



References

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FDA Launches a Strategy to Strengthen Safeguards for Children Treated with Antidepressant Medications⁷

What the research tells us

Background

The safe and effective use of medications for the treatment of certain medical conditions and illnesses has enabled many children to attend school and achieve academic success.¹ In medical practice, widespread acceptance of drug therapy for behavioral disorders has facilitated diagnosis and treatment of these conditions in ambulatory care.²

Recent increases in the use of psychotropic medications by children and adolescents, limited information on the benefits of these therapies for children, and concerns about the adverse consequences of certain drugs have prompted the U.S. Food and Drug Administration to revise their guidance for prescribers and patients. Because some of these drugs will be brought to school for administration during the school day, the Center has developed this fact sheet to summarize key information on the topic.

Please see details of new FDA safeguards on the next page of this Fact Sheet.

Emotional and Behavioral Health Problems Among Children

- Of the population ages 9 – 17, an estimated 21 percent experience the signs and symptoms of a *DSM-IV* disorder in the course of the year, 11 percent experience significant impairment, and 5 percent experience extreme emotional impairment.³
- Results of a national survey of pediatricians showed that 19 percent of pediatric visits involved a psychosocial problem requiring attention or intervention. Psychosocial problems are the most common chronic condition for pediatric visits, eclipsing asthma and heart disease.²
- Almost 5 million children 3 – 17 years of age (8%) have been identified as having a learning disability (such as dyslexia). An estimated 4 million children (6%) have been identified as having attention deficit hyperactivity disorder (ADHD). Ten percent of boys had a learning disability, compared with 6 percent of girls; 10 percent of boys had ADHD compared with 4 percent of girls.⁴
- The combined prevalence of anxiety disorders is higher than that of all other mental disorders of childhood and adolescence. The 1-year prevalence in children ages 9 – 17 is 13 percent.³
- Depression estimates vary but a recent report indicates that depression is present in 1 percent of children and 5 percent of adolescents at any given time. Before puberty, boys and girls are at equal risk for depression, after puberty onset the rate of depression is twice as high for girls.⁵
- Conduct disorder, or oppositional defiant disorder, affects 1 to 4 percent of 9- to 17-year-olds. Children with conduct disorder act out their feelings or impulses in destructive ways, including aggression, lying, theft, setting fires, and vandalism, the degree of offense growing more serious over time.⁶

Psychotropic Drugs and Children

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- ¹³ Medco Health Solutions, Inc. Medco study reveals pediatric spending spike on drugs to treat behavioral problems. 2004. Accessed at <http://www.drugtrend.com/medco/consumer/drugtrend/trends.jsp>

Definition

Psychotropic drugs are those that affect the function, behavior, or experience of the mind.¹⁴ While their exact mechanism of action is not known, psychotropic drugs are thought to act upon the biochemistry of the brain and positively affect thinking mechanisms, emotional control, mood, and other behavioral processes. Included are neuroleptics (such as Haldol), antipsychotics (such as Zyprexa), antidepressants (such as Prozac), stimulants (such as Ritalin), and anti-anxiety agents (such as BuSpar).¹⁴

