

FDA panel backs 3 psychiatric drugs for kids

June 11 2009, By MATTHEW PERRONE , AP Business Writer

(AP) -- Advisers to the Food and Drug Administration said Wednesday that three blockbuster psychiatric drugs appear safe and effective for children and adolescents, despite side effects that can increase the risk of diabetes.

The FDA's panel of psychiatric experts voted to approve the use of drugs from AstraZeneca, Eli Lilly and Pfizer for treating schizophrenia and bipolar disorder in patients ages 10 to 17.

The [FDA](#) is not required to accept the group's advice, though it usually does.

"We'll take all of this into consideration, but I can't make any promises about when we'll take action," said Dr. Thomas Laughren, FDA's director of psychiatric drugs.

All three drugs already are approved for adults with schizophrenia and bipolar disorder. Their side effects include weight gain, high blood sugar and sleepiness.

A positive FDA decision will expand the use of drugs that already make up the top-selling class of prescriptions in the U.S., with 2008 sales of \$14.6 billion, according to health care analysis firm IMS Health.

The panel - mainly comprised of psychiatrists - largely brushed aside concerns from patient and consumer advocates that the companies should have been required to conduct longer studies of the drugs' side

effects.

The panel voted 11-4, with four abstentions, that Lilly's drug Zyprexa is safe for treating bipolar, despite evidence the drug causes significantly more weight gain than other treatments. The Indianapolis-based company is only seeking approval for the drug as a second-choice, after other drugs have been tried.

"I had concerns about the metabolic side effects but if this is going to be used as the last treatment option then I think having other treatments available to physicians is worthwhile," said Dr. Frank Greenway, of Pennington Biomedical Research Center in Baton Rouge, La.

On the first day of the two-day meeting, more than a half-dozen nonprofit groups complained about the short length of the studies submitted to the FDA. The studies averaged between four and six weeks in length.

"Schizophrenia and bipolar disorder last for decades, often for life, and treatment is needed during all those years," said Dr. Diana Zuckerman of the Research Center for Women and Families in Washington. "These studies provide almost no useful information about long-term adverse reactions."

Schizophrenia affects about 2.4 million Americans and is characterized by hallucinations, delusions and social withdrawal, according to the National Institute of Mental Health. About 5.7 million Americans experience bipolar disorder, which causes rapid mood swings and shifts in energy.

Many doctors already prescribe the medications to children and adolescents. Doctors are free to prescribe drugs as they see fit, though companies can only market them for FDA-approved indications.

Prescriptions of anti-psychotic drugs for patients under 19 years old have more than doubled since 2001, according to pharmacy benefit manager Medco Health.

AstraZeneca and Lilly are seeking approval of their drugs - Seroquel and Zyprexa, respectively - for adolescents with schizophrenia and bipolar mania, also called manic depressive disorder. Pfizer is seeking approval to market its pill Geodon for bipolar patients ages 10 to 17.

The FDA panel voted 8-1 that Geodon is safe for children and adolescents with bipolar disorder, though nine panelists abstained, complaining of incomplete data from the company.

With only two anti-psychotic drugs currently approved for younger patients, a positive decision for the three drugs would significantly increase competition in the market for anti-psychotics.

Currently, only Bristol-Myers Squibb's Abilify and Johnson & Johnson's Risperdal are approved for those uses. Abilify was the second best-selling anti-psychotic [drug](#) in the U.S. last year with sales of \$3 billion. Risperdal was fourth with \$1.6 billion in sales, according to IMS Health.

Those drugs and the three under FDA consideration are known as atypical anti-psychotics, a class of treatments introduced in the 1990s that were designed to be safer and more effective than older drugs.

But recent studies have concluded the newer drugs are no more effective than those first developed in the 1950s. And while atypical anti-psychotics do not have the older drugs' risks of tremors and muscle spasms, they have their own side effects which can increase the risk of diabetes and heart problems.

Because the newer drugs are still under patent they generally sell for

between \$300 and \$500 per month, compared with the \$100 price on original anti-psychotics.

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