

Will Wrinkle-Smoother Restylane Be Approved as Lip Enhancer?

An advisory panel to the Food and Drug Administration will vote today (April 27) on whether to recommend the injectable filler Restylane for use as a lip enhancer. But future FDA approval may not make a difference in how the dermal filler is used in clinical practice, doctors say.

If the advisory panel votes to recommend Restylane for use in the lips, that information will then go to the FDA, which will then vote for final approval, said FDA spokeswoman Karen Riley.

Restylane works by adding volume to facial tissue with injections of hyaluronic acid, which is produced by bacteria. The results last for about six months, according to the FDA.

The filler was approved by the FDA in 2003 to [smooth deep wrinkles](#) like the nasolabial fold -- the line that forms between the side of the nose and the corner of the mouth -- but it's often used for off-label purposes, like to enhance, define and plump up the lips, said Dr. Farhad Rafizadeh, a plastic surgeon who has a private practice in Morristown, N.J.

However, FDA approval for Restylane to be used in the lips likely wouldn't make a difference in his own practice, said Rafizadeh, who already uses it for that purpose with his patients.

"It doesn't make it any safer or any more dangerous," Rafizadeh told MyHealthNewsDaily. "It is what it is."

[Injectable dermal fillers](#) like Restylane are extremely popular in the United States, with more than 1.2 million people getting hyaluronic acid injections in 2010, according to the American Society of Plastic Surgeons.

What Restylane does

Rafizadeh sees at least a couple patients a month who are seeking plumper lips. He often recommends Restylane because it stays put and doesn't seep into other areas of the face as other dermal fillers, such as Juvederm, do.

"The difference is Restylane is like Jell-O and Juvederm is like honey, which is a liquid and it tends to diffuse more," he said. While Juvederm is also effective at plumping the lips, "Restylane allows me to [define the shape](#) of the lip in a more precise manner."

Rafizadeh always has a [conversation with his patients](#) before the procedure to explain that Restylane is only FDA-approved for the nasolabial fold, but is effective for other uses as well, he said.

The filler can also be used for the tear trough (the saggy skin under the eyes) and frown lines, he said. It can also be used to make earlobes appear more youthful.

Off-label use and FDA approval

Dr. Judith Hellman, a New York City-based dermatologist in private practice, also said an FDA approval wouldn't impact her business much. However, it could help less-experienced doctors feel more comfortable using Restylane if they are afraid of using products for non-FDA-approved purposes.

Hellman said she and many other doctors are confident in using Restylane for off-label use because its off-label purpose is the same as the FDA-approved purpose -- to fill in pockets beneath the skin.

"Once the substance is approved for a certain application, using it off-label is not as severe as taking a substance that's not approved by the FDA and then injecting it or applying it to a human being," Hellman said. "So off-label use is a little bit different from not using something that's not approved at all."

It's legal for doctors to prescribe drugs for off-label uses—meaning, uses that aren't approved by the FDA and aren't marketed by the drug manufacturer. But for a drug manufacturer to be able to market a drug for a certain purpose, it has to have FDA approval (along with studies to prove its effectiveness) for that purpose, she said.

But ultimately, the success of the [cosmetic procedure](#) always depends on the expertise and experience of the person conducting the procedure, Hellman said.

"As long as it's done carefully and not overdone, and in the hands of somebody who has a lot of experience with fillers in general, it's a routinely and successfully used filler, including for the lips," Hellman told MyHealthNewsDaily.

Pass it on: An FDA advisory panel will vote today (April 27) on whether to recommend the dermal filler Restylane for the lips (it's already approved for filling facial wrinkles). But doctors say FDA approval would make little difference in their practice.

- [7 Foods You Can Overdose On](#)
- [5 Ways Relationships are Good for Your Health](#)
- [7 Weirdest Medical Conditions](#)