

Miracle diet pill? A safe drug is elusive

February 24 2012, By MATTHEW PERRONE , AP Health Writer



In this July 7, 2011 file photo, people walk on the street in Montpelier, Vt. The battle of the bulge so far has been a big, fat failure for U.S. drugmakers. But that hasn't stopped them from trying. For nearly a century, scientists have struggled to come up with a diet pill that helps people lose weight without causing side effects that range from embarrassing digestive issues to dangerous heart problems. (AP Photo/Toby Talbot, File)

(AP) -- The battle of the bulge has been a big, fat failure for U.S. drugmakers. But that hasn't stopped them from trying.

For nearly a century, scientists have struggled to make a [diet pill](#) that helps people lose weight without side effects that range from embarrassing digestive issues to dangerous [heart problems](#).

But this week, federal health advisers [endorsed the weight loss pill Qnexa](#) even though the FDA previously rejected it over concerns that it

can cause heart palpitations and birth defects if taken by pregnant women.

The vote of confidence raises hopes that the U.S. could approve its first anti-obesity drug in more than a decade. It also highlights how challenging it is to create a pill that fights fat in a variety of people without negative side effects.

"Having a drug for obesity would be like telling me you had a drug for the fever," said Dr. Mitchell Roslin, chief of bariatric surgery at Northern Westchester Hospital in New York. "There can be millions of different reasons why someone is obese; it's really a symptom of various underlying mechanisms."

An effective and safe diet pill would be an easy sale in the U.S.: With more than 75 million [obese adults](#), the nation's obesity rate is nearing 35 percent. But the biggest challenge in creating a weight-loss drug is that there doesn't appear to be a safe way to turn off one of the human body's most fundamental directives.

For millions of years, humans have been programmed to consume calories and store them as energy, or fat. It's this [biological mechanism](#) that makes it almost impossible to quickly lose weight by not eating. Cutting down on food instead sends stronger signals to the body to store more calories.

"Throughout most of human history calories were scarce and hard to get, so we have numerous natural defenses against starvation," said Dr. David Katz of Yale University's Prevention Research Center. "We have no defenses against overeating because we never needed them before."

The drug industry has been on a nearly 100-year search for a drug that can help the body shed pounds. They've mostly failed to come up with

an effective one and many of their experiments have proven fatal to patients:

- Early attempts focused on speeding up metabolism to burn more calories. In the 1930s, doctors prescribed an industrial chemical called dinitrophenol, which accelerated metabolism, but also caused fever, swelling and deadly toxicity in some patients. The 1938 law establishing the Food and Drug Administration was a response to untested drugs like dinitrophenol.

- In the '50s and '60s, amphetamines became a popular weight loss treatment because they boost metabolism and suppress appetite. But the pills proved to be highly addictive, and doctors discovered they increase blood pressure and heart rate. The amphetamine phentermine remains approved for short-term weight loss, usually less than 12 weeks, though it is seldom prescribed because of the potential for addiction.

- Perhaps the worst diet pill safety debacle came in the 1990s and involved the combination of phentermine and another weight loss drug marketed by Wyeth called fenfluramine. The combination of the two pills, dubbed fen-phen, was never approved by the FDA but more than 18 million prescriptions were written for it by the mid-90s.

But after studies in 1997 suggested that up to a third of patients taking fen-phen experienced heart valve damage, Wyeth was forced to recall two versions of fenfluramine and eventually paid more than \$13 billion to settle tens of thousands of personal injury lawsuits.

- In the last decade, drugmakers have moved toward other weight loss concoctions. Currently, the only drug approved for long-term weight loss in the U.S. is orlistat, which is sold as the prescription drug Xenical and over the counter as alli. The drug works by blocking the absorption of fat.

When launched in 2007, alli received a high-profile marketing push from drugmaker GlaxoSmithKline, complete with TV ads and a celebrity endorsement by country singer Wynonna Judd. But it never took off due to unpleasant side effects, including loose bowel movements. Educational pamphlets for alli even recommend people start the program when they have a few days off work, or bring an extra pair of pants to the office.

- Most drugmakers now are focusing on medications that block brain signals associated with food craving and appetite. Vivus' Qnexa is one of a trio of drugs seeking FDA approval. The diet pill, which was initially rejected due to the risks of [heart palpitations](#) and other safety issues, is a combination of two older drugs.

It uses the amphetamine phentermine, which suppresses appetite. The other drug is topiramate, an anticonvulsant sold by Johnson & Johnson as Topamax. Topiramate is believed to make patients feel more satiated, though it's unclear exactly how. J&J initially studied Topamax alone as a weight loss treatment but concluded the psychiatric side effects, such as memory loss and difficulty concentrating, were too significant.

Still, on Wednesday, a panel of FDA doctors and other advisers voted 20-2 in favor of approving Vivus' Qnexa pill, which the drugmaker has resubmitted to the FDA for a second review.

The group touted the drug's benefits, which include [weight loss](#) of nearly 10 percent for most patients taking the drug over a year - the highest reduction reported with any recent diet pill. But panelists stressed that the drugmaker must be required to conduct a large, follow-up study of the pill's effects on the heart.

The FDA is expected to issue its decision on Qnexa by mid-April.

"The potential benefits of this medication seem to trump the side effects," said FDA panel member Dr. Kenneth Burman of the Washington Hospital Center in Washington DC. "But in truth, only time will tell."

Tammy Wade of McCalla, Ala., is confident that the diet pill works. She lost nearly 40 pounds, dropping down to 167 while in a two-year [Qnexa](#) study.

"I never lost that much weight on any of the programs I've tried," said Wade, who's done everything from Weight Watchers to workouts with a personal trainer.

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Citation: Miracle diet pill? A safe drug is elusive (2012, February 24) retrieved 10 May 2024 from <https://medicalxpress.com/news/2012-02-miracle-diet-pill-safe-drug.html>

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