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ADD & ADHD Health Center

ADHD Drugs: Hallucinations Not Uncommon

FDA Examines Incidence of Psychotic Symptoms in Children Taking ADHD Medications

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WebMD Health News

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Jan. 26, 2009 -- Treatment-related hallucinations and other psychotic symptoms in children with attention deficit hyperactivity disorder (ADHD) may be more common than previously thought, FDA officials report in the latest issue of the journal *Pediatrics.*

In an earlier investigation, FDA researchers identified more than 850 separate incidences of hallucinations and other psychotic episodes among children taking stimulants used to treat ADHD.

The investigation prompted federal officials to require new labeling on the drugs, including Ritalin LA, Concerta, Adderall XR, Focalin, Focalin XR, Metadate CD, Daytrana, and Strattera, warning of possible psychiatric side effects.

An estimated 2.5 million children and teens take these and other stimulant-based medications to treat ADHD symptoms.

Nearly half of the cases of hallucination and other psychiatric side effects reviewed by FDA researchers involved children younger than age 11.

And in more than nine out of 10 cases, the children had no reported history of psychiatric events.

Bugs, Worms, and Snakes

Hallucinations involving insects, snakes, or worms were among the most commonly reported psychiatric events among children and teens, FDA medical epidemiologist and drug safety expert Kate Gelperin, MD, MPH, tells WebMD.

"Some children described feeling a sensation of bugs or worms crawling on their skin," she says.

One case detailed in the report involved a 12-year-old boy with cerebral palsy who said he saw roaches surrounding him two hours after taking an ADHD drug containing methylphenidate. The hallucination lasted several hours, recurred when the boy took an additional dose of the drug, but stopped altogether when the drug was discontinued.

An analysis of 49 randomized clinical trials found that for every 100 children who take ADHD drugs for a year, between one and two experience a drug-related psychotic event.

But in the *Pediatrics* report, the FDA researchers conclude that this estimate is probably low, in part because the clinical trials often excluded children with a history of adverse reactions to ADHD drugs.

"Patients and physicians should be aware of the possibility that psychiatric symptoms consistent with psychosis or mania, when they arise in the course of drug treatment of ADHD, may represent adverse drug reactions," the FDA researchers write.

Cardiovascular Concerns

ADHD researcher William Pelham Jr., PhD, tells WebMD that hallucinations and similar psychiatric symptoms are well known to clinicians who specialize in treating children with the disorder.

Pelham is a professor of psychology, pediatrics, and psychiatry at the State University of New York at Buffalo.

"Off the top of my head, I would say I have seen this in about one out of every 100 kids I've treated," he says.

But he adds that pediatricians and other clinicians who don't specialize in treating ADHD may fail to associate psychotic episodes with stimulant drug use.

He notes that the drugs have also been linked to sudden death in children with heart problems. It is now recommended that children be evaluated for heart problems before beginning treatment with ADHD medications.

"The hope is that reports like this one will raise awareness that these are not benign medications. They are psychoactive drugs with side effects," he says.

Warnings Included on Labels

A spokesman for Shire Pharmaceuticals, which markets extended-release Adderall XR, tells WebMD that there is little new information in the published FDA report and that the drug's labeling now includes a warning about possible psychiatric side effects, including hallucination.

"Stimulant medications are proven, safe treatments for people with ADHD," says Shire Director of Corporate Communications Matt Cabrey. "But with any medication there is a risk for adverse events, and these drugs are no exception."

Eli Lilly and Co. spokesman David Shaffer also noted that the labeling for Strattera was altered to warn of possible psychiatric side effects after the FDA first made its concerns public.

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