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## Antipsychotics Cause Weight Gain in Kids

By JONATHAN D. ROCKOFF

Antipsychotic drugs widely used in children caused youths to gain as much as 19 pounds on average after just 11 weeks on the medications, according to a new study published in the *Journal of the American Medical Association*.

The findings about the drugs, known as atypical antipsychotics, bolster concerns about giving the medicines to patients under 18 years of age. The study's authors urged child psychiatrists to exercise caution before deciding to prescribe, and to closely monitor patients taking the drugs.

The powerful drugs are used to treat schizophrenia and bipolar disorder. They have faced growing scrutiny, not only because of concerns about weight gain that could lead to diabetes, but also because of the aggressive marketing tactics by their makers that have helped make them the highest-selling class of drugs in the U.S.

The study results come as the Food and Drug Administration considers approving younger patients' use of a few of the drugs. Atypical antipsychotics have limited approval for youths, but doctors are free to prescribe them as they see fit and often give them to children and adolescents, say analysts and psychiatrists.

Psychiatrists turned to the new drugs after they began going on sale in the 1990s because they didn't cause involuntary facial tics and other problems, as an earlier generation of medicines did. Last year, the drugs collectively generated \$14.6 billion in sales in the U.S., according to IMS Health. But a growing number of studies suggest they have their own side effects.

"The weight gain is much larger than we thought," said Christoph Correll, the study's lead author, who is a psychiatrist and a scientist at the Feinstein Institute for Medical Research in Manhasset, N.Y. "It's massive, and it's the medication" that caused it, he said.

The JAMA study, conducted in 272 youths ages 4 to 19 years, is the largest and most definitive to date to establish a link between the drugs and weight gain, the authors said. Unlike earlier studies, it looked only at patients who hadn't previously taken the medicines.

The drugs examined were four top-selling atypical antipsychotics: Abilify, sold by Bristol-Myers Squibb Co. and Otsuka Pharmaceutical Co.; Risperdal from Johnson & Johnson; Seroquel from AstraZeneca PLC; and Zyprexa from Eli Lilly & Co.

Zyprexa caused the most weight gain, the study found. Over 11 weeks of use, children on Zyprexa gained the most weight on average, nearly 19 pounds, or a 15% increase. The drug was also found to significantly raise levels of blood sugar, cholesterol, insulin and triglycerides, which can lead to diabetes and heart problems.

Patients taking the other three drugs gained from 10 to 13 pounds on average, according to the study. The impact on users' blood sugar and other metabolic levels varied, depending on the drug.

The drugs' makers say that the potential for increased weight gain is well known and that they have already updated labels to reflect possible side effects. Atypical antipsychotics are a valuable treatment option for severe mental illnesses, the companies add, and physicians and parents should weigh the risks from taking the medicines against the benefits.

Should the FDA approve Zyprexa's use in adolescents, physicians should consider prescribing another drug first, a Lilly spokesman added.

In January, Lilly agreed to pay \$1.42 billion to settle a federal probe into alleged improper marketing of Zyprexa. And other pharmaceutical companies have come under fire for allegedly promoting off-label uses of atypical antipsychotics and playing down the side effects.

The connection between the drugs and weight gain is poorly understood. As concerns about the side effects have mounted, prescriptions for children have slowed. Dr. Correll encouraged child psychiatrists to be even more careful about giving the drugs to youths and, when they do, to encourage a healthy diet and to check weight and metabolic levels every three months.


"The onset of the weight gain was so pronounced and so significant there's probably an argument for doing those measurements every few weeks," said Christopher Varley, a child psychiatrist at Seattle Children's Hospital, who wrote an editorial accompanying the study.

The FDA will soon decide whether to approve younger patients' use of Seroquel, Zyprexa and Geodon, another atypical antipsychotic. (Geodon wasn't part of the study because it's not often used in new patients and too few users enrolled in the trial, Dr. Corell said.) Each drug is currently FDA-approved for use by adults.

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