

April 12, 2005

## Popular Drugs for Dementia Tied to Deaths

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**W**ASHINGTON, April 11 - Older patients with dementia who are given antipsychotic medicines are far more likely to die prematurely than those given dummy pills, federal drug regulators said Monday. The warning adds to growing worries about the safety of the widely prescribed drugs.

The Food and Drug Administration said that it would now require manufacturers of the medicines to place black-box warnings - the agency's most severe - on the labels of all the drugs. In 2003, the agency required manufacturers to add a warning about an increased risk of diabetes from antipsychotic medications.

Zyprexa and Symbyax from Eli Lilly, Risperdal from Johnson & Johnson, Seroquel from AstraZeneca, Abilify from Bristol-Myers Squibb, Clozaril from Novartis and Geodon from Pfizer are all affected by the warning.

The drugs belong to a class of medicines developed since 1989 that are supposed to be safer than the older class of medicines for psychosis, like Haldol. In high doses, Haldol and drugs like it can cause a debilitating condition called tardive dyskinesia, a lifelong affliction that can involve uncontrollable trembling, tics and jerky movements.

Doctors have become so comfortable with the safety of the newer medicines that they are now among the biggest selling in the world, with some physicians using them to treat a wide range of conditions, including schizophrenia, depression and dementia in the elderly. Indeed, some psychiatrists prescribe cocktails of antipsychotics to patients with persistent mental problems.

Zyprexa is the biggest drug expense for many state Medicaid programs, the health insurance for the poor.

But the safety of the pills has come under increasing scrutiny. Studies now suggest that the newer drugs are only slightly less likely to cause tardive dyskinesia, and worries about other side effects are mounting.

The Food and Drug Administration said that it had analyzed the results of 17 placebo-controlled trials involving the drugs, which are known as atypical antipsychotics. The agency found that elderly patients with dementia who were given the pills were 1.6 to 1.7 times as likely to die as those given placebos.

The causes of death varied, although most died of heart-related problems like heart failure or infections like pneumonia, the drug agency said.

Representatives for Eli Lilly, AstraZeneca and Johnson & Johnson said the companies were reviewing the F.D.A.'s requirement and would work with the agency to develop new warnings.

The representatives from Eli Lilly and Johnson & Johnson noted that the companies put warnings on their labels about an increased risk of stroke more than a year ago.

The drug agency said it was considering adding the new warning to the older class of medicines "because limited data also suggest a similar increase in mortality for these drugs."

