



Citizens Commission on Human Rights of Florida

**THE PSYCHOTROPIC DRUGGING OF  
FLORIDA'S MEDICAID CHILDREN**

A WHITE PAPER



## EXECUTIVE SUMMARY

In July 2003, the Florida Statewide Advocacy Council disclosed in their “Red Item Report” that an inexplicable **55% of foster children** in the state of Florida had been put on powerful mind altering psychotropic drugs.

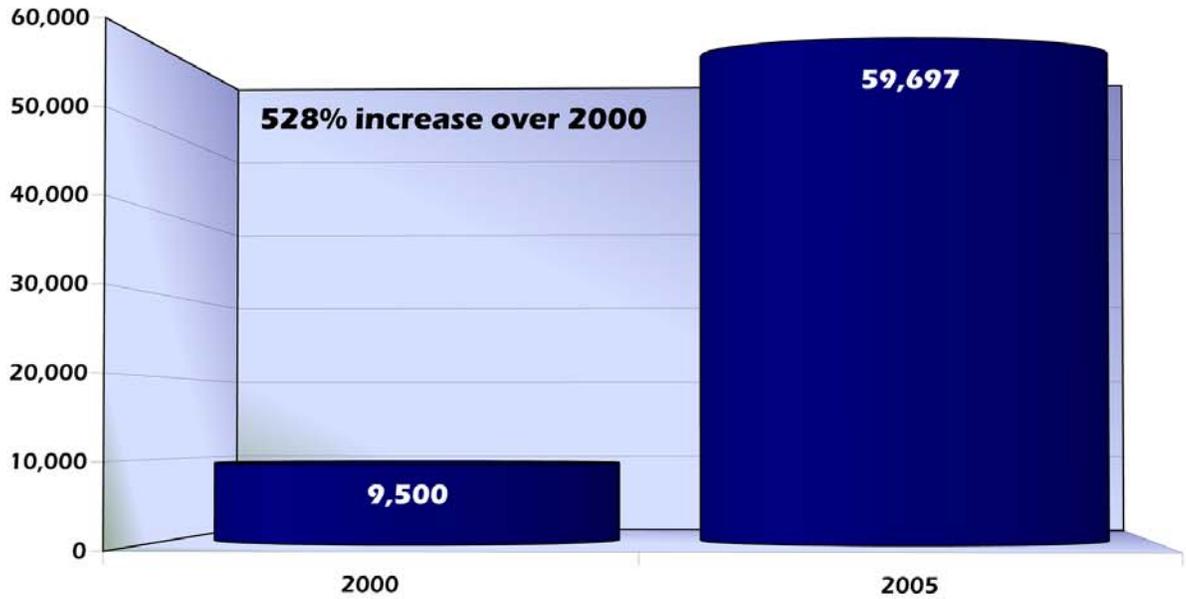
Prompted by this report, the Citizens Commission on Human Rights in Florida (CCHR) launched an investigation into the current number of Florida children prescribed psychotropic drugs through the State’s Medicaid Program.

CCHR’s investigation has brought to light several startling trends. Foremost among these is the radical increase in the number of children receiving Medicaid benefits in Florida that are being prescribed psychotropic drugs.

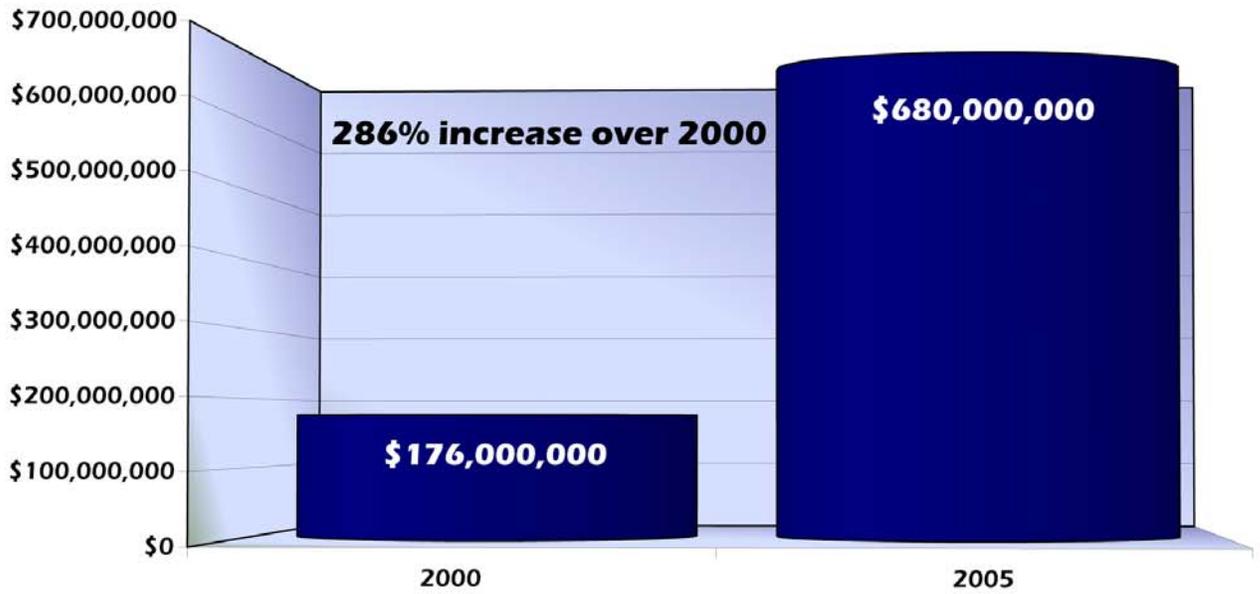
In just five years, the annual number of children placed on these powerful mind-altering drugs has increased by an alarming **528%**.

