

FDA weighs approval of psychiatric drugs for kids

5 June 2009, By MATTHEW PERRONE , AP Business Writer

(AP) -- Three blockbuster psychiatric drugs currently approved for adults also appear to work in adolescents, though federal health officials have concerns about exposing younger patients to the drugs' side effects.

The [Food and Drug Administration](#) is reviewing drugs from [AstraZeneca](#) PLC, Eli Lilly & Co. and Pfizer Inc. for use in patients between the ages of 10 and 17. The drugs - already approved to treat schizophrenia and bipolar mania in adults - had combined sales of more than \$7.4 billion last year, according to IMS Health.

FDA reviewers on Friday said they were wary of exposing youngsters to the drugs' side effects, including weight gain and high blood sugar, "because they may be exposed for many decades."

"These risks are of particular concern in pediatric patients because of the lifelong nature of these disorders," FDA director for psychiatric products, Dr. Thomas Laughren, wrote in documents posted online.

The FDA released its review of the drugs ahead of a meeting Tuesday where outside experts will weigh in on the drugs' risks and benefits. The agency is not required to follow the group's advice, though it usually does.

Many doctors already prescribe the medications to children and adolescents, although regulators have not officially cleared that use. Physicians are free to prescribe medicines as they see fit, though companies can only promote them for FDA-approved indications.

[AstraZeneca](#) and Lilly are seeking permission to market their drugs - Seroquel and Zyprexa, respectively - to [adolescents](#) with schizophrenia and bipolar mania, also called manic depressive disorder. Pfizer is seeking a pediatric [bipolar](#)

[disorder](#) indication for its drug Geodon.

Despite the safety concerns, Laughren and other FDA officials acknowledged the need for additional drugs to treat schizophrenia and bipolar disorder in teenagers and older children. Currently only two drugs are cleared for those uses: Johnson & Johnson's Risperdal and Bristol-Myers Squibb's Abilify.

"Schizophrenia and bipolar disorder are serious illnesses in pediatric patients and represent substantial burden for both patients and their families," Laughren said.

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