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## Adult antipsychotics can worsen troubles; Critics: Look at other causes before medicating children

**BYLINE:** Marilyn Elias

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Evan Kitchens, a cheerful fourth-grader who loves basketball and idolizes his 16-year-old brother, had been hospitalized for mental illness by the time he was 8.

The boy from Bandera, Texas, was aggressive and hyperactive and had been diagnosed with a variety of other ailments, including obsessive-compulsive disorder and an autism spectrum disorder.

A couple of years ago, Evan was taking five psychiatric drugs, says his mother, Mary Kitchens. Two were so-called atypical antipsychotics, a group of relatively new drugs approved by the Food and Drug Administration for treating adults with schizophrenia or bipolar disorder.

"Evan was a walking zombie on all those drugs," Kitchens says. At the harrowing nadir two years ago, she wondered whether her son would survive, let alone live a normal life.

Evan shook with severe body tremors and hardly talked. He had crossed eyes, a dangerously low white blood cell count and a thyroid disorder, all symptoms that emerged after he started the atypical antipsychotic drugs, Kitchens says. Now, he has been weaned from the drugs and takes medicine only for attention-deficit disorder, she says. And he is mentally healthier than he has ever been.

These six new antipsychotic drugs -- Clozaril, Risperdal, Zyprexa, Seroquel, Abilify and Geodon -- are not approved for children, but doctors can prescribe them to kids "off label." And prescribing atypical antipsychotics for aggressive children such as Evan is leading the field in a growing pediatric business, according to a new analysis of a federal survey by Vanderbilt Medical School researchers.

Outpatient prescriptions for children ages 2 to 18 jumped about fivefold -- from just under half a million to about 2.5 million -- from 1995 to 2002, the survey shows.

At the same time, reports of deaths and dangerous side effects potentially linked to the drugs are increasing. A USA TODAY analysis of Food and Drug Administration data shows at least 45 deaths of children from 2000 to 2004 where an atypical was considered the "primary suspect." More than 1,300 cases reported bad side effects, including some that can be life threatening, such as convulsions and a low white blood cell count.

### Non-drug treatments

Treating children's disruptive behavior with pills is a complicated issue and the subject of debate among experts.

"In my experience, and that of many psychiatrists, antipsychotics are often overused for aggression in young patients,"

says Ronald Pies, a clinical professor at Tufts University and author of Handbook of Essential Psychopharmacology.

That doesn't mean it's necessarily wrong to give the pills, he adds.

Nobody disputes that the lives of schizophrenic or severely manic children might be saved by antipsychotics. But many non-drug treatments can help to keep aggressive, disruptive children off the atypicals, says John March, chief of child and adolescent psychiatry at Duke University School of Medicine.

So much hinges on whether safer treatments can work for a child.

Kids who show up on antipsychotics for aggression often can be weaned off if there are family changes, says behavioral pediatrician Lawrence Diller of Walnut Creek, Calif. For instance, adolescents may lash out angrily if their parents are fighting or discipline is inconsistent, Diller says. In a divorce, the child sometimes ends up with the less effective parent.

Last year, Diller saw an 8-year-old boy on four psychiatric drugs, including an atypical. He lived with his mother, "a highly anxious, incompetent parent." When he went to live with his father, his symptoms virtually disappeared, and he didn't need any drugs, Diller says.

Child psychiatrist George Stewart says he has seen dozens of aggressive children weaned off the atypical antipsychotic drugs in his consulting work and as medical director of a residential treatment facility in Concord, Calif. Too often, he says, doctors give the drugs without considering family conditions or life experiences that cause aggressive behavior, which can be changed with intensive counseling. Three examples he offers:

\*A boy younger than 3 was treated with two antipsychotics at a therapeutic preschool for kids with severe behavior problems. Stewart got a full family history, discovering his teen mother had a series of abusive boyfriends. "He was acting out due to that, but nobody took the time to find out what was going on at home," says Stewart, who worked with the mom to improve conditions. "She settled down."

The child was taken off atypicals and is doing fine.

\*A 12-year-old boy with out-of-control rage -- "we're talking smearing poop all over the 'quiet room'" -- was treated at Stewart's center. Intensive therapy identified the sources of his rage and taught the boy how to cope. He returned home, off all meds.