Treatment: What we know

- The effectiveness of stimulants for short-term treatment of attention deficit-hyperactivity disorder is well documented. A smaller number of studies demonstrates that stimulants or stimulants in combination with behavioral treatments produce long-term improvements when the drug continues to be taken.⁸
 - The effectiveness of selective serotonin reuptake inhibitors (SSRIs) and clomipramine [Anafranil] for obsessive-compulsive disorder (OCD) has been indicated by a number of studies. In 1999, the US Food and Drug Administration approved the use of two SSRIs, fluvoxamine [Luvox] and sertraline [Zoloft], for use in pediatric OCD. Fluoxetine [Prozac] also is approved for use in pediatric OCD.⁸
 - The use of antidepressants to treat major depression in children and adolescents has been controversial. Many studies of antidepressant treatment of major depression among adolescents have shown these agents to be only modestly effective.⁹ Additional concerns have focused on possible associations between antidepressant drug use and increases in serious depression and suicide attempts. However, a recent large study by the National Institute of Mental Health concluded that Prozac, which is approved for treatment of depression in pediatric patients, paired with cognitive behavioral therapy (a form of talk therapy) was most successful in helping 71 percent of the study's teenagers overcome depression. The Treatment for Adolescents with Depression Study also showed that Prozac alone was effective in 61 percent of subjects, while talk therapy alone worked with 43 percent. Thirty-five percent of those who received a placebo also improved. Researchers found that patients became significantly less suicidal, no matter which treatment they were given.¹⁰
- FDA Safeguards. On October 4, 2004, the FDA issued a public health advisory announcing that a “black box” warning and expanded cautionary statements will be required on the labels of all antidepressants, to alert prescribers to an increased risk of suicidal thinking and behavior in pediatric patients treated with antidepressant medication. In addition, the FDA cautions that pediatric patients should be “closely observed” for signs of worsening illness, or agitation, irritability, suicidality, and unusual changes in behavior, especially during the initial few months of a course of medication, or at times of dose changes. Patients will also receive a MedGuide with their prescription, informing them of the risks associated with taking antidepressant medication.¹¹
- An NIMH-funded study to test the efficacy and safety of medications commonly used by practitioners to treat children and adolescents (in off-label applications), found that fluvoxamine [Luvox], an SSRI antidepressant approved for treating OCD in children, was both safe and effective in treating social phobia, separation anxiety disorder, and generalized anxiety disorder in children 6 to 17 years of age.¹²
 - Data reported by a pharmacy benefits manager indicated that, among children and youth taking at least one medication overall, the percentage taking one or more prescription drugs to treat behavioral and emotional health problems reached nearly 9%.¹³ Another study documented rapid growth in the use of antidepressants.⁹ See table below.

Antidepressant Prescriptions Among Commercially Insured School-Age Children and Youth⁹

	Percent of children & youth prescribed antidepressants		
	1998	2000	2002
Preschool (<5 years)			
Girls	.08	.12	.16
Boys	.14	.14	.23
Elementary (6-10 years)			
Girls	.57	.72	.84
Boys	1.21	1.18	1.60
Middle school (11-14 years)			
Girls	1.44	1.63	2.36
Boys	2.56	2.64	3.12
High school (15-18 years)			
Girls	3.74	4.73	6.36
Boys	3.00	3.49	4.23

Psychotropic Drugs and Children

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- ²⁵ Prozac [package insert]. Indianapolis, IN: Eli Lilly and Company; 2003.
- ²⁶ Paxil [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2003.
- ²⁷ Zoloft [package insert]. New York, NY: Roerig, Division of Pfizer, Inc; 2002.
- ²⁸ Celexa [package insert]. St. Louis, MO: Forest Pharmaceuticals, Inc; 2002.
- ²⁹ Luvox [package insert]. Marietta, GA; Solvay Pharmaceuticals, Inc; 2000.
- ³⁰ Anafranil [package insert]. St. Louis, MO: Mallinckrodt Inc; 2004.

Psychotropic Drugs That May Be Encountered in the Health Suite

* Symptoms associated with diagnosis.

** Observed effects of medication (side effects), improper dosing, medication conflicts, missed doses, discontinued medication, or individual adverse reactions.

