

FDA-Approved Fat-Fighting Pill Hits Market With Big Promises

Federal regulators' approval of a new weight-loss drug this month marked the third time a new diet medication has hit the market since 2012. Called Contrave, the latest drug can be used by obese and overweight adults who have at least one other obesity-related condition, such as high blood pressure or Type 2 diabetes.

In an interview on *Newsmax TV's Meet the Doctors* program, two leading health experts note that Contrave is only the latest in a long line of diet pills, many of which have proven to be ineffective or risky. But the new pill, manufactured by Orexigen Therapeutics of La Jolla, Calif., has a few things going for it that past fat-fighting medications did not.

First, it is a combination of two previously approved medications—naltrexone, which treats alcohol and drug addiction, and bupropion, used to combat depression and help smokers quit—that have proven safety records. Secondly, Orexigen has agreed to conduct continuing safety trials that will look at possible heart risks and safety of use in children and teens down the road, the Food and Drug Administration said.

In addition, Contrave is not being sold as a cure-all for weight loss and isn't for everybody. According to the FDA, it is only effective when used in combination with a healthy lifestyle—including a nutritious low-calorie diet and exercise—and is only to be prescribed as part of an overall weight-loss plan.

For these reasons, endocrinologist Rachel Pessah-Pollack, M.D., says the new medicine holds great promise for people who

combine its use with regular exercise and a reduced-calorie diet.

"Of course obesity is a major problem we're dealing with every day ... [and] this drug is especially targeted for patients that are having issue with obesity despite increasing their activity and following a good diet," she notes. "It's [to be used] in combination with everything else in their lifestyle."

She adds that Contrave works by changing brain chemistry, which is an entirely new way to combat obesity.

"We're working with the brain, we're trying to help people lower their appetite ... and lower the enjoyment they get from eating food, and that's a different way of losing weight than what we've been used to," she explains.

Medical entrepreneur Joseph V. Gulfo, M.D. notes Contrave was first recommended for approval by an FDA advisory panel in 2011, but the agency rejected it at the time. On *Meet the Doctors*, Dr. Gulfo argues the FDA should have approved the drug years ago, when it had all the evidence it needed that the medication is not only effective, but also safe.

He says the FDA's delayed action on Contrave is only the latest to indicate that effective new treatments are being kept from American consumers because government red tape has tied the agency's hands.

"Contrave should have been approved 3.5 years ago because they had a positive ... FDA panel of experts who voted 13 to 7 in favor of the drug, but the FDA rejected it," says Dr. Gulfo, author of *Innovation Breakdown: How the FDA and Wall Street Cripple Medical Advances*. He adds: "This poor company got victimized ... and that's what it's really all about: [the need to] get drugs that are safe and effective in the hands of the doctors."

According to the U.S. Centers for Disease Control and

Prevention, more than one-third of adults in the United States are obese, while another third are considered overweight.

The FDA approved Contrave for people unable to lose weight through diet and exercise alone who aren't ready for weight-loss surgery. The FDA decision was based on the results of multiple trials involving 4,500 people. One study found that 42 percent of people who took Contrave lost 5 percent of their body weight, compared to 17 percent who took an inactive placebo. A second study found 36 percent of people with Type 2 diabetes who took Contrave lost 5 percent of their weight, while only 18 percent of those on a placebo did.

Contrave is not the first pharmaceutical weapon in the nation's war on obesity. In fact, the first diet pills were developed more than 100 years ago. Since then, a host of fat-fighting medications have been marketed—some of which have been linked to dangerous side effects, including abnormal heartbeats, high blood pressure, and even death.

In the 1950s and '60s, stimulants, hormones and laxatives became weight-loss drugs of choice, but nearly all posed health hazards. In the 1990s, about 18 million prescriptions were written each year for the popular drug combo fen-phen at the height of its popularity—until increased heart risks tied to the medication led to its removal from the market in 1997.

Since then, other diet pills have entered the market, including Orlistat, sold by prescription as Xenical and over-the-counter as Alli, which works by reducing the amount of dietary fat absorbed by the digestive tract.

And the FDA has approved two other weight-loss drugs in just the past two years—Qsymia and Belviq. But neither has sold well, despite the hype they both received when they hit the market.

Dr. Pessah-Pollack says the FDA's approval for Contrave gives doctors another option to help patients who are already making

efforts to lose weight by adopting healthy habits.

But it is not for everyone, and—like past diet pills—Contrave can cause risky side effects. Because it contains bupropion, the label will include a boxed warning about the increased risk of suicidal thoughts and behaviors associated with antidepressants. It can also increase blood pressure, and should not be used in people with uncontrolled high blood pressure, according to the FDA. In addition, Contrave increases the risk for seizures, and should not be used by those with seizure disorders. If it does not work after 12 weeks, the patient should stop taking it, the agency said.

“I am still very hesitant about using weight-loss drugs, and that needs to be reiterated, we don’t have long-term data,” Dr. Pessah-Pollack notes. “[But] for the right patient who’s exercising and watching their diet, it’s great.”

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