

Update 6: Panel Considers New Warnings on ADHD Drugs

Associated Press

By ANDREW BRIDGES

Stronger warnings about rare but serious side-effects could scare people away from drugs for attention deficit-hyperactivity disorder, raising a whole new set of concerns, federal health advisers were told Wednesday.

Psychiatrists and mental health advocates said leaving the disease untreated could rival the risks the drugs may pose.

"It is important to not let the discussion of ADHD medications overshadow the public health crisis of untreated mental health disorders in children," said Cynthia Wainscott of the National Mental Health Association. Her 16-year-old granddaughter has ADHD.

A Food and Drug Administration advisory committee spent Wednesday reviewing reports of heart and psychiatric risks associated with the drugs and considered how best to relay that information to the public.

A vote was scheduled for late Wednesday after hours of testimony by drug makers and the public about Ritalin, Adderall, Strattera and other medications.

The FDA is not required to follow the recommendations of its advisory committees, but usually does.

A different committee voted last month to recommend that the FDA add the strongest possible warning to some of the drugs. The warning would alert doctors, patients and parents to the uncertainty regarding the risk that the drugs may pose to the cardiovascular system.

The FDA asked the pediatric panel to examine that same issue, as well as reports that psychosis or mania can occur in some juvenile patients when taking normal doses of any ADHD drug. The reviews included 100 studies of the drugs and reports from doctors, parents and others.

But adding "black-box" warnings to some or all the drugs could cause more harm than good, some experts said.

"I suggest confusion, polarizing viewpoints, initial press hysteria. But then what?" asked Julie Zito, associate professor in pharmacy and psychiatry at the University of Maryland.

ADHD drugs were used by nearly 3.3 million patients age 19 and younger last year, according to Medco Health Solutions Inc., a prescription drug benefit program manager.

Among the ADHD drugs are Ritalin, manufactured by Novartis Pharmaceuticals Corp. and in generic form by other companies; Adderall, made by Shire Pharmaceuticals Inc.; and Strattera, produced by Eli Lilly and Co.

FDA officials say patients and doctors should be aware that the small number of psychiatric episodes could be side effects of the drugs, although they cannot point to a definitive link.

The officials did note a "complete absence" of similar reports in children treated with dummy pills during dozens of clinical trials of the ADHD drugs. In many children, the events ceased once they stopped taking the drugs - and resumed in some once they restarted.

"That's unlikely to be due to random chance, suggesting some effect of the drugs," said Dr. Andrew Mosholder of the FDA's division of drug risk evaluation.

McNeil Consumer & Specialty Pharmaceuticals said in briefing documents that it is customary to weigh the "therapeutic benefits and potential risks" of treatment. The unit of Johnson & Johnson makes Concerta, a long-acting form of methylphenidate, the drug in Ritalin.

Novartis believes current Ritalin labels are adequate, company medical safety director Dr. Todd Gruber said.

Jacqueline Bessner of Ishpeming, Mich., said her daughter, Leanne, 15, hanged herself last year two months after starting treatment with Concerta. Bessner said more black-box warnings would be useless without increased counseling and monitoring of patients.

"It's being handed out like it's candy," Bessner said of ADHD drugs. "It's too easily accessible."

A different FDA panel planned to consider on Thursday an application by Cephalon Inc. to sell its sleep-disorder drug Provigil, or modafinil, as an ADHD treatment for children.

The FDA wants members of its psychopharmacologic drugs advisory committee to examine that request, including whether serious skin rashes seen in children treated with modafinil should merit special warnings, follow-up studies and steps to limit the risk.

Copyright 2005 Associated Press. All rights reserved. This material may not be published broadcast, rewritten, or redistributed