashes	Unusual bleeding or bruising
Increased appetite	Pancreatitis (inflammation of pancreas, a gland near the stomach that helps digestion)	Unusual tiredness
Increased salivation	Poor concentration	Violence
Indigestion	Restlessness or pacing	Vomiting
Insomnia	Seizures or convulsions	Weakness
Involuntary movements	Sexual dysfunction	Weight gain
Itching		Yellowing of the skin or eyes <sup>86</sup>
Jaw, neck, and back muscle spasms		
Joint pain		
Lack of energy		

\***Akathisia:** A, meaning “without” and kathisia, meaning “sitting,” an inability to keep still. Patients pace about uncontrollably. The side effect has been linked to assaultive, violent behavior.<sup>87</sup>

\***Neuroleptic malignant syndrome:** A potentially fatal toxic reaction where patients break into fevers and become confused, agitated and extremely rigid. An estimated 100,000 Americans have died from it after taking the older antipsychotics.<sup>88</sup>

\***Tardive Dyskinesia:** *Tardive*, meaning “late” and *dyskinesia* meaning, “abnormal movement of muscles.” Tardive Dyskinesia is a permanent impairment of the power of voluntary movement of the lips, tongue, jaw, fingers, toes and other body parts.<sup>89</sup>

## GENERAL WARNINGS AND STUDIES ON ANTIPSYCHOTICS:

**2001:** *The Journal of Toxicology* reported that the newer antipsychotics “will soon account for the majority of poisonings from antipsychotic agents that get presented to health care facilities in the U.S.”<sup>90</sup> Researchers found, “[T]he ingestion of a single tablet of clozapine (Clozaril), olanzapine (Zyprexa) and risperidone (Risperdal) may cause significant toxicity in a toddler. Ataxia (involuntary muscular movement), confusions, EPS (extrapyramidal symptoms – nerve damage), coma and respiratory arrest have been reported following ingestion of 50-200 mg of clozapine in toddlers.”<sup>91</sup>

**September 2003:** The FDA requested the makers of six newer antipsychotic drugs add a caution to their labeling language about the potential risk of diabetes and blood sugar abnormalities.<sup>92</sup>

**June 2004:** The Australian Therapeutic Goods Administration published an Adverse Drug Reactions Bulletin reporting that the newer antipsychotics could increase the risk of diabetes.<sup>93</sup>

**September 22, 2005:** Dr. Jeffrey Lieberman of Columbia University and other researchers published a study in *The New England Journal of Medicine* that compared the older generation of antipsychotics with several newer ones. Far from proving effectiveness, of the 1,493 patients who participated, 74% discontinued taking antipsychotic drugs before the end of their treatment due to inefficacy, intolerable side effects or other reasons. After 18 months of taking Zyprexa, 64% of the patients stopped taking it—most commonly because it caused sleepiness, weight gain or neurological symptoms like stiffness and tremors.<sup>94</sup>

**December 1, 2005:** Researchers found that 18% of nearly 23,000 elderly patients taking the *older* antipsychotics died within the first six months of taking them.<sup>95</sup>

**May 2, 2006:** *USA Today* released the results of an analysis of FDA data that showed at least 45 children died between 2000 and 2004 from the side effects of antipsychotic drugs (Clozaril, Risperdal, Zyprexa, Seroquel, Abilify and Geodon). Despite an adults-only FDA approval for these drugs, according to *USA Today*, up to 2.5 million children were prescribed them. As the FDA’s Adverse Drug Reactions reporting database only collects 1% to 10% of drug-induced side effects and reported deaths, the true child death rate could be between 450 and several thousand. Further, there were 1,328 reports of other side effects, some life-threatening, such as convulsions and low white blood cell count.<sup>96</sup>

**January 5, 2008:** *The Lancet* (Britain) published a study where the authors concluded “that the routine prescription of antipsychotic drugs early in the management of aggressive challenging behavior, even in low doses, should no longer be regarded as a satisfactory form of care.”<sup>97</sup>

**April 2008:** The American Geriatrics Society published a study entitled, “Antipsychotic Drug Use and Risk of Pneumonia in Elderly People,” which reviewed 22,944 elderly people with at least one antipsychotic prescription. The results of the study showed that “antipsychotics were associated with an almost 60% increase in the risk of pneumonia...” concluding that elderly people are at greater risk of pneumonia, especially during the first week of antipsychotic drug treatment.<sup>98</sup>

