

Antidepressants and Suicide Fact Sheet

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The FDA has taken action regarding antidepressant use in pediatric populations.

On October, 15, 2004 the FDA announced that it was implementing new regulations regarding the use of antidepressant medication, based on the recommendations of an advisory panel which held hearings on September 13 and 14, 2004. The hearings were held in response to a number of reports suggesting that there was an increased rate of suicidality (thoughts or acts of self harm) associated with the use of antidepressants in children and adolescents. It is important to note that there were **no deaths** in any of the 24 trials that were reviewed, which involved 4,555 adolescents. Of this total, 33 or 0.72 percent of the subjects engaged in suicidal behavior and 45 additional subjects experienced suicidal ideation, bringing the total affected to 1.7 percent. However, the subjects who did experience suicidality were about twice as likely to be taking an antidepressant as a placebo. Based on these data, and the recommendations of the advisory panel, the FDA will require the following:

- A “black-box” warning related to an increased risk for suicidality in pediatric patients for all antidepressant drugs (advisory committee recommended this action by a split decision; 15-yes, 8-no).
- A patient information sheet for this class of drugs to be provided to the patient or their caregiver with every prescription.
- Antidepressants should not be contraindicated (banned) because access is important for those who can benefit from their use.
- Results of controlled pediatric trials of depression should be included in the labeling for antidepressant drugs.

Depression is a very serious and inherently dangerous illness that affects adolescents as well as adults. Recent studies show an incidence rate of clinical depression in adolescents ranging from 5% (1) to over 8% (2). Suicide is the third leading cause of death among 10 to 24 year olds (3).

Treatment of depression in adolescence can be effective and life-saving. In August of this year, the National Institute of Mental Health reported findings from the first stage of the largest community effectiveness trial ever conducted in this country (4). The Treatment of Adolescent Depression (TADS) examined 439 youth ages 12 to 17 with moderate to severe major depressive disorder. A positive response to the combination of fluoxetine and Cognitive Behavioral Therapy (CBT) was found in 71% of patients- a rate double the 35% response rate for patients on placebo. The response rate on fluoxetine alone was 61% and CBT alone was 43%. There is **no evidence** that use of antidepressants is causing an increase in suicide among adolescents. In fact, the Centers for Disease Control report a 25% decline in completed suicide rates among 10 to 19 year olds since 1992(5). Fluoxetine, the oldest of the SSRI antidepressants, was released in the mid-1980s.

The action by the FDA could lead to both positive and negative outcomes. The initial days of treatment have long been recognized as a period of increased risk for suicide attempts because physiological response (increased energy) precedes psychological response (improvement of mood) in the recovery process. Therefore, close monitoring during this time of vulnerability is crucial. The patient’s physician and family should be engaged in this process. The new warnings may help to promote an increased awareness in everyone involved in a patient’s recovery. However, the American Psychiatric Association has expressed concern that the new warnings could also have a “chilling” effect on appropriate prescribing for patients, putting seriously ill patients at grave risk (6). Some successfully treated patients could stop taking antidepressants and relapse. The biggest threat to a depressed child’s well-being is to receive no care at all. Russel Katz, MD; Director of FDA’s Division of Neuropharmacological Drug Products stated “It is absolutely critical that we get this right. The wrong answer, in either direction, could have profound consequences for public health.”

Conclusion

Depression is a very serious and inherently dangerous illness. It is crucial for persons with the illness and their family, friends, coworkers and physicians to recognize the signs and symptoms of the illness so that they can receive effective, potentially life-saving treatment. Counseling, close monitoring and social support are important elements of this treatment, along with antidepressant medication.

Questions and Answers

**** If placebo pills have a positive impact on depression, why don't we just use placebos?***

The problem with placebos is when there is deception is involved. I would think it would be acceptable to use a placebo as long as you obtained informed consent first i.e. the patient understood and agreed that they might receive a placebo.

**** Why was only Prozac used in the TADS study?***

I cannot speak for the research team but here are some possibilities. Perhaps they did not want too many variables because they were comparing no treatment to psychotherapy alone, drug alone and psychotherapy to drug. That is already a lot of variables. Prozac is the oldest of the new generation antidepressants, so old that it is now generic, and thus, very inexpensive.

**** What is the difference in time between the improvement of energy and improvement of mood?***

Patients can experience a sense of activation due to increased energy and better sleep in a matter of days after starting the drug, whereas the improvement in mood (and diminished hopelessness and helplessness) may take several weeks or longer to be felt. This is why the early days of antidepressant treatment require such close monitoring and professional follow up.

**** Adolescent brains and adult brains are different. Do antidepressant medications work in the same ways for both?***

I am not aware of evidence of significant differences in how antidepressants work in adolescent versus adult brains.

**** Is it as true for adults as adolescents that a combination of drug therapy and talk therapy is more effective than either alone?***

Yes. Studies going back 30 years have repeatedly shown the combination of medication and psychotherapy in adults to be superior to either modality alone.

**** Is a person's reaction to antidepressants likely to change over time?***

No. Antidepressants do not induce tolerance or dependence. An effective dose for a particular patient today should be an effective dose next week, next month or next year. A typical episode of clinical depression lasts about two years, so the length of treatment should be for at least one or two years.

References

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6. American Psychiatric Association News Release; October 15, 2004; www.psych.org.

