



FDA Talk Paper

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FDA

FDA Issues Public Health Advisory on Cautions for Use of Antidepressants in Adults and Children

The Food and Drug Administration today issued a Public Health Advisory that provides further cautions to physicians, their patients, and families and caregivers of patients about the need to closely monitor both adults and children with depression, especially at the beginning of treatment, or when the doses are changed with either an increase or decrease in the dose.

FDA has been closely reviewing the results of antidepressant studies in children, since June 2003, after an initial report on studies with paroxetine (Paxil), and subsequent reports on studies of other drugs, appeared to suggest an increased risk of suicidal thoughts and actions in the children given antidepressants. There were no suicides in any of the trials. On close examination of the initial reports, it was unclear whether certain behaviors reported in these studies represented actual suicide attempts, or other self-injurious behavior that was not suicide-related.

FDA has initiated a full review of these reported behaviors by experts in such evaluation. However, it is not yet clear whether antidepressants contribute to the emergence of suicidal thinking and behavior. The agency is advising clinicians, patients, families and caregivers of adults and children that they should closely monitor all patients being placed on therapy with these drugs for worsening depression and suicidal thinking, which can occur during the early period of treatment. The agency is also advising that these patients be observed for certain behaviors that are known to be associated with these drugs, such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia (severe restlessness), hypomania, and mania, and that physicians be particularly vigilant in patients who may have bipolar disorder.

FDA is asking manufacturers to change the labels of ten drugs to include stronger cautions and warnings about the need to monitor patients for the worsening of depression and the emergence of suicidal ideation, regardless of the cause of such worsening.

The drugs under review include bupropion, citalopram, fluoxetine, fluvoxamine, mirtazapine, nefazodone, paroxetine, sertraline, escitalopram and venlafaxine. It should be noted that the only drug that has received approval for use in children with major depressive disorder is fluoxetine (Prozac). Several of these drugs are approved for the treatment of obsessive-compulsive disorder in pediatric patients, i.e., sertraline (Zoloft), fluoxetine (Prozac), and fluvoxamine (Luvox). Luvox is not approved as an antidepressant in the United States.

These interim actions follow recommendations made by FDA's Psychopharmacologic Drugs and Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committees, which met on February 2, 2004. The advisory committee members advised FDA that the labeling should draw more attention to the need to monitor patients being treated with certain antidepressants.

FDA has previously noted (in Public Health Advisory and a Talk Paper T03-70 published Oct. 27, 2003) the possible finding of increased suicidal thinking or behavior, but emphasized that it was not clear that the drugs caused such events and additional analyses were being done to allow FDA to seek more definitive answers.

The Public Health Advisory containing the new label warnings and cautions is available online at <http://www.fda.gov/cder/drug/antidepressants/default.htm>.

Later this summer, FDA plans to update the Advisory Committees on the results of the expert analyses and its own analyses of the pediatric suicidality data.

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