

# **STRATTERA: A SECOND WARNING**

KENNETH M. COFFEY AND S. JOHN OBRINGER

*Mississippi State University*

## **Author Note**

Kenneth M. Coffey and S. John Obringer, Department of Curriculum, Instruction, and Special Education, Mississippi State University.

Correspondence concerning this article should be addressed to Kenneth M. Coffey, Department of Curriculum, Instruction, and Special Education, Box 9705, Mississippi State University, Mississippi State, MS 39762. E-mail: [kcoffey@colled.msstate.edu](mailto:kcoffey@colled.msstate.edu)

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An article published in the Fall 2004 issue and updated in the Spring 2006 issue of this journal discussed a recently approved drug, Strattera, which is used for children and adults with ADHD. The article noted that one of the main attributes of the drug is the fact that it is not a stimulant medication, but rather works by blocking or slowing the reabsorption of norepinephrine, a brain chemical considered important in regulating attention, impulsivity and activity levels.

The original article listed popular stimulant medications: Ritalin, Adderall, Concerta, and Cylert. Since that time Cylert was withdrawn from distribution due to liver toxicity (Food and Drug Administration, 2005). The stimulant medications had the potential for substance abuse, especially among at-risk populations. Also, some individuals with physical disabilities, such as spasticity, found that these popular medications exacerbated motor problems. As a result, Strattera seemed to be a logical alternative.

The original update on Strattera reported the bolded FDA warning. The warning indicated, in part, the potential for “severe liver injury in rare cases and markedly elevated hepatic enzymes and bilirubin” (“Warning of,” 2005). In spite of this warning, up to 3.4 million people have been prescribed Strattera.

## 2 PHYSICAL DISABILITIES: EDUCATION AND RELATED SERVICES

On June 9, 2010 the FDA warned doctors that children and adolescents who used Strattera were at increased risk of suicidal ideation. This black box warning states, “Strattera increased the risk of suicidal ideation in short-term studies in children or adolescents with attention-deficit/hyperactivity disorder (ADHD). Anyone considering the use of Strattera in a child or adolescent must balance this risk with the clinical need. Co-morbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behavior. Patients who have started on therapy should be monitored closely for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior. Family and caregivers should be advised of the need for close observation and communication with the prescriber. Strattera is approved for ADHD in pediatric and adult patients. Strattera is not approved for major depressive disorder (Drug Facts, 2011).

A statement from Lilly’s chief medical officer stated, “While suicidal thinking was uncommon in patients on the medication during clinical trials, it is important for parents to be aware it can occur and to discuss any unusual symptoms with a physician” (Lumpkin, 2005, para. 19).

It is important to note that the increased risk is for suicidal thoughts, rather than suicide attempts. The concern is that the increase in suicidal thoughts may lead to an increase in suicide attempts. Additionally, this risk is higher when an individual first begins Strattera or during a dosage adjustment. The overall risk is relatively low, 0.4% (Drug Facts, 2011) and appears to be limited to children and adolescents with no reports of increased suicidal ideation among adults taking Strattera. The FDA does not advise people to stop taking Strattera but to watch for signs of suicidal thinking (“ADHD medicines,” 2010).

### **REFERENCES**

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