

# FDA urges caution in weighing risks of ADHD drugs

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(AP) -- Federal health regulators are urging parents to keep their children on attention deficit drugs like Ritalin and Adderall, despite new evidence from a government-backed study that the stimulants can increase the risk of sudden death.

Published Monday in the American Journal of Psychiatry, the study suggests a link between use of the stimulant drugs and sudden death in children and adolescents. The drugs, used to treat attention deficit and hyperactivity disorder, already carry warnings about risks of heart attack and stroke in children with underlying heart conditions, but researchers have questioned whether they pose the same risks to children without those problems.

Healthy children taking the medications were more likely to die suddenly for unexplained reasons than those not taking the drugs, according to the study from the National Institute of Mental Health.

The study was partially funded by the [Food and Drug Administration](#), but agency experts said its methods - which relied on interviews with parents and physicians years after the children's deaths - may have caused errors.

"Since the deaths occurred a long time ago, all of this depended on the memory of people - relatives and physicians - involved with the victims," said Dr. Robert Temple, the FDA's director of drug review.

The agency urges parents to discuss safety concerns with their doctor, but to keep children on the treatments.

The study compared a sample of 564 children who died of unexplained causes to 564 children who were killed in car accidents. Among the unexplained deaths, 10 children were taking an ADHD [drug](#) compared with two of the patients killed in car accidents.

The researchers used car accident victims as a comparison group because sudden childhood deaths are rare and difficult to track.

"While the data have limitations that preclude a definitive conclusion, our findings draw attention to the potential risks of stimulant medications for children and adolescents," the authors conclude.

But the FDA said it is collecting data for a larger, more in-depth study of the drugs that should be completed by the fall.

"We're not sure this study tells us something we didn't know," Temple said of Monday's publication. "We didn't think it gave an unequivocal answer as to whether there is such a risk."

About 2.5 million U.S. children currently take drugs for ADHD, according to government researchers. The American Heart Association recommends doctors consider giving children echocardiograms before starting them on ADHD drugs, though experts stress there is little hard data about the drugs' risks.

Sales of the drugs topped \$4.8 billion last year, according to health care analysis firm IMS Health. The most popular brands include Shire's Adderall, Johnson & Johnson's Concerta and Novartis' Ritalin.

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