

## New Antidepressant Suicide Warning FDA Expands Suicide Warning to Add Young Adults Taking Antidepressants

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May 2, 2007 -- Antidepressant labels should warn young adults aged 18 to 24 that the drugs may increase their risk of suicide, the FDA says.

The FDA in 2005 required antidepressants to carry a "black box" label warning that children and teens who use the drugs have an increased risk of "suicidality" -- suicidal thoughts and behavior.

It is not clear that antidepressants actually cause children or young adults to kill themselves. But evidence from clinical trials hints that kids who take the drugs have a slightly higher risk of suicidality than kids who received inactive placebo pills. None of the children or teens in antidepressant studies died of suicide.

The FDA now says the available evidence is strong enough to warn anyone under age 25 that any kind of antidepressant drug may increase suicide risk.

It's a "quite small" risk, says Thomas Laughren, MD, director of the FDA's Division of Psychiatry Products.

"If you look at 1,000 patients treated, for those under 18 we expect to see 14 cases with increased suicidal thinking and behavior linked to taking these drugs," Laughren said in a news conference. "In young adults aged 18 to 24, you'd see five additional cases of suicidality out of 1,000 people."

There is no evidence that the drugs raise suicide risk in people over age 25, the FDA says. Instead, Laughren says antidepressants appear to decrease suicidality in older adults.

"As you move into the 25 to 64 age group, antidepressants have essentially no effect on suicidality -- maybe one fewer case in 1,000 patients treated," he says. "And over age 65, you see a decrease: six fewer cases of increased suicidality per 1,000 patients."

In a divided vote, an FDA advisory panel in 2006 agreed that the black-box suicide warning was a good idea. But the panel was far more united in recommending that the labels state clearly that psychiatric disorders are the major cause of suicide and suicidality.

"The disorders treated with these drugs are themselves the most important cause of suicide," Laughren says. "These drugs do have value across the age spectrum, but their use requires certain precautions. Anyone taking these drugs should be monitored carefully."

Since the black-box warnings appeared on the labels, antidepressant use among children and teens plummeted. At the same time, the suicide rate among U.S. teens rose sharply -- bucking a decades-long trend.

"CDC data shows an 8% increase in suicides among children age 10-14 and a 12% increase in the 15-19 age group. This is coincident with the finding of a decrease in antidepressants in these age groups," Laughren says. "We and others are concerned about this. ... We don't know specifically whether or not the black box has been the cause of either decreased antidepressant prescribing or the increase in suicide."

Laughren says if new CDC data continue to show declining antidepressant use and increased suicide among children, the FDA will reconsider its recommendations.

"Labeling is dynamic, and we will continue to look at this issue over time," he says.

- Do [black box warnings](#) influence your decisions about prescribed drugs? Talk about it on WebMD's Depressed & Bipolar Kids message board.

SOURCES: News release, FDA. Bridge, J.A. *The Journal of the American Medical Association*, April 18, 2007; vol 297: pp 1683-1696. WebMD Medical News: "[Antidepressant/Child Suicide Risk Slim.](#)"