

# **Anti-Depressant Use In Children & Adolescents**

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Parents of children and adolescents who suffer from major depression or severe anxiety, or who have attempted suicide or voiced intentions of self-harm, are understandably concerned about FDA's "Black-Box Warning" regarding the use of anti-depressants in children under age 18 years. This handout attempts to address these concerns, and explain a little more about the warning.

## **The Back Story**

In October of 2004, the FDA ordered pharmaceutical companies to add to anti-depressant advertisements, package inserts, and information sheets developed for patients and doctors a "black-box" warning (a statement in prominent, bold-faced type and framed by a black border) regarding pediatric use. Two committees charged with examining the occurrence of suicidality (suicidal thinking, behavior, or attempts) in teens with major depressive disorder (MDD) had recently concluded that there was a causal link between the newer antidepressants and pediatric suicidality.

An intense controversy and debate quickly followed within the medical profession, and within the greater society. Pediatric associations in a wide number of other countries voiced their disagreement with the FDA's recommendations, as did the American Association of Child Psychiatry. Many experts outside the FDA have questioned the data used by the FDA to make its decision. As we'll discuss further on, there's more here than meets

## **Suicide & Depression in Older Children and Teens**

Suicide is the third leading cause of death among young people aged 10 to 24 years, accounting for 7 percent of total deaths in youths aged 10 to 14 years and 12 percent of youths aged 15 to 24. Research has consistently found that between 15 and 20 percent of high-school students at some point have considered suicide, and that 3 percent had made an injurious suicide attempt. One in five adolescents will suffer a major depressive disorder at some time before graduation.

## **What Are the "Newer" Anti-Depressants?**

The "newer" antidepressants targeted by the FDA are in the category of selective serotonin reuptake inhibitors (SSRIs), which include Prozac, Paxil, Zoloft, Celexa and others. These antidepressants have far fewer side effects than earlier generations of anti-depressants, and to date approximately 1 in 100 pre-teens or teens have been prescribed an SSRI at some time and for some period. SSRIs are generally used to treat – in conjunction with cognitive-behavioral therapy – major depression or severe anxiety. About 60 percent of prescriptions are written by psychiatrists, 20 percent by pediatricians, and 20 percent by family physicians.

## **The Warning**

The "black-box" warning does not prohibit the use of SSRIs in pediatric patients, but warns of a potential increased risk of suicidality in the first 4-8 weeks of taking medication. Physicians and parents are warned to more closely monitor the child or teen during this period of high-risk, including scheduling weekly visits, and never permitting the child or teen to be alone for extended periods.

But is it the medication that is increasing suicidality? Or is there another phenomenon ongoing? One study found that upon autopsy of several dozen teens who successfully committed suicide within 4-6 weeks of starting an SSRI,

not one had detectable levels of the antidepressant in the bloodstream. Are perhaps adolescents, impulsive and impatient, more likely to consider or attempt suicide in the first few weeks after starting medication, simply because although medication takes 4-6 weeks to work, when it doesn't immediately make them feel better some become fatally despondent?

It is important to note that follow-up studies of thousands of adolescents who recently started an SSRI, the average risk of developing suicidal ideation (thoughts of suicide) while confirmed as taking the medication was 4 percent, as compared to a 2 percent risk while taking placebo. One in 50 children, therefore, developed suicidal ideation that might be attributed to the medication, although there were no completed suicides among the 4400 patients studied.

### **The Bottom Line**

While the "black-box" warning is the strongest caution from the FDA to prescribers and patients regarding possible effects, but it does *not* prohibit using SSRIs in children. Antidepressant medication is an important treatment for the appropriate pediatric patient, though its use should not be taken lightly, nor should it ever substitute for cognitive-behavioral therapy. The two should always go hand-in-hand.

Large legitimate studies have repeatedly demonstrated that for every three adolescent patients treated with an SSRI for major depression, one will improve from the medication, one will improve because of the placebo effect, and one will not improve. Stated differently, there is a significant subset of adolescents for whom medication is very helpful, and an equally significant subset for whom the placebo effect is strong and equally beneficial.

If your child or teen suffers from major depression, or from severe anxiety, and despite counseling is not showing significant improvement, the prescribing of an SSRI should be considered. Taking the FDA's concerns seriously, we will partner with you in monitoring your child closely for the first 4-8 weeks on medication. We have specially designed chart forms to aid in this monitoring process, and we will want to see your child at least once in the first four weeks of therapy.

But we urge parents to understand that a child, especially a teenager, suffering from major depression that is not improving despite counseling is *already* at high risk for suicidal thoughts or attempts. Choosing *not* to employ an SSRI, out of fear of the FDA's "black-box" warning, quite likely places your child at *higher* risk of suicidality than the known small increased risk of suicidal thoughts caused by the medication.