\*A teen girl seemed to be intractably violent. "She was trying to stab pencils in people's eyes," Stewart says. It turned out she had been raped and experienced other severe trauma. She was weaned off antipsychotics and counseled. Now in her late teens, she's living independently and doing well with no psychiatric drugs.

One of the most disturbing, potentially dangerous trends linked to atypicals is called "polypharmacy": routinely giving kids several psychiatric drugs, says child psychiatrist Joseph Penn of Bradley Hospital and Brown University School of Medicine in Providence. "We know very little about the interaction of these drugs, the effects they could be having on kids," he says.

The benefits of prescribing multiple drugs may outweigh risks in some cases, but Penn says he is appalled at how many times he has seen the mega-powerful atypicals prescribed to children suffering from insomnia when they're taking other medicines.

"I've seen hundreds of cases," he says, "and often parents don't seem to have been told about the many less risky prescription and non-prescription options out there."

Sometimes medical conditions or drugs for attention-deficit hyperactivity disorder cause the insomnia. Rather than attacking causes, doctors add an atypical to the mix, he says.

More research needed

There has been little carefully controlled, long-term research on children taking most psychiatric drugs, including the atypical antipsychotics. The FDA is trying to get more pediatric research on the atypicals, says Thomas Laughren, the

agency's director of the psychiatry products division.

The FDA has asked five pharmaceutical companies that make the drugs to test them in children with schizophrenia and bipolar disorder, the uses they're approved for in adults. Under law, they can get a six-month extension on their patents for doing these studies.

Also, the drug companies are doing their own pediatric studies on children with disorders as diverse as ADHD, autism, conduct disorder and Tourette's syndrome.

Janssen LP has applied to the FDA for approval to use its atypical antipsychotic, Risperdal, in the treatment of symptoms of autism, says Ramy Mahmoud, vice president of medical affairs for Janssen.

The National Institute of Mental Health also is conducting pediatric studies, but the research is primarily funded and supervised by pharmaceutical companies.

Even if the companies win approval, it won't guarantee safety or effectiveness of the drugs in children, says David Graham of the FDA Office of Drug Safety, who emphasizes he doesn't speak for the agency. "You basically know the drug isn't cyanide. You don't know much else," says Graham, who was the whistle-blower in the 2004 Vioxx heart disease scandal. Industry-funded trials are four to five times more likely than independent studies to show effectiveness for a drug, he says.

According to a research review published in February, 90% of drug-company-funded studies come up with findings that support the company's drug.

In head-to-head research testing more than one atypical antipsychotic drug, the outcomes are contradictory, coming down on the side of whichever company is paying for the research. (The research included studies of Risperdal, Zyprexa, Clozaril and Geodon, but none on Seroquel or Abilify.)

"It appears that whichever company sponsors the trial produces the better antipsychotic drug," writes lead author Stephan Heres of the Technical University of Munich in the American Journal of Psychiatry.

And the short-term, smaller studies required of companies rarely detect any but the most glaring problems, Graham says.

"The American public is operating under the illusion that a drug is safe just because it's approved by the FDA," says Jeffrey Lieberman, chairman of psychiatry at the Columbia College of Physicians and Surgeons in New York. Studies lasting a few weeks to a few months, with a couple of thousand patients total, won't reveal all that's wrong with a drug, he says.

Laughren agrees that "it's very difficult to answer every question we'd like to answer with these studies, because obviously they're not huge. Sometimes bad things that happen are going to be discovered only when a drug is used more widely."

He says he, too, shares concern about the antipsychotics prescribed for children without proof of safety or effectiveness. Much more pediatric information on the atypicals will be available within five years, he says.

#### Recommended changes

Others favor fundamental changes to get the needed facts about drug safety. Lieberman thinks one solution would be for the FDA to be given a new legal authority: the right to require drug companies seeking to gain approval of a drug to contribute to a collective pool at the National Institutes of Health. The NIH could supervise larger safety and effectiveness studies of medicines after they're on the market.

A national electronic medical records database that would capture all bad side effects of drugs, and require ages and diagnoses, could do a lot to protect children from careless prescribing and reveal the effects of antipsychotics, Duke's March says.

"We know so little about what's happening to all the kids who are getting these powerful antipsychotics," he says.

March also thinks more private insurers ought to insist that aggressive children with short fuses try non-drug therapies proven to help before doctors jump in with antipsychotics. These pills can seem like an appealing "quick fix," he says, so they're popular.

