

December, 2004

## **FDA Warning About Using Antidepressants in Children and Adolescents**

Dear Parent/Guardian,

You may have heard or read news reports on prescribing antidepressant medications for children and adolescents. The news reports were about the recent meetings and decision by the Food and Drug Administration (FDA). The FDA reviewed all the studies that used newer antidepressant medications to treat depression and anxiety disorders in children and adolescents. The FDA carefully examined the effectiveness of antidepressant medications, as well as concerns about increased risk of suicidal behavior (such as a suicide attempt or suicidal thoughts) in children and adolescents who were taking these medications.

This letter should explain some of the FDA information and answer some of the questions that you may have about antidepressant medications in children and adolescents.

### **What did the Food and Drug Administration (FDA) Find and Decide?**

After two days of hearings and reviewing all the studies, the FDA concluded that there is some increased risk of suicidal behavior (such as a suicide attempt or suicidal thoughts) for some children or adolescents taking antidepressants. The studies showed that 3-4 out of 100 children or adolescents with depression who took an antidepressant medication had some type of suicidal behavior and that 1-2 out of 100 children and adolescents taking a placebo (inactive pill) had some type of suicidal behavior. Therefore, there was almost a 2-fold increase in suicidal behavior in youth taking an antidepressant medication to treat their depression. There were NO deaths from suicide in any of these studies, which included over 4,000 children and adolescents. For children and adolescents with an anxiety disorder, there was no difference in risk of suicidal behavior between those being treated for their anxiety disorder with an antidepressant compared to those taking a placebo (inactive pill).

As a result of the hearings and their review, the FDA now requires the strictest warning label be placed on all antidepressants regarding their use with children and adolescents. This type of warning label is called a "black box". Whenever a physician prescribes any one of the antidepressant medications, he/she now has to clearly warn patients and their families about the increased risk of suicidal thoughts and behaviors in youth taking these medications.

## How does the FDA decision and warning affect your child?

Suicidal thoughts are often a symptom of depression. From the recent review of the research, it is difficult to say precisely whether suicidal thoughts and behaviors in depressed individuals are due to the illness itself or the antidepressant medication. It can be either or both of these factors. As the FDA's warning states, in some children and adolescents, antidepressant medications may increase these types of thoughts.

If your child is already being treated with one of the antidepressant medications and is doing well, then your child should continue with that treatment. If you have questions, doubts or concerns, you should talk with your child's physician.

If your child has recently started one of these medications or is about to start, then you and your child's physician will need to closely monitor him/her for any changes in behavior. In most cases, the increased risk of suicidal behavior occurs during the first 4-6 weeks of treatment.

If you are considering starting your child on one of the antidepressant medications, then you should have a full discussion with your child's physician of the possible benefits as well as the possible risks (including increased suicidal behavior).

## What should you do as a parent?

- ◆ Be clear and honest when talking with your child about the possible risks and benefits of taking an antidepressant medication.
- ◆ Talk to your child or adolescent about whether they are having any suicidal thoughts, and let them know they should come to you immediately if they start having suicidal thoughts or any other troubling symptoms while they are taking antidepressant medication.
- ◆ Working with your child and your child's physician, you should develop a "safety/crisis plan" for your child. This can include identifying an adult your child can call if he/she is thinking about suicide.
- ◆ You and your child's physician should closely monitor your child - especially during the first months of treatment. Any child or adolescent starting an antidepressant medication should be followed weekly (in person or by telephone) for the first month, every other week (preferably in person) for the second month, and at least once a month (in person) thereafter by the treating physician to check for the severity of depressive symptoms, suicidal behavior and any other problems.
- ◆ It is important that you do not suddenly stop or change the dose of your child's antidepressant medication without first talking to your child's physician.

## What should you look for when monitoring your child on an antidepressant medication?

- ◆ Watch for any behaviors or symptoms/complaints that appear in your child for the first time, seem worse, or worry you or your child.
- ◆ Watch for any suicidal symptoms in your child - such as ideas of hurting oneself, thoughts or threats of committing suicide or any self-harming behaviors or suicide attempts.
- ◆ Watch for signs of new or increased depressed mood or anxiety (including nervousness, panic attacks) in your child.
- ◆ Also watch for any of the following symptoms that may appear in your child: insomnia, irritability, hostility, aggressiveness, and impulsivity.
- ◆ If any of these behaviors or symptoms appear, you should immediately contact your child's physician for guidance.

REMEMBER: Only you, your child and your physician can look at all the specific information and make an informed and appropriate decision about using an antidepressant medication.

If you have any questions about the information in this letter, we recommend you speak with your child's physician. We hope that this information has been helpful.

Sincerely,



James MacIntyre, M.D.  
Interim Chief Medical Officer



David J. Woodlock  
Deputy Commissioner and Director,  
Division of Children and Family Services

Cc: Sharon E. Carpinello, R.N., Ph.D., Commissioner  
Barbara L. Cohn, Executive Deputy Commissioner