**April 9, 2008:** *Pharmacoepidemiology and Drug Safety* published a study entitled, “The use of central nervous system [CNS] drugs and analgesics [painkillers] among very old people with and without dementia.” The study compared the use of CNS drugs in people aged 85 years or older, with and without dementia and concluded: “[T]he use of antipsychotics in people with dementia should arouse particular concern, because of the high risk of severe adverse events and the limited evidence of positive effects.”<sup>99</sup>

**May 26, 2008:** *The Archives of Internal Medicine* published a study about “Antipsychotic Therapy and Short-term Serious Events in Older Adults With Dementia” that found: “Serious events...are frequent following the short-term use of antipsychotic drugs in older adults with dementia. Antipsychotic drugs should be used with caution even when short-term therapy is being prescribed.”<sup>100</sup>

**June 2008:** The FDA issued a warning to healthcare professionals that conventional and atypical antipsychotics are associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis. It specified that antipsychotics are not indicated for the treatment of this condition. Additionally, the FDA required the manufacturers of these drugs to add a boxed warning about this risk to the prescribing information. Older, conventional antipsychotics were also to carry a “black box” warning about an increased risk of death in some elderly people.<sup>101</sup>

**April 2009:** The Irish Medicines Board published in their *Drug Safety Newsletter*, a warning about antipsychotics causing a risk of stroke and now increased risk of mortality in elderly patients treated for dementia. This risk covers both typical and atypical antipsychotics.<sup>102</sup>

## **WARNINGS ON SPECIFIC ANTIPSYCHOTICS:**

### **ABILIFY (aripiprazole):**

Abilify and other antipsychotic drugs have caused a potentially fatal condition called neuroleptic malignant syndrome. Patients who develop this may have high fevers, muscle rigidity, altered mental status, irregular pulse or blood pressure, rapid heart rate, excessive sweating, and heart arrhythmias (irregularities).<sup>103</sup>

Body temperature regulation—disruption of the body’s ability to reduce core body temperature—has been attributed to antipsychotic agents such as Abilify.<sup>104</sup>

**April 2003:** The U.S. consumer advocacy group Public Citizen conducted a review of information published on Abilify, basing their evaluation primarily on publicly available FDA reviews of information submitted by the manufacturer to gain FDA approval for Abilify. Approval was based on five trials only lasting four to six weeks. According to Public Citizen, “...nothing in these five trials can lead one to believe that aripiprazole (Abilify) is a meaningful advancement in the treatment of schizophrenia.”<sup>105</sup>

The information insert on Abilify lists hyperglycemia (abnormally high blood sugar—usually associated with diabetes), hypoglycemia (abnormally low blood sugar) and diabetes as possible side effects.<sup>106</sup>

#### **CLOZARIL (clozapine):**

**May 2008:** *Medsafe* (New Zealand) posted a prescriber update called “Clozapine and Achy Breaky Hearts” warning that clozapine can cause myocarditis [inflammation of the heart muscle] that may be fatal. It was also associated with cardiomyopathy [disease of the heart muscle]. While risk factors are unknown, pre-treatment cardiovascular screening was recommended.<sup>107</sup>

**May 2008:** *Medsafe* posted their June 2008 “Watching Briefs,” a report in which they included a warning: “Use of clozapine in older patients carries a higher risk of adverse reactions such as postural hypotension [low blood pressure], falls, sedation and constipation, compared to use in younger patients. Therefore, increased clinical monitoring of the elderly is necessary to ensure their safety.”<sup>108</sup>

#### **HALDOL (haloperidol):**

**September 17, 2007:** The FDA issued an alert to Healthcare Professionals about haloperidol (marketed as Haldol), stating: “Due to a number of case reports of sudden death, TdP [Torsades de Pointes] and QT prolongation [TdP and QT prolongation are types of heart abnormalities] in patients treated with haloperidol (especially when the drug is given intravenously or at doses higher than recommended), the sponsor has updated the labeling for haloperidol.” ECG (Electrocardiogram—a graphical recording of the cardiac cycle produced by a special machine, a.k.a. EKG) monitoring was recommended if haloperidol is given intravenously, even though haloperidol is not approved for intravenous administration.<sup>109</sup>