- **59,697 Medicaid children were put on psychotropic drugs in the year 2005 as compared to 9,500 children in the year 2000 (a 528% increase).**
- **62% (37,142 children) were prescribed “off label” psychotropic drugs (not tested or approved for children).**
  - **4,556 of the children given “off label” drugs were 5 years old or less.**
  - **1,728 of the children were infants (3 years of age or less) and were prescribed these dangerous “off label” drugs.**
- **19,080 children were given “antipsychotic” drugs. (4,556 of these children were five years of age or younger)**
- **15,240 children were prescribed 3 or more different psychotropic drugs.**
- **1,953 infants and toddlers (3 years of age or less) were put on powerful psychotropic drugs such as antidepressants and Ritalin.**
- **260 infants and toddlers (3 years of age or less) were routinely prescribed 4 or more psychotropic drugs. (Most of the drugs were “off label” and have not been tested or approved for infants.)**
- **351 children were written 50 or more prescriptions.**
- **One child was issued 111 prescriptions in just one year.**
- **In the state of Florida alone, \$680,000,000 of Medicaid funds was expended on “behavioral health drugs” in 2005, which represents a 286% increase in five years.**

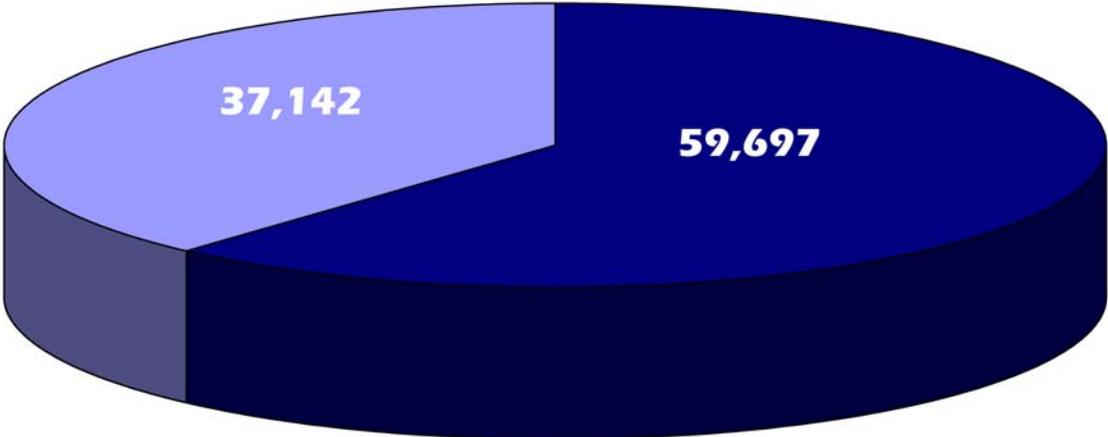
## Number of Medicaid Children Supplied Psychotropic Drugs



## Medicaid Funds Expended on Behavioral Health Drugs

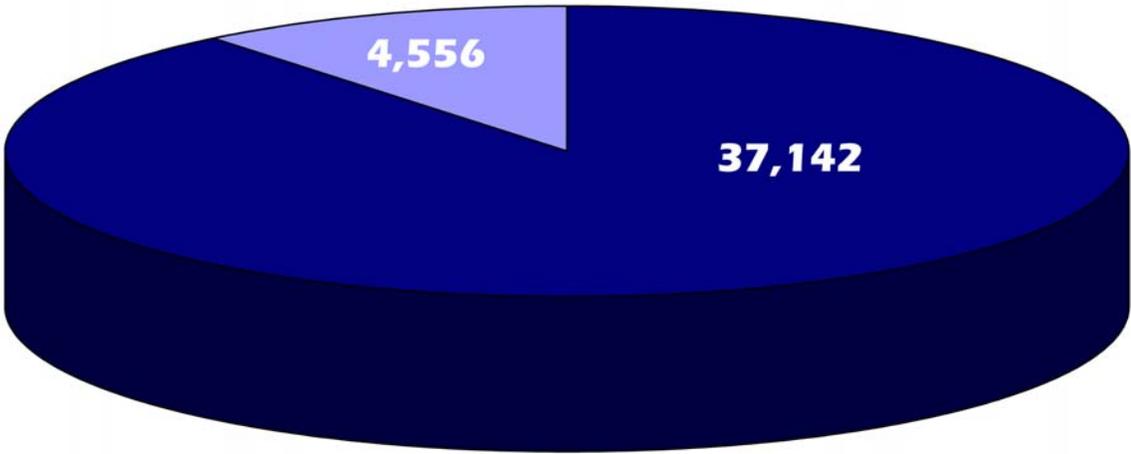


# Children Prescribed "Off Label" Psychotropic Drugs



- Total Medicaid Children Prescribed Psychotropic Drugs
- Medicaid Children Prescribed "Off Label" Psychotropic Drugs

# "Off Label" Prescriptions Given to Children 5 Years or Less in 2005



- Medicaid Children Prescribed "Off Label" Psychotropic Drugs
- Children 5 Years or Younger

# DOCUMENTED SIDE EFFECTS OF DRUGS BEING PRESCRIBED TO INFANTS, TODDLERS AND CHILDREN

## STIMULANT SIDE EFFECTS:

Abdominal pain	Hallucinations	Loss of appetite	Tachycardia (heart irregularity)
Aggression	Headaches	Mental/mood changes	Toxic psychosis
Angina (sudden acute pain)	Heart palpitations	Moodiness	Unusual weakness or tiredness
Anorexia	Hypersensitivity	Nausea	Violent behavior
Blood pressure and pulse changes	Increased irritability	Nervousness	Vomiting
Blurred vision	Insomnia	Psychosis	Weight loss
Depression	Involuntary tics and twitching called	Restlessness	“Zombie” demeanor
Dizziness	Tourette’s Syndrome	Seizures	
Drowsiness		Stomach pain	
Fever	Liver problems	Stunted growth	
		Suicidal thoughts	

## ANTIDEPRESSANT SIDE EFFECTS:

Agitation	Hallucinations	Loss of appetite	Suicidal thoughts or behavior
Akathisia (severe restlessness)	Headache	Mania	Violent behavior
Anxiety	Heart attacks	Memory lapses	Weight loss
Bizarre dreams	Hostility	Nausea	Withdrawal symptoms include deeper depression
Confusion	Hypomania (abnormal excitement)	Panic attacks	
Delusions	Insomnia	Paranoia	
Emotional numbing		Psychotic Episodes	
		Seizures	

