

*The Truth*  *About Health*

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FDA Continues to Advance ADHD Drugs

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Even though a study has shown an increased likelihood of sudden death occurring in children being treated with stimulants for attention deficit hyperactivity disorder (ADHD), the U.S. Food and Drug Administration (FDA) continues to urge parents to keep on providing the drugs to their youngsters.

The FDA, in conjunction with the National Institute of Mental Health, funded a study to determine why sudden unexplained death sometimes occurs in healthy children who have no evidence of pre-existing heart disease. The study was conducted by researchers at the Columbia University College of Physicians & Surgeons and the New York State Psychiatric Institute. Results were recently published in the American Journal of Psychiatry.

Through the past 2 decades of stimulant prescription to treat ADHD, enough evidence has been collected to promote FDA warnings regarding children with pre-existing heart problems. With about 2.5 million U.S. children currently taking drugs for ADHD, even the American Heart Association recommends that doctors should give children an echocardiogram before starting them on ADHD drugs. And while the FDA continues to receive data regarding risks to healthy children, experts continue to advance the position that there is little conclusive data regarding the drug's risk.

In looking at the results of this recent study and how it was conducted, it is easy to see why the FDA would refuse to take a position that ADHD drugs should be further restricted or bear stronger warnings for healthy children. The data collected by researchers involved looking at the records of 564 children and adolescents who had died suddenly. These children had no apparent physical disorders that would have caused their death. At the same time, researchers examined comparison data of children who had died suddenly in a traffic accident. In all cases, the deaths occurred between 1985 and 1996.

What the researchers did find was that 10 of the healthy children who had died suddenly were taking ADHD drugs, while only 2 of the sudden death children in car accidents were on the medication. This led the study authors to conclude that there may have been an association between stimulant medications and sudden death in healthy children.

Considering the make up of the test, it seems that regardless of the findings, it was pretty well predetermined little would change in the eyes of FDA. It was easy for them to point out the weaknesses of a study where data was collected between 10 and 20 years after deaths had occurred. Even the comparison of healthy children deaths to those in auto accidents appears to be comparing apples to oranges. All in all, it seems like a pretty weak study aimed at continuing the status quo of advancing ADHD drugs. After all, it's a \$4.8 billion per year business for products like Ritalin® from Novartis, Adderall® from Shire Pharmaceuticals and Concerta® from Johnson & Johnson.

To its credit, the FDA is currently in the process of collecting more data aimed at further evaluation of the risks of stimulant medications used to treat ADHD in children. Along with the Agency for Healthcare Research and Quality, the FDA is sponsoring another large epidemiological study that apparently is aimed at providing further information about the potential risks of the drugs. Data collection for this study will be completed in late 2009.

Source: The National Institute of Mental Health. "Questions raised About Stimulants and Sudden Death." June 2009.

<http://www.nimh.nih.gov/science-news/2009/questions-raised-about-stimulants-and-sudden-death.shtml>. The U.S. Food and Drug Administration. "Communication about an Ongoing Safety Review of Stimulant Medications used in Children with Attention Deficit Hyperactivity Disorder." June 2009.

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm165858.htm>