

Weight-loss drug wins US approval

Obesity treatment shows promise for patients with diabetes despite concerns that it could cause heart complications.

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After 13 suspenseful years, the US Food and Drug Administration (FDA) has approved a pill that could help to fight the US obesity epidemic.

Belviq (lorcaserin) is no wonder drug, but it can help people to lose about 3–4% of their body weight when combined with a healthy diet and exercise. The drug has been approved for use by obese people with a body mass index (BMI) greater than 30, and for a subset of overweight people (with a BMI of more than 27) who have health conditions such as high blood pressure, elevated cholesterol and type 2 diabetes.

“It’s a start in the right direction,” says Abraham Thomas, head of endocrinology at the Henry Ford Hospital in Detroit, Michigan, who chairs the FDA’s Endocrinologic and Metabolic Drugs Advisory Committee. “We don’t have the tools to really treat obesity.”

Developed by Arena Pharmaceuticals of San Diego, California, Belviq faced a high bar for safety. In 1997, the weight-loss drug fenfluramine was pulled from the market for causing heart-valve problems. In the past two years, the FDA has rejected a total of three obesity drugs because of concerns over safety or lack of efficacy. The FDA advisory committee recommended in March that all obesity drugs should go through tests for cardiovascular risks, which would extend already lengthy clinical trials.

The FDA had already rejected Arena’s first application for approval of Belviq in September 2010 because the compound seemed to produce tumours in rats and because the company could not statistically rule out an increase in the risk of heart-valve problems. Similar to fenfluramine, Belviq suppresses food cravings by mimicking the effects of serotonin in the brain, making people eat less and feel full. However, Belviq seems to activate only the serotonin 2C receptor in the brain, not the serotonin 2B receptor that is present in heart muscle.

The FDA’s turnaround this week came after Arena performed echocardiograms in nearly 8,000 people to measure heart-valve function, which revealed that there was no increase in heart-valve abnormalities among those taking the drug. The firm has agreed to run six post-marketing studies, including a long-term cardiovascular trial, and patients with congestive heart failure are advised not to take the drug.

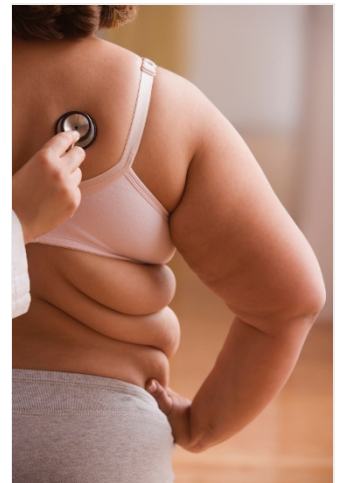
“I felt the benefits outweighed the risk,” says Ida Johnson Spruill, the consumer representative on the FDA advisory committee and a diabetes specialist at the Medical University of South Carolina in Charleston. One-third of adults in the United States are obese, so regulators must balance the risks of a new weight-loss drug with the health consequences of obesity, including rising diabetes rates.

Weighing the benefits

Compared to the placebo, Belviq’s efficacy is about the same as that of orlistat, which was first approved in 1999 and blocks the uptake of fat calories. A 90-kilogram patient on Belviq loses, on average, an extra 3 kilograms (6–7 pounds) or so after a year. “The good minimum weight loss would be in the 10–15-pound range,” notes endocrinologist Peter Savage of the National Heart, Lung, and Blood Institute in Bethesda, Maryland, “That doesn’t mean that people who lose 5–8 pounds don’t do well.”

It would also be a mistake to reject a drug that works well for a subset of the patient population, says Thomas. About 20% of people on the drug lost 10% or more of their body weight. The FDA recommends that patients who have not lost 5% of body weight by week 12 stop taking the drug.

Belviq has also shown promise for people with type 2 diabetes¹, who were twice as likely to keep their blood sugars under control than



Jose Luis Pelaez, Inc./Blend Images/Corbis

People with a high body mass index who lose weight reduce the risk of health problems such as diabetes or heart disease.

those on the placebo.

“No medication works by itself,” says Patrick O’Neil, a clinical psychologist at the Medical University of South Carolina and lead author of the diabetes study. “It’s not a replacement for diet, exercise, and lifestyle modification, but it can augment such programmes.”

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References

1. O’Neil, P. M. *et al. Obesity* **20**, 1426–1436 (2012).