

← Back to Original Article

FDA accuses 1-800-GET-THIN of using misleading Lap-Band ads

The agency says the marketing company's billboard, radio and television ads that tout Lap-Band weight-loss surgery underplay serious risks to patients.

December 14, 2011 | By Stuart Pfeifer, Duke Helfand and W.J. Hennigan, Los Angeles Times

The Food and Drug Administration has accused the 1-800-GET-THIN marketing company of using misleading advertising in its promotion of Lap-Band weight-loss surgery, saying the billboard, radio and television ads underplay serious risks to patients.

The billboards, plastered across Southern California freeways, display the smiling faces of thin people and catchy phrases about the benefits of Lap-Band surgery. There are warnings about the risks, but the typeface is so small it's not legible, the FDA said. On the radio, the company uses a catchy jingle, and recently included the endorsement of celebrity doctor Drew Pinsky.

Five Southern California Lap-Band patients have died since 2009 after surgeries at centers affiliated with the advertising campaign, according to lawsuits, autopsy reports and other public records.

On Tuesday, the FDA said it had sent warning letters to 1-800-GET-THIN and eight affiliated surgery centers, saying the ads, which promise patients a chance to "let your new life begin," must do a better job describing the risks associated with Lap-Band surgery.

The FDA's action followed criticism of the ads by the chief of the Los Angeles County public health agency, relatives of deceased patients and even Lap-Band manufacturer Allergan Inc. of Irvine. It marked the first crackdown on the ads by a government agency, and experts say it could lead to fewer people getting the surgery.

"It's certainly going to discourage a lot of people from pursuing the option," said Lars Perner, an assistant professor of clinical marketing at the USC Marshall School of Business. "This is telling people information they might not otherwise receive. It will certainly help people make more accurate decisions."

The Lap-Band is a silicone ring surgically implanted around the stomach to discourage overeating. The surgeries vary in cost — from \$12,000 to about \$20,000, according to Allergan — and often are covered by insurance.

A lawyer who represents 1-800-GET-THIN said the marketing company will work with the FDA to resolve the problems and remains committed to patient safety.

"1-800-GET-THIN does not provide medical services, nor do they manufacture, distribute or sell the Lap-Band medical device," attorney Robert Silverman said in a statement. "All individuals who call 1-800-GET-THIN are referred to licensed physicians and accredited facilities where every individual will receive a full and complete disclosure of the risks and benefits of surgical weight loss."

Steve Silverman, an FDA director who oversaw the investigation, said the agency took action after receiving a complaint about the ads from Dr. Jonathan Fielding, who heads Los Angeles County's public health agency. Fielding filed the complaint after The Times published a series of articles about the ad campaign and patient deaths.

The ad campaign doesn't tell prospective patients all they need to know, Silverman said.

"They're speaking to a very vulnerable patient population," he said. "People who are obese have often struggled through their whole lives to lose weight."

"I was in Los Angeles earlier this year and I was astonished at the number of billboards I saw," he added. "I was driving along the 405 ... and it was billboard after billboard after billboard after billboard."

1-800-GET-THIN and its eight affiliated surgery centers each have 15 days to tell the FDA what steps they will take to correct the ads — or to explain why they'll need additional time. If they don't respond in time, the FDA could seize the firms' inventory of Lap-Bands and impose monetary penalties.

In California, Insurance Commissioner Dave Jones also is investigating the Lap-Band industry over questions about alleged fraudulent billings and misrepresented charges. He did not single out the surgical centers named by the FDA but said his office is generally aware of complaints about deceptive advertising.

"We are continuing to look at the operations of these facilities," Jones said.

The patients' deaths and injuries have also prompted a series of wrongful-death and personal injury lawsuits against 1-800-GET-THIN, its affiliated surgery centers and doctors who performed the procedures. There's also a class-action lawsuit, filed on behalf of patients, that accuses 1-800-GET-THIN of false advertising for failing to adequately disclose risks of the surgery and disciplinary problems of some affiliated doctors.

Word of the FDA's enforcement was received warmly by relatives of patients who died after the surgeries. But one attorney questioned why it took so long.

"They've gone out of their way to make it sound like it's a drive-through surgery, a one-hour safe procedure. So I'm glad the FDA is doing this," said Alex Robertson, a Westlake Village lawyer who filed the class action and two wrongful-death lawsuits. "It's unfortunate it's taken so long. It doesn't do any good for the five people who've lost their lives."

Orange County resident Paula Rojeski was the most recent patient to die. Her Lap-Band surgery was performed at a San Fernando Valley clinic affiliated with 1-800-GET-THIN. The Los Angeles County coroner has not yet determined the cause of her Sept. 8 death.

Rojeski's friend Marni Rader said she believes the advertising crackdown is overdue.

"I think about her every time I see one of those billboards," Rader said. "They're everywhere. I don't remember seeing anything in that advertising that said this is a serious surgery.

"It's not worth losing your life over 20 pounds. She was maybe a size 14. You need surgery if you're a size 14? That's insanity."

More than 100,000 people called 1-800-GET-THIN in its first 15 months of business — starting in March 2010 — leading to more than 10,000 scheduled surgeries, the company said in a trademark lawsuit.

An Allergan spokeswoman said it issued its own voluntary advertising guidelines this year that call for doctors who use the Lap-Band device to present "balanced information" about the procedure and to base claims of success on scientific evidence.

"Advertising about medical procedures, including surgery involving the Lap-Band system, should convey the benefits and risks of the treatment and be truthful and not misleading," the one-page set of guidelines says.

In all, the FDA sent letters to Bakersfield Surgery Institute Inc., Beverly Hills Surgery Center, Palmdale Ambulatory Center, Valley Surgical Center of West Hills, Valencia Ambulatory Center, Cosmopolitan Plastic & Reconstructive Surgery of Beverly Hills, San Diego Ambulatory Center, 1-800-GET-THIN and Top Surgeons of Beverly Hills.

Dr. Amir Mehran, director of bariatric surgery at the David Geffen School of Medicine at UCLA, said he thought the FDA's action would better inform patients.

"The patients will start seeing beyond the ads. They will look at benefits and risks, and make some proper choices based on information that is properly given to them," Mehran said. "We think there are better options than the band."

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