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Strongest warnings on ADHD drugs rejected

FDA advisers instead recommend simpler language on labels

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WASHINGTON - Ritalin and other drugs for attention deficit hyperactivity disorder should not have to carry the government's strongest warning about potential cardiovascular and psychiatric risks, a federal advisory panel says.

Instead of having the "black-box" warnings, the drug labels should caution users about possible dangers in plain language that they can understand, the Food and Drug Administration pediatric advisory committee recommended Wednesday.

By rejecting the black-box warnings in a consensus decision, the FDA advisers broke with another committee that voted just last month to include them on some ADHD drugs.

The FDA was poised Wednesday to follow the more recent recommendations.

"I think we are likely to follow them, yes," said Dr. Robert Temple, director of the FDA's office of medical policy, following the meeting.

Any updated language may not appear on labels until pharmaceutical companies begin using a recently adopted format, something that could take several years. And the FDA may yet require black-box warnings on stimulants to treat ADHD that would alert adults to increased risk of heart attacks, strokes and other similar problems, Temple said.

Nearly 3.3 million Americans age 19 and younger used an ADHD drug last year, according to Medco Health Solutions Inc., a prescription drug benefit program manager.

Psychiatrists and others had urged the committee to move cautiously before recommending strengthened warnings associated with the drugs.

In February, the FDA's Drug Safety and Risk Management advisory committee voted to recommend the agency add the strongest possible warning to some of the drugs regarding their potential cardiovascular risk.

The FDA then asked the pediatric panel to examine that same issue, as well as reports that psychosis or mania can occur in some juvenile patients at normal doses of any ADHD drug.

Confusion and press hysteria forewarned

Adding black-box warnings to some or all the drugs, which also include Adderall and Strattera, could cause more harm than good, some experts told the panel.

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

The FDA has struggled since last year with the question of how to communicate the potential risks associated with ADHD drugs. It now appears likely the warnings will come in the form of

highlighted language on drug labels, as well as guides distributed — admittedly infrequently, FDA officials said — to patients.

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.

Ritalin is manufactured by Novartis Pharmaceuticals Corp. and in generic form by other companies; Adderall is made by Shire Pharmaceuticals Inc.; and Strattera, which is produced by Eli Lilly and Co.

Earlier Wednesday, FDA officials say patients and doctors should be aware that the small number of reported psychiatric events, including hallucinations, could represent side effects of the drugs, although they cannot point to a definitive link.

The new labels should counsel parents to watch for such events and to both talk to their doctors and consider halting treatment, Nelson said.

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.

'Handed out like candy'

“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 psychopharmalogic 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.

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