Drug	Symptoms *	What To Watch For **
Drugs used for ADD and ADHD, including stimulants and non-stimulants		
STIMULANTS		
Ritalin, Methylin, Focalin, Concerta, Metadate, (methylphenidate in various forms for administration)	Inattention, distractibility, agitation, behavior problems Impulsiveness; hyperactivity ¹⁹	Nervousness, insomnia, decreased appetite, weight loss, headaches, stomachaches, skin rash, jitteriness, and social withdrawal. ²¹
Adderall, Dexedrine (amphetamine and dextroamphetamine in various forms)	Symptoms of inattention include making careless mistakes, lack of sustained attention, not listening, failing to finish tasks, poor organization, failing to follow directions, avoiding tasks requiring sustained mental effort, forgetting, losing things, and being easily distracted. ^{19,20}	Rare adverse events can include tachycardia, blood pressure changes, nausea, dizziness, and palpitations. ²²
Cylert (pemoline)	Symptoms of hyperactivity and impulsiveness include at least six of the following: fidgeting or squirming, leaving the seat, talking excessively, running or climbing at inappropriate times, difficulty with quiet activities, inability to wait for a turn, blurting out answers, and interrupting others. ^{19,20}	Overdose is characterized by vomiting, agitation, tremors, muscle twitching, convulsions, hallucinations, delirium, sweating, and cardiac arrhythmias. Contact a poison control center. ²⁰
NON-STIMULANT		
Strattera (atomoxetine)	Symptoms of ADD and ADHD, above	Headache, nasal symptoms; nausea, vomiting, and stomach pain, dizziness, tiredness; mood swings. ²¹ Irritability insomnia, sedation; blood pressure effects. ²¹ Weight loss may occur early, followed by weight gain. ²³
SSRI Antidepressants for depression, mood disorders, obsessive-compulsive disorder		
Prozac (fluoxetine) This is the only SSRI currently FDA-approved for use with depression in pediatric populations. Prozac also is approved for pediatric OCD ²⁵	Depression —Prominent and relatively persistent depressed mood that usually interferes with daily functioning, and includes at least five of the following nine symptoms: depressed mood; loss of interest in usual activities; significant change in weight and/or appetite; insomnia or hypersomnia; psychomotor agitation or retardation; increased fatigue; feelings of guilt or worthlessness; slowed thinking or impaired concentration; a suicide attempt or suicidal ideation. ²⁴ Obsessive-compulsive disorder —Recurrent and persistent ideas, thoughts, impulses, or images (obsessions) that are ego-dystonic and/or repetitive, purposeful, and intentional behaviors (compulsions) that are recognized by the person as excessive or unreasonable. ²⁴ Panic disorder —Occurrence of unexpected panic attacks, and associated concern about having additional attacks, worry about the implications or consequences of the attacks, and/or a significant change in behavior related to the attacks. ²⁴	Anxiety, nervousness, insomnia. Mania, agitation, decreased appetite. Rash or hives; thoughts of suicide, attempted suicide, or actual suicide; in rare cases, seizure. ^{21,25,26,27,28,29,30}
Paxil (paroxetine), Zoloft (sertraline), Celexa (citalopram), Luvox (fluvoxamine maleate, generic), approved for pediatric OCD ²⁹		A recent public health advisory from the FDA cautions that patients beginning treatment with antidepressant medication—or having their dose adjusted up or down—should be closely observed for any worsening of the illness, as well as agitation, irritability, suicidality (suicidal thinking or behavior), and any unusual changes in behavior. ¹¹
Anafranil (clomipramine), approved for pediatric OCD ³⁰		

Psychotropic Drugs and Children

References, cont.

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- ³³ National Library of Medicine Medline Plus. Propranolol (Inderal) Drug Information. 2003. Accessed at <http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a682607.html>
- ³⁴ Effexor [package insert]. Philadelphia, PA: Wyeth Laboratories, Inc; 2001.
- ³⁵ Risperdal [package insert]. Titusville, NJ: Janssen Pharmaceutica Products, Inc. 2003.
- ³⁶ National Institute of Mental Health: *Child and Adolescent Bipolar Disorder*. Bethesda, MD: NIMH; 2000. Pub. #00-4778.
- ³⁷ Depakote [package insert]. North Chicago, IL: Abbott Laboratories; 2003.
- ³⁸ Spearing M. National Institute of Mental Health. *Eating Disorders*. Bethesda, MD: NIMH; 2001. Pub. #01-4901.