**ZYPREXA (olanzapine):**

**July 22, 2005:** Eli Lilly & Co., the manufacturer of Zyprexa, agreed to pay \$1.07 billion to settle more than 8,000 claims against the drug, alleging it could potentially cause life-threatening diabetes.<sup>110</sup>

**September 22, 2005:** Dr. Jeffrey Lieberman of Columbia University and other researchers published a study in *The New England Journal of Medicine* comparing an older generation of antipsychotics with several newer ones.<sup>111</sup> After 18 months of taking Zyprexa, 64% of the patients stopped taking it, most often because it was not well tolerated and caused sleepiness, weight gain or neurological symptoms like stiffness and tremors.<sup>112</sup>

**October 5, 2007:** Eli Lilly issued an important Safety Information update on its website and product labels for Zyprexa and Symbyax (combination of Zyprexa and fluoxetine, or Prozac) warning of the risk of weight gain, hyperglycemia (increased blood sugar) and hyperlipidemia (elevated fats in the blood and cholesterol).<sup>113</sup>

**2008:** The current Zyprexa Safety Information includes a “black box” warning of increased risk of death in elderly patients with dementia, as well as the following warnings: High level of fats in the blood, weight gain, high blood sugar, strokes and “mini strokes” (in elderly people with dementia), neuroleptic malignant syndrome, tardive dyskinesia, low blood pressure, trouble with judgment, thinking, and reflexes, trouble swallowing, body temperature problems...and “this is not a complete list...”<sup>114</sup>

# ANTI-ANXIETY DRUGS

(Called Minor Tranquilizers, Benzodiazepines or Sedative Hypnotics)

## BRAND NAMES (GENERIC NAMES):

Ambien (zolpidem)	Placidyl (ethchlorvynol)
Ativan (lorazepam)	Prosom (estazolam)
Azene (clorazepate)	Reepam (prazepam)
BuSpar (buspirone)	Restoril (temazepam)
Centrax (prazepam)	Rivotril (clonazepam)
Champix (varenicline - in the UK)	Rohypnol (flunitrazepam)
Chantix (varenicline - in the U.S.)	Rozerem (ramelteon)
Dalmane (flurazepam)	Serax (oxazepam)
Doral (quazepam)	Serepax (oxazepam)
Equanil (meprobamate)	Serestra (oxazepam)
Halcion (triazolam)	Sonata (zaleplon)
Klonopin (clonazepam)	Stesolid (diazepam)
Lexomil (bromazepam)	Stilnox (zolpidem)
Lexotan (bromazepam)	Temesta (lorazepam)
Lexotanil (bromazepam)	Tranxene (clorazepate)
Librax (chlordiazepoxide and flidinium)	Valium (diazepam)
Libritabs (chlordiazepoxide)	Valrelease (diazepam)
Librium (chlordiazepoxide)	Versed (midazolam)
Lunesta (eszopiclone)	Verstran (prazepam)
Miltown (meprobamate)	Vistaril (hydroxyzine)
Niravam (alprazolam)	Xanax (alprazolam)
Paxipam (halazepam)	

## SIDE EFFECTS:

Acute hyperexcited states	Confusion	Feeling that the throat is closing
Aggressive behavior	Constipation	Fever
Agitation	Diarrhea	Frequent urination
Agranulocytosis (condition affecting white blood cells causing susceptibility to infection)	Difficulty urinating	Hallucinations
Akathisia	Disorientation	Hangover effect (grogginess)
Amnesia	Dizziness or lightheadedness	Headache
Anxiety	Drowsiness	Heartburn
Blurred vision	Dry mouth	Hives
Changes in appetite	Epileptic seizures and death have resulted from suddenly stopping	Hoarseness
Changes in sex drive or ability	Fast or irregular heartbeat	Hostility
Chest pain	Fatigue	Increased salivation
	Fear	Insomnia
		Irritability

Itching	Psychosis	Suicide attempt
Jaundice	Rage	Swelling of the eyes, face, lips, tongue, or throat
Jaw, neck, and back muscle spasms	Restlessness or excitement	Talkativeness
Lethargy	Sedation	Tiredness
Liver problems	Seizures	Transient amnesia
Memory impairment	Severe depression	Tremors
Muscle tremors	Severe skin rash	Unusual movements of the head or neck muscles
Nausea	Sexual problems	Upset stomach
Nervousness	Shuffling walk	Vomiting
Nightmares	Sleep disturbances	Weakness
Numbness	Slow or difficult speech	Weight changes <sup>115</sup>
Problems with coordination	Slurred speech	
	Stomach pain	

