Popular Weight-Loss Drugs Pose Serious Risks for Pregnant Women — But Warnings Are Buried

The U.S. Food and Drug Administration warns that Ozempic — approved for diabetes but taken off-label for weight loss — and Wegovy should be discontinued at least two months prior to pregnancy, but those warnings are buried and long-term testing won't be completed for years.

By Brenda Baletti, Ph.D.

Ozempic and Wegovy, the drugs at the center of the latest weight-loss craze, carry serious and under-discussed risks for pregnant women.

The U.S. Food and Drug Administration (FDA) warns that the use of Ozempic — approved for diabetes but taken off-label for weight loss — and Wegovy should be discontinued at least two months prior to pregnancy because it takes that long for the body to eliminate the drug.

But the National Institutes of Health (NIH) reports that nearly half of the pregnancies in the U.S. are unplanned. And the drug is popular among women and marketed to women of childbearing age.

The drugs' side effects for pregnant women aren't clear in the marketing, neuroscientist Martha Bagnell, Ph.D., told Vox. "Given the prevalence of Ozempic ads with women in them," she said, "you'd think that's a pretty big side effect to draw attention to."

Ozempic and Wegovy are brand names for semaglutide, a GLP-1 agonist that reduces food intake by curbing appetite and slowing digestion. The drugs are taken via weekly self-administered injections.

When the FDA approved Wegovy for weight loss in 2021, it required the drug's maker, Novo Nordisk, to conduct follow-up, post-market studies on health outcomes for pregnant women, their fetuses and infants exposed to the drug during pregnancy.

Neither drug was studied in pregnant women in clinical trials. But in animal studies, when rats, rabbits and monkeys were treated with injectable semaglutide drugs, they experienced increased rates of miscarriage and their offspring were born smaller and had higher rates of birth defects than normally expected.

They 'should really have a black box warning'

Buried in the 44-page Ozempic drug label and the 34-page Wegovy drug label, Novo Nordisk says there are limited data on semaglutide use in pregnant women — because there have been no clinical trials — but that studies of pregnant animals indicate there are potential risks to the fetus from exposure to the drug during pregnancy.

Both labels draw on the same studies, which show harm to the fetuses of rats, rabbits and monkeys that received semaglutide drugs during pregnancy.

Researchers found embryo-fetal mortality, stillbirths and "structural abnormalities" when mothers were given semaglutide below the maximum recommended human dose.

The animal studies also found reduced growth, heart blood vessel and skeletal abnormalities, and miscarriages at human exposure levels.

Lactating animals also had the drug in their breast milk.

Ozempic, the label says, should therefore "be used during pregnancy only if the potential benefit justifies the potential risk to the fetus." Wegovy, the stronger version of semaglutide, states when pregnancy is discovered, use should stop.

"This is a terrifying scenario, like a massive freight train coming down the train tracks that you're not going to be able to stop," Dr. James Thorp, a board-certified obstetrician and gynecologist, told The Defender.

He added:

> "The problem is that the whole industry is captured. Some people are calling it a miracle drug and a lot of women are flocking to it. That means they're pushing these drugs to the exact population that is going to have inadvertent pregnancies. So this is a disaster."

Thorp, who also is a board-certified maternal-fetal medicine specialist with more than 40 years of experience, said the drugs "should really have a black box warning for pregnancy risk. Because when you put it out in the general population, there's going to be women that are going to get on it and they're going to end up hurting a pregnancy."

Black box warnings are the FDA's most serious type of warning.

Ozempic and Wegovy included warnings about pregnancy but buried them in the instructions — at the bottom of the list of possible side effects.

The FDA told Vox the agency would make a pregnancy warning more prominent only if teratogenic events — fetal abnormalities from drug exposure that usually are discovered after an increased prevalence of a particular birth defect, similar to what happened with thalidomide in the 1960s — had been observed in humans.

The FDA also told Vox that "the agency takes the view that the pregnancy complications are likely caused by weight loss and poor nutrition," implying that the problem is with the weight loss, not the drug.

The FDA spokesperson said "taking semaglutide during pregnancy may increase the risk of birth defects and miscarriage above background for the US general population," but the extent of increased risk has not yet been quantified, Vox reported.

According to the FDA's timeline for approving Novo Nordisk's weight-loss drug, the company must conduct a prospective study that will create a registry to follow the health outcomes of pregnant women who take Wegovy and compare the maternal, fetal and infant outcomes of those women to women not on the drug.

"The registry will detect and record major and minor congenital malformations, spontaneous abortions, stillbirths, elective terminations, small for gestational age, preterm birth, and any other adverse pregnancy outcomes."

But the studies won't be completed until 2027 and 2033.

In the meantime, Thorp said, millions of women will likely be taking these drugs.

"These are relatively novel drugs and we don't have any safety profile on pregnancy in humans," Thorp said. "Why wouldn't they be advising women more seriously about the risks? This is a recipe for disaster,"

he said.

No long-term studies on side effects

Since the FDA approved Wegovy, the drug has become a sensation, with celebrities and social media influencers routinely sharing before-and-after pics on Instagram and TikTok, helping to fuel a massive new drug market that could be worth $100 billion a year for drug makers.

Wegovy was so popular that there were shortages, and patients turned to other pharmaceuticals — like Novo Nordisk's Ozempic — that can be used off-label for weight loss and which have become equally popular.

Drugmakers aren't the only ones profiting from weight-loss drugs. Telehealth companies have sprung up online offering a prescription for the drugs in just 15 minutes.

Companies such as Ro and Calibrate launched telehealth services dedicated to prescribing Wegovy and Ozempic and they've plastered ads for their services around places like New York City.

Last week the stock value for WW International (formerly "Weight Watchers) jumped 46% when it announced the acquisition of a new telehealth platform, "Sequence," which the company said will help it tap into the booming market for new obesity drugs — projected to hit $4.3 million by 2032.

The drugs caused weight loss in clinical trials. Users can pay more than $1,300 per month for the drugs, which often aren't covered by insurance for weight loss.

But the drugs are not made for short-term use — when people stop taking them, they regain much of the weight they lost, studies show.

There are no long-term studies on the effects of the drugs. And other known side effects include pancreatitis, thyroid cancer, gallbladder swelling, renal failure and diabetic retinopathy.

Earlier this year, the American Association of Pediatrics issued new recommendations for childhood obesity, advising that even obese children as young as 8 years old can be treated with weight loss drugs, including semaglutide.

The FDA also mandated Novo Nordisk complete post-marketing studies in children ages 6 and older and for other serious side effects, including medullary thyroid carcinoma, pancreatic and gallbladder disorders, acute kidney injury, serious hepatic events, malignant neoplasms, serious hypoglycemia and serious gastrointestinal disorders.

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