



DOCTORS ASSESS RISKS OF ADHD MEDICATIONS

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A government panel has recommended the strongest safety warning -- a “black box” label -- for Ritalin, Adderall and other drugs used to treat Attention-Deficit/Hyperactivity Disorder or ADHD.

The Food and Drug Administration (FDA), the government agency that studies medicines to make sure they’re safe and really work, has been studying ADHD drugs, such as Ritalin, since 1955.

Last month, the FDA assembled a panel of doctors to assess reports of heart problems, including 25 instances of sudden death, in patients taking ADHD drugs and concerns that the drugs are over-prescribed.

The panel voted unanimously to recommend “medication guides” for ADHD drugs warning patients of potential heart risks.

The vote for the stronger “black box” warning was close – passing on a vote of 8 to 7.

“We have to elevate the level of concern” about the “out-of-control use of drugs that [may] have profound cardiac effects,” Dr. Steven Nissen, a heart specialist from the Cleveland Clinic, said during the meeting in Gaithersburg, Md.

The FDA will decide whether to follow the panel’s advice later this year.

What is ADHD?

Almost 8 percent of Americans, mostly children, have been diagnosed with ADHD. The rates are especially high among teenage boys at 11 percent.

People with ADHD have difficulty concentrating and controlling their behavior.

Like many behavioral problems, there is no official test for ADHD, and diagnosis is subject to the doctor’s interpretation of symptoms.

Roughly half of those diagnosed are treated with medical stimulants.

Even though increased activity is a symptom of the disorder, for reasons doctors don't fully understand, stimulants like Ritalin, help calm impulsive behavior and activity and boost the attention of kids with ADHD.

Medication comes with risk

But the drugs are not without their risks.

ADHD drugs are in the same class of drugs as amphetamines and ephedra, which carry black box warnings due to the risk of heart problems.

Although the effects of Ritalin and Adderall are not as strong as amphetamines, they are known to raise blood pressure and heart rates.

There have been scattered reports of heart attacks in adult patients taking ADHD -- but the data does not solidly link them to the drugs.

Novartis, the company that makes Ritalin, says the drug is safe.

"Ritalin has a long record as a safe and effective medication for the symptoms of ADHD," Todd Gruber, medical-safety director for Novartis, told Bloomberg News.

The doctor who recommended the warning, Nissen, was among the first physicians to link the drug Vioxx to increased risk of heart attacks and strokes.

Nissen is concerned by the length of time the average ADHD patient takes medications.

"Raising blood pressure of a child or adult continuously over many years worries me," he said.

The FDA has asked for a panel that handles medicine for children to address the issue during meetings scheduled for March 22.

Treatment on the rise

The FDA panel also was concerned that doctors are too quick to prescribe ADHD drugs.

"Prescriptions for adults jumped 90 percent from March 2002 to about 1 million filled each month as of June 2005," FDA researcher Andrew Mosholder told the panel.

The number of prescriptions for children is twice as high at 2 million prescriptions per month.

Prescriptions rates vary widely by community. In many rural and minority communities, very few teens are diagnosed or treated for ADHD.

By contrast, children in suburban, city and private schools are much more likely to be diagnosed with ADHD. In some schools, as many as one in five children take Ritalin.

“When we have communities -- and I think there are a number of them -- where we have so many children being labeled with ADHD and treated pharmacologically for this disorder, we have a major public health issue,” Gretchen LeFever, a clinical psychologist from Eastern Virginia Medical School, told the NewsHour.

LeFever says the problem is caused by two overlapping forces: local pediatricians who are inclined to diagnose ADHD, and parents who want their children to perform well in school.

--Compiled by Anne Bell for NewsHour Extra

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