CHILD SAFETY BLOG

PATRICK MALONE & ASSOCIATES, P.C.
From Tragedy To Justice - Attorneys For The Injured

Toll Free: 888.625.6635
(888.MaloneLaw)
Local: 202.742.1500

Panel Recommends Suicide Warning Be Added to ADHD Drug Label

February 13, 2012 by Patrick A. Malone

A panel of pediatric experts has recommended that the FDA change the label for Focalin to address the risk of suicidal thoughts by children, according to Reuters.

The drug is prescribed for attention deficit disorder and is manufactured by Novartis AG. It was approved for children 6 and older in 2001.

Children with ADHD are excessively restless, impulsive, easily distracted and often have behavioral issues. Symptoms generally are relieved with behavioral therapy and medication (at least short term; the long term benefits of medication are less clear).

The FDA is not required to follow the advice of its panels, but usually does. It is required to hold regular advisory meetings to review the safety of drugs used by children. The panel also recommended that Focalin's label acknowledge the risk of anaphylaxis, an allergic reaction, and angioedema, a type of swelling beneath the skin.

Patrick A. Malone
Patrick Malone & Associates, P.C.
1331 H Street N.W.
Suite 902
Washington, DC 20005

pmalone@patrickmalonelaw.com
www.patrickmalonelaw.com
202-742-1500
202-742-1515 (fax)

The current label for Focalin advises patients about psychotic or manic side effects, but does not mention suicidal thoughts.

The FDA received eight reports of suicidal thoughts by children or adolescents who took the drug over the last six years. This risk did not present during the clinical trials of the drug, and the number of such reports is tiny in comparison to the number of patients taking it. If your child is taking Focalin, he or she shouldn't stop taking it. But do consult your pediatrician.

Diagnoses of ADHD (attention deficit hyperactivity disorder) have boomed in recent years; an estimated 3 to 5 kids in 100 are affected. Some experts question whether these diagnoses are made too quickly and drugs prescribed too easily. We've addressed the suitability of prescription drugs for ADHD.

According to Reuters, approximately 2.7 million people in the U.S. have prescriptions for ADHD drugs. Approximately 1.8 children received prescriptions for Focalin or its generic versions from 2005 to 2011.

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