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Lap-Band Clinics Are Warned by the FDA for Overly Rosy Promotions of Weight Loss

For a couple of years now, Southern California drivers have become used to seeing billboards for a medical procedure that promises to turn overweight people into the thin creatures they want to be. By calling 1-800-GET-THIN, you could sign up for a gastric Lap-Band surgery at an outpatient facility and change your life. So they claimed.

Several people who took up the offer did change their life—they died.

Last week the FDA finally noticed. The agency issued a **warning letter** to eight of the surgical centers promoted on the oversized advertisements. The feds told GET-THIN to stop posting misleading advertisements. It's a violation of federal law for advertising to minimize significant risks and complications of a procedure. It's also illegal to fail to make clear that for Lap-Band to be truly effective, it must be accompanied by a significant change in the patient's eating habits and lifestyle.

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Los Angeles Times columnist Michael Hiltzik said **it was about time**. "For nearly two years, my colleagues and I have been reporting on the 1-800-GET-THIN ad campaign," he wrote. "In my very first column on the topic, in February 2010, I identified the people behind it as brothers Julian and Michael Omid, and reported that Julian's medical license had been revoked by the Medical Board of California and Michael's medical license had been placed on probation. (Michael's probation has since expired.)"

The L.A. Times has reported the deaths of local patients after their surgeries were performed at advertised clinics, and on the lawsuits and coroners' reports that detailed them. "So far," Hiltzik wrote, "the known toll is four, with a coroner's ruling still pending on the death of a fifth patient, who expired after being rushed to a hospital in September from the surgery center where she had just undergone the procedure.

"We've reported on the shocking sanitary and safety conditions at one of the surgery centers affiliated with the ad campaign, and noted questions about whether the surgery centers' insurance billing has been proper.

"And we've reported that effective oversight of a potentially life-threatening procedure has been hampered by California's patchwork system of medical regulation, in which the medical board and the state Department of Public Health essentially pass the buck to each other over who should keep an eye on non-hospital surgery clinics like these."

The Lap-Band is a cinch placed around the upper part of the stomach creating a smaller organ that minimizes the amount of food you can ingest. Although the procedure is approved by the FDA, and often is preferable to the more invasive and complicated weight-loss surgery that diverts food from being absorbed in the small intestines, it is not without risks that can be exacerbated if it's performed in facilities whose personnel are less than vigilant or qualified.

Complications include the band moving out of position and eroding through the stomach wall. Nausea, vomiting, difficulty swallowing, gastroesophageal reflux disease (GERD) and pain can result. **One study** said as many as 1 in 3 10 Lap-Band patients experience band erosion and almost half will have the band removed.

Still, in some circumstances and for some people, it's a suitable treatment for obesity.

But not the way GET-THIN promotes it. The billboards have included disclaimers that Lap-Band surgery has certain "risks, side effects, and contraindications," and that you should check with your own doctor before undergoing the procedure. That caution was too feeble for the FDA, especially because the disclaimers appear in such tiny type that they're "illegible."

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The California insurance commissioner is investigating the Lap-Band industry for alleged fraudulent billings and misrepresented charges. Patient deaths and injuries have prompted a series of wrongful-death and personal injury lawsuits against GET-THIN, its affiliated surgery centers and doctors who performed the procedures. And a class-action lawsuit accuses GET-THIN of false advertising for failing to adequately disclose risks of the surgery and disciplinary problems of some of its doctors.

Hiltzik reported that the director of the L. A. County Department of Public Health complained about GET-THIN to the FDA, and the Omidis filed an administrative complaint against him, asserting that he was biased against them because he was a shareholder in Johnson & Johnson, which markets a competing weight-loss device they don't use. The director recused himself from matters involving weight-loss devices.

When the county coroner blamed the death of a Lap-Band patient at least partially on the "suboptimal" care she had received at a clinic affiliated with GET-THIN, the clinic accused the coroner's expert of a conflict of interest because she had once worked at UCLA, which they claimed was Lap-Band competitor.

As Hiltzik notes, the Omidis are less concerned about quality of care than they are in suing anybody who challenges their shaky performance. "[T]hey've sued me and my colleagues at The Times for reporting about them. So far, three of these lawsuits against us have been thrown out of court by state and federal judges. The plaintiffs have appealed the dismissals and filed more suits against us and commenters on our website.

"The public record is brimming with material — including complaints of wrongful death, negligence and irregularities in billing practices — that could fall well within the jurisdiction of several state regulatory agencies. It may be that the FDA has fired the first shot in what could be a barrage."

Although this is a local issue, the fact that the Feds have finally taken notice is a cautionary lesson for anyone in search of an invasive weight-loss treatment. Often, these patients are desperate, depressed and vulnerable to claims that aren't true, or only under certain conditions.

Always research the procedure to be informed about whom it suits, and what are the risks. Always investigate the background of the surgeon with your state medical board. Always investigate the facility at which it is to be performed with your state health department and insurance provider.

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