

## How do drugs like Ozempic work? And why are they on trial?

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You don't often see a "science day" in a Philadelphia courtroom. But that's exactly what happened last week in a potentially ground-shifting legal fight brought by patients against the manufacturers of blockbuster



drugs for diabetes and weight loss.

At the heart of the case are the drugs in question: Ozempic, Wegovy, and others that work in a similar way. The drugs—which help regulate blood sugar levels and reduce <u>body weight</u>—have been hailed as a "miracle," and have become a hot commodity, used by one in eight U.S. adults, according to a recent poll.

Now, some patients are suing Novo Nordisk and Eli Lilly, the manufacturers of the medications, claiming they were not adequately warned of the potentially serious side effects of the medication. The drug companies disagree. Dozens of such cases from across the nation have been consolidated for a future courtroom showdown in the Eastern District of Pennsylvania.

To explain their positions, each side had to first present the science behind Ozempic and similar drugs at the United States District Courthouse at Sixth and Market streets.

## How do Ozempic and drugs like it work?

The drugs largely mimic the effect of a hormone that acts on many parts of the body. For instance, the hormone—known as GLP-1—triggers the pancreas to produce insulin, which moves glucose (sugar) out of the bloodstream and into the cells, where it can be used for energy. As a result, multiple drugs in this class—called GLP-1 receptor agonists—have been approved to treat diabetes.

But drugs that mimic the GLP-1 hormone also act on other parts of the body, making them key tools for weight loss. They affect the <u>digestive</u> <u>tract</u>, slowing down the time it takes for the stomach to empty after eating, which can make people feel full for longer. They also appear to have several effects on the brain, including reinforcing the feeling of not



being hungry.

There is also emerging evidence that the drugs impact the kidneys and cardiovascular system; one, Wegovy, was recently approved by the U.S. Food and Drug Administration to prevent heart attack and stroke in people who are overweight or obese.

(Most of the drugs included in the case are GLP-1 receptor agonists. One, Mounjaro, acts on GLP-1 receptors and another receptor (GIP); the two hormones are similar but exhibit some key differences.)

## The science behind the need

In the Philadelphia courtroom, both sides agreed on one thing: These drugs treat conditions for which there is a desperate need.

According to the U.S. Centers for Disease Control and Prevention, nearly three in four U.S. adults are either overweight or obese. This places them at increased risk of a host of medical conditions, which can have a dramatic effect on life span. Extreme obesity, for instance, can take away 14 years of a person's life.

Meanwhile, one in 10 U.S. adults has diabetes, which is often associated with obesity and comes with its own list of life-threatening complications, as high levels of sugar in the blood can damage the body's organs, including the kidney, nerves, and heart.

## The science behind the lawsuit

The patients suing Novo Nordisk and Eli Lilly claim that the drugs increase the risk of serious, long-lasting digestive problems, about which they were not properly warned.



At science day, representatives for the plaintiffs argued that the drugs' effect on the stomach put them at risk of a complication known as gastroparesis, in which the stomach slows down to the point where it becomes paralyzed.

Gastroparesis can lead to pain, nausea, and vomiting, and cause lifethreatening malnutrition by depriving people of key nutrients. They cited a number of studies showing people who took GLP-1 receptor agonists were more likely to develop gastroparesis and other problems such as bowel obstruction.

Paul Pennock, an attorney at Morgan & Morgan representing the plaintiffs, said the companies did not do enough to communicate these risks. The information on the drug labels "was not really ringing a lot of alarm bells in terms of what was happening to people out there," he told the court.

Representatives for Novo Nordisk and Eli Lilly, in turn, argued that the side effects described by patients were well known. The slowing of the emptying of the stomach is part of why the drugs work, they said—but if this effect becomes intolerable, patients can stop taking the drugs, and the problem will disappear.

The research on gastroparesis is problematic, the companies argued. The condition is rare but has common symptoms (pain, nausea, and vomiting), so is often overdiagnosed. One 2023 paper they cited found that, among more than 300 people diagnosed with gastroparesis, more than 80% had been misdiagnosed. And among patients with legitimate gastroparesis, a significant number develop the condition from diabetes itself, not the drugs that treat diabetes.

These drugs have been the subject of dozens of rigorous trials, and produced more than 10 years of real-world evidence from millions of



patients who have taken them, Mark Premo-Hopkins, an attorney at Chicago firm Kirkland & Ellis representing Eli Lilly, told the court. There is "no reliable evidence" that these drugs cause the long-lasting damage alleged by the plaintiffs, he said.

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