## ANTIPSYCHOTIC SIDE EFFECTS:

Akathisia	Extreme inner-anxiety	Insomnia	Sleepiness
Abnormal gait (manner of walking)	Fatal blood clots	Light-headedness	Spasms
Blindness	Headache	Manic reaction	Suicidal thoughts
Blood disorders	Heart arrhythmia	Muscle rigidity	Swollen and leaking breasts
Blood-sugar abnormalities	Heart failure	Nausea	Tachycardia (heart irregularity)
Blurred vision	Heart palpitation	Nervousness	Tardive dyskinesia
Cardiac arrest	Heat stroke	Nightmares	Tremors
Confusion	Hemorrhage	Painful skin rashes	Violence
Death from liver failure	Hostility	Pancreatitis (inflammation of pancreas, a gland near the stomach that helps digestion)	Vomiting
Depression	Hyperglycemia (abnormally high blood sugar)	Poor concentration	Weakness
Diabetes	Hypoglycemia (abnormally low blood sugar)	Seizures	Weight gain
Drowsiness			

## ANTI-ANXIETY DRUG SIDE EFFECTS:

Acute hyperexcited states	Depression	Hostility	Nausea
Aggressive behavior	Disorientation	Hysteria	Nervousness
Agitation	Drowsiness	Insomnia	Nightmares
Akathisia	Epileptic seizures and death	Irritability	Psychosis
Amnesia	Excitability	Jaundice	Rage
Anxiety	Extreme restlessness	Lethargy	Sedation
Coma	Fear	Liver problems	Severe depression
Confusion	Hallucinations	Memory impairment	Sleep disturbances
		Muscle tremors	Suicidal attempt

## INTRODUCTION

In response to information published in an investigation conducted by the Florida Statewide Advocacy Council (SAC) into the widespread psychotropic drugging of foster children, the Citizens Commission on Human Rights Florida (CCHR) launched an investigation to ascertain the full scope of an escalating trend to prescribe psychotropic drugs to minor children in Florida's Medicaid Program. CCHR's findings were even more disturbing than expected and in fact disclosed that since the report period investigated by the SAC report, the number of Medicaid children prescribed psychotropic drugs has increased an alarming **528%**.

In July 2003, the Florida Statewide Advocacy Council ("SAC") published a Red Item Report on the widespread administration of psychotropic drugs to children in foster care. The SAC investigation found that **55%** of Florida children under foster care were being treated with psychotropic drugs.

The SAC report also stated that, "*information received from the Agency for Health Care Administration (AHCA) revealed that **more than 9,500 children in Florida on Medicaid had been treated with psychotropic drugs in the year 2000.***"<sup>1</sup>

The SAC expressed particular concern that many children as young as five years old or less were being drugged through Medicaid, and in that context stated:

*"...the use of psychotropic drugs by preschoolers was a disturbing discovery, since most of these drugs have not been approved for use in young children by the Federal Food and Drug Administration (FDA). While physicians are permitted to prescribe medications in ways that have not received FDA approval, there is very little data on the possible long-term consequences of using these drugs at such an early age. Further, diagnosing mental illness in children at such a young age is extremely difficult as these children are unable to describe their symptoms adequately, if at all."*<sup>2</sup>

Further, in relation to all foster children being treated with psychotropic medication, the report stated, "*There was little documentation that appropriate **written informed consent** to give these medications to minor children was obtained from parents or guardians.*"<sup>3</sup>

The SAC report highlighted the very real danger of the use of these drugs by children:

*"Side effects of these drugs are very serious and include decreased blood flow to the brain, cardiac arrhythmias, disruption of growth*

*hormone leading to suppression of growth in the body and brain of a child, weight loss, permanent neurological tics, dystonia, addiction and abuse, including withdrawal reactions, psychosis, depression, insomnia, agitation and social withdrawal, suicidal tendencies, possible atrophy in the brain, worsening of the very symptoms the drugs are supposed to improve, and decreased ability to learn, tardive dyskinesia and malignant neuroleptic syndrome. The FDA is currently reviewing reports of a possible increased risk of suicidal thinking and suicide attempts in children and adolescents under the age of 18 treated with the drug, Paxil.”<sup>4 5</sup>*

The SAC report concluded that “unnecessary dispensing of psychotropic medication remains a threat” to Florida’s foster children and made recommendations including implementing a quality assurance program to monitor the use of these drugs in foster children and ensuring “appropriate standardized written informed consent is obtained prior to starting any child on psychotropic medication.”

In the 2005 legislative session, a new law was created which instituted additional controls on the use of these drugs with foster children including a procedure for obtaining informed consent from parents or guardians. The drugging of Florida’s children is much farther reaching than our foster children. While instituting controls and informed consent requirements for the foster children was long overdue, even longer overdue is instituting these same requirements for all children in Florida, particularly the underprivileged who are normally served through the Medicaid program.

## **THE CURRENT INVESTIGATION**

In 2006 the Citizens Commission on Human Rights of Florida (CCHR) investigated the current state of the problem as described in the 2003 SAC report. While CCHR was denied access to records of Florida foster children, Florida Medicaid records for the year 2005 were obtained through a public records request.

In response to CCHR’s request, the Agency for Health Care Administration (AHCA) produced a Microsoft Access database labeled, “Florida Medicaid – CY2005 – Recipients Under 19 Years, Behavioral Drug Scripts.”

The database included five separate sections, listing prescriptions in the categories of ADHD drugs, anti-anxiety drugs, anticonvulsants, antidepressants and anti-psychotics.

Each database contained all prescriptions for that category of drug, with columns of data as follows:

- A unique ID number for each child
- Age of each child
- Gender of the child
- Drug name and dosage
- The prescribing physician's name, license number and location

The findings demonstrate a very real and escalating problem not just among foster children but all Florida children receiving care through Medicaid.

