FDA Talk Paper

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FDA Issues Public Health Advisory for Antipsychotic Drugs used for Treatment of Behavioral Disorders in Elderly Patients

The Food and Drug Administration (FDA) today issued a public health advisory to alert health care providers, patients, and patient caregivers to new safety information concerning an unapproved (i.e., "off-label") use of certain drugs called "atypical antipsychotic drugs." These drugs are approved for the treatment of schizophrenia and mania, but clinical studies of these drugs to treat behavioral disorders in elderly patients with dementia have shown a higher death rate associated with their use compared to patients receiving a placebo (sugar pill).

Today's advisory applies to such antipsychotic drugs as Abilify (aripiprazole), Zyprexa (olanzapine), Seroquel (quetiapine), Risperdal (risperidone), Clozaril (clozapine) and Geodon (ziprasidone). Symbyax, which is approved for treatment of depressive episodes associated with bipolar disorder is also included in the agency's advisory.

FDA is requesting that the manufacturers of all of these kinds of drugs add a boxed warning to their drug labeling describing this risk and noting that these drugs are not approved for the treatment of behavioral symptoms in elderly patients with dementia. Patients receiving these drugs for treatment of behavioral disorders associated with dementia should have their treatment reviewed by their health care providers. In analyses of seventeen placebo-controlled studies of four drugs in this class, the rate of death for those elderly patients with dementia was about 1.6 to 1.7 times that of placebo. Although the causes of death were varied, most seemed to be either heart-related (such as heart failure or sudden death) or from infections (pneumonia).

The atypical antipsychotics fall into three drug classes based on their chemical structure. Because the increase in mortality was seen with atypical antipsychotic medications in all three chemical classes, the agency has concluded that the effect is probably related to the common pharmacologic effects of all atypical antipsychotic medications, including those that have not been studied in the dementia population.

The agency is considering adding a warning to the labeling of older antipsychotic medications because limited data also suggest a similar increase in mortality for these drugs. The review of the data on these older drugs, however, is still on-going.

Additional information concerning today's announcement is available on FDA's Web site at http://www.fda.gov/cder/drug/infopage/antipsychotics/default.htm and http://www.fda.gov/cder/drug/advisory/antipsychotics.htm.

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