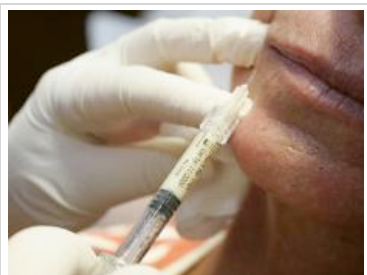


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**INJECTION:** Dr. Nancy Silverberg demonstrates Evolence, a new dermal filler from Johnson & Johnson, as she gives Lynn Vanderuk an injection.

STEVE ZYLIUS, THE ORANGE COUNTY REGISTER

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## Evolence enters the filler wars

New facial-fold fighter Evolence is coming to challenge Restylane and Juvederm.



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The makers of Botox, Juvederm and Restylane cosmetic injections are bracing for trouble.

The reason: Health care giant **Johnson & Johnson** is bringing its injectable wrinkle-fighter Evolence to the United States market starting this month.

Evolence poses a direct challenge to Juvederm, the up-and-coming filler from Irvine-based **Allergan**, and to Restylane, the filler from Scottsdale, Ariz.-based **Medicis Pharmaceutical** that was undisputed No. 1 in revenues before Juvederm came along in late 2006.

Competition in the filler market is good news for people who hate the deep folds that can develop in middle age between the nose and the corners of the mouth. With the arrival of Evolence, those patients will be able to choose from more varieties of filler to smooth away that sign of age.

Injections of fillers to soften those so-called nasolabial folds and to plump up lips, cheeks and other parts of the face are a multi-million-dollar business.

Last year, Americans had more than 1.6 million injections of fillers, quadruple the number a decade earlier, according to data compiled by the American Society for Aesthetic Plastic Surgery. Injection of a syringe full of filler typically costs \$500-plus, so Americans are spending more than \$800 million a year on those shots.

"It's pretty exciting," says dermatological surgeon Dr. David Sire of Fullerton about the commercial launch of Evolence, which is a form of collagen extracted from pig tendons. "It's easy to inject, and I've not seen any bruising yet."

The effects of an Evolence shot last at least six months, perhaps a year – as long or longer than the most popular fillers now on the market. Sire and many other doctors say Evolence also causes less redness and bruising than the leading fillers, Restylane and Juvederm. Both of them are made from hyaluronic acid, a component of human connective tissue in skin and joints.

"I typically bruise a lot with fillers, but I had no trouble with Evolence" says Yvonne O'Reilly, 49, of Huntington Beach, one of the first local patients to be injected with it.

O'Reilly, who is office coordinator for dermatologist Dr. Nancy Silverberg of Newport Beach, says she didn't even need to apply makeup to cover the Evolence injection site, as she does after injections of Restylane or Juvederm. Even before Johnson & Johnson starts its anticipated marketing campaign, patients are excited about Evolence and have signed up on a waiting list for the filler, which is expected to arrive "any day now," O'Reilly says.

Evolence, which has been used in Europe since 2004, also provides some competition for Botox, although it works differently from Botox and is too thick to smooth shallow wrinkles such as those of the forehead, as Botox can. Evolence is approved for use on the nasolabial folds, but some doctors also use it to remove wrinkles near the eyes by filling out the tissue underneath them. Botox, a weakened form of botulinum toxin, is also used against those wrinkles by blocking muscle contractions that cause them.

Allergan sees Evolence as a modified version of the collagen fillers that fell out of favor after hyaluronic acid fillers were developed.

"While it is a natural substance in essence, it is not natural to the human body" and must be modified to minimize the differences arising from its origin as pig tissue, said Allergan spokeswoman Leslie Bryant. "Given these key differences, we do not consider Evolence a direct competitor to Juvederm."

### **EAGER TO INJECT**

Silverberg says Evolence has the potential to remove patients' biggest criticism of fillers – that their effects fade too soon.

So far, the FDA so far has only authorized Evolence's maker, the ColBar LifeScience division of Johnson & Johnson, to label it as effective for six months, but the agency notes that clinical trials in Europe have shown that its effects last for up to a year. Juvederm works for up to a year and Restylane works for up to six months, the FDA says.

In her experience, Silverberg says, Restylane makes a difference for six months and Juvederm does for eight to nine months.

Dermatologists and other cosmetic doctors cite a variety of reasons for their enthusiasm about Evolence, which won FDA approval in June. After being trained in the use of Evolence during the summer, they're eager to start injecting it into patients.

"It's an exciting new product in the world of dermal fillers," says dermatologist Dr. Don Mehrabi of Beverly Hills. Unlike older types of collagen, "it does not require a skin test prior to treatment," he says.

"It provides instant correction," says Sire.

"Patients look good immediately after the injection with minimal swelling and therefore can return to normal social activities immediately," says plastic surgeon Dr. Michael A. Persky of Encino.

### **DRAWBACKS**

Doctors still have some reservations.

Dermatologist Dr. Arnold W. Klein, professor at UCLA's Geffen School of Medicine, isn't convinced that enough testing has been done to guarantee that Evolence won't sometimes cause allergic reactions, as older forms of collagen could. He also questions whether the particular type of collagen in Evolence will remain as flexible as when it's first injected.

"The composition of [its] collagen resembles what happens as the result of the aging process and can become hardened, so I have some concerns

about this product long term," Klein says.

Silverberg and others are waiting to see whether the effects of Evolence will actually last as long as they hope.

Persky notes that he tells his Jewish, Islamic and vegetarian patients that it's made from pig tissue, because they might object.

Evolence is too thick to be injected into the lips, but a thinner version called Evolence Breeze is available in Europe. Johnson & Johnson reportedly plans to seek FDA approval to market it here within a few years.

### COMPETITIVE THREAT

Dr. Christopher Zachary, head of the UCI Department of Dermatology, predicts that Evolence will soon gain fans among both doctors and patients because it is effective and easy.

"I believe it will be used extensively in the U.S.," he says.

Several doctors surveyed predicted that Evolence will account for 20 percent to 50 percent of their filler business by this time next year, if it performs as expected.

If that forecast is on target, Evolence would take millions of dollars of revenue away from Allergan and Medicis. Those companies' investors seem unconcerned, however.

Since the FDA approved Evolence in late June, shares of Allergan are up about 6 percent and Medicis is up about 3 percent. Like the wider stock market, both companies' share prices are down from a year ago.

From doctors' and patients' point of view, though, Evolence poses a threat to the dominance of those companies' fillers. O'Reilly, for example, expects that many women will prefer Evolence if it in fact causes as little swelling and bruising as it's supposed to, just as she experienced.

That would boost its appeal to women who don't want their husbands to know they're getting injected with fillers.

"With Restylane and Juvederm, they do it when their husbands are out of town," O'Reilly says. That allows time for side effects to vanish before the spouse returns.

With Evolence, women should be able to schedule an injection session when their husbands are in town, even on the day of a holiday party where they want to look their best, she says.

"No one needs to know," she says.

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