FDA Public Health Advisory

Suicidality in Children and Adolescents Being Treated With Antidepressant Medications

October 15, 2004

This information is out-of-date. For current information on antidepraessant drugs, please see http://www.fda.gov/cder/drug/antidepressants/default.htm

Today the Food and Drug Administration (FDA) directed manufacturers of all antidepressant drugs to revise the labeling for their products to include a boxed warning and expanded warning statements that alert health care providers to an increased risk of suicidality (suicidal thinking and behavior) in children and adolescents being treated with these agents, and to include additional information about the results of pediatric studies. FDA also informed these manufacturers that it has determined that a Patient Medication Guide (MedGuide), which will be given to patients receiving the drugs to advise them of the risk and precautions that can be taken, is appropriate for these drug products. These labeling changes are consistent with the recommendations made to the Agency at a joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Drugs Advisory Committee on September 13-14, 2004.

The drugs that are the focus of this new labeling language are all drugs included in the general class of antidepressants; they are listed at the end of this Advisory.

The risk of suicidality for these drugs was identified in a combined analysis of short-term (up to 4 months) placebo-controlled trials of nine antidepressant drugs, including the selective serotonin reuptake inhibitors (SSRIs) and others, in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders. A total of 24 trials involving over 4400 patients were included. The analysis showed a greater risk of suicidality during the first few months of treatment in those receiving antidepressants. The average risk of such events on drug was 4%, twice the placebo risk of 2%. No suicides occurred in these trials. Based on these data, FDA has determined that the following points are appropriate for inclusion in the boxed warning:

- Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with MDD and other psychiatric disorders.

- Anyone considering the use of an antidepressant in a child or adolescent for any clinical use must balance the risk of increased suicidality with the clinical need.
- Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.
- Families and caregivers should be advised to closely observe the patient and to communicate with the prescriber.
- A statement regarding whether the particular drug is approved for any pediatric indication(s) and, if so, which one(s).

Among the antidepressants, only Prozac is approved for use in treating MDD in pediatric patients. Prozac, Zoloft, Luvox, and Anafranil are approved for OCD in pediatric patients. None of the drugs is approved for other psychiatric indications in children.

Pediatric patients being treated with antidepressants for any indication should be closely observed for clinical worsening, as well as agitation, irritability, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. This monitoring should include daily observation by families and caregivers and frequent contact with the physician. It is also recommended that prescriptions for antidepressants be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

In addition to the boxed warning and other information in professional labeling on antidepressants, MedGuides are being prepared for all of the antidepressants to provide information about the risk of suicidality in children and adolescents directly to patients and their families and caregivers. MedGuides are intended to be distributed by the pharmacist with each prescription or refill of a medication.

FDA plans to work closely with the manufacturers of all approved antidepressant products that are the subject of today"s letters to optimize the safe use of these drugs and implement the proposed labeling changes and other safety communications in a timely manner. The labeling changes at issue will be posted on FDA's website http://www.fda.gov/cder/drug/antidepressants/default.htm.

• Anafranil (clomipramine HCl) • Aventyl (nortriptyline HCl) • Celexa (citalopram HBr) • Cymbalta (duloxetine HCl) • Desyrel (trazodone HCl) • Effexor (venlafaxine HCl) • Elavil (amitriptyline HCl) • Lexapro (escitalopram oxalate) • Limbitrol (chlordiazepoxide/amitriptyline) • Ludiomil (Maprotiline HCl) • Luvox (fluvoxamine maleate) • Marplan (isocarboxazid) • Nardil (phenelzine sulfate) • Norpramin (desipramine HCl) • Pamelor (nortriptyline HCl) • Parnate (tranylcypromine sulfate)	• Paxil (paroxetine HCl) • Pexeva (paroxetine mesylate) • Prozac (fluoxetine HCl) • Remeron (mirtazapine) • Sarafem (fluoxetine HCl) • Serzone (nefazodone HCl) • Sinequan (doxepin HCl) • Surmontil (trimipramine) • Symbyax (olanzapine/fluoxetine) • Tofranil (imipramine HCl) • Tofranil-PM (impiramine pamoate) • Triavil (Perphenaine/Amitriptyline) • Vivactil (protriptyline HCl) • Wellbutrin (bupropion HCl) • Zoloft (sertraline HCl) • Zyban (bupropion HCl)

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