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# **Child's Ordeal Shows Risks of Psychosis Drugs for Young**

By DUFF WILSON

OPELOUSAS, La. — At 18 months, Kyle Warren started taking a daily antipsychotic drug on the orders of a pediatrician trying to quell the boy's severe temper tantrums.

Thus began a troubled toddler's journey from one doctor to another, from one diagnosis to another, involving even more drugs. Autism, bipolar disorder, hyperactivity, insomnia, oppositional defiant disorder. The boy's daily pill regimen multiplied: the antipsychotic Risperdal, the antidepressant Prozac, two sleeping medicines and one for attention-deficit disorder. All by the time he was 3.

He was sedated, drooling and overweight from the side effects of the antipsychotic medicine. Although his mother, Brandy Warren, had been at her "wit's end" when she resorted to the drug treatment, she began to worry about Kyle's altered personality. "All I had was a medicated little boy," Ms. Warren said. "I didn't have my son. It's like, you'd look into his eyes and you would just see just blankness."

Today, 6-year-old Kyle is in his fourth week of first grade, scoring high marks on his first tests. He is rambunctious and much thinner. Weaned off the drugs through a program affiliated with Tulane University that is aimed at helping low-income families whose children have mental health problems, Kyle now laughs easily and teases his family.

Ms. Warren and Kyle's new doctors point to his remarkable progress — and a more common diagnosis for children of attention-deficit hyperactivity disorder — as proof that he should have never been prescribed such powerful drugs in the first place.

Kyle now takes one drug, Vyvanse, for his attention deficit. His mother shared his medical records to help document a public glimpse into a trend that some psychiatric experts say they are finding increasingly worrisome: ready prescription-writing by doctors of more potent drugs to treat extremely young children, even infants, whose conditions rarely require such measures.

More than 500,000 children and adolescents in America are now taking antipsychotic drugs, according to a September 2009 report by the Food and Drug Administration. Their use is growing not only among older teenagers, when schizophrenia is believed to emerge, but also among tens of thousands of preschoolers.

A Columbia University study recently found a doubling of the rate of prescribing antipsychotic drugs for privately insured 2- to 5-year-olds from 2000 to 2007. Only 40 percent of them had received a proper mental health assessment, violating practice standards from the American Academy of Child and Adolescent Psychiatry.

"There are too many children getting on too many of these drugs too soon," Dr. Mark Olfson, professor of clinical psychiatry and lead researcher in the government-financed study, said.

Such radical treatments are indeed needed, some doctors and experts say, to help young children with severe problems stay safe and in school or day care. In 2006, the F.D.A. did approve treating children as young as 5 with Risperdal if they had autistic disorder and aggressive behavior, self-injury tendencies, tantrums or severe mood swings. Two other drugs, Seroquel from AstraZeneca and Abilify from Bristol-Myers Squibb, are permitted for youths 10 or older with bipolar disorder.

But many doctors say prescribing them for younger and younger children may pose grave risks to development of both their fast-growing brains and their bodies. Doctors can legally prescribe them for off-label use, including in preschoolers, even though research has not shown them to be safe or effective for children. Boys are far more likely to be medicated than girls.

Dr. Ben Vitiello, chief of child and adolescent treatment and preventive research at the National Institute of Mental Health, says conditions in young children are extremely difficult to diagnose properly because of their emotional variability. "This is a recent phenomenon, in large part driven by the misperception that these agents are safe and well tolerated," he said.

Even the most reluctant prescribers encounter a marketing juggernaut that has made antipsychotics the nation's top-selling class of drugs by revenue, \$14.6 billion last year, with prominent promotions aimed at treating children. In the waiting room of Kyle's original child psychiatrist, children played with Legos stamped with the word Risperdal, made by Johnson & Johnson. It has since lost its patent on the drug and stopped handing out the toys.

Greg Panico, a company spokesman, said the Legos were not intended for children to play with — only as a promotional item.

### **Cheaper to Medicate**

Dr. Lawrence L. Greenhill, president of the American Academy of Child and Adolescent Psychiatry, concerned about the lack of research, has recommended a national registry to track preschoolers on antipsychotic drugs for the next 10 years. "Psychotherapy is the key to the treatment of preschool children with severe mental disorders, and antipsychotics are adjunctive therapy — not the other way around," he said.

But it is cheaper to medicate children than to pay for family counseling, a fact highlighted by a Rutgers University study last year that found children from low-income families, like Kyle, were four times as likely as the privately insured to receive antipsychotic medicines.

Texas Medicaid data obtained by The New York Times showed a record \$96 million was spent last year on antipsychotic drugs for teenagers and children — including three unidentified infants who were given the drugs before their first birthdays.

In addition, foster care children seem to be medicated more often, prompting a Senate panel in June to ask the Government Accountability Office to investigate such practices.

In the last few years, doctors' concerns have led some states, like Florida and California, to put in place restrictions on doctors who want to prescribe antipsychotics for young children, requiring a second opinion or prior approval, especially for those on Medicaid. Some states now report that prescriptions are declining as a result.

A study released in July by 16 state Medicaid medical directors, which once had the working title "Too Many, Too Much, Too Young," recommended that more states require second opinions, outside consultation or other methods to assure proper prescriptions. The F.D.A. has

also strengthened warnings about using some of these drugs in treating children.

#### No Medical Reason

Kyle was rescued from his medicated state through a therapy program called Early Childhood Supports and Services, established in Louisiana through a confluence of like-minded child psychiatrists at Tulane, Louisiana State University and the state. It surrounds troubled children and their parents with social and mental health support services.