For foster children with mental health problems, medication is a mainstay, says Ira Burnim, legal director at the Bazelon Center for Mental Health Law, an advocacy group for those with mental disabilities. There's proof that the most effective care is "wraparound," he says, meaning that caseworkers touch base regularly with a child's school, doctor, foster and perhaps birth families, in addition to ensuring therapy or medication as needed.

"Now they're medicating many kids instead of giving them the services they need. But there's very little time spent with psychiatrists and not much attention paid to side effects from these heavy drugs," Burnim says.

States vary in how much wraparound care they provide for foster kids, "but a typical pattern is patches here and there," Burnim says. "They rely heavily on medications like the antipsychotics. This costs more than wraparound in the long run, and it's less safe for the kids."

March considers the widespread use of antipsychotics on children without proof of safety or effectiveness "a very large experiment." Many kids are getting the short end of the stick, he says. "We're not even gathering good data on the outcome of the experiment. It's the worst of all possible worlds."

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Contributing: Susan O'Brian

Data analysis by Anthony DeBarros, USA TODAY

Behavioral options are available

A number of behavioral treatment programs may help keep children off antipsychotic drugs. Among the options:

\*Webster-Stratton program: A five-month weekly program for parents and their severely defiant kids ages 3 to 8, it was developed by psychologist Carolyn Webster-Stratton more than 25 years ago. Children learn anger management, problem solving and social skills. Parents learn how to reinforce and teach positive behaviors to kids and how to reduce discipline problems by setting consequences for aggressive behavior. Parents also learn to manage their own anger and depression and how to work with teachers to set plans that encourage and reward positive behavior at school.

Webster-Stratton tracks graduates and says the method works for at least two-thirds of these very disturbed children. It's available at her home base, the University of Washington in Seattle, along with some areas of Delaware, Maine, California and Colorado. Costs vary.

For more information, e-mail her at [cws@u.washington.edu](mailto:cws@u.washington.edu).

\*Multi-systemic therapy (MST): Developed by psychologist Scott Henggeler in the 1980s to treat juvenile delinquents, it's now also being used for aggressive, impulsive kids who aren't lawbreakers. It typically lasts four to six months and also involves the child's family, school and friendship groups. This intensive treatment is available in 32 states. Cost varies but averages \$6,000. For information, visit [www.MSTServices.com](http://www.MSTServices.com).

\*Parent management training: This program teaches parents how to shape and control the behavior of hostile or violent kids 2 to 14 years old. It's an hour a week for three months, and kids 8 to 14 attend their own groups. Hundred of studies over three decades show it works for most children, says Alan Kazdin, director of the Yale Child Study Center, who developed the treatment. It's also available in Oregon, Washington state and Florida. Costs vary. For more information, visit [alan.kazdin@yale.edu](mailto:alan.kazdin@yale.edu).

\*Cognitive behavioral therapy: Parents and children can participate in a week-long or a more intensive several-week program at the University of Florida Medical School that helps kids with obsessive-compulsive disorder. It's cognitive behavioral therapy, a structured, goal-oriented treatment, says psychologist Eric Storch, who developed the specialized program. Research supports its effectiveness, he says. Cost averages \$1,250 a week at Florida, varies by location. Other CBT programs are available in many states.

For information: [www.ufocd.org](http://www.ufocd.org) or [www.ocfoundation.org](http://www.ocfoundation.org).

\*Floortime: For children with autism or defiance disorders, Bethesda, Md., child psychiatrist Stanley Greenspan has

created this program of intensive, structured exercises that promote communication and problem solving, he says. It's available in many states and described in Greenspan's new book, Engaging Autism. Costs vary. For information, visit [www.floortime.org](http://www.floortime.org).

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## New antipsychotic drugs carry risks for children; Side effects can lead to bigger health problems

**BYLINE:** Marilyn Elias

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Nancy Thomas remembers the bad old days when she had to wear long-sleeve clothes to church to cover bite marks all over her arms from her daughter Alexa's rages.

At age 8, Alexa was diagnosed with bipolar disorder. She was a violent child with sharp mood swings and meltdowns that drove her to tear up the house. Antidepressants and drugs for attention-deficit disorder had only made Alexa more aggressive, Thomas says.

A mix of medicines including so-called atypical antipsychotics -- drugs approved only for adults -- finally stabilized Alexa's moods. Now at 15, she is able to live a more normal life -- as long as she takes the medication.

