



ADHD Drugs Linked to Sudden Death

Some Parents Believe New Study Reinforces Link Between Stimulants, Cardiac Death

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For Ann Hohmann, Oct. 21, 2004, began just about like any other day.

On that morning, the 54-year-old mother of two living in McAllen, Texas, was preparing to take her eldest son to school. She had an early appointment, so her husband, Rick Hohmann, would be dropping off younger son, 14-year-old Matthew, at his school that day.

About a month earlier, Matthew had been diagnosed with [attention deficit hyperactivity disorder](#), or [ADHD](#). And like an estimated [2.5 million other children](#) in the United States, he was taking [medication](#) for the condition.

It was Ann Hohmann who gave Matthew his [Adderall XR](#) pill that morning with a glass of water. But it was her husband who later found him after he had collapsed on the bathroom floor.

"To me, he seemed fine," she recalled. "My husband had seen him walking around, brushing his teeth. Then he walked in and found him flat down on the floor in the bathroom.

"When he turned him over, his lips were blue," Hohmann said.

She said that her husband called her first, and then he called 911. He performed CPR until the ambulance arrived. But it was too late.

"They worked on him for a while, but he was dead," she said.

Ann Hohmann is one of a handful of parents across the country who believes that their children's [sudden death](#) was due to the use of drugs to control ADHD. And she said she hopes a new study released this morning, which suggests that the use of stimulants is tied to an increased risk of sudden unexplained death among children and teens, will open the eyes of the public to what she sees as the cause of her son's demise.

"When my doctor gave this to my son, I thought it was a light dose," she said. "I had no idea that it was going to kill him. It ruined our lives. ... There was no warning."

Findings May Add Fuel to ADHD Drug Debate

In the study of 564 children and teens who died suddenly, researchers led by Madelyn Gould of the New York State Psychiatric Institute and Columbia University in New York City found that those who

died suddenly were 7.4 times more likely than not to have been taking the stimulant medications. The results of the study are reported online in *The American Journal of Psychiatry*.

"Although sudden unexplained death is a rare event," the researchers said, "this finding should be considered in the context of other data about the risk and benefit of stimulants in medical treatment."

ADHD Medication Concerns Have Arisen in Past

Reports of cases of sudden unexplained death among children taking stimulants for ADHD have raised concerns over use of the medications in the past. The U.S. Food and Drug Administration's adverse event reporting system identified 11 sudden deaths in pediatric patients taking methylphenidate -- the active ingredient in Ritalin and other ADHD drugs -- from January 1995 to February 2005.

While this rate of sudden death appears very low, the researchers there may be more cases that go unreported.

In 2006, the issue saw two FDA advisory committees come to opposite conclusions regarding the need to include a boxed warning of the risk of sudden death on the labels of stimulants. Later that year, information was added to the regular warnings section of the medication labels noting the association between sudden death and stimulant use at standard doses in children with serious heart problems.

Currently, however, it appears unlikely that this new study will have an effect on the FDA's approach to these drugs.

"Given the limitations of this study's methodology, the FDA is unable to conclude that these data affect the overall risk and benefit profile of stimulant medications used to treat ADHD in children," the FDA said in a statement released this morning. "Therefore, the FDA believes that this study should not serve as a basis for parents to stop a child's stimulant medication. Parents should discuss concerns about the use of these medicines with the prescribing healthcare professional."

The companies that manufacture these medicines maintain that these products are safe and that their risks are properly disclosed.

"Based on several reviews of these reports, the frequency of sudden cardiac death in children and adolescents taking a stimulant medication at the time of their death has not been shown to be higher than the incidence seen in the general population," Shire Pharmaceuticals, which produces Adderall XR, said in a statement issued Friday before the study's release.

A spokesperson for Novartis, the company that manufactures the ADHD drug Ritalin, said that a review of the company's safety data "failed to detect an increased risk in sudden cardiac death associated with [Ritalin] use." McNeil Pediatrics, the company that manufactures the ADHD drug Concerta, had no comment when contacted by ABC News.

Still, the findings will likely reignite a debate within the medical community over the safety and proper use of the popular medications.

"It is astonishing that these drugs are used so widely with children -- 5 percent of the school-aged population on a daily basis," said William Pelham, professor of psychology, pediatrics and psychiatry at the State University of New York at Buffalo. "When this study is published, I suspect that the professional and advocacy groups that continue to ignore the accumulating evidence showing absence of

benefit on long-term outcomes will have a more difficult time defending the widespread practice of using stimulants as first line and sole treatment for ADHD in children."

Controversy Remains Over Stimulant Drugs for ADHD

Other medical professionals said more research is necessary before making any conclusions. "As far as the study design goes, I'm reminded of the old adage that 'correlation is not causation,'" said Jay Reeve, chief executive officer of the mental health services organization Apalachee Center Inc. in Tallahassee, Fla. "The downside of this study may be a wholesale rejection of the use of stimulants for children, which would be terrible.

"While caution is an excellent practice in child psychiatry, too many children are helped by the use of these meds ... to abandon prescribing these meds entirely," he said.

Daniel Cox, professor of psychiatry and neurosciences at the University of Virginia in Charlottesville, agreed, adding that he fears the study will have an overall negative effect on the health of these young patients if the public misinterprets its findings.

"This article cannot address a possible large question: How many lives are saved because of stimulant medications," he said. "How many children do not impulsively run out in the street, are inattentive to a car turning into their lane of traffic, don't climb out on a roof and fall because they are appropriately medicated and less impulsive and inattentive because of the therapeutic effects?"

Still, Ann Hohmann said that the circumstances behind her son's death are hard to ignore.

"We didn't know anything until we saw the death certificate, which said 'sudden cardiac death, myocarditis,'" she said. "When I saw that, it blew me away. How can a healthy 9-year-old have a heart attack?"

And while Shire noted that it provides warning language about the use of these medicines by patients with serious heart problems, Ann Hohmann said that her son had no such history.

"He had seen doctors several times prior to that, and he had a physical a year before that. The last time he saw a doctor, they listened to his heart."

Keeping Kids With ADHD Safe

Last year, the American Heart Association recommended considering routine heart screening tests known as electrocardiograms, or ECGs, prior to starting children with ADHD on stimulant drugs and called for future studies to assess the risk of sudden death.

Reeve said that he feels such testing could go a long way in determining which children should not be taking the medications.

Some Support Heart Screenings for Kids on ADHD Drugs

"I think that the AHA recommendations on ECG screening made a lot of good sense and go along with the idea that caution should be the first standard in medicating children," he said.

Not all doctors agreed, however. "There is no evidence that suggests doing [ECGs] on all children

taking stimulant medication will decrease incidences of sudden death," noted Dr. Francisco Xavier Castellanos, professor of child and adolescent psychiatry at the New York University's Langone Medical Center in New York City. "What we need is to move from spasmodic concern -- 'let's do something fast' -- to an urgency to get targeted research going that will provide crucially needed knowledge about who is at risk."

As for Hohmann, she said that she has started telling her friends to make sure that they do not put their children on stimulant ADHD medications. She added that she would advise any parents who had children who were taking an ADHD medication to have their children's hearts checked on a regular basis, both prior to beginning treatment with the drug and while they are taking it.

"When you lose a child, it's the most devastating thing you could ever, ever go through," she said. "Something needs to be done."

ABC News' Cathy Becker contributed to this report.

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