

FDA Approves Weight Loss Drug Qsymia

By CARRIE GANN, ABC News Medical Unit

The U.S. Food and Drug Administration has **approved the diet drug Qsymia**, the agency's latest move to give doctors and their patients more tools to fight excessive weight gain as obesity rates continue to bulge in the U.S. and around the world.

An advisory panel voted 20 to two to approve the drug in February, the first time the FDA voted to approve a weight-loss drug in more than a decade. Originally known as Qnexa, the FDA required Vivus, the manufacturer of the drug, to change its name in order to prevent its confusion with other drugs with similar-sounding names. Data presented by the company showed that it **helped patients lose about 10 percent of their body weight**.

The committee's recommendation and Tuesday's approval by the FDA drew both praise and criticism, reflecting concern over the drug's side effects as well as the need to give patients more choices beyond diet, exercise and bariatric surgery.

"Considering the heavy toll of obesity in our society, this agent has tremendous potential," said Dr. Chip Lavie, medical director of cardiac rehab and prevention at the Ochsner Medical Center in New Orleans.

"I do think it will help a subpopulation lose weight. However, **I am concerned that mass marketing of this drug will perpetuate the magic bullet approach to weight loss**, which is limiting and **does not address the root problem**," said Dr. Gerard Mullin, an associate professor at Johns Hopkins School of Medicine.

About one-third of Americans are obese, and many have chronic, expensive medical conditions as a result, such as heart disease, diabetes and arthritis. Until recently, the array of available options has been frustratingly sparse for many doctors and their patients: diet, exercise and, for those overweight enough to qualify, bariatric surgery.

"I think it's **clear from current research that there are problems with weight-regulating mechanisms in the brain that make it difficult for people to lose and maintain weight**," said Dr. Louis Aronne, director of the Comprehensive Weight Control Program at New York Presbyterian Hospital. "We need to come to that realization that we're better off treating people who are obese than blaming them."

Weight loss was a struggle for Meg Evans, a 63-year-old mother of four in San Diego, until she took Qsymia. She said she was the quintessential jock in high school and college: physically active, involved in sports and always staying fit and trim. After she had her children, she started to put on weight.

Evans said she tried several diets over the years and continued to stay active, playing goalie for her soccer team. But she couldn't seem to get the scale to tick downward.

"My weight was inching up and up, and by 2007, I was at 230 pounds. I was not OK with that," she said.

When her doctor told her for the first time that her blood pressure was high, Evans realized it was time to try something different. Her doctor recommended that she enroll in the clinical trials for Qsymia, and she readily agreed.

She started taking the drug in February 2008 and also worked with a counselor once a week to develop a diet and exercise plan.

"Once I did those three things, I started losing that weight," Evans said.

By March 2009, she had lost 48 pounds. She said the only noticeable effect of the drug was that it decreased her hunger pangs.

"Honestly, I thought I was on the placebo. I really thought I was doing it myself," she said. "For me, there was just not that need to eat."

Qsymia is a combination of two FDA-approved drugs: phentermine, a stimulant related to the amphetamines that suppresses the appetite, and topiramate, a drug used to treat migraines and epilepsy that has weight-loss side effects. Vivus emphasizes that the drug is **intended to be used in combination with diet and exercise.**

In June, the **FDA approved another diet drug, lorcaserin or Belviq.** The drug is also an appetite suppressant and intended for patients who are obese and have one additional weight-related health problem, such as high blood pressure, type 2 diabetes or high cholesterol. However, studies of Belviq found that **patients lost about 4 percent of their body weight, compared with the 10 or 12 percent lost by Qsymia patients.**

But **Qsymia is not without drawbacks.** When Qsymia's manufacturer, Vivus, initially submitted the drug for approval in 2010, the FDA voted it down, citing concerns over the *potential for dangerous heart problems, birth defects and cognitive effects such as mental foggy or lack of concentration in patients taking the drug.*

The 2012 panel voted to approve the drug only with Vivus' assurances that the company would provide detailed information to physicians about the risks of the drug and how to manage them.

Still, doctors are mixed in their concern over the potential for side effects, particularly in light of the history of diet drugs, such as fen-phen, approved by the FDA, then withdrawn from the market over concerns about heart risks and other dangerous side effects.

"Honestly, I won't be surprised if adverse effects over time result in a reversal of the approval," said Dr. David Katz, director of the Yale Prevention Research Center. "But in the interim, it will help some people lose weight, and many others will try it, dislike it and stop, and gain the weight back."

Evans said she's gained about 20 pounds since she stopped taking Qsymia in 2009. She said the gain is due in part to an injury to her Achilles tendon that has kept her from being as active as she was. But she said she would definitely consider taking it again to help her bring her weight down.

"Just to know that it's available if I need it, that's a real nice little prize," she said.