## FLORIDA MEDICAID CHILDREN

In summary, an analysis of the 2005 Florida Medicaid facts revealed the following:

- 59,697 children were prescribed psychotropic drugs. Of these, 7,444 were 5 years old or younger.
- 520,348 total psychotropic drug prescriptions were written for Medicaid children.
- 19,080 children were prescribed antipsychotic drugs. 4,556 were five years old or younger.
- 15,240 children were prescribed 3 or more *different* psychotropic drugs during the year.
- 351 children were written 50 or more different prescriptions during 2005. One child was written 111 prescriptions.

Given the earlier data contained in the SAC Report also obtained from the AHCA that 9,500 children on Medicaid in Florida were treated with psychotropic drugs in 2000, this new figure of 59,697 represents an increase of **528%** in just five years.

A significant increase in the number of infants prescribed psychotropic drugs has also occurred. Of the 59,697 children put on these drugs, 1,953, or 3% of the children were aged 3 years or younger. This is compared to the 1% of Medicaid children found in the 2003 SAC report.

CCHR's study also revealed that **260 infants and toddlers (ages 0-3) were prescribed four or more different psychotropic drugs, including many potent antidepressants, such as Effexor, Wellbutrin and Doxepin, none of which have been tested or approved for use with children.**

## INDIVIDUAL PHYSICIANS

Three doctors wrote more than 5,000 prescriptions each for psychotropic drugs given to Medicaid children. Nine doctors prescribed the drugs to 500 or more children and 227 doctors prescribed them to 100 or more children. It is difficult to imagine a doctor who could fill over 50 prescriptions for psychotropic drugs every day to children, each working day of the year, but that in fact is what is being claimed.

The most voluminous prescriber is Dr. Mohammed Bhaghani, a psychiatrist in Clermont, Florida. Dr. Bhaghani, who received his medical degree from Dow Medical College, University of Karachi, Pakistan. Dr. Bhaghani billed Medicaid for a total of 5,572 psychotropic drug prescriptions for 735 different children ages 1 to 18. This represents an average of 7.5 prescriptions per child under his care. Dr. Bhaghani issued a total of 2,236 prescriptions for anti-psychotic drugs, 1,427 prescriptions for ADHD drugs, and 1,191 prescriptions for anti-depressants.

## MEDICAID SPENDING

According to a presentation at a December 2003 conference of the National Mental Health Association, the cost of Medicaid in State budgets has more than doubled in 10 years and now consumes about 25% of every State budget. The fastest growing category of Medicaid expense is pharmacy with national Medicaid pharmacy expenditures in 2002 reaching \$24 billion. The fastest growing drug classes within the Medicaid pharmacy budget is behavioral health drugs (anti-psychotics, anti-convulsants/mood stabilizers, anti-depressants, anti-anxiety agents and sedative hypnotics).

In Florida, Medicaid spending on behavioral health drugs for the year 2004-2005 was \$680,000,000, which represented a 286% increase over spending just five years earlier.<sup>6</sup> In comparison, the 528% increase in drug usage by Medicaid children in Florida over the same five years demonstrates that child drugging is a significant factor in the increase in Medicaid spending in Florida.

## “OFF LABEL” DRUGS

CCHR’s investigation found that 57% of the psychotropic prescriptions for Florida Medicaid children in 2005 were prescribed “off-label”, and that 37,142 children were irresponsibly given off-label drugs. Medicaid children in Florida are being used as subjects in a gigantic experiment, although the “results” are not being codified, reported or analyzed.<sup>7</sup>

When the FDA approves a prescription drug, it clearly states the manner in which it can be used, including the age of patients to which prescriptions may be made, standard dosage, and the conditions which may be treated with that drug. This approval process is based on the testing conducted on the drug. Use of the drug in patients in a manner, or for an age or condition that was not tested and approved is called “off label”. A physician *may* prescribe medications off-label to patients at the physician’s discretion.

Almost all psychotropic drug prescriptions for preschool children are considered “off label”. That means that the drug is being prescribed for populations for which no standards of dosage have been established, or for medical conditions for which the product is not indicated and has not been tested.<sup>8</sup>

A recent study published in the Archives of Internal Medicine found that 21 percent of the 725 million prescriptions written in 2001 in the United States were for off-label uses. Further, the study found that most of the off-label uses lacked strong scientific justification, such as a clinical trial and were based solely on observational studies or no discernable evidence whatsoever. In psychiatry, the researchers found that 96 percent of off-label prescriptions lacked strong scientific support.<sup>9</sup>

#### **More 2005 Florida Medicaid “off label” Prescription Facts:**

- 4,556 children and infants, 5 years old or less, were prescribed “off label” **antipsychotic** drugs.
- 37,142 children received “off label” psychotropic drugs. This represents more than 60% of the total of 59,697 children put on psychotropic drugs.
- **1,728 of the “off label” prescriptions written were given to infants 3 years of age or less.**

### **MEDICAID FRAUD**

Further, most off-label prescriptions for children may not be covered under Medicaid, and such reimbursements constitute Medicaid fraud. 42 U.S.C. 1396r-8(d)(1)(B)(i), authorizes a State to exclude Medicaid coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication.

Medicaid reimbursement for prescription drugs in Florida requires that the drug be both medically necessary and prescribed for medically accepted indications and dosages as found in the FDA approved drug labeling or in specifically named drug compendia, i.e. *Drug Facts and Comparisons*, *USP-Drug Information*, *AMA Drug Evaluations*, *AHFS-Drug Information*, or *DRUGDEX*

*Information System. (see Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook [Florida Handbook], page 9-2.)*

The 2005 Florida Medicaid records reveal that more than 60% of the psychiatric drug prescriptions for children age 0-18 that were reimbursed by Medicaid were neither medically necessary or prescribed for a medically accepted indication because they were prescribed for children younger than permitted either under the drug label or the above named compendia. Assuming an average cost of \$100 per prescription (likely underestimated), that comes to some \$25 million in Medicaid fraud from child drugging.

