



MOST ANTIDEPRESSANTS DEEMED UNSAFE IN CHILDREN

Most antidepressants are ineffective and may actually be unsafe for children and adolescents, according to a study published in the April 24 edition of the British medical journal Lancet.

With the widespread use of drugs like Prozac and Paxil to treat depression, government agencies and scientists have been studying whether children and adolescents who use certain antidepressants are more likely to have suicidal thoughts or behaviors. In the United States, the Food and Drug Administration is reviewing the issue but has yet to reach any conclusions.

The Lancet study

The British study is a "meta-analysis" -- the first comprehensive scientific review of both published studies and unpublished data that pharmaceutical companies have said they own and have the right to withhold. The British government allowed the scientists access to the unpublished, largely negative, data.

The report concluded that young patients, aged 5-18, should not take four popular antidepressants -- Paxil, Zoloft, Effexor and Celexa -- because there was a clear risk of suicidal behavior among those taking the drugs and no benefit. The fifth drug studied -- Prozac -- was found to be effective for depressed children and did not have an elevated risk of suicide.

The authors of the study said the unpublished research had a major impact on the report's findings.

"In each of the published articles, the authors concluded the drug was either effective, safe or both," said Tim Kendall, one of the authors of the study. "When you look at the combined evidence, it is ineffective, unsafe or both."

The drug companies contend that their products are safe and deny they are risking the lives of younger patients in order to sell more prescriptions.

"The use in children of our drug in particular, is a very, very, very small percentage of the overall total prescriptions of this product," Mariann Caprino, spokeswoman for Pfizer Inc., which makes Zoloft, told The Washington Post. "To suggest that we are motivated by profiting off of children is ludicrous."

What is depression?

It is estimated that between 2 percent and 6 percent of all children and adolescents suffer from depression. Depression is 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 in an upcoming report.

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

One class of antidepressant drugs are known as selective serotonin reuptake inhibitors (SSRIs). They work by increasing the levels of serotonin, a neurotransmitter, in the brain. These increases can change a person's mood. All five antidepressants in the Lancet study are 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 surrounding antidepressants and children is that few of the drugs are specifically created for them. Instead, physicians prescribe them for "off-label" use. Off-label means the drugs have not been systematically studied for safety and effectiveness for the purpose the doctors prescribe them -- for example, to treat depression in children or adolescents -- but can be given to patients based on clinical experience and medication knowledge.

Only Prozac is approved for use in children to treat some forms of depression, which was the only issue the researchers examined in the Lancet study.

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, the Lancet researchers said.

Governments respond

In England studies like the one in Lancet and the growing concern of a link between the antidepressants and suicide caused the British government to recommend against most antidepressants, except Prozac, for children.

On Thursday European Union regulators recommended that Paxil not be given to children and adolescents.

In the United States, the FDA has been more cautious. In March the agency requested that drug manufacturers strengthen their warnings about the possible links between the drug use by adolescents and suicidal thoughts and behaviors.

The agency also asked an expert committee at Columbia University to review drug-company data and to create a definition of what is suicidal thinking and suicidal behavior. The report, due this summer, could influence any final FDA decision.

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