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FDA Approves Wrinkle Filler; A Rival Frowns

By **RHONDA L. RUNDLE**

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The Food and Drug Administration has approved an injectable wrinkle treatment called Radiesse that its maker boasts lasts longer than rival treatments in temporarily correcting smile lines. The agency's action has sparked competing claims over whether Radiesse (pronounced Ray-dee-ESS) will prove cheaper and better over time than established wrinkle fillers like Restylane.

BioForm Medical Inc., which is set to announce FDA clearance today, is predicting that Radiesse will ignite the wrinkle-filler market with mainstream Americans who can't afford **Medicis Pharmaceutical Corp.**'s Restylane, the dominant player. BioForm says that Radiesse lasts a year or more, twice as long as Restylane and Juvéderm, a third rival that will be arriving in cosmetic physicians' offices in January.



KRT/NewsCom

A patient receives an injection of the wrinkle filler Restylane, which has a new rival as the FDA has cleared the use of Radiesse.


Restylane, twice a year, to achieve what one syringe of Radiesse can do for 12 months.

"Right now, [dermal] fillers are too expensive. Many people are thinking about these treatments, but aren't doing them. We will displace a lot of this market, but will grow it too," proclaims Steven Basta, BioForm chief executive officer. Radiesse

will cost a patient roughly \$850 a year versus \$2,400 for comparable enhancement with Restylane, he estimates. His estimate, based on average retail prices and including the physician's fees, assumes it takes two \$600 syringes of

Restylane, twice a year, to achieve what one syringe of Radiesse can do for 12 months. Medicis disputes that analysis, largely because it says Restylane lasts "probably well over a year with the second and third injection." The duration of a product's wrinkle-smoothing effect largely determines annual treatment costs. Costs also vary based on each patient's own face and physicians' professional fees.

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Fillers have become increasingly popular as an alternative to a face-lift, and consumer demand for them would explode if the prices dropped, analysts say. Cost has also discouraged the spread of "facial contouring," which requires several syringes of material.

While fillers are typically used sparingly to plump up wrinkly folds and creases in the lower face, larger quantities can restore volume to sunken cheeks. Many filler patients also use the muscle-relaxer Botox, typically around the eyes and forehead. Botox and Juvéderm are sold by **Allergan Inc.**, Irvine, Calif. BioForm is a closely held company in San Mateo, Calif.

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Radiesse has been sold in the U.S. since 2002 and was previously approved for certain facial reconstructive surgery procedures. Many aesthetic physicians have legally used it "off label" as a dermal filler, but the safety bar is higher for an elective procedure than for a medically necessary one.

Physicians can prescribe products for any use after the FDA has granted approval for one use. Mr. Basta says Radiesse shouldn't be used in the lips. It causes "lip nodules," but these are different from foreign body reactions, called granulomas, that need medical intervention, he says.

Beauty Shots

How two injectable wrinkle treatments compare

Radiesse

List price of syringe: \$295

Size of syringe: 1.3 cc

Duration*: 12-18 months

Typical uses: Smile lines, cheek augmentation

Restylane

List price of syringe: \$240

Size of syringe: 1.0 cc

Duration*: 6-12 months

Typical uses: Smile lines, lips

*Company's claim

Sources: the companies; WSJ research

BioForm maintains that Radiesse is as safe as other approved fillers, including collagen, for other parts of the face. In the FDA study of 117 patients who received Radiesse on one side of the face and a collagen, Cosmoplast, on the other, there was no difference in adverse events, says Lawrence Bass, a New York plastic surgeon and the study's lead investigator. As is common with all fillers, he says, some patients had swelling, redness, bruising and tenderness at the injection site for a few days.

Radiesse contains microscopic particles of a synthetic bone-like material, suspended in a white gel carrier.

BioForm says the microspheres create a scaffold that stimulates the growth around them of natural collagen. The FDA on Friday approved Radiesse for use in the so-called nasolabial folds, or smile lines, as well as for treatment of facial fat loss in people with HIV.

The FDA data didn't compare Radiesse to Restylane, which is hyaluronic acid. But BioForm says that a study by a German dermatologist, Marion Moers-Carpi, shows that Radiesse lasted significantly longer than Restylane and that it offered "better correction throughout the course of treatment." Experience shows that Radiesse lasts "on average 12 to 18 months," about twice as long as Restylane, Dr. Bass said.

Medicis is quick to point out that the longer-lasting treatment could have some negative effects.

"I can't comment directly on that study, except to say that the longer something lasts, the longer your adverse event can last," counters Mitchell Wortzman, executive vice president and chief scientific officer for Medicis, based in Scottsdale, Ariz. The European data on 'semi-permanent fillers' show a much higher risk of [a safety problem]" over time, he says. By contrast, "Restylane has a greater than 10-year history with over four million people world-wide injected."

Physicians who have used Radiesse say it lasts longer than Restylane but is trickier to inject. "I've been using it more and more, but it takes more time to inject than Restylane or Juvéderm, so I charge more," says New York dermatologist Rhoda S. Narins. Kenneth Beer, a dermatologist in West Palm Beach, Fla., says he has used Radiesse for four or five years. "For the right person it's great -- for men more than women," he says.

The questions about Radiesse safety appear likely to continue, despite the FDA's nod. Arnold Klein, a prominent Beverly Hills dermatologist, says Radiesse is harmful and he won't use it. Dr. Klein says he has a laboratory report from the University of California at Los Angeles showing that one Radiesse patient developed a granuloma.

Amy Newburger, a Scarsdale, N.Y., dermatologist on the FDA panel that reviewed BioForm's submission, voted against approval, citing a lack of long-term safety data and information about the science behind the product.

Some physicians who think Radiesse is safe are skeptical that the FDA approval will dramatically spur sales. Some doctors may shy away from a one-year filler because they want more frequent opportunities to sell patients skin-care products and other services. Also, Radiesse is already well-known to beauty mavens.

Patients read about it on the Internet, says Dr. Beer. "They are asking about it, but not clamoring for it. I don't see approval will change that."

Indeed, BioForm has for sometime been a highly visible presence in doctors' offices. In recent weeks, for instance, the company has been offering "holiday packs" to physicians who order a large quantity of Radiesse syringes. The pack includes a free 17-inch television, complete with side-loading DVDs, to put "in your waiting or treatment room to educate your patients about your practice and various treatment options."

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