## **ILLEGAL USE OF PRESCRIPTION DRUGS**

It is undisputed that the legal use of prescription drugs is increasing at an alarming rate. In the ten years between 1992 and 2002, the number of prescriptions filled for “controlled” prescription drugs increased by 154 percent. This dramatic increase occurred while the U.S. population increased by only 13 percent and the number of prescriptions written for “non-controlled” drugs increased by just 57 percent.

Increases in “controlled” drug prescriptions correlate with the increases seen in the illegal use of prescription drugs. During this same period, there was a 90 percent increase (from 7.8 million to 14.8 million) in the number of people who admitted abusing controlled prescription drugs. Also, there was a 203 percent increase among 12-17-year olds abusing these drugs and a 78 percent increase among adults. By the year 2003, these numbers had comparably risen to 212 percent for teens and 81 percent for adults.

Prescription drug abuse accounts for 30% of the Nation’s drug problem and is fast overtaking drugs like marijuana and cocaine. Controlled prescription drugs like OxyContin, Ritalin and Valium are now the fourth most abused substances in America behind only marijuana, alcohol and tobacco.<sup>10</sup> The sharp increase in controlled prescription drug abuse is twice the increase seen in the number of people abusing marijuana, it is five times the increase in the number abusing cocaine and 60 times the increase in the number of people abusing heroin. Particularly alarming is the 212 percent increase that occurred between 1992 to 2003 in the number of 12 to 17 year olds abusing controlled prescription drugs. An increasing number of these are teens trying drugs for the first time.

In 2002, Florida experienced 9,116 drug overdose deaths. Of these, 3,324 deaths (36%) were caused by prescription drugs. In 2002, Florida suffered more deaths from the prescription Schedule IV benzodiazepines than cocaine. Illegal prescription drugs now constitute the fastest growing segment of the illicit drug market.<sup>11</sup>

## DRUGS LINKED TO CHILD SUICIDES

An increasing number of recent retrospective studies have found that a great many psychotropic drugs are associated with increased suicidality in children. In response to these published findings, CCHR conducted an investigation to determine if there is a significant causal link between taking psychotropic drugs, receiving psychiatric/mental health treatment and suicide. The study looked at Florida youth who committed suicide during a five-year period.

The study looked for children, 18 years or younger, who committed suicide either a) with psychotropic drugs in their system at the time of death, b) with a history of use of psychotropic drugs, or c) with a history of psychological, psychiatric or other mental health treatment.

Public records requests were submitted to each of 24 medical examiner districts in Florida requesting a list of every death of 18 year olds or younger who committed suicide from 2000 to 2004 (a 5 year period). A total of 252 cased histories were thereby obtained.

**It was found that a total of 52% (131 cases) of the child suicides during this five-year period either used psychotropic drugs or had a history of psychiatric treatment.<sup>12</sup> Psychotropic drug use was verified in 38.1% of the suicides (96 cases). An additional 13.9% of suicides had a verified history of psychological, psychiatric or mental health treatment (35 cases).**

The number of children who commit suicide and who are using or have used psychotropic medication validate recent strong FDA warnings for both stimulants and antidepressants that are being prescribed to children. Furthermore, it raises serious questions regarding the efficacy, risk and comparable worth of the use of psychotropic medication in children.

## INFORMED CONSENT

Black's Law Dictionary defines "informed consent" as "A person's agreement to allow something to happen, made with full knowledge of the risks involved and the alternatives."<sup>13</sup> Informed consent to any sort of medical treatment is a fundamental right and is required by law and by oath for medical doctors. Doctor's should insist that patients, or their parents or guardians in the case of children, provide informed consent prior to any program of treatment. However, it is proving impractical and unreliable to rely on doctors or pharmaceutical companies, whose financial gain depends on the patient accepting treatment as recommended, to be responsible for obtaining genuine and properly deliberated, informed consent.

As most Medicaid children are school aged, it is highly probable that their referral to a psychiatrist or other medical doctor who prescribed psychotropic drugs came through the public school system. Any student who is suspected by school personnel to be emotionally or mentally disabled is required to be evaluated by the school under the Individuals with Disabilities Education Act (IDEA).

IDEA contains a specific requirement that “informed consent” be obtained from parents prior to any evaluation or treatment of their children through the public school system.<sup>14</sup> The IDEA 2004 Regulations, updated August 2006, and published in the Federal Register, strengthen informed consent requirements and specifically require public schools, **“to make reasonable efforts to obtain the informed consent from the parent for an initial evaluation”**. The new rules clarify that references to “consent” throughout the regulations means, **“informed consent”**, and that for a public agency to meet the **“reasonable efforts requirement,”** the agency **“must document its attempts to obtain parental consent.”**<sup>15</sup>

CCHR conducted a survey of Florida School Districts and found that in practice, informed consent is *not* being obtained from parents prior to evaluation. Parents *are* required to sign a consent form that articulates their legal rights, and the legal rights of the school to override their consent. However, true informed consent by definition is not being obtained from most Florida parents. Parents of children who are being evaluated for apparent behavioral or emotional dysfunction as reported by teachers, are not being told or provided information on the risks or consequences of psychological or psychiatric evaluation or treatment, including the many disastrous side effects of psychotropic drugs on children.

In short, Florida Schools are non-compliant with IDEA informed consent requirements.

It was the classification of ADHD as a disability under IDEA in 1991 by the U.S. Department of Education which likely contributed to the skyrocketing epidemic-like increase in the prescription of Ritalin and other ADHD drugs to children.<sup>16</sup> Therefore, it is only appropriate that IDEA regulations are applied to ensure that parents are properly informed and can best determine whether their children should risk psychotropic drugs or pursue non-drug approaches to handling children’s problems with attention and learning.

