



U.S. REQUIRES NEW WARNING ON ANTIDEPRESSANTS FOR CHILDREN

October 18, 2004

Antidepressant drugs can cause increased suicidal thoughts and behaviors in children and adolescents, according to the Food and Drug Administration (FDA), and must now contain a special warning.

The FDA, which watches over the safety of food and medicine, ruled that within the next few months, antidepressant packages must have a "black box" warning -- the strongest government alert.

The decision comes after years of research and after the government in Great Britain warned doctors not to prescribe antidepressants for teenagers.

The FDA's Plan

According to FDA analysis, two or three of every 100 young people who are treated with antidepressants may face elevated risk of suicidal thoughts. No child or teen actually committed suicide in the nine trials of antidepressants.

The FDA says the black box is only a warning for the potential risk.

"The new warning language does not prohibit the use of antidepressants in children and adolescents. Rather it warns of the risk of suicidal (behavior) and encourages prescribers to balance this risk with clinical need," the FDA said.

The medication packaging will also contain an information guide advising parents to look for warning signs in their children.

Understanding Depression

It is estimated that between 2 percent and 6 percent of all children and adolescents suffer from depression -- a mood disorder in which sad, lonely, irritable or weary feelings don't go away and prevent a person from living a productive life.

"All I can see at that moment when I'm feeling depressed is the problems and how I'm unhappy right now, and it seems like it's not worth it. So it makes sense at that time, when I'm in that mind state, to just end life as soon as possible," Chris Drell, a 24-year old who was first diagnosed with bipolar disorder when he was 11 years old, told the NewsHour.

There isn't a medical test for depression but researchers have linked it to an imbalance of neurotransmitters -- the chemical messengers that allow brain cells to communicate with each other.

One class of antidepressant drugs known as selective serotonin reuptake inhibitors (SSRIs) work by increasing the levels of serotonin, a neurotransmitter, in the brain. The drugs that were linked to an increase in suicidal thoughts were all SSRIs.

In 2002 U.S. psychiatrists, as well as pediatricians and family practitioners, wrote almost 11 million SSRIs and other antidepressant prescriptions for children ages 1 to 17.

'Off-label' Medications

Much of the controversy stems from the fact that few antidepressants were created for children. Instead, physicians prescribe them for "off-label" use, meaning that although the drugs have not been systematically studied for safety and effectiveness in treating depression in children or adolescents, doctors still give them to patients based on experience and medication knowledge.

Only Prozac is approved to treat some forms of depression in children.

Zoloft is approved for the treatment of another mental health problem in children -- obsessive compulsive disorder. The drugs might be safe and effective in treating children who suffer from obsessive compulsive disorder, anxiety or other problems, according to a study published in April by the British medical journal Lancet.

Concerns About New Warning

Following the FDA announcement, the American Psychiatric Association raised concerns over the new requirement, stating that the warning may deter patients from using antidepressants.

"We restate our continued deep concern that a 'black box' warning on antidepressants may have a chilling effect on appropriate prescribing for patients. This would put seriously ill patients at grave risk," the statement said.

They added that the number of people taking antidepressants has decreased due to the recent controversy.

--Compiled by Sheryl Silverman for NewsHour Extra

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