Antidepressants' benefits exceed risks-US study

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Chicago (Reuters) - The benefits of drugs that treat depression in children and teens far outweigh the risk of suicide, and U.S. regulators should revise strict warnings that may have scared off some doctors and patients, researchers said on Tuesday.

A wide-reaching review of studies on antidepressants in young patients showed the risk of suicidal behavior is smaller than previously thought and should be viewed in light of the relief these drugs can offer, the researchers said.

"The benefits seem to be much stronger than the risks," said Dr. David Brent, a researcher at the University of Pittsburgh School of Medicine, whose study appeared in the Journal of the American Medical Association.

The research calls into question strict "black box" warnings on the labels of antidepressants called selective serotonin reuptake inhibitors (SSRIs) that warn of a higher risk of suicidal behavior among children and teenagers.

The U.S. Food and Drug Administration introduced those warnings on the most popular antidepressants in October 2004 after studies in the United States and Britain suggested the drugs may raise the risk of suicide in children and adults.

Millions of Americans use antidepressants, which include Wyeth's Effexor, Pfizer Inc.'s Zoloft, GlaxoSmithKline Plc's Paxil, Eli Lilly and Co's Prozac and Forest Laboratories Lexapro.

MORE HARM THAN GOOD?

Brent said it's now time for the FDA to revisit its policy.

"Clearly, their intent was to protect people, but you have to then reevaluate whether your warning may be doing more harm than good," Brent said in a telephone interview.

Brent noted that the number of antidepressant prescriptions written for adolescents has fallen, while suicide rates in adolescents recently have begun to rise. "That is after 10 consecutive years of a decline in the rate," he said.

He pointed to a February study in the journal Pediatrics that found deaths from suicide in 10 to 19-year-olds rose 18.2 percent in 2004 from 2003. No other causes of child death increased during that period.

"It is possible that people who would benefit from this medication are being frightened away," he said.

Physician groups, including the American Medical Association and the American Psychiatric Association, have voiced concern that the FDA's warnings may limit access to the drugs.

For the study, Brent and colleagues reviewed data from 27 major clinical trials assessing antidepressant use in 4,400 children and adolescents with major depressive disorder, obsessive-compulsive disorder and anxiety disorders.

The analysis, funded by the National Institute of Mental Health, included data from an additional 700 patients not available when the FDA issued its warning.

The study showed an increased risk for suicidal thoughts and attempts, but the size of the effect was smaller than in the FDA report. There were no completed suicides.

Brent said young people on the drugs should be monitored closely and taken off them if they derive no benefit.

He stressed that untreated depression is not without risk, adding, "The risk of no treatment can be deadly."

"The reported findings in JAMA are very consistent with FDA's analysis on these products and our recommendations/warnings to consumers who use these drugs," an FDA spokeswoman said.❑

Source: Reuters Health