Even so, the Russellville, Mo., teen is paying a price: On one of the atypical antipsychotics, Alexa gained about 100 pounds in a year, putting her at risk for a host of health problems, including diabetes. It has taken her three years to lose a third of that extra weight; she is still struggling with the rest.

Atypicals are a new generation of antipsychotic drugs approved by the Food and Drug Administration for adult schizophrenia and bipolar disorder (manic depression). None of the six drugs -- Clozaril, Risperdal, Zyprexa, Seroquel, Abilify and Geodon -- is approved for kids, but doctors can prescribe them as "off-label" medications.

Psychiatrists say the drugs can be helpful for children with serious mental illnesses and have been known to save young lives. But diagnosis often is difficult, making appropriate prescribing tricky. And many experts, including behavioral pediatrician Lawrence Diller, author of *Should I Medicate My Child?*, say there is growing overuse of these powerful antipsychotics.

Schizophrenia is rare in children under 18: It strikes about 1 in 40,000, as opposed to 1 in 100 adults, according to the National Institute of Mental Health. Nobody knows exactly how many kids have bipolar disorder; psychiatrists don't even agree on criteria to diagnose the disease in childhood.

Research on how the drugs affect children is sparse, and experts increasingly are concerned that the drugs are being prescribed too often for children with behavior problems, such as attention-deficit disorder and aggression.

John March, chief of child and adolescent psychiatry at Duke University School of Medicine, prescribes the drugs to kids in some cases of serious illness when he thinks the benefits outweigh the risks. But he says prescribing them for behavior problems alone may be a mistake. "We have no evidence about the safety of these agents or their effectiveness in controlling aggression," he says. "Why are we doing this?"



At the same time, reports of deaths and dangerous side effects linked to the drugs are mounting. A USA TODAY study of FDA data collected from 2000 to 2004 shows at least 45 deaths of children in which an atypical antipsychotic was listed in the FDA database as the "primary suspect." There also were 1,328 reports of bad side effects, some of them life-threatening.

Drug companies are required to file any reports they have to the FDA, but consumers and doctors report such events on a voluntary basis. Studies suggest the FDA's Adverse Events Reporting System database captures only 1% to 10% of drug-induced side effects and deaths, "maybe even less than 1%," says clinical pharmacologist Alastair J.J. Wood, an associate dean at Vanderbilt Medical School in Nashville. So the real number of cases is almost certainly much higher.

"We're conducting a very large experiment on our children," March says.

#### Side effects that linger

Some parents tell stories of serious effects that linger long after their kids stop taking the drugs.

Rex Evans' parents are bitter about what happened to their son. They believe the 13-year-old Colorado Springs boy was harmed permanently by an atypical antipsychotic he took several years ago. Rex now has a serious case of tardive dyskinesia (TD), suffering daily episodes of involuntary jerking movements and facial grimacing, says Erin Evans, his mother.

Antipsychotics are known to cause TD, but it's thought to be a rare effect for the newer atypicals.

Despite such reports, outpatient prescriptions for kids ages 2 to 18 leaped fivefold -- from just under half a million to about 2.5 million -- from 1995 to 2002, according to a new analysis of a federal survey by Vanderbilt Medical School researchers. This doesn't include prescriptions at psychiatric hospitals or residential treatment centers.

And even though the drugs are approved only for adults, the rate of children treated with atypicals "is growing dramatically faster than the rate for adults," says Robert Epstein, chief medical officer for Medco Health Solutions, pharmacy benefit managers.

Medco did an analysis of outpatient prescriptions for USA TODAY and found that, in a sampling of about 2.5 million of Medco's 55 million members, the rate of children 19 and under with at least one atypical prescription jumped 80% from 2001 to 2005 -- from 3.6 per 1,000 to 6.5 per 1,000. And that only represents kids who are privately insured, not those in foster care or others on Medicaid.

"We know these are very strong medicines," Epstein says. "You'd want to be absolutely sure the child needs it."

#### The more serious risks

Because of the nature of the FDA data, they don't prove that these drugs caused the deaths or the side effects. Many side effects for which an atypical is listed as the "primary suspect" occurred in the normal course of using the drug, but the database also includes cases involving drug abuse, overdoses, suicides and homicides. Entries are sometimes cryptic, and the FDA enters verbatim -- misspellings and all -- what's reported on the form.