Dr. Mary Margaret Gleason, a professor of pediatrics and child psychiatry at Tulane who treated Kyle from ages 3 to 5 as he was weaned off the heavy medications, said there was no valid medical reason to give antipsychotic drugs to the boy, or virtually any other 2-year-old. "It's disturbing," she said.

Dr. Gleason says Kyle's current status proves he probably never had bipolar disorder, autism or psychosis. His doctors now say Kyle's tantrums arose from family turmoil and language delays, not any of the diagnoses used to justify antipsychotics.

"I will never, ever let my children be put on these drugs again," said Ms. Warren, 28, choking back tears. "I didn't realize what I was doing."

Dr. Edgardo R. Concepcion, the first child psychiatrist to treat Kyle, said he believed the drugs could help bipolar disorder in little children. "It's not easy to do this and prescribe this heavy medication," he said in an interview. "But when they come to me, I have no choice. I have to help this family, this mother. I have no choice."

Ms. Warren conceded that she resorted to medicating Kyle because she was unprepared for parenthood at age 22, living in difficult circumstances, sometimes distracted. "It was complicated," she said. "Very tense."

#### **Behavior Problems**

Kyle was a healthy baby physically, but he was afraid of some things. He spent hours lining up toys. When upset, he screamed, threw objects, even hit his head on the wall or floor — not uncommon for toddlers, but frightening.

"I'd bring him to the doctor and the doctor would say, 'You just need to discipline him,' " Ms. Warren said. "How can you discipline a 6-month-old?"

When Kyle's behavior worsened after his brother was born, Ms. Warren turned to a pediatrician, Dr. Martin J. deGravelle.

"Within five minutes of sitting with him, he looked at me and said, 'He has autism, there's no doubt about it,' "Ms. Warren said.

Dr. deGravelle's clinic notes say Kyle was hyperactive, prone to tantrums, spoke only three words and "does not interact well with strangers."

He prescribed Risperdal. At the time, Risperdal was approved by the F.D.A. only for adults with schizophrenia or acute manic episodes. The following year it was approved for certain children, 5 and older, with autism and extremely aggressive behavior. It has never been approved by the F.D.A. for use in children younger than 5, although doctors may legally prescribe for any use they see fit.

"Kyle at the time was very aggressive and easily agitated, so you try to find medication that can make him more easily controlled, because you can't reason with an 18-month-old," Dr. deGravelle said in a telephone interview. But Kyle was not autistic — according to several later evaluations, including one that Dr. deGravelle arranged with a neurologist. Kyle did not have the autistic child's core deficit of social interaction, Dr. Gleason said. Instead, he craved more positive attention from his mother.

"He had trouble communicating," Dr. Gleason said. "He didn't have people to listen to him."

After the neurologist review, the diagnosis changed to "oppositional defiant disorder" and the Risperdal continued.

"Yes, I did ask for it," Ms. Warren said. "But I was at my wit's end, and I didn't know what else to do."

Dr. deGravelle referred her to Dr. Concepcion, who in turn diagnosed Kyle's condition as bipolar disorder.

"Some children, when they come to me, the parents are really so frustrated," Dr. Concepcion said in a phone interview. "Especially the mothers are so scared or desperate in getting help. Their children are really acting psychotic."

Dr. Concepcion also spoke with Dr. Charles H. Zeanah, a Tulane medical professor, who disagreed with both the diagnosis and the treatment. "I have never seen a preschool child with bipolar disorder in 30 years as a child psychiatrist specializing in early childhood mental health," Dr. Zeanah said.

#### **More Pills**

"It's a controversial diagnosis, I agree with that," said Dr. Concepcion. "But if you will commit yourself in giving these children these medicines, you have to have a diagnosis that supports your treatment plan. You can't just give a nondiagnosis and give them the atypical antipsychotic."

He also prescribed four more pills.

Kyle's third birthday photo shows a pink-cheeked boy who had ballooned to 49 pounds. Obesity and diabetes are childhood risks of antipsychotics. Kyle smiles at the camera. He is sedated.

"His shell was there, but he wasn't there," Ms. Warren said. "And I didn't like that."

Dr. Concepcion referred Kyle to the early childhood support program, which has helped about 3,000 preschoolers from low-income families at risk for mental health problems since 2002.

His speech improved. He threw fewer tantrums. "They started working with us as a family," said Ms. Warren, who also received parenting advice. "That helps."

Kyle's treatment was directed by Dr. Gleason, a Columbia medical graduate who had led a team that wrote 2007 practice guidelines for psychopharmacological treatment of very young children.

"Families sometimes feel the need for a quick fix," Dr. Gleason said. "That's often the prescription pad. But I'm concerned that when a child sees someone who prescribes but doesn't do therapy, they're closing the door that can make longer-lasting change."

Off most drugs, Kyle started losing weight and his behavior improved. Ms. Warren's life also improved. She met a man and they moved into their own house five miles out of Opalousas, a town of 25,000. They were married last Saturday.

At their home recently, Kyle and his brother, Jade, ran and played while their baby sister watched from a playpen. Their clothes were neatly folded in a shared bedroom. They often responded "Yes, ma'am" or "Yes, sir."

"They're respectful, but they're hyper kids," Ms. Warren said. "Once he came off the medication, he's Kyle. He's an intelligent person. He's loud. He's funny. He's smart. He's bouncy. I mean, there's never a dull moment. He has a few little behavior issues. But he's like any other normal 6-year-old."

Kyle paused to show a reading report card from the end of his kindergarten year, with an A grade.

"Awesome job, Kyle!" his kindergarten teacher wrote.

This article has been revised to reflect the following correction:

#### Correction: September 2, 2010

An earlier version of this article misspelled the name of the Louisiana town Opelousas in one instance.