## RECOMMENDATIONS

1. The Florida Attorney General Medicaid Fraud Unit should investigate the prescription of psychotropic drugs to children which are either medically unnecessary or not for accepted medical indications and the concerned physicians should be held accountable.
2. Stronger warnings are needed for all medical doctors in Florida of the requirements that prescription drugs covered by Medicaid must be both medically necessary and for a medically accepted indication, and exactly what this means.
3. Exactly as recommended by the Statewide Advocacy Council in 2003, we recommend, “that appropriate standardized written informed consent is obtained prior to starting any child on psychotropic medication.” We further recommend that the Florida Legislature enact law, which provides the content of informed consent required for students referred by public schools for evaluation as emotional, mental or behavioral disabled under IDEA.
4. AHCA or the Florida Department of Children and Families need to develop a system for monitoring the use of these drugs in children and investigating doctors who are heavy prescribers.<sup>17</sup>
5. The Florida Department of Health should require that medical doctors and pharmacies provide parents and guardians report forms to report any adverse reactions for drugs to the FDA and any other relevant regulatory agencies.
6. The Florida Department of Law Enforcement and the Medical Examiners Commission should require Medical Examiners report toxicology analyses that indicate psychotropic drug use in suicides to the FDA as an adverse reaction report to any psychotropic drug which a suicide victim has been using.

## References

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<sup>1</sup> “Psychotropic Drug Use in Foster Care,” Florida Statewide Advocacy Council, Red Item Report, July 2003, p. 3.

<sup>2</sup> *Ibid.*

<sup>3</sup> *Ibid.*

<sup>4</sup> *Ibid.*

<sup>5</sup> On October 15, 2004 the FDA placed the most serious level of warning, the “black box”, on virtually all antidepressants, that they could cause suicidal thoughts and actions in persons under age 18. See the Appendix for additional information on health warnings associated with psychotropic drugs.

<sup>6</sup> Medicaid Formulary Presentation, Aug. 18, 2005, Florida Council for Community Mental Health.

<sup>7</sup> As stated by Dr. John March, a professor of child and adolescent psychiatry at Duke University, in the article “Antipsychotic Drug Care for Children Soars” *New York Times*, June 6, 2006: “We are using these medications and don’t know how they work, if they work, or at what cost. It amounts to a huge experiment with the lives of American kids, and what it tells us is that we’ve got to do something other than we’re doing now.”

<sup>8</sup> Greenhill LL, “The use of psychotropic medication in preschoolers: indications, safety, and efficacy,” *Canadian Journal of Psychiatry*, Vol. 43, No. 6 (Aug. 1998), p.576-7.

<sup>9</sup> Radley, David C., et. al., “Off-label Prescribing Among Office-Based Physicians,” *Archives of Internal Medicine*, 2006;166:1021-1026.

<sup>10</sup> Califano, Joseph, “Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.,” The National Center on Addiction and Substance Abuse, Columbia University, July 2005.

<sup>11</sup> 2005 Report of the Florida Office of Drug Control, James McDonough, Director.

<sup>12</sup> Suicides of Young Persons in Florida Associated with Psychotropic Drugs – A Five-Year Study, February 2006, By Ken Kramer.

<sup>13</sup> Black’s Law Dictionary, Seventh Edition, 1999.

<sup>14</sup> 20 U.S.C. § 1414 (a) (1) (C) (I).

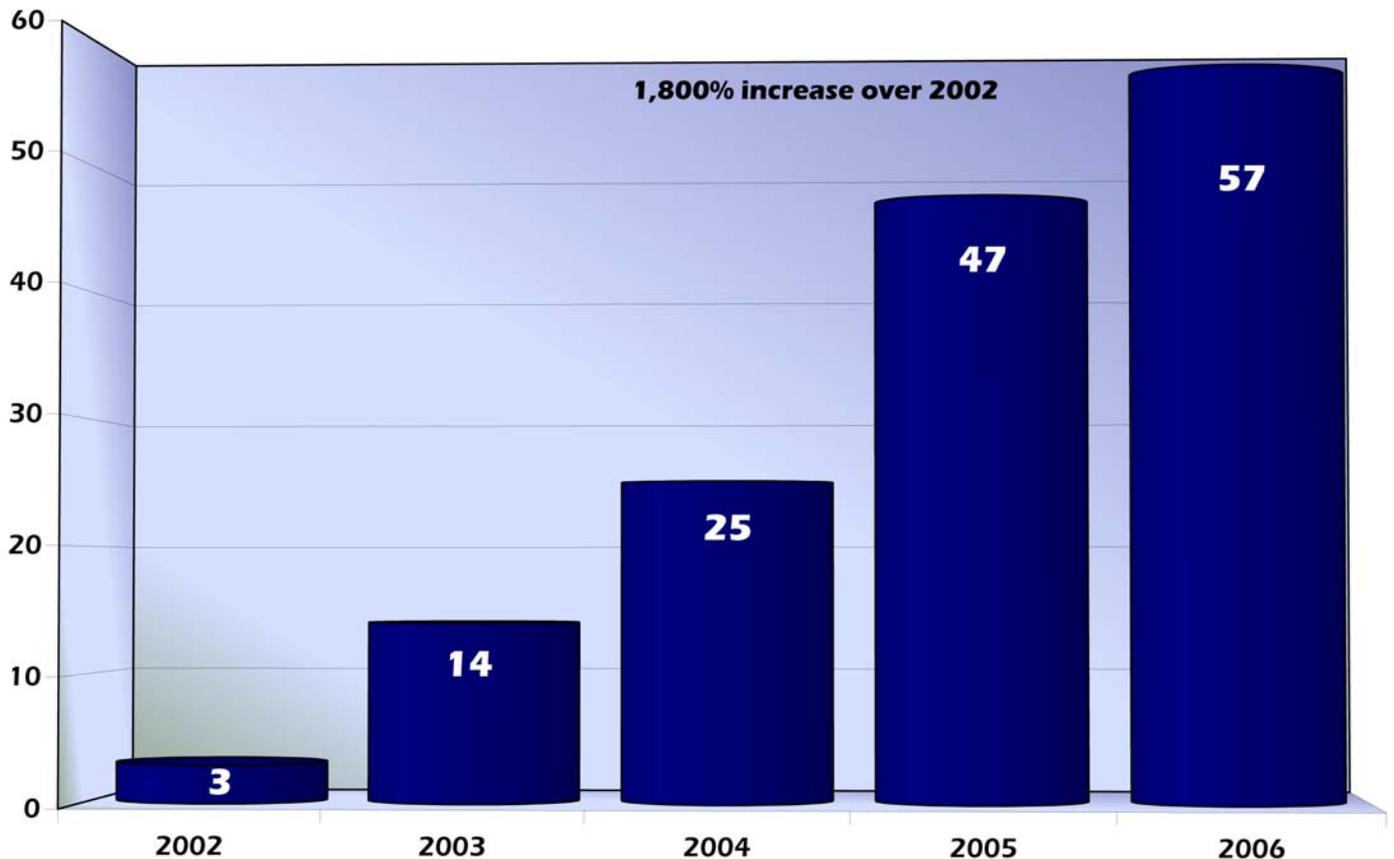
<sup>15</sup> 34CFR300.