Still, the data "can be a useful signaling device" suggesting problems with a drug that warrant conclusive studies, says Jerome Avorn, a pharmacology specialist at Harvard Medical School and author of the book *Powerful Medicines*.

One-fourth of the cases in the database studied by USA TODAY did not list the patient's age. But in cases that listed an age under 18:

\*A condition called dystonia was most often cited as an "adverse event" suffered by someone taking one of the drugs, with 103 reports. Dystonia produces involuntary, often painful muscle contractions.

\*Tremors, weight gain and sedation often were cited, along with neurological effects such as TD. Symptoms of TD can vary from slight twitching to full-blown jerking of the body.

\*A condition called neuroleptic malignant syndrome, with 41 pediatric cases over the five years, was the most

troubling effect listed, says child psychiatrist Joseph Penn of Bradley Hospital and Brown University School of Medicine. It is life-threatening and can kill within 24 hours of diagnosis. It's been linked to drugs that act on the brain's dopamine receptors, which would include the atypicals, Penn says.

The FDA office of drug safety checks the database, "and we haven't been alerted to any particular or unusual concern," says Thomas Laughren, director of the agency's division of psychiatry products. "The effects (in kids) are similar to what we're seeing in adults. We have not systematically looked at the data for children" because the drugs aren't approved for them, he says.

#### The 45 deaths

Among the 45 pediatric deaths in which atypicals were the primary suspect, at least six were related to diabetes -- atypicals carry warnings that the drugs may increase the risk of high blood sugar and diabetes. Other causes of death ranged from heart and pulmonary problems to suicide, choking and liver failure.

An 8-year-old boy had cardiac arrest. A 15-year-old boy died of an overdose. A 13-year-old girl experienced diabetic ketoacidosis, a deficiency of insulin.

More than half of the kids who died were on at least one other psychiatric drug besides the atypical antipsychotic, and many were taking drugs for other ailments.

The youngest, a 4-year-old boy whose symptoms suggested diabetes complications, was taking 10 other drugs.

The reports don't tell the child's general state of health or other factors that could predispose him to trouble. Also, neither Clozaril, which is rarely used, nor Abilify, the newest atypical, was listed as a primary suspect in any deaths.

All the drugmakers emphasize that their products are not approved for children, and they say the drugs are safe and effective for adults with schizophrenia or bipolar disorder who are monitored for side effects. Still, "there are worrisome questions here," says Avorn. Large, longer-term database studies could provide answers, he says.

There's some evidence that the drugs can help young schizophrenics and may be helpful in treating bipolar disorder in children, says Robert Findling, a child psychiatrist at University Hospitals of Cleveland.

But the data from controlled studies "are too few to guide treatment decisions" on bipolar disorder, concluded Findling's research team in a summary of pediatric studies published in the *Journal of Clinical Psychiatry*.

These antipsychotics are the most widely used class of drugs to treat disruptive kids who attack others and defy adults, Findling says. Again, there's a paucity of proof that the drugs help.

There are only a handful of carefully controlled, sizable studies testing the drugs for any pediatric disorder, and they're mostly short-term, says Benedetto Vitiello, chief of child and adolescent psychiatry at the national mental health institute. The most serious, widespread problem found to be caused by the medicines is weight gain, he says. The effect varies by drug, but kids typically put on twice the pounds they should in their first six months on atypicals.

In the first three months on the drugs, children add about 2 to 3 inches to their waistlines, says research psychiatrist Christoph Correll of Zucker Hillside Hospital in Glen Oaks, N.Y. A lot of this is abdominal fat, which increases the risk of diabetes and heart disease. Obese children are twice as likely as normal-weight children to have diabetes, according to a new University of Michigan study.

"Some patients gain weight on Zyprexa and others do not," says Calvin Sumner, a medical adviser to Eli Lilly Research Laboratories. Lilly makes the drug, which has been associated with weight gains in adult studies. Sumner stresses that Zyprexa isn't approved for kids.

There's no proof atypicals cause diabetes, says Ramy Mahmoud of Janssen LP, maker of Risperdal. He says the FDA added a label warning of increased diabetes risk "to make people aware of the possibility."

One key question about atypicals is whether they will have long-term, unknown effects on the brains of children.



The brain system that the drugs work on develops through childhood and adolescence, says Cynthia Kuhn, a Duke University pharmacologist. "We really don't know the impact of chronically perturbing that system in childhood."

