

FDA Cautions on Antidepressants and Youth

by Marc Kaufman
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The Washington Post correctly reports: "The association between antidepressants, particularly the selective serotonin reuptake inhibitors (SSRIs), and suicide has been controversial since the first SSRI, Prozac, came on the market in the late 1980s." But stakeholders in this profitable enterprise have until recently succeeded in concealing the documented evidence.

Given that two to three times as many children taking SSRIs in controlled clinical trials conducted by these drugs' manufacturers exhibited suicidal behavior compared to those taking sugar pills, and given FDA's acknowledgment that antidepressants have no demonstrable benefit above placebo for children, it is difficult to fathom FDA's timid inaction and failure to protect children from harm.

The FDA's failure to issue any meaningful restrictions to guide physicians and the public contrasts sharply with the responsible precautionary action taken by the British Medicines Healthcare Products Regulatory Agency (MHRA, the equivalent to the U.S. FDA). Whereas the MHRA acted to protect children by restricting the use of SSRIs in children, the FDA failed to use its authority to protect children. FDA is postponing any action that would curtail drug industry profits—even as such inaction may result in additional preventable suicides.

It is hard to argue with Lisa Van Syckel who says her daughter became suicidal on Paxil: "parents can't rely on the government or anyone else to monitor children who are prescribed antidepressants."

For links to documents about this controversy see: www.ahrp.org

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Concerned about studies that showed antidepressants may be leading some adolescents and children to suicidal activity, the Food and Drug Administration issued a public health advisory yesterday telling doctors to be especially careful in prescribing the drugs.

The agency, which has been overseeing studies into the effects of eight popular antidepressants on patients under 18, said the data does not clearly establish an association between the drugs and suicide. But it also said that a increase in suicidal behavior in young people taking the drugs cannot be ruled out.

Thomas Laughren, the FDA's team leader for psychiatric drug products, said the agency has found enough reason for concern to request additional information from the drug companies that make antidepressants, and to schedule an expert advisory committee hearing on the subject for February.

"We're not saying these drugs can't be used" with children and adolescents, Laughren said. "We're saying one should proceed with caution. . . . Once we analyze the data more fully, we'll be in a better position to make a more formal recommendation."

Only Prozac has been approved by the FDA for use in adolescents and children — having shown an effectiveness that others have yet to show — but doctors often prescribe other antidepressants for youngsters.

The concern over antidepressants and adolescent suicidal behavior was sparked this summer in Britain, when health regulators warned doctors not to prescribe the antidepressant Paxil for people under 18 years old because

data showed a heightened suicide risk. Those patients were diagnosed with major depression.

The FDA issued its own warning for Paxil soon after and then asked the makers of eight antidepressants to give them more information about suicidal behavior by teens using their drugs. Last month, Wyeth Pharmaceuticals sent out letters to doctors saying that clinical studies on its antidepressant, Effexor XR, had found an increased incidence of "hostility and suicide-related adverse events, such as suicidal ideation and self-harm."

Laughren said that some of the data "signaled" a possible association between antidepressants and increased suicidal behavior, but that it wasn't specific enough to come to any firm conclusions. The agency has now asked the companies for specific information on the 4,100 patients who participated in 20 clinical studies of young people taking antidepressants.

Detailed information on how many young people are taking antidepressants is unavailable, but experts agree that the practice is on the rise. Mark Olfson, an associate professor at Columbia University's College of Physicians and Surgeons, published a study last year that estimated that in 1996, 1 percent of children under 18 were using an antidepressant.

At the same time that the FDA and others are voicing increased concern about the effects of antidepressants on adolescents, Laughren, Olfson and others also note statistics showing that the overall rate of teen suicide has declined over the past 15 years. Studies have not been done to test whether antidepressant use is contributing directly to the decline in teen suicides, but the researchers say a correlation is possible.

"I think the FDA needs to be cautious about attributing particular adverse effects to a potentially helpful medication for the general public," said David Shaffer, chief of child and adolescent psychiatry at Columbia University. "Adolescents are a population where suicidal [thinking] is quite common, and we have to be sure that the data isn't just picking up that reality."

Shaffer said that the federal studies have typically shown that around 20 percent of American teens think about suicide, or act out such thoughts, some time during a year.

The association between antidepressants, particularly the selective serotonin reuptake inhibitors (SSRIs), and suicide has been controversial since the first SSRI, Prozac, came on the market in the late 1980s. An FDA expert advisory panel studied the issue of antidepressants and suicide in adults in 1991 and concluded that there was no association, although some lawsuits continue to allege a connection. Researchers such as Shaffer say they see no reason SSRIs should have significantly different effects on young people than on adults.

Doctors continue to increase the number of antidepressant prescriptions they write each year. According to IMS Health, which collects information on drug prescribing patterns, antidepressants make up the second-largest class of drugs prescribed in the United States. They report that more than 136 million prescriptions for antidepressants were filled between mid-2002 and mid-2003, an increase of 13 percent over the previous year.

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