## GENERAL WARNINGS AND STUDIES ON ANTI-ANXIETY DRUGS:

Daily use of therapeutic doses of benzodiazepines is associated with physical dependence. Addiction can occur after 14 days of regular use.<sup>116</sup> The withdrawal from drugs like Valium “is more prolonged and often more difficult than [withdrawal from] heroin,” Dr. Conway Hunter, Jr. of Atlanta’s Peachford Hospital stated in 1979. In 2008, Dr. Patrick Holford from the UK wrote “How To Quit Tranquilizers” and said, withdrawal and tolerance to benzodiazepines “describe an addiction that can be as difficult as heroin to break.”<sup>117</sup>

The typical consequences of withdrawal are anxiety, depression, sweating, cramps, nausea, psychotic reactions and seizures. There is also a “rebound effect” where the individual experiences even worse symptoms than they started with as a result of chemical dependency.<sup>118</sup>

**1990-1996:** Benzodiazepines caused 1,810 deaths in Britain, making them more lethal than heroin, cocaine and methadone, which combined accounted for 1,623 deaths.<sup>119</sup>

**1997:** A study in the *Journal of the American Medical Association* (JAMA) found that elderly people taking benzodiazepines for anxiety or insomnia were at increased risk for motor vehicle crashes. Brenda Hemmelgarn, M.N., Samy Suissa, Ph.D., and colleagues from McGill University and Royal Victoria Hospital, Montreal, Quebec, studied 224,734 drivers aged 67 to 84 years and determined a 45% increased rate of motor vehicle crashes involving injuries for elderly patients during the first seven days of taking a long-acting form of benzodiazepine.<sup>120</sup>

**2001:** A British study reported an “increase in hostility and aggression may be reported by patients taking benzodiazepines. The effects range from talkativeness and excitement to aggressive and antisocial acts.”<sup>121</sup>

**February 2001:** British professor C. Heather Ashton reported cases of baby-battering, wife-beating and “grandmother-bashing” could be attributed to people taking benzodiazepines.<sup>122</sup>

**March 2005:** The UK government’s House of Commons (Parliament) Health Committee released findings of its inquiry into benzodiazepines and reported the side effects “are now known to include excessive sedation, decreased attention, amnesia and sometimes intractable dependence. Abrupt cessation can lead to severe withdrawal symptoms, including convulsions in some patients. Short-term treatment and a long tapering period is now recommended to limit these risks.”<sup>123</sup>

**January 2008:** *The Journal of Clinical Nursing* published an article entitled, “Falls and Fall Risk Among Nursing Home Residents,” that concluded, “A higher intake of medicine was associated with an increase in fractures and thus with more serious consequences of falls which jeopardize these patients’ safety. Although freedom-restricting actions cannot eliminate falls totally, our results support the hypothesis that they might be protective when used selectively together with fewer sedatives, especially benzodiazepines.”<sup>124</sup>

## **WARNINGS AND STUDIES ON SPECIFIC ANTI-ANXIETY DRUGS:**

### **CHAMPIX (varenicline in the UK):**

**December 14, 2007:** The British Medicines and Healthcare Products Regulatory Agency in conjunction with the European Medicines Agency (EMA) published a warning that stated: “Doctors are already aware of the risk of using Champix [a benzodiazepine-based drug, promoted for smoking cessation] in patients who have an underlying mental illness. They also need to be aware of the possibility that patients who are trying to stop smoking can develop symptoms of depression, and they should advise their patients accordingly. Patients who are taking Champix and develop suicidal thoughts should stop their treatment and contact their doctor immediately.”<sup>125</sup>

### **CHANTIX (varenicline in the U.S.):**

**November 20, 2007:** The FDA issued “Early Communication About an Ongoing Safety Review Varenicline (marketed as Chantix, a benzodiazepine based drug, promoted for smoking cessation).” The FDA warned that drug companies had reported incidents of suicidal thoughts, aggressive and erratic behavior, and drowsiness in patients who had taken Chantix.<sup>126</sup>

**February 1, 2008:** The FDA warned that serious neuropsychiatric symptoms had occurred in patients taking Chantix. The drug can cause changes in behavior, agitation, depressed mood, suicidal ideation, and attempted and completed suicide.<sup>127</sup>

### **ROHYPNOL (flunitrazepam):**

**Note:** The U.S. has not approved Rohypnol for medical use. It is legally sold in Latin America and Europe for insomnia and is smuggled into the U.S. from Mexico and South America.