#### Why atypicals get prescribed

Given all the potential problems, why would doctors prescribe these drugs to children to begin with?

Nobody disputes that the lives of schizophrenic or severely manic children may be saved by antipsychotics. "I use them myself for patients," says March, the Duke psychiatrist. "I have a 9-year-old who threatened to jump out of a second-story window if her mom didn't give her the car keys to drive down to the 7-Eleven to get a Coke. If I took her off antipsychotics, she'd disintegrate."

But several factors can lead to misprescribing of antipsychotics.

It can be difficult to tell one behavioral disorder or illness from another in kids. For example, the aggression and irritability of bipolar disorder can mimic attention-deficit hyperactivity disorder or depression, the mental health institute says. Also, the environment can be a key cause of symptoms that may be mistakenly diagnosed as mental disorders, says Diller, the behavioral pediatrician. Some events in a child's life can trigger acting-out or other symptoms. Adults can explain what happened to them; children, especially the youngest, may be more reticent.

Doctors often face time pressures that prevent them from finding out what's going on in kids' lives, knowledge that might suggest alternative treatments, Penn says. For example, abuse of drugs such as methamphetamine, OxyContin and cocaine is fairly common among teens, he says. Kids begin acting strangely, hearing voices, becoming paranoid. The symptoms can mimic psychosis or behavioral disorders, and doctors can end up giving these children unneeded antipsychotic drugs, he says.

Insurance coverage rules may encourage the soaring use of antipsychotics for children, as well. "With some companies, the only thing they reimburse for is prescribing. There's little or no therapy," says Ronald Brown, editor of the *Journal of Pediatric Psychology* and a dean at Temple University.

Also, kids with serious mental health problems often have at least one hospitalization, but policies cover only a week or two.

It can take a couple of weeks just to get medical records and family histories, Penn says, but insurers often extend time if there's a new medicine started, which encourages drug dabbling for children who are not ready to go home.

In the end, some parents say their children have such severe behavior disorders or mental illness that the benefits outweigh risks.

Parents of children such as Alexa Thomas, who have bipolar disorder, say the atypicals often help. "We were very fortunate," says Alexa's mother, special-education director for the Russellville, Mo., school district. "The medication worked for my daughter. It doesn't work for everybody."

#### Misdiagnosis common

The Vanderbilt study of antipsychotic prescribing finds at least 13% of pediatric prescriptions are for bipolar disorder. But there is some concern about over-diagnosis and "jumping to this (bipolar) label too quickly," says psychiatrist Peter Jensen, head of the Center for the Advancement of Children's Mental Health at Columbia University.

Sandra Spencer's son, Stephen, was diagnosed as bipolar at age 6 and put on atypicals. He developed liver abnormalities and obesity, his mother says. "He's been on a smorgasbord of meds," she says. None worked well for very long.

By the time he was in sixth grade, doctors said they weren't sure Stephen was bipolar after all. Now 15, he is on low doses of an antidepressant and mood stabilizer. He's being weaned off both, says Spencer, executive director of the Federation of Families for Children's Mental Health, a support group.

She worries about how the drugs have affected Stephen, who is black: As little psychiatric drug research as there is on

children, there's least of all on minority kids. Some drugs are known to affect black adults differently from whites. "He probably had ADHD all along," Spencer says. "Psychiatry is so not an exact science."

Child psychiatrist Barbara Geller, a bipolar expert at Washington University in St. Louis, agrees: "The science is nowhere near where it is in other branches of medicine."

So parents struggle to make the right decisions for very troubled kids. "There's a lot of fear among parents," Spencer says. "You don't know what the effects of these drugs are going to be. You're at the mercy of your doctor."

"I have had to make a lot of decisions, and they were fear-driven. You don't have enough information to make an intelligent decision."

Contributing: Susan O'Brian

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## For Evan, more drugs made things worse; One family's nightmare

**BYLINE:** Marilyn Elias

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Rising numbers of U.S. children are taking a new generation of antipsychotic drugs called atypicals.

Although the six drugs -- Clozaril, Risperdal, Zyprexa, Seroquel, Abilify and Geodon -- can be helpful in treating children with mental illness, critics say that the drugs are overprescribed and that many kids suffer serious side effects from drugs they never needed.

USA TODAY's Marilyn Elias talks to one mother who believes that's what happened to her son.

