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FDA opts for stronger anti-depressant warnings

Labels will cite the drugs' risk to people 18 to 24 years old

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Los Angeles Times

## AT A GLANCE

- **How many** : About 19 million people in the U.S. have depression and 16 million are treated with anti-depressants.
- **Those affected** : People younger than 25 account for about 8 percent of prescriptions.

The Food and Drug Administration on Wednesday approved the strongest possible warning for anti-depressants to alert doctors and patients that the drugs could increase the risk of suicidal thinking and behavior in adults 18 to 24.

The so-called black box warning extends a similar labeling change approved in 2004 for children and adolescents.

The action comes nearly five months after an FDA advisory committee recommended the warnings after finding a small increase in suicidal thoughts and behavior among young adults taking 11 commonly used anti-depressants. The agency said five of every 1,000 patients age 18 to 24 were at increased risk.

"The risk is small but the risk is real, and it is something that needs to be paid attention to," Dr. Thomas Laughren, director of the FDA's division of psychiatry products, said during a news conference.

The FDA's action requires drug companies to submit proposed labeling and updated medication guides within 30 days. A total of 36 drugs would display the new warning.

## Weighing the risks

In an unusual move, Laughren said the new labels would carry both a warning and positive information on the benefits of anti-depressants. The labels would emphasize weighing the risks associated with the drugs against the danger of failing to treat depression and other psychiatric disorders that contribute to suicide.

Some psychiatrists and advocacy groups had been concerned that a black box might discourage young adults who need help from taking the drugs, which many consider among the most effective treatments for depression. In 2004, when the agency began publicly debating suicide risks for minors taking anti-depressants, children's prescriptions rates tapered off. In that year, the suicide rate among adolescents rose significantly for the first time in more than a 10 years, and some experts say the trends are linked.

Dr. Carolyn Robinowitz, president-elect of the American Psychiatric Association, said it was unprecedented for the FDA to include positive information in its black box warning and said the new labeling would provide a more balanced message.

## Effect on older adults

"We continue to be concerned about 'black box panic' on the part of the public," she said. "But we are very relieved and happy that the labeling made the point about the need for treatment."

The new labels would also state that anti-depressants reduced the risk of suicidal thoughts and behaviors in adults 65 and older, the opposite of what was seen in young adults, the FDA said.

The drug agency reached its conclusions after analyzing 295 anti-depressant studies, including 77,000 adults from college students to retirees. The analysis found no increased risk of completed suicides in patients taking the medications.

But 21 suicide attempts were reported among the 3,810 19- to 24-year-olds taking the drugs, working out to a 0.55 percent risk, twice the risk in adults of the same age who took placebo pills, the analysis found.

By age 25, the risk was not significantly different, the agency said. The agency said it did not know why the risk would drop suddenly after 25.

The New York Times contributed to this report.