<sup>16</sup> The situation was clearly articulated in February 2002 by Robert Holland, Senior Fellow of the Lexington Institute, in his article, “The Reaction Against Ritalin”: “The United Nations reported that the U.S. was manufacturing and consuming 90 percent of the world’s supply of Ritalin, a powerful stimulant that’s been on Schedule II of the Controlled Substances Act since 1971. Between 1991 and 1999, domestic sales of Ritalin increased 500 percent. Some critics believe a 1991 federal Department of Education decision to classify attention deficit (hyperactivity) disorder (ADHD or ADD) as a learning disability for which schools could receive reimbursement under the Individuals With Disabilities Education Act (IDEA) contributed to this questionable Ritalin boom. It is impossible to look at the explosive increase in Ritalin use in the USA over the past decade without concluding that something more than student behavior is out of control.”

<sup>17</sup> A Department of Children and Families (DCF) report of February 2005, which appeared to have been an attempt to lessen the seriousness of the SAC report of 2003, found that 5,137, or 25%, of the State’s foster children were being treated with psychotropic drugs, prompting concerns that the medication is inappropriate, too costly and simply dangerous. DCF notified 442 doctors involved in prescribing the drugs to 1,273 children that they were engaging in “questionable” practices. It is not known whether or not DCF ever conducted an investigation of these doctors, but the magnitude of the 2005 report pales in comparison to the instant report with almost 60,000 Medicaid children being prescribed these drugs.

## APPENDIX

### Number of International Studies and Warnings on Psychiatric Drugs Cumulative, 2002-2006



#### 2004

**February 2:** FDA official Dr. Andrew D. Mosholder testified before the FDA's Psychopharmacological Advisory Committee on the Office of Drug Safety Data Resources for the Study of Suicidal Events, warning that children being prescribed the newer antidepressants were at risk of suicide.

**March 22:** The FDA warned that Prozac-like antidepressants (called Selective Serotonin Reuptake Inhibitors or 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]."

**June:** The Australian Therapeutic Goods Administration published an Adverse Drug Reactions Bulletin reporting that the latest antipsychotics could increase the risk of diabetes.

**June:** The FDA ordered that the packaging for the stimulant Adderall include a warning about sudden cardiovascular deaths, especially in children with underlying heart disease.

**August 20:** A Columbia University review of the pediatric (child) clinical trials of Zoloft, Celexa, Effexor, Wellbutrin, Paxil and Prozac, found that young people who took them could experience suicidal thoughts or actions.

**September 21:** Following a BBC news report on antidepressants causing aggression and homicidal behavior, the British Healthcare Products Regulatory Authority advised that it had issued guidelines that children should not be given most SSRIs because clinical trial data showed an increased rate of harmful outcomes, including hostility.

**October 15:** The FDA ordered a "black box" warning for antidepressants that they could cause suicidal thoughts and actions in under 18 year olds taking them.

**October 21:** 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.

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

**December 9:** The European Medicines Agency's Committee for Medicinal Products for Human Use confirmed that product information should be changed for antidepressants to warn of the risk of suicide-related behavior in children and adolescents and of withdrawal reactions on stopping treatment.

**December 17:** The FDA required that packaging for the "ADHD" drug Straterra carry a new warning advising, "Severe liver damage may progress to liver failure resulting in death or the need for a liver transplant in a small percentage of patients."

## **2005**

**February 9:** 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.

**February 18:** 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.

**April:** The British House of Commons (Parliament) Health Committee issued a damning report that SSRI antidepressants had been "indiscriminately prescribed on a grand scale" and that drug companies have marketed the drugs without punishment to treat "unhappiness [that] is part of the spectrum of human experience, not a medical condition."

**April 11:** The FDA warned that antipsychotic drugs in elderly patients could increase the risk of death.

**April 21:** A national non-government organization, Partnership for a Drug-Free America, released its findings of a study that determined that 10% of teens (2.3 million) had abused the stimulants Ritalin and Adderall.

**April 25:** The European Medicines Agency's Committee for Medicinal Products for Human Use reaffirmed that *all* the latest antidepressants could cause increased suicide-related behavior and hostility in young people.

**June 28:** The FDA announced its intention to make labeling changes to Concerta and other Ritalin products to include the side effects: "visual hallucinations, suicidal ideation [ideas], psychotic behavior, as well as aggression or violent behavior."

**June 30:** The FDA warned that the latest antidepressant Cymbalta could increase suicidal thinking or behavior in pediatric patients taking it.

**June 30:** The FDA also warned about a potential increased risk of suicidal behavior in adults taking antidepressants, broadening its earlier warning that related only to children and adolescents taking the drugs.

**July 1:** An FDA "Talk Paper" said that it had requested antidepressant manufacturers to provide all information from their clinical trials on possible increased suicidal behavior in adults taking the drugs.

**July 7:** 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." that determined 15 million Americans were getting high on painkillers and psychiatric drugs such as the tranquilizer Xanax and the stimulants Ritalin and Adderall. Between 1992 and 2003, the number of 12 to 17 year olds abusing these drugs had risen 212%. Teens who abused prescription drugs were 12 times likelier to use heroin, 15 times likelier to use Ecstasy and 21 times likelier to use cocaine, compared to teens that did not abuse such drugs.

