# FDA panel rejects experimental weight loss pill

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(AP) -- A panel of federal health experts dealt a surprising setback Thursday to a highly anticipated anti-obesity pill from Vivus Inc., saying the drug's side effects outweigh its ability to help patients lose weight.

The Food and Drug Administration panel voted 10-6 against Vivus Inc.'s Qnexa citing unknown safety risks of long-term use with the drug. The FDA will consider the panel's ruling and make its own decision on the drug in coming months.

Panelists unanimously agreed the drug helps patients lose pounds, with most reporting more than 10 percent weight loss. But those benefits were outweighed by a slew of safety concerns that cropped up in company trials, including memory lapses, suicidal thoughts, heart palpitations and birth defects.

"Some of these side effects are serious and could be life-threatening and must be weighed against a relatively modest weight loss," said the panel's chair, Kenneth Burman of the Washington Hospital Center.

The vote deals a major blow to the Mountainview, Calif., drugmaker, which is racing to market the first new U.S. prescription weight loss drug in over a decade.

The negative opinion also suggests a higher bar for the company's two California competitors - Arena Pharmaceuticals and Orexigen Therapeutics Inc. - which are schedule to have their own weight loss pills

reviewed later this year.

Shares of Vivus were halted ahead of the meeting, but the outcome is sure to sink the company's stock price, which has doubled over the past year on high expectations for the drug. The stock closed at $12.11 on Wednesday.

Shares of Arena Pharmaceuticals rose 13 percent to $4.48 in after-hours trading, extending earlier gains from a positive medical journal review of the company's drug lorcaserin.

Orexigen Therapeutics fell 9 percent to $4.55 in extended trading on a tougher approval environment for the company's drug Contrave.

With U.S. obesity rates nearing 35 percent of the adult population, doctors and patients say new pharmaceutical treatments are needed. And Wall Street analysts say even a modestly effective drug has blockbuster potential.

Qnexa has shown the best weight loss results of the three drugs, but it also had the highest rate of patient dropouts due to the side effects.

Several panelists said they wanted to vote in favor of the drug, but needed more information about its long-term effects on the heart. Qnexa only tracked patients for about a year.

"I don't think we have enough data to say whether these are serious issues or not," said Michael Prochan, a statistician with the National Institutes of Health. "I think if we had had longer follow-up I could have voted the other way."

Panelists who favored the drug said they hoped the FDA would still approve Qnexa, despite the vote results.

"I think if this drug is disapproved we're going to send a very negative signal to the overweight and obese that drives them away from medical treatment," and toward more unproven weight loss methods, said Ed Hendricks, director of the Center for Weight Management in Sacramento.

Even FDA staff expressed surprise at the panel's ruling.

"You got the sense that a lot of people had a little bit of hesitancy," said Eric Coleman, deputy director of the FDA's metabolism division. "They weren't strongly against the drug but they had enough concerns to make them lean towards 'no.'"

Qnexa is a combination of two older drugs: the amphetamine phentermine and topiramate, an anticonvulsant drug sold by Johnson & Johnson as Topamax. According to the company, phentermine helps suppress appetite, while topiramate makes patients feel more satiated.

Vivus representatives told panelists the company's drug fills an important gap between current treatment options.

Current weight loss drugs on the market such as Roche's Xenical and Abbott Laboratory's Meridia offer weight loss in the five percent range. Bariatric surgery can help patients lose 30 to 35 percent, though complications with the operation can be life-threatening.

The quest for a blockbuster weight loss drug has been plagued for decades by safety issues. The most notable was Wyeth's diet pill-drug combination, fen-phen, which was pulled off the market in 1997 because of links to heart-valve damage and lung problems.