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Antipsychotic Drugs Seen Effective in Kids

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A Food and Drug Administration panel Wednesday backed the use of AstraZeneca PLC's Seroquel in children and adolescents, saying the antipsychotic was "acceptably safe" and effective to treat schizophrenia and bipolar disorder.

The panel said another drug Zyprexa, by Eli Lilly & Co., could also be used to treat both disorders in certain pediatric patients, but only after other drugs were tried first because of concerns about significant weight gain in many patients. Officials from Eli Lilly acknowledged the weight problem during the meeting and agreed with recommendations that other drugs be tried first.

The panel said it thought Pfizer Inc.'s Geodon was effective for use in treating bipolar disorder in children ages 10 to 17, but split on whether the drug was safe.

All three products are currently approved for use in adults, but the companies are seeking FDA approval to market the products in younger patients.

Seroquel is AstraZeneca's second-best-selling drug with \$4.45 billion in sales in 2008, while Zyprexa is Lilly's top-selling drug with \$4.7 billion in sales last year. Doctors already use the products to treat children and adolescents, so it is unclear how receiving FDA approval to market the drug for use in younger patients would add to annual sales figures.

The agency brought the drugs before an FDA panel of outside medical experts to discuss "significant risks" seen with the drugs such as weight gain, sedation, and changes in cholesterol and blood-sugar levels. The concern is whether such risks would eventually cause other problems like diabetes and cardiovascular disease.

Thomas Laughren, director of the FDA's psychiatric product division, said schizophrenia and bipolar disorder are "serious" diseases that need additional treatment options. Risperdal, by a unit of Johnson & Johnson, and Abilify, by Bristol-Myers Squibb Co. and Otsuka Pharmaceutical Co., are currently approved to treat pediatric patients.

On Pfizer's Geodon, many panel members said they were concerned about a high number of patients who didn't complete clinical studies of the product, making its safety difficult to access. In a statement, Pfizer said it would address any outstanding questions with the FDA.

AstraZeneca is seeking FDA approval to market Seroquel in patients aged 13 to 17 with

schizophrenia, and in patients aged 10 to 17 with bipolar disorder. Pfizer is seeking FDA approval for Geodon to treat bipolar disorder in children aged 10 to 17.

Lilly is seeking the agency's approval for Zyprexa in patients aged 13 to 17 with schizophrenia or bipolar disorder, but only after other drugs are tried first.

Schizophrenia afflicts about 1% of Americans. Bipolar disorder, also known as manic-depressive illness, is believed to affect about 1% to 3% of the U.S. population.

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