ADHD pills need warning, panel says

Ricardo Alonso-Zaldivar | Los Angeles Times

Posted February 10, 2006

E-mail this article
Printer friendly version
Most e-mailed articles
News on your cell

WASHINGTON -- A Food and Drug Administration advisory panel Thursday urged tha strongest-possible safety warning be issued for drugs used by millions of children an treat attention-deficit hyperactivity disorder because of emerging concern that they the risks of heart attacks, strokes and sudden death.

The FDA had called the drug-safety experts together to help design further research risks. But in an unexpected twist, a majority of the panel members concluded the ev serious risks was so great that a strong new warning -- not just more research -- wa

"This is out-of-control use of drugs that have profound cardiovascular consequences," said Dr. Steven Nissen, a Cleveland Clinic cardiologist and member of the panel.

Although ADHD is commonly associated with children, members of the safety panel emphasized that the drugs could pose a greater danger to adults.

The FDA has received reports of several dozen deaths linked to the drugs, and a larger number of cases involving serious health consequences, such as heart attacks.

The safety panel voted 8-7 to call for a "black box" warning on literature distributed with the drugs, which include well-known brands such as Ritalin, Adderall and Concerta.

As many as 4 million Americans take the medications, and government figures show that almost 10 percent of all 10-year-old boys in the United States get the drugs; only about 4 percent of girls that age use them.

The safety experts also voted unanimously to recommend that a brochure be provided to patients and families them in greater detail about the risks and benefits of using the drugs. And it urged the FDA to expedite studie understand the drugs' effects.

Senior FDA officials said they would study the panel's recommendations and that they planned to refer the issu advisory panel dealing with psychological problems in children. The agency has been criticized in the past for b respond to evidence of health risks associated with drugs, including painkillers and anti-depressants.

"You don't want to over-scare people and make them not use an important drug," said Dr. Robert Temple, a t official at the FDA. "But you don't want people using drugs if they don't have to."

Drug makers said Thursday that the attention-deficit medications are safe when taken as directed. They noted have been in use for more than 50 years.

Shire, the maker of Adderall, said it would work with the FDA to make sure patients have all the information tl
that stronger warnings are not needed. Novartis, which makes Ritalin, said it has reviewed its own data and h
any increase in heart risks for patients.

The companies suggested there probably were other explanations for the deaths and serious health issues rep
FDA, such as heart problems that had gone undetected before the patient was taking the medication.

Most of the attention-deficit drugs are derived from powerful stimulants, including amphetamines. They are th
patients concentrate, though exactly how they work is not clear. But they also raise blood pressure, a major ri
heart disease and stroke.

Attention-deficit hyperactivity disorder can make it difficult for children to apply themselves in school; adult pa
have trouble with multitasking. In the United States, an estimated 2.5 million children and 1.5 million adults a
medication for the condition.

Though the drugs have been widely used by children since the 1990s, their use to treat adults is relatively nev
Prescriptions written for adults increased by 90 percent from 2002 to 2005. And the risks for adults may be gr
because high blood pressure and heart conditions are more prevalent among adults.

Currently, 10 percent of those taking ADHD drugs are 50 or older.

FDA officials convened Thursday's meeting after they began to worry that the drugs could be present problem

"We wouldn't be going through this exercise if we didn't think there was a real possibility of an increase in risk
David Graham, the FDA drug-safety investigator who was one of the first to call attention to the heart risks of
leading painkiller withdrawn from the market in 2004.

The risks appear to be different for children and adults. Graham and his colleagues undertook a preliminary st
information in the databases of large health insurers and government programs. Their early findings indicated
than-expected number of heart attacks and strokes among adults taking the medications.

Among children and teens through age 18, the number of strokes was higher than expected but the number o
attacks was lower.

Not all ADHD drugs are the same. One medication, Strattera, is not classified as a stimulant. But several pane
said the warnings should apply to the entire class of drugs, without exception. That may put a brake on overp
they said.

The FDA's Temple said that agency officials would discuss internally how to address the problem of the emergi
adults.

The panel members suggested several types of studies to look at safety issues for all patients.

The studies could take two years or more to complete.

Canada halted sales of Adderall last year after health authorities there received 20 reports of sudden deaths ir
the drug was allowed back on the market after statistical studies indicated it was no riskier than other medicat

It is not recommended for patients with underlying heart problems, however.

'Black box' label urged after deaths of some on Ritalin, other drugs

The Los Angeles Times is a Tribune Publishing newspaper.