Drug	Symptoms *	What To Watch For **
Other psychotropic drugs used to manage ADD/ADHD, anxiety, or depression		
BuSpar (buspirone)	Symptoms of anxiety: shakiness, jumpiness, trembling, tension, muscle aches, fatigability; inability to relax, twitching, fidgeting, restlessness, easy to startle. Also sweating, heart pounding; apprehensiveness; vigilance; Generalized Anxiety Disorder (GAD). ³¹	Dizziness, nausea, headache, nervousness, lightheadedness, and excitement; slowness or sedative effect. ³¹ Agitation, anxiety, insomnia; hypertension; possible hallucinations or delusions. Weight loss. Dose-related risk of seizure. ³²
Wellbutrin, Zyban (bupropion)	Depression, as defined above ³²	
Inderal (propranolol)	Anxiety, nervous tension; panic attacks. Aggressive behavior	Dizziness, insomnia, excessive tiredness, upset stomach, vomiting, rash, diarrhea; difficulty breathing, sore throat, unusual bleeding, swelling of feet or hands, slow heartbeat, chest pain. ³³
Effexor (venlafaxine)	Depression, as defined above	Dizziness, drowsiness; trouble with sleep, difficulty breathing, cold hands / feet, hallucinations, irregular heartbeat; hypertension. In rare cases, fever, depression. ^{21, 34}
Atypical Antipsychotics used in psychotic disorders and dementia		
Risperdal (risperidone), Clozaril (clozapine), Zyprexa (olanzapine), Seroquel (quetiapine)	Indicated for schizophrenia, bipolar disorder, mania; the drugs have not been tested in children but may be prescribed off-label for certain cases with multiple conditions occurring together.	Hyperglycemia, diabetes mellitus; hypotension; cognitive and motor impairments. Rare: serious cardiac and neuromuscular effects. ³⁵
Mood Stabilizers used for bipolar disorder and mania		
Lithobid, Lithostat (lithium carbonate); Depakote, Depakene (valproate)	Severe changes in mood—extremely irritable to overly silly—overly inflated self-esteem; increased energy, decreased need for sleep; talkativeness, distractibility; hypersexuality; increased goal-directed activity or agitation. ³⁶	Nausea, drowsiness, dizziness, vomiting, abdominal pain; headache; tremor. Severe abdominal pain, nausea, and vomiting may be symptomatic of rare but severe pancreatitis and liver disease. ³⁷ Do not take aspirin with Depakote.
Drugs used with eating disorders, specifically bulimia nervosa and binge-eating disorder; occasionally in anorexia nervosa, after weight regain		
Prozac (fluoxetine) Other SSRIs or SNRIs may be used	Bulimia nervosa —Recurrent episodes of binge eating, followed by forced purging through self-induced vomiting, or use of laxatives, diuretics, enemas, or other medications; fasting; excessive exercise. ³⁸ Binge-eating disorder —Uncontrolled eating (often rapidly and in great quantities) without forced purging or compensating behavior. ³⁸ Anorexia nervosa —Abnormal restriction of eating due to intense fear of gaining weight or becoming fat; resistance to maintaining weight at or above a minimally normal weight for the age and height. ³⁸	Denial of illness, refusal to maintain treatment; may require hospitalization. ³⁸ Side effects: Impaired judgment, thinking, motor skills; anxiety, nervousness, insomnia; mania; agitation; decreased appetite; rash or hives; seizure; thoughts of suicide, attempted suicide, or actual suicide. ^{11, 25} In anorexia, psychotropic medication used only after weight regain established. ³⁸

Psychotropic Drugs and Children

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- ¹⁸ AAP Policy Statement—Guidelines for the Administration of Medication in School. *Pediatrics*. 2003;112(3):697-699.

The Five Rights of medication administration

- The **right** patient
- Receives the **right** drug
- In the **right** dose
- By the **right** route
- At the **right** time.

Schools and Medication Administration

- 37 states and the District of Columbia have statutes, regulations, and/or mandatory or recommended policies addressing medication administration at school.¹⁵
- A US General Accounting Office survey reported that 90% of the schools it had surveyed received district regulations or policies regarding the administration of prescription medications.¹⁵
- Most schools report keeping medications in a locked space.¹⁵ 74% of schools report having a medical supply cabinet with a lock.¹⁶ A recent study found that 96% of schools report that students are observed when ADHD medications are administered.¹⁵ In 2003, the annual prevalence of illegal use of Ritalin was reported as 2.6% among 8th graders, 4.1% among 10th graders, and 4.0% among 12th graders.¹⁷
- In response to Congressional concerns regarding the diversion or abuse of stimulant medications (e.g., Ritalin) in school, a federal agency conducted a study and concluded that schools had identified few incidents of abuse or diversion.¹⁵

Who Dispenses Medications at School?¹⁵

Personnel	Percent approved to administer attention disorder medication*	Percent most often administering attention disorder medications**
Nurse	75	59
Other health care personnel	13	7
Principal	32	2
Teacher	12	2
Other, non-health care personnel	51	28
Students self-administer	6	1

* The column does not total 100% because more than one person may be approved to dispense medication

** The column total does not equal 100% because of rounding.

Role of Schools: What parents and school staff need to know^{1, 18}

- Know the policies of your state and local governments as well as school board regarding the administration of medications in school, whether psychotropic medication or other.
- Learn about the drugs being administered to students—at home and at school—whether school staff are doing the dosing or not.
- Get to know the resources on pediatric antidepressants offered by the US FDA, especially those available on the FDA Web site, and be aware of public health advisories issued by the agency. This information is available at <http://www.fda.gov/cder/drug/antidepressants/default.htm>.
- Make yourself aware of the possible side effects of the drugs being administered; learn to recognize symptoms of missed doses or overdose.
- Have an emergency plan for each student taking psychotropic medications, in case there is ever a need to use one.