Evan Kitchens had problems from birth. He suffered from lack of oxygen during a difficult delivery. As a baby, he wouldn't nurse properly, didn't want to be held and screamed for hours.

"He hardly slept at all," says his mother, Mary Kitchens, a florist in Bandera, Texas.

At 18 months old, Evan was diagnosed with an autism spectrum disorder and prescribed Adderall, a drug to treat attention-deficit hyperactivity disorder.

But Evan just got more aggressive and hyperactive. When he was 2, he knocked out the front teeth of his younger brother with a flashlight. The family began a constant round of appointments with child psychiatrists and other doctors.

At 2 1/2, Evan was diagnosed with obsessive-compulsive disorder. When he was 3, doctors put him on Risperdal, his first antipsychotic. But in a "special needs" preschool, his aggressive behavior continued. He was out of control, racing out of the classroom, hitting other kids.

At 5 Evan was hospitalized for the first time. He was still on Risperdal and two other drugs, supposedly to stabilize his moods and curb hyperactivity. But nothing had worked well for long.

Kitchens says she tried doctor after doctor. She had insurance only on and off; her husband disappeared when twins were born 16 months after Evan, she says, so she became the family's sole support.

"Every drug created new symptoms, and then you had to treat those symptoms," she says. "We were constantly changing meds. I see now what we were really managing was symptoms of the drugs, not his underlying problem."

In April 2004, at age 8, Evan set fire to the bedroom carpet with a candle. Fortunately, 14-year-old Ethan, Evan's older brother, saw the fire before anyone was hurt.

Evan was hospitalized in San Antonio. The family drove three hours every day, Kitchens says, to bring Evan dinner and spend time with him. Now doctors said he might have bipolar disorder.

Evan had been on Risperdal and the mood stabilizer Lithium. Doctors added Seroquel to the mix. Within a month, he showed tremors, Kitchens says. "They got so bad, he was shaking all the time." Evan's eyes started to cross. Still, doctors thought it was important to keep him on the drugs. They added two more mood stabilizers. Soon Evan had a thyroid disorder and an abnormally low white blood cell count, Kitchens says.

In August, Evan was transferred to another center and weaned off everything but Seroquel and a drug for attention-deficit disorder. His alertness returned, but other symptoms lingered for months.

In January 2005, Evan came home. Kitchens gradually took him off Seroquel and says he's doing better than ever just taking medicine for ADD. He has had intensive behavior-management therapy; so has the whole family. His alarming symptoms are gone, but his eyes still cross occasionally if he's tired.

Many child psychiatrists are frustrated by the lack of drugs to treat kids with mental disorders, says Wayne Macfadden, U.S. medical director for Seroquel, which is made by AstraZeneca. But Seroquel isn't approved for children, he says. "Obviously, prescribers have to weigh the risks and benefits."

Evan made the honor roll in regular school his first semester home, Kitchens says. He sang in the school's Christmas choir, played basketball and is making friends.

His mother wishes she had gone the non-drug route earlier. "I didn't even know what was available ... I totally relied on the doctors."

Evan says his time of live-in care "is like a blur. I remember my stomach would hurt, and my head would hurt. I slept a whole lot. And then I started to see two of things. I was very scared." He says he's happy to be home: "Nothing hurts anymore."

If doctors recommend the drugs he took for other kids, Evan has some advice for their parents: "Sometimes it's good for them, sometimes it's bad for them. I would warn them about the bad things that can happen."

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How to be an advocate for a child

If a doctor recommends antipsychotic drugs for a child, parents should ask some key questions and watch for "red flags" that might signal the need for another opinion, says David Fassler, a child psychiatrist and clinical professor at the University of Vermont.

"If you have any questions or concerns, you should always try to get a second opinion," he says. "Sometimes the chemistry just doesn't feel right with that doctor. Nobody has all the answers, and parents really need to be advocates for their children."

#### Questions to ask

\*Why do you advise this medication? Have you treated others with it? Was it helpful?

\*How will we know whether the medicine is helping? "Push for specific criteria," says Fassler. "Are we measuring frequency of tantrums, school attendance or what?"

\*How long should it take to work? How long would my child need to be on this medicine if it is working?

\*What are the common and uncommon side effects?

\*What are the alternatives to this treatment? What are the risks and benefits of each?

\*Where can I get more information on the drug and on other treatment options?