**July 16:** 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 were no more effective than a placebo (fake pill) and do not reduce depression. In a media interview on the study, Dr. Moncrieff stated, "The bottom line is that we really don't have any good evidence that these drugs work."

**August:** The Australian Therapeutic Goods Administration found a relationship between antidepressants and suicidality, akathisia (severe restlessness), agitation, nervousness and anxiety in adults. Similar symptoms could occur during withdrawal from the drugs, it determined.

**August 19:** The European Medicines Agency's Committee for Medicinal Products for Human Use issued its strongest warning against child antidepressant use, stating that the drugs caused suicide attempts and thoughts, aggression, hostility, aggression, oppositional behavior and anger.

**August 22:** Norwegian researchers found that patients taking antidepressants were seven times more likely to experience suicide than those taking placebo.

**September 7:** The Australian Therapeutic Goods Administration warned that antidepressant use during pregnancy could cause "withdrawal effects that can be severe or life-threatening."

**September 13:** 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 there were no trials showing 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."

**September 22:** Dr. Jeffrey Lieberman of Columbia University and other researchers published a federally funded study in the *New England Journal of Medicine* about the effectiveness of certain antipsychotic drugs, comparing an older generation of antipsychotics with several newer ones. Far from proving effectiveness, of the 1,493 patients who had participated, 74% discontinued their 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 taking this stopped, most commonly because it caused sleepiness, weight gain or neurological symptoms like stiffness and tremors.

**September 26:** *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 (tricyclic) antidepressants 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.

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

**September 28:** The British National Health Service's Institute for Health and Clinical Excellence released a Clinical Guideline for treatment of "Depression in Children and Young People." It advised "all antidepressant drugs have significant risks when given to children and young people" and instead, they should be "offered advice on the benefits of regular exercise," "sleep hygiene," "nutrition and the benefits of a balanced diet."

**September 29:** 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.

**September 29:** The UK Medicines and Healthcare Products Regulatory Agency issued a press release that it had begun a review of the risks of Strattera in light of the FDA's direction.

**October:** The sales and marketing of the stimulant Cylert were stopped in the U.S. because of the risk of liver damage that could lead to death.

**October 17:** The FDA ordered Eli Lilly & Co. to add a warning to the packaging of its antidepressant Cymbalta, that it could cause liver damage.

**October 19:** A study in the *Journal of the American Medical Association* concluded that atypical (newer) antipsychotic drugs could increase the risk of death in elderly people.

**October 24:** The FDA withdrew Cylert from the market because of its "overall risk of liver toxicity" and liver failure.

**November:** The FDA approved updated labeling for the antidepressant Effexor XR which noted that this antidepressant can cause homicidal ideation.

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

**December 8:** The FDA warned that Paxil taken by pregnant women in their first trimester may cause birth defects, including heart malformations.

## 2006

**January 5:** 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.

**February 4:** A University of Texas study published in *Pediatric Neurology* reported cardiovascular problems in people taking stimulants.

**February 5:** An analysis of World Health Organization medical records found that infants whose mothers took antidepressants while pregnant could suffer withdrawal effects.

**February 6:** 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.

**February 9:** The FDA's Drug Safety and Risk Management Advisory Committee urged that the strongest "black box" warning be issued for stimulants, including Ritalin, Adderall and Concerta and that they may cause heart attacks, strokes and sudden death.

**February 11:** The Australian Therapeutic Goods Administration announced it would review the FDA advisory committee recommendation for stronger warnings against stimulants.

**February 20:** British authorities warned that the "ADHD" drug Strattera was associated with seizures and potentially lengthening period of the time between heartbeats.

**February 25:** A study in the journal, *Drug and Alcohol Dependence*, and reported in *The Washington Post* revealed that seven million Americans were estimated to have abused stimulant drugs and a substantial amount of teenagers and young adults now appeared to show signs of addiction.

**March 10:** 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.

**March 22-23:** Two FDA advisory panels held hearings into the risk of stimulants and another new "ADHD" drug called Sparlon. 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 on special handouts called "Med Guides" that doctors must give to patients with *each* prescription. The second committee recommended not to approve Sparlon, which the manufacturer, Cephalon, estimated would lose them \$100 million in drug sales.

**March 28:** The Australian Therapeutic Goods Administration announced its review of reports of 400 adverse reactions to stimulants in children taking them. CCHR had filed a Freedom of Information Act request with the TGA to obtain the reports and released this to the media that ran the story internationally.

**May 1:** An *American Journal of Psychiatry* study revealed that elderly people prescribed 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.

**May 3:** FDA adverse drug reaction reports linked 45 child deaths to new antipsychotic drugs. There were also more than 1,300 reports of other potentially life-threatening adverse reactions such as convulsions and low white blood cell count.

**May 12:** GlaxoSmithKline, the manufacturer of Paxil, sent a letter to doctors warning that its antidepressant increases the risk of suicide in adults. It was the first warning of its kind by a manufacturer.

**July 19:** The FDA said antidepressant packaging should carry warnings that they may cause a fatal lung condition in newborns whose mothers took SSRI antidepressants during pregnancy. Migraine sufferers also need to be warned that combining migraine drugs with SSRIs could result in a life-threatening condition called serotonin syndrome.

**August:** The *Archives of General Psychiatry* published a study by Mark Olfson, MD, MPH; Steven C. Marcus, PhD; David Shaffer, MD, on "Antidepressant Drug Therapy and Suicide in Severely Depressed Children and Adults." The study determined that children taking antidepressants were 1.52 times more likely to attempt suicide and 15 times more likely to succeed in the attempt than those not taking the drugs.

**August 21:** The FDA issued a Black Box warning on the ADHD drug Dexedrine, as the drug causes sudden death in children and adolescents with structural cardiac abnormalities or other serious heart problems.

**August 21:** The FDA ordered warnings on all ADHD drugs. The warnings include: "Sudden deaths, strokes and myocardial infarction [heart attack] have been reported in adults taking stimulant drugs at usual doses." In addition to appearing on Ritalin, the warnings will be put on the labels of Adderall and Concerta. The warning will also state that one in a thousand children on the drugs suffers from hallucinations.



