FDA Launches a Multi-Pronged Strategy to Strengthen Safeguards for Children Treated With Antidepressant Medications

The Food and Drug Administration (FDA) today issued a Public Health Advisory announcing a multi-pronged strategy to warn the public about the increased risk of suicidal thoughts and behavior ("suicidality") in children and adolescents being treated with antidepressant medications.

The agency is directing manufacturers to add a "black box" warning to the health professional labeling of all antidepressant medications to describe this risk and emphasize the need for close monitoring of patients started on these medications. FDA has also 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, and is in the process of developing one.

"Today's actions represent FDA's conclusions about the increased risk of suicidal thoughts and the necessary actions for physicians prescribing these antidepressant drugs and for the children and adolescents taking them. Our conclusions are based on the latest and best science. They reflect what we heard from our advisory committee last month, as well as what many members of the public have told us," said Dr. Lester M. Crawford, Acting FDA Commissioner.

In letters issued today, FDA directed the manufacturers of all antidepressant medications to add a "black box" warning that describes the increased risk of suicidality in children and adolescents given antidepressant medications and notes what uses the drugs have been approved or not approved for in these patients. FDA's letters to the manufacturers also discuss other labeling changes designed to include additional information about pediatric studies of these drugs. These labeling changes are applicable to the entire category of antidepressant medications because the currently available data are not adequate to exclude any single medication from the increased risk of suicidality.

Prozac is currently the only medication approved to treat depression in children and adolescents. The analyses of the placebo controlled trials in children and adolescents summarized in the revised labeling are based on studies of five selective serotonin reuptake inhibitors (SSRIs) (Celexa, Prozac, Luvox, Paxil and Zoloft) and four "atypical" antidepressants (Wellbutrin, Remeron, Serzone and Effexor XR). In these studies, there was no reported case of a suicide.

A "black box" warning is the most serious warning placed in the labeling of a prescription medication. Advertisements that serve to remind health care professionals of a product's availability (so-called "reminder ads") are not allowed for products with "black box" warnings. Until now, only ten drug products approved for children contained a black box warning about their use in children. The new warning language does not prohibit the use of antidepressants in children and adolescents. Rather, it warns of the risk of suicidality and encourages prescribers to balance this risk with clinical need.

FDA recognizes that depression and other psychiatric disorders in pediatric patients can have significant consequences if not appropriately treated. The new warning language recognizes this need but advises close monitoring of patients as a way of managing the risk of suicidality.

The second element of the agency's strategy is a Patient Medication Guide (MedGuide), FDA-approved user-friendly information for patients. MedGuides are intended to be distributed by the pharmacist with each prescription or refill of a medication. FDA will work with the manufacturers of antidepressant medications to make the MedGuides available as soon as possible.

In addition, FDA intends to work with manufacturers to implement "Unit of Use" packaging for all antidepressants as a means of ensuring that patients receive a MedGuide with every prescription or refill. "Unit of use" packaging is a method of preparing a medication in an original container, sealed and pre-labeled by the manufacturer, and containing sufficient medication for one normal course of therapy.

Today's actions are consistent with the recommendations made at the September 2004 joint meeting of the FDA's Psychopharmacologic Drugs Advisory Committee and Pediatric Drugs Advisory Committee.

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