\*Is this the lowest dose that might be effective?

\*How will this medication interact with other drugs my child is taking?

\*How can I contact you quickly if I have concerns?

\*What will we do if it doesn't help? What is the next step?

#### Red flags

\*The doctor hasn't done a full evaluation before prescribing the drug, including reviews of the child's developmental, medical and psychiatric history; family medical and psychiatric history; and the child's behavior at school, with friends and family.

\*The doctor has no plan for regular follow-up.

\*The doctor doesn't discuss any other options, such as counseling, to accompany the medication, or instead of it.

#### Helpful websites

\*[www.nimh.nih.gov/HealthInformation/childmenu.cfm](http://www.nimh.nih.gov/HealthInformation/childmenu.cfm)

\*[www.ffcmh.org](http://www.ffcmh.org)

\*[www.bpkids.org](http://www.bpkids.org)

\*[www.aacap.org/publications/factsfam/index.htm](http://www.aacap.org/publications/factsfam/index.htm)

\*[www.firstsigns.org](http://www.firstsigns.org)

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## Drug therapy caused some scary side effects; A family feels misled

**BYLINE:** Marilyn Elias

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Erin Evans is one parent who wishes she had never heard of antipsychotics.

As a military couple, she and her husband, Joe, moved around frequently. Their son, Rex, 13, was babied a lot. His mother now feels that he was not ready for school when he reached kindergarten age.

He had trouble focusing in the classroom and was diagnosed with attention-deficit disorder at age 6. He started on an ADHD medicine and began hallucinating about worms and bugs in his food.

Soon he was also on Prozac for anxiety, but the nervousness and paranoia persisted.

At age 8, Rex was given Risperdal by a Tennessee child psychiatrist in private practice who consulted for the military. He said the boy probably had obsessive-compulsive disorder, too, Evans says.

"(He) didn't tell us it had never been approved for children or warn us about any side effects," she says.

For the first few weeks, Risperdal helped a little; Rex became less anxious and hyper. "But then it wore right off, so the doctor kept increasing the dose," she says.

After one month on Risperdal, Rex started having tremors; within a few months, his hands shook so severely that he could barely write at school, "and I'd have to guide the cup of milk to his mouth in the morning," Evans says.

But the psychiatrist said the tremors weren't so bad, Evans says, and urged the family to continue the drug.

The psychiatrist didn't pressure them, she says, "but I'm from the generation where, when a doctor says something, you believe it."

Then, about a year after Rex started Risperdal, the Evanses found out that he might have schizoaffective disorder, a psychotic illness that children rarely get. A doctor's report said Rex probably would need to be institutionalized.

That year, when Rex was 9, the family moved to Colorado Springs. The parents started to learn more about Risperdal and, for the first time, they realized that Rex's symptoms could be side effects, so they started to wean him off the drug. In a few weeks they noticed his jaw was scrunching up and his facial expressions were becoming distorted. By then, Evans says, she had read up on tardive dyskinesia (TD), a neurological disorder that can be caused by antipsychotics.

Rex became less anxious, but the TD worsened. "He had a horrible, ugly look on his face all the time," Evans says.

Friends no longer came to play. Rex went from winning an award for best reader in the third grade to claiming he couldn't remember how to spell his own name in fourth grade.

Then in fifth grade, Rex slowly began to improve. A medical exam showed spasms in his thorax, perhaps linked to the upper body spasms, restricting the flow of oxygen to his brain.

He began oxygen therapy, and he quickly became more responsive to others and did better at school, Evans says. He also had behavioral therapies. At the end of elementary school, Rex had episodes only a few times a week.

But junior high has brought more stress and bullying, and the episodes have become more frequent. "His movement-disorder specialist said he expected Rex to have this for the rest of his life," Evans says.

Now she is bitter. "I trusted the doctors, I trusted the FDA ... and I feel betrayed by both," she says.

The Food and Drug Administration "does not regulate the practice of medicine," says Thomas Laughren, head of the division of psychiatry products. He adds that he's concerned about the use of such drugs in kids without systematic safety data.

Nobody knows how many children on atypicals get TD, says Ramy Mahmoud of Janssen LP, maker of Risperdal, but it's rare in adults. "Our drug isn't indicated for children," he says. "It's a strong drug. It has risks and benefits. Doctors and patients together have to weigh the benefits, at the start and on a continuing basis, along with the harm and suffering."

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