

New Warning Highlight Risks of ADHD Drugs

The packages for many common treatments for attention deficit hyperactivity disorder (ADHD) will soon contain informational booklets warning patients about the possible risks associated with taking these drugs.

The U.S. Food and Drug Administration (FDA) has recently requested that the manufacturers of these drugs include detailed Patient Medication Guides to help patients understand the risks of taking these drugs, as well as the precautions that can be taken to prevent an adverse effect. "Medicines approved for the treatment of ADHD have real benefits for many patients but they may have serious risks as well," said Dr. Steven Galson, director of the Center for Drug Evaluation and Research (CDER), in a press release.

According to the FDA, ADHD affects about 3 to 7 percent of all school-aged children and about 4 percent of adults. It causes difficulty in maintaining concentration, hyperactivity and impulsiveness leading to difficulty in school, at work and in social interactions. Approximately 2.5 million children and 1.5 million adults in the United States take medication to treat ADHD. The number of adults between the ages of 20 and 44 taking ADHD medications increased more than 139 percent between 2000 and 2005.

Last year, an FDA pediatric advisory panel recommended that all ADHD drugs carry a "black box" warning on their packages alerting patients to the potential side effects of the drugs, which can include cardiac and psychiatric problems. Strattera already has a black-box warning that it may induce suicidal thoughts in children.

These guides, however, would be a simpler, more informative form of a warning that would be included in all packages for many ADHD treatments, including Adderall, Concerta, Daytrana, Desoxyn, Dexedrine, Focalin, Metadate, Methylin, Ritalin and Strattera. The new booklets will include information about the heart risks associated with these drugs. The drugs are associated with adverse affects in patients with underlying heart defects, but they also seem to raise the risk of stroke and heart attacks in some adults.

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