A 2000 Swedish study of 47 juvenile delinquents found that 40% were acute abusers of a minor tranquilizer, Rohypnol—known as the “fear reducer” and “date rape” drug—that enabled them to commit extremely violent crimes. Abusers showed no guilt about their violent offenses: “When I stabbed him, it felt like putting a knife into butter,” states the report. “I didn’t feel any emotion when I stabbed him five times,” a teenager reported.<sup>128</sup>

It is also known as a “club drug,” a general term for a number of illicit drugs, primarily synthetic, that are most commonly encountered at nightclubs and “raves.” The drugs have gained popularity primarily due to the false perception that they are not as harmful, nor as addictive, as mainstream drugs such as cocaine and heroin. The drug chemically induces amnesia and often causes decreased blood pressure, drowsiness, visual disturbances, dizziness, confusion, gastrointestinal disturbances, and urinary retention.<sup>129</sup>

### **STILNOX (AMBIEN, zolpidem):**

Zolpidem is a non-benzodiazepine hypnotic prescribed often for insomnia. It includes Adormix, Ambien, Edluar, Damixan, Hyprogen, Invelald, Lioran, Nytamel, Sanval, Stilnoct, Stilnox, Sucedal, Zoldem, Zolnod and Zolphihexal.

**February 21, 2008:** The Australian Therapeutic Goods Administration (TGA) imposed a boxed warning in the product information for medicines containing zolpidem (Stilnox). The boxed warning stated: “Zolpidem may be associated with potentially dangerous complex sleep-related behaviors which may include sleep walking, sleep driving and other bizarre behaviors. Zolpidem is not to be taken with alcohol. Caution is needed with other CNS [Central Nervous System] depressant drugs. Limit use to four weeks maximum under close medical supervision.” The TGA said it would carry warnings of possible side effects, “including rage reactions, worsening insomnia, confusion, agitation, hallucinations and other forms of unwanted behavior.”<sup>130</sup>

**May 7, 2008:** The FDA approved safety labeling revisions to advise of the risks for abnormal thinking and behavioral changes in patients taking zolpidem and other sedative-hypnotic drugs. Use of sedative-hypnotics in primarily depressed patients has been linked to worsening depression, including suicidal thoughts and actions and completed suicide. Behavioral changes include “sleep-driving.” The FDA also warned that rare cases of angioedema (allergic skin disease) have been reported in patients taking the first or subsequent doses of sedative-hypnotics. Symptoms can include throat closing, or nausea and vomiting requiring emergency care. Because airway obstruction can cause death,

patients in whom angioedema develops after taking zolpidem should not be “rechallenged with the drug.”<sup>131</sup>

### **XANAX (alprazolam):**

**December 1990:** Dr. John Steinberg, medical director of the Chemical Dependency Program at the Greater Baltimore Medical Center and president of the Maryland Society of Addiction Medicine, confirmed that patients taking one Xanax tablet each day for several weeks could become addicted. Further, after a patient stops taking Xanax, it takes the brain six to *eighteen months* to recover. Xanax patients should be warned, he said, that it could take a long time to get over painful withdrawal symptoms.<sup>132</sup>

**1984:** A study of Xanax, “Extreme anger and hostile behavior emerged from eight of the first 80 patients we treated with alprazolam [Xanax]. The responses consisted of physical assaults by two patients, behavior potentially dangerous to others by two more, and verbal outbursts by the remaining four.” The study reported that a woman who had no history of violence before taking Xanax “erupted with screams on the fourth day of taking alprazolam treatment, and held a steak knife to her mother’s throat for a few minutes.”<sup>133</sup>

**1985:** Another study found that more than half of the Xanax study group experienced “dyscontrol,” meaning violence or loss of control of aggressive behavior. The violence included “deep neck cuts...wrist cuts...tried to break own arm...threw chair at child...arm and head banging...jumped in front of a car.”<sup>134</sup>

**2001:** Drug experts said Xanax is more addictive than most illegal drugs, including cocaine or heroin, and once someone is hooked, getting off it can be a tortuous and even deadly experience.<sup>135</sup>

