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FDA's Lap-Band decision is a boon for Allergan

The FDA's approval to widen Lap-Band eligibility presents opportunity for Allergan but raises concerns about patient risks.

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Pharmaceutical giant Allergan Inc. stands to win big from the federal government's decision to make Lap-Band weight-loss surgery available to more overweight Americans.

The Food and Drug Administration on Wednesday cleared the way for marketing the procedure to patients who are significantly less obese than those who qualify now — a decision that would make an estimated 26.4 million more Americans eligible to consider the Irvine company's device. The approval also means that, according to company officials, 45.6 million Americans meet the criteria for Lap-Band surgery. That's more than 1 in 7.

But some in the medical community worry that it could encourage overweight people to abandon traditional diet and exercise for a surgery that carries some serious risks.

"I'm very concerned," said Dr. Ted Khalili, former director of bariatric surgery at Cedars-Sinai hospital and founder of the Khalili Center for Bariatric Care in Beverly Hills. "You can't be driving down a street and have a flashbulb go off and think that this will be an easy fix."

Allergan spokeswoman Cathy Taylor said Thursday that although the Lap-Band is now available to a broader base of patients, it "is not intended for everyone." Instead, she said, it is designed for a particular subset of people "with a health condition, who have failed conservative weight-loss therapies like diet and exercise and pharmacotherapy."

The approval allows Allergan to market the device to patients with a body mass index, or BMI, as low as 30 if they have at least one weight-related medical condition, such as diabetes or high blood pressure, the company said. For a 5-foot-9 patient, that translates to a weight of about 203 pounds.

The Lap-Band is an inflatable ring that is surgically implanted around the upper portion of the stomach. Once the surgical wounds have healed, saline solution is injected into the ring to expand it, limiting the amount of food that can be consumed during a meal.

Over the last two years, four Southern California patients have died shortly after undergoing Lap-Band weight-loss surgery at two clinics connected to a television, radio and billboard marketing campaign touting the toll-free number 1-800-GET-THIN, according to lawsuits, family interviews and coroners reports.

Allergan does not pay for the ads, which were created by a marketing company that directs prospective patients to clinics that perform the procedure using Allergan's device. Robert Silverman,

the lawyer who represents 1-800-GET-THIN 1-800-GET-THIN and the two clinics named in the lawsuits, said the advertisements include warnings about the risks of Lap-Band surgery. He said the lawsuits were without merit.

Allergan's chief executive, David E.I. Pyott, told The Times this month that he didn't support the ads.

Allergan said it requires all surgeons who want to order and perform a surgery with the Lap-Band device to first complete a comprehensive proctorship and training program; have advanced laparoscopic skill; and "have the staff and resources needed to comply with the long-term follow-up requirements of obesity procedures."

FDA spokeswoman Karen Riley said the agency can't control how doctors use the procedure because it has no authority over the practice of medicine. But she pointed out that the FDA did not give Allergan all it asked for.

Allergan wanted approval of the device for use in patients with a BMI of at least 35 and no other diseases and in patients with a BMI of at least 30 with one or more diseases. FDA gave approval only for use in patients with a BMI of 30 and one or more diseases, with the additional stipulation that those diseases be obesity-related, Riley said.

Obesity, as well as vanity, have transformed Allergan. Allergan markets Natrelle breast implants, Latisse eyelash lengthener and Botox, a toxin that temporarily paralyzes facial muscles.

On Thursday, after news of the FDA decision was released, Allergan's shares reached a 52-week high and closed at $75.58, up 81 cents.

Analysts said they had expected Wednesday's news after an FDA panel in December voted 8 to 2 in favor of expanding the device's potential pool of patients; such votes typically foreshadow final approval by the agency. The FDA decision recognizes that obesity is a disease that proceeds along a continuum as measured by BMI, said Dr. John Kral, a surgeon who supported expanded use of the Lap-Band procedure as a member of the FDA advisory committee reviewing Allergan's request last year.

Dr. Robert Kushner, an obesity specialist at Chicago's Northwestern Memorial Hospital, said expanded access to the technology was a welcome development, but that other treatments are needed.

Kushner noted that the FDA was willing to accept the inherent hazards of surgery but recently rejected three diet drugs — Lorcaserin, Qnexa and Contrave — because it judged that the drugs' risks outweighed benefits.

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