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## Lipodissolve proves popular despite lack of FDA nod

By Rita Rubin, USA TODAY

Many people celebrate their 50th birthday with a blowout party or an exotic trip.

Ellen Promisloff's wish list is not quite so glamorous.

"I've always said to my husband that for my 50th birthday, I want two things," Promisloff, 49, says. "I want long-term care insurance, and I want a tummy tuck."

Her husband can cross off tummy tuck. Promisloff now wears low-slung jeans to show off her newly flat stomach. Yet a scalpel never touched her abdomen. Promisloff swears by an increasingly popular and controversial treatment called lipodissolve, touted as a non-surgical alternative to liposuction.

The American Society of Non-surgical Aesthetics, a trade group, estimates that 50,000 to 100,000 lipodissolve treatments have been performed in the USA and Europe. That's nothing compared with the 300,000 liposuction procedures performed last year in the USA, but the lipodissolve group predicts its U.S. market will grow to 500,000 a year.

Lipodissolve practitioners inject small amounts of a chemical found in lecithin — better known as a food ingredient derived from soybeans — into pesky protrusions of pudge, aka love handles, muffin tops and bra rolls.

But phosphatidylcholine deoxycholate, the compound generally used in lipodissolve shots, isn't Food and Drug Administration-approved, so safety and effectiveness questions — namely, if the fat cells are dissolved, where do they go? — remain.

### Kansas moves to ban procedure

Promisloff, of Rockville, Md., says she did her homework before signing up in January at one of two Washington, D.C.-area MedSculpt centers. "The FDA thing didn't bother me at all," says Promisloff, who works in marketing and advertising sales. "They've been doing it in Europe for however long. There have been no cases of death or sickness or anything that would have dissuaded me." She says she spent \$2,500 to \$3,000 on four treatment sessions and plans more, this time for her flabby flanks.

Another satisfied customer, Jodi Kusick, 62, says "it kind of bothered me that it had been going on in other countries, but the FDA doesn't approve it yet." Still, Kusick, of Safford, Ariz., has periodically been making seven-hour round trips to Scottsdale for lipodissolve shots in her abdomen at Fig (for figure), one of a chain of centers based in St. Louis.

Luckily, Promisloff and Kusick don't live in Wichita. In a few days, lipodissolve might not be in Kansas anymore, except in clinical trials. On Aug. 18, the State Board of Healing Arts, which regulates Kansas doctors, became the nation's first to ban marketing and sales of lipodissolve, which was to go into effect this Friday. The Physicians

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Coalition for Injectable Safety, formed by three plastic surgery groups, supports the move.

Fig sought a temporary injunction, but the court did not reach a decision at a hearing Monday, says Mark Stafford, general counsel of the healing arts board. At a special meeting before the hearing, he says, the board moved to replace its permanent lipodissolve ban with a temporary ban to allow public comment on the move, which could still begin Friday.

The Kansas board has received complaints from lipodissolve patients of pain, nausea, diarrhea, elevated liver enzymes and lumps at the injection site, Stafford says. He acknowledges it's impossible to tell whether the side effects stemmed from the shots.

That's the problem, he says: "We don't know much about this product, because it has not been clinically studied. There might be some longer-range problems, but again, we don't know. If this product is as effective and safe as its proponents say, then let's have some clinical research."

The non-surgical aesthetics group says lipodissolve isn't a drug but a treatment, and treatments aren't FDA-regulated. And, proponents note, compounding pharmacists, who don't need FDA approval, make lipodissolve.

The FDA disagrees. "These are unapproved drugs for unapproved uses," spokeswoman Karen Riley said in an e-mail, noting the FDA is "investigating and evaluating" lipodissolve. Meanwhile, she said, "Consumers need to know that this is a buyer-beware situation."

### Too good to be true?

So far, though, the FDA has issued only one warning letter about lipodissolve, in 2003, to Ayoula Dublin in New York City. Dublin's website marketed phosphatidylcholine injections to "burn fat away," the letter said. The site claimed the shots were a nutritional supplement not regulated by the FDA. But supplements are swallowed, not injected, the FDA said, calling Dublin's product an unapproved new drug.

Dublin now sells lipodissolve pills. A check Monday of Dublin's website found this pitch: "These tablets contain the same active ingredients as the liquid injectable form that is applied to your problem areas. Instead of localized fat removal, you will get a complete body makeover." Messages to the website's phone number and e-mail address went unanswered.

Practitioners say they can't afford the clinical trials the FDA requires. "It's a multimillion-dollar thing to get something through the FDA," says Rockville, Md., plastic surgeon Roger Friedman, MedSculpt medical director.

"The FDA issue is a very important one," says St. Louis plastic surgeon David Caplin, Fig's national medical adviser. "The reality is that it's very expensive to take a new drug through" the FDA approval process, he says.

Yet, Kythera Biopharmaceuticals of Calabasas, Calif., recently announced that it is conducting clinical trials to win FDA approval for an injectable to trim double chins. And the Aesthetic Surgery Education and Research Foundation just received FDA permission to conduct a 20-patient trial comparing lipodissolve with placebo shots.

"While this does sound almost too good to be true," says Great Neck, N.Y., plastic surgeon Alan Gold, foundation president and president-elect of the American Society for Aesthetic Plastic Surgery, "hopefully this turns out to be something that is safe and effective for our patients."

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