**July 2005:** The National Center on Addiction and Substance Abuse at Columbia University issued a report called “Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.” stating that 15 million Americans were getting high on prescription drugs, painkillers and psychiatric drugs such as Xanax and the stimulants Ritalin and Adderall. They were abusing these drugs more than cocaine, heroin and methamphetamines combined. Teens who abused prescription drugs were 12 times likelier to use heroin, 14 times likelier to use Ecstasy and 21 times likelier to use cocaine, compared to teens that do not abuse such drugs.<sup>136</sup>

# BARBITURATES

## BRAND NAMES (GENERIC NAMES):

Amytal (amobarbital)  
Butalan (butabarbital)  
Butisol (butabarbital)  
Luminal (phenobarbitone)  
Mebaral (mephobarbital)

Nembutal (pentobarbital)  
Seconal (secobarbital)  
Sodium Amytal (amobarbital)  
Solfoton (phenobarbital)  
Tuinal (secobarbital and amobarbital)

## SIDE EFFECTS:

Addiction  
Breathing difficulties  
Chronic tiredness  
Depression  
Disorientation  
Dizziness  
Fever

Hallucination  
Kidney disease  
Lack of coordination  
Liver disease  
Menstrual irregularities  
Rash  
Slowed reflexes & response

Sluggishness  
Tightness in chest  
Upset stomach  
Vision problems  
Swelling of eyelids, face,  
or lips

Barbiturates are prescribed for anxiety, depression and insomnia. However, they are infrequently used today, replaced by tranquilizers. They are highly dangerous because of the small difference between a normal dose and an overdose. The lethal dosage of barbiturates varies greatly with tolerance from one individual to another.

**Barbiturate intoxication** symptoms include: respiratory depression, lowered blood pressure, fatigue, fever, unusual excitement, irrational, dizziness, poor concentration, sedation, confusion, impaired coordination, impaired judgment, addiction and respiratory arrest that may lead to death.

**Withdrawal Effects** include elevated blood pressure and pulse, sweating, tremors, and possible seizures.

# LITHIUM

## BRAND NAMES (GENERIC NAMES):

Cibalith-S (lithium)	Lithobid (lithium)
Eskalith (lithium)	Lithonate (lithium)
Lithane (lithium)	Lithotabs (lithium)
Lithizime (lithium)	

## SIDE EFFECTS:

Acne	Frequent urination	Rash
Birth defects if given to a pregnant woman	Gas	Restlessness
Blackout spells	Giddiness	Ringings in the ears
Blurred vision	Hair loss	Seizures
Cardiac arrhythmia	Hallucinations	Sexual problems
Change in the ability to taste food	Incontinence	Slurred speech
Chest tightness	Increased thirst	Stomach pain or bloating
Coma	Indigestion	Stupor
Confusion	Insomnia	Swelling of the eyes, face, lips, tongue, throat, hands, wrists, feet, ankles, or lower legs
Constipation	Itching	Thin, brittle fingernails or hair
Decreased appetite	Joint or muscle pain	Thyroid problems
Depression	Lethargy	Tiredness
Diabetes	Lightheadedness	Tongue pain
Diarrhea	Loss of appetite	Tremors
Difficulty thinking	Loss of coordination	Uncontrollable tongue movements
Dizziness	Movements that are unusual or difficult to control	Unusual discomfort in cold temperatures
Drowsiness	Muscle weakness, stiffness, twitching, or tightness	Vomiting
Dry mouth	Nausea	Weight gain or loss <sup>137</sup>
Excessive saliva in the mouth	Painful, cold, or discolored fingers and toes	
Fast, slow, irregular, or pounding heartbeat	Paleness	
	Persistent headache	

## GENERAL WARNINGS AND STUDIES ON LITHIUM:

Lithium is a mineral given in salt form. It is found in tiny amounts in minerals, water, plant, animal and human tissues. However, just because it is a naturally occurring substance, do not make the mistake of thinking it is safe.

One of the most dangerous effects of lithium prescribed to patients is that in order to achieve a “sedating” effect, the “therapeutic” dosage that psychiatrists use is near toxic; i.e., so poisonous that it can cause serious harm or even death.<sup>135</sup>

Medical experts state that the almost inevitable result of lithium not being metabolized is that it can lead to kidney damage. Lithium is even more hazardous when too much of it accumulates in the body and the toxicity from this can also lead to permanent brain damage and death.<sup>136</sup>

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