References, cont.

- ³⁹ US Food and Drug Administration. FDA Proposed Medication Guide: About using antidepressants in children or teenagers. October 21, 2004. Accessed at <http://www.fda.gov/cder/drug/antidepressants/SSRIMedicationGuide.htm>, November 10, 2004.

Role of Schools: What school staff needs to do ^{1, 11, 18, 39}

- Keep medications in a locked cabinet (or a locked refrigerator) in a secure place.
- Require that medications be delivered to school in the original prescription container, bearing the student's name, the dosing and frequency, the physician's name, a copy of the package insert, and a copy of the MedGuide, now to be included with all prescriptions for antidepressants.
- Ask parents to notify the school when dosing begins, when any changes or adjustments are made to dosing, or when medication is changed or discontinued. These are the times when the child or adolescent is most likely to experience changes or additional effects of the medication.
- Whenever possible, talk with the prescribing physician directly, to maximize accuracy. If you observe any of the behavioral warning signs—worsening illness, or agitation, irritability, suicidality, and unusual changes in behavior—contact the physician or parent immediately.
- Keep careful records of all administration of medication. Some schools use a signature and log form, others track administration with a computer program.
- Safeguard the privacy of students and protect them from any stigma that may be associated with the administration of medications during school hours.

Resources

The American Academy of Child and Adolescent Psychiatry
3615 Wisconsin Avenue, NW
Washington, DC 20016-3007
202-966-7300
www.aacap.org

Bright Futures
The American Academy of Pediatrics
141 Northwest Point Boulevard
Elk Grove Village, IL 60007-1098
847-434-4000
<http://brightfutures.aap.org/web/>

American Psychiatric Association
1000 Wilson Boulevard, Suite 1825
Arlington, VA 22207-3901
703-907-7300
www.psych.org/

The American Psychiatric Nurses Association
1555 Wilson Blvd., Suite 515
Arlington, VA 22209
703-243-2443
www.apna.org

American Psychological Association
750 First Street, NE
Washington, DC 20002-4242
800-374-2721
800-964-2000
www.apa.org

Attention Deficit Information Network
475 Hillside Avenue
Needham, MA 02194
781-455-9895
www.addinfonetwork.org

Center for Health and Health Care in Schools
The George Washington University
School of Public Health and Health Services
1350 Connecticut Ave., NW, Suite 505
Washington, DC 20036
202-466-3396
www.healthinschools.org

Healthy Youth Program
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, Georgia 30333
800-311-3435
404-639-3534
<http://www.cdc.gov/HealthyYouth/index.htm>

Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD)
8181 Professional Place, Suite 201
Landover, MD 20785
800-233-4050
www.chadd.org

Learning Disabilities Association of America
4156 Library Road
Pittsburgh, PA 15234
412-341-1515
www.lidaamerica.org

National Association of School Nurses
1416 Park Street, Suite A
Castle Rock, CO 80109
866-627-6767
303-663-2329
www.nasn.org

National Attention Deficit Disorder Association (ADDA)
1788 Second Street, Suite 200
Highland Park, IL 60035
847-432-2332
www.add.org

National Center for Learning Disabilities
381 Park Avenue South, Suite 1401
New York, NY 10016
888-575-7373
212-545-7510
www.ld.org

National Information Center and Youth with Disabilities (NICHY)
P.O. Box 1492
Washington, DC 20013
800-695-0285
www.nichcy.org

National Institute of Mental Health (NIMH)
6001 Executive Boulevard
Room 8184, MSC 9663
Bethesda, MD 20892-9663
301-443-4513
www.nimh.nih.gov

US Department of Education
400 Maryland Avenue, SVV
Washington, DC 20202-0498
800-872-5327
www.ed.gov

US Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville MD 20857-0001
888-INFO-FDA (888-463-6332)
<http://www.fda.gov/cder/drug/antidepressants/default.htm>

This project was supported by grant number IR13HS014208 from the Agency for Healthcare Research and Quality and by a grant from The Robert Wood Johnson Foundation.



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December 2004