

## Teens and Antidepressants: Did Warnings Go Too Far?

Did an effort to reduce teen suicides backfire?

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July 16, 2007 issue - Seventeen-year-old Michael didn't want to end up crazed and suicidal like the Columbine killers. The Massachusetts teen had read that Eric Harris and Dylan Klebold were taking antidepressants when they rampaged murderously through their Colorado high school in 1999, and he didn't want to snap as they had. "He'd say it was like there was an evil guy on his left shoulder and a good guy on his right, but the evil guy just kept winning," Michael's mother, Lorraine, recalls. Despite his pain, Michael feared that antidepressants would "put him over the edge." Lorraine wasn't so sure. After consulting a specialist, she persuaded Michael in January to try Prozac, one of a family of drugs known as selective serotonin reuptake inhibitors, or SSRIs. By spring, the "good guy" was winning: Michael made the honor roll for the first time.

Lorraine can't know for certain whether Prozac saved Michael's life, although she's convinced it did. These days, however, fewer parents or doctors are following her lead. According to a new study in *The Journal of American Psychiatry*, the number of SSRI prescriptions for pediatric depression (ages 5 to 18) tumbled more than 50 percent between 2003 and 2005. In a troubling parallel development, the number of teen suicides jumped a record 18 percent between 2003 and 2004, the most recent year for which data exist.

Are the two trends connected? Many experts say yes. "All the data point in one direction: antidepressants save lives and untreated depression kills people," says Dr. Kelly Posner, a Columbia University child psychiatrist. She and others cite an unwitting instigator: the Food and Drug Administration—which may have scared parents and doctors away from SSRIs in 2003 when it issued a health-advisory warning of a potential link between the popular drugs and teen suicide. The agency, assisted at the time by Posner, followed up in 2004 with a "black box" warning of an "increased risk of suicidal thinking and behavior among children and adolescents." Now, amid fears that it's done more harm than good, there are calls for the FDA to modify and even repeal its black box. "I think the FDA has made a very serious mistake. It should lift its black-box warning because all it's doing is killing kids," says Dr. Robert Gibbons, of the University of Illinois's Center for Health Statistics. (Gibbons was a dissenting member of the FDA advisory committee that voted for the black box.) Others agree, including Dr. John Mann, a suicide expert at Columbia University, who fought the warning on the ground that it would have a chilling effect on treatment. "Short of rescinding, the FDA should shift its balance to reflect new wisdom about the beneficial effects of antidepressants," he says. Drugmakers continue to support the FDA but also suspect its actions have had a dangerous impact.

These new attacks are in contrast to the praise the FDA elicited with its move for more-stringent labeling, which followed searing public testimony from parents whose children killed themselves while taking SSRIs. The pendulum has since swung back. "If I had known how much the label would rattle parents, I wouldn't have voted for it," says Gail Griffith, who was the patient representative on the panel. Today, few doubt the FDA's good intentions, or its conclusion that teens taking the drugs should be closely monitored. Psychiatrists have long thought that treatment can put people at a temporary risk of suicide, but untreated depression is considered the far more lethal course. "You may induce two suicides by treatment, but by stopping treatment you're going to lose dozens to hundreds of kids. You're losing more than you're saving. That's the calculus," says Dr. Robert Valuck, of the University of Colorado Health Sciences Center, coauthor of the new paper. (The research, partly funded by Prozac maker Eli Lilly, passed a peer review for bias.)

The FDA has already taken steps to modify the box in reaction to reports that its message was being misunderstood. "Our goal was to inform people of a risk, not halt treatment," says Dr. Thomas Laughren, head of psychiatry products, the division responsible for the warning. "But it's still only one year of data," he cautions. In May, his office mandated revisions "to reflect the apparent beneficial effect of antidepressants" and remind people that mood disorders are "the most important cause" of suicide.

The next test for the FDA will come this December, when the CDC releases suicide figures for 2005. "If the rates are up again, it's likely we'll go back to the board of advisers," says Laughren. The agency has repealed only one black box in its history, on the acid-reflux medication Prilosec, pulled in 2003. "But I wouldn't rule it out," Laughren adds. "The evidence is very compelling."

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