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HEALTH JOURNAL

Popular Treatment That Aims To Melt Fat Draws Scrutiny

By RHONDA L. RUNDLE
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The rise of cosmetic fat-busting injections, called lipodissolve, is spurring warnings from doctors who are alarmed about the spread of the pricey procedures, which use concoctions that aren't approved by the Food and Drug Administration.

Lipodissolve, sometimes called medical lipolysis, is touted as a nonsurgical alternative to liposuction. It involves a series of tiny shots meant to melt fat deposits in various parts of the body, including bellies and buttocks.

The treatment, which originated in Europe decades ago, has been taking off in the U.S. on the wings of local ad campaigns. A number of medical spas -- which offer aesthetic treatments like Botox -- have begun doing lipodissolve. And specialty centers are popping up, such as a chain called fig., which operates 11 clinics in the U.S. and plans to open more this year. Fig. declined to answer questions about its business.

HEALTH MAILBOX

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But as the popularity of the injections has grown, so have complaints. Last month, the American Society for Aesthetic Plastic Surgery warned that the shots are "scientifically unproven, lacking any objective data on safety and efficacy." The surgeons' group, which is sponsoring human tests to evaluate one such treatment, urged the public "to steer clear" until more data come in.

Physicians who offer lipodissolve say the injections can be effective in skilled hands. Diane Duncan, a plastic surgeon in Fort Collins, Colo., cites a 2006 retrospective study that she co-authored in the Aesthetic Surgery Journal, based on data submitted by 75 physicians in 17 countries from 17,376 patients. The study found that roughly 12% of patients expressed disappointment with the aesthetic result. The authors concluded that the treatments have a good safety record; complications included temporary hyperpigmentation, pain and allergic reactions.

Many studies have been done in Europe and Brazil, adds Dr. Duncan, who says the injections account for about 10% of her practice. However, U.S. physicians say those studies don't meet rigorous scientific standards.

One fact isn't in dispute. There are no fat-busting injectables approved by the FDA. Practitioners use different recipes that are prepared by a compounding pharmacy or in a physician's office. Such custom mixes, using ingredients approved for other uses, fall into a regulatory gray area. One combination used by many practitioners is phosphatidylcholine and sodium deoxycholate, or PCDC for short. Phosphatidylcholine is a soybean-derived ingredient in food supplements; sodium deoxycholate is an emulsifier typically derived from cattle bile. Lipodissolve is often described as a form of mesotherapy, which may use different ingredients, including herbs, in its shots.

DETAILS

The components of PCDC, a compound often used in lipodissolve injections:

- **Phosphatidylcholine:** derived from soybeans; a common ingredient in food supplements believed to improve cardiovascular health.
- **Sodium deoxycholate:** an emulsifier typically derived from cattle bile.

Lipodissolve clinics say their injections are legal because states regulate pharmacy practice, including compounded drugs. Some doctors, however, including Joel Schlessinger, an Omaha dermatologist and president of the American Society of Cosmetic Dermatology and Aesthetic Surgery, have written to the FDA, urging the agency to halt "the practice of unapproved medicine."

Separately, Kythera Biopharmaceuticals Inc. of Woodland Hills, Calif., wrote to the FDA to request enforcement action against businesses that market PCDC for fat reduction. Kythera says it's conducting clinical trials under an investigational new drug application with the FDA of a proprietary drug to reduce fat deposits.

The FDA says that "in virtually all cases," it "regards compounded drugs as unapproved drugs." The agency says it's evaluating lipodissolve, but "we do not discuss pending investigations or enforcement matters."

Clinics typically sell packages of three lipodissolve treatments. Spaced a month apart, the treatments cost \$900 to \$2,000 for each body part. "We've mostly had people sign up for two areas, but plenty have three or four," says Matt Freeman, owner of Aurora Medical Spa in St. Louis, where he says lipodissolve accounts for 20% of his business.

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