

## As youth suicides increase, FDA's label rule criticized

### Experts suggest link between warnings, startling new trend

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Suicide rates for preteens and teenagers increased sharply when the Food and Drug Administration slapped a "black box" warning on anti-depressants and doctors started writing fewer prescriptions for young people, according to federal data released Thursday.

The FDA's warning, publicly debated in 2003 and enacted in 2004, highlighted a link between anti-depressant use by young people and suicidal thoughts and behavior. But now some experts are asking whether the message backfired.

In 2004, the number of 10- to 24-year-olds taking their own lives rose by 8 percent, the Centers for Disease Control and Prevention reported. Over the previous 14 years, suicide rates had fallen 28.5 percent in that age group.

Although the numbers do not prove a connection between suicide and the drop in anti-depressant use, several experts suggested Thursday that the FDA re-evaluate its warnings on the medications in light of the new CDC report.

"It's time for the agency's warnings to be modified," said Dr. David Schaffer, a leading expert on teen suicide and chief of child and adolescent psychiatry at Columbia University Medical Center in New York City.

Thomas Laughren, director of the FDA's division of psychiatry products, acknowledged the suicide numbers are "clearly a dilemma for us" and "not what you would want to see," but cautioned that firm conclusions should not be drawn from a one-year increase.

#### Girls show sharpest increase

The new numbers documented a particularly startling rise in the rate for girls, with suicides rising 41 percent among 10- to 19-year-olds. Suicides for boys in the age group climbed 8.5 percent.

Ileana Arias, director of the CDC's Center for Injury Prevention and Control, called the report's findings "sobering" and said she was troubled that the increase was concentrated almost entirely in preteens and teenagers. Rates were relatively flat for adults 20 to 24 years old.

In all, the agency's numbers show that 4,599 people ages 10 to 24 committed suicide in 2004, 367 more deaths than the previous year.

The FDA was prompted to issue warnings about anti-depressants by two dozen studies showing that young people were twice as likely to consider killing themselves or start taking steps to do so after taking the drugs. None of the subjects in the studies committed suicide, and the risks were relatively small (4 percent versus 2 percent), but the agency decided it had to act.

In 2003 and 2004, the FDA issued public health advisories warning that anti-depressants appeared to increase suicidal thoughts and behavior among teens. Late in 2004, it ordered drugmakers to place a black box warning - the agency's strongest signal of serious risk -- on the medications' labels.

The move contributed to a steep decline in anti-depressant prescriptions for teens, as pediatricians and family doctors re-evaluated their risks and benefits. Firms tracking drug use report declines of 25 percent or more since 2003.

On Wednesday, University of Illinois at Chicago psychiatry professor Robert Gibbons published a paper in the American Journal of Psychiatry that documented a close correlation between declining use of the anti-depressants known as SSRIs and rising suicide rates among young people up to age 19.

It concludes that if the FDA's warnings had been correct, "we would have expected to see decreases in the suicide rate during the period of declining SSRI prescription rates." Instead, "we saw an increase."

The FDA's black box warning has had a "horrible and unintended effect" and should be withdrawn, Gibbons said Thursday. The benefits of anti-depressants far exceed the risks, he said.

Hard questions raised

Many of the suicide numbers issued Thursday raised more questions than could be readily answered.

The CDC data show that 453 girls ages 10 to 19 killed themselves in 2004, up from 321 deaths the year before. The numbers for boys committing suicide were much larger, but the percentage increase was smaller: 1,530 suicides in 2004, compared with 1,410 with 2003.

Why did suicide rates rise so steeply among young girls? "Unfortunately, we don't know that," said Arias of the CDC. It could be a statistical fluke, because the actual numbers are relatively small. Or it could be that there are troubling changes in girls' stress levels or ability to cope, she said.

The numbers also show that more young people are ending their lives by hanging or suffocating themselves, especially girls. CDC officials noted that the means to commit suicide this way tend to be readily available and that more adolescents are playing a dangerous "choking game," a way of getting high by temporarily restricting oxygen flow.

But the game is more common among boys, making the significant rise in hangings and suffocations among girls harder to explain, officials suggested.

It's also unclear whether the increase in teen suicides truly represents an emerging trend. "Until the CDC publishes data for 2005 we won't really know," Schaffer said.

He suggested more research is needed to understand the connection between teens' growing misuse of prescription drugs and suicide. Changing patterns of alcohol use by teens also are important, insofar as two-thirds of suicides by older teens are linked to alcohol abuse.

Dr. Louis Kraus, chief of child and adolescent psychiatry at Rush University Medical Center, said the key point for anxious parents is this: "If your kid is troubled, get him to a child mental-health expert to be assessed, and make sure there's good follow-up" if medication is prescribed.

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