



FASHIONISTA

The Danger of Using Injectables Like Botox for Off-Label Proposes

Welcome to the wild, wild West of aesthetics

By Jessica L. Yarbrough | July 17th, 2019



To be fair, science isn't static. Medicine is constantly evolving, and cutting-edge innovations — from anti-inflammatories to fillers — are often built on uncharted territory. "Imagine the first person who ever injected Botox," muses [Dr. Anna Guanche](#), a board-certified dermatologist and celebrity beauty expert based in Calabasas, Calif. "It's a toxin, it's a poison. It was 1971 and somebody injected freakin' poison into someone and we slowly, slowly got used to the idea that it's a purified toxin, and it's not going to give you botulism."

She tells Fashionista that "every new frontier has its terrifying stage," which is more or less true. But considering the fact that the "terrifying stage" of injectable experimentation takes place on your face, you should be fully aware of the risks (and rewards) before you go off-label.



WHAT TREATMENTS ARE APPROVED BY THE FDA?

On-label use is otherwise known as "approved treatment area" use. "An 'approved treatment area' means that a product has been evaluated and approved by the FDA to help a specific indication for that area," a representative for Allergan, the maker of Botox Cosmetic and Juvéderm, tells Fashionista. "In order for a treatment to receive FDA approval, it needs to prove its efficacy by meeting certain criteria defined within clinical trials."

Clinical trials can take years and cost millions of dollars — even billions, according to Dr. Guanche — so it's no surprise that there are fewer approved treatment areas than there are off-label options.

Botox Cosmetic and other neurotoxins are FDA-approved for the crow's feet, frown lines and forehead lines. Dermal fillers, including Juvéderm in its many forms — Ultra XC, Volbella XC, Voluma XC, et al. — have been cleared for use on the lips, nasolabial folds, cheeks and "moderate to severe facial wrinkles and folds," according to Allergan. Kybella, an injectable that destroys fat cells, is only approved for use under the chin.

Approved treatments still come with potential complications, which are thoroughly outlined in ads and on the pharmaceutical companies' websites. "The risks of Botox include droopiness, asymmetry, infection at the injection site, bruising and allergic reaction," Dr. Guanche summarizes. "The risks of filler include infection, bruising, allergic reaction, redness and swelling, vessel occlusion or blockage and poor cosmetic result." Most unfavorable outcomes involving fillers can be reversed by dissolving the filler with an enzyme treatment, if caught in time.

WHAT TREATMENTS ARE CONSIDERED OFF-LABEL?

"Off-label means the FDA hasn't approved the injectable for human use, but the doctor has determined it's OK to use it on a different area of the body, based on their knowledge of anatomy," Dr. Guanche explains. Essentially, once a pharmaceutical has been cleared for human use in any capacity, licensed medical practitioners have the right to determine the best way to employ said pharmaceutical based on the patient's needs.

This kind of carte blanche power is a holdover from a time long before injectables were a thing. "We've been doing this for many years; for example, antihistamines are approved for seasonal allergies, but we use them for eczema," Dr. Guanche says. "Tetracycline is approved for infectious diseases. Rosacea is not infectious, it's inflammatory, but we use it for that."

The dermatologist notes that since doctors go through at least eight years of medical training, they're deeply aware of the anatomy of the face — what nerves are where, what areas to avoid



and so on. Based on this knowledge, it's common for doctors to extrapolate information from one clinical trial and apply it to a new use scenario. "As far as injectables, Kybella is for the double chin area and it's been studied extensively for faces — but we know it can get rid of little bulges of bra fat," Dr. Guanche says. "In this particular case, understanding there are more sensitive nerves in the chin and neck area, and Kybella is approved for that area, we can extrapolate and know it's OK for use in [a less-risky] area."

That's not exactly how most off-label experimentation works, though. Considering the common use of fillers in the tear troughs (right under the eyes) and liquid rhinoplasties (in the nose), it could be argued that the majority of off-label innovations, uh, swing the other way: They take clinical trial findings from one area of the face and apply that information to an area with significantly more risk.

Some popular off-label treatments include: Tear trough fillers; nose reshaping with fillers; the "Botox brow lift;" fillers around the jawline; neurotoxins around the jawline; "Baby Botox," a shallow injection of the material aimed at millennials; chin reshaping (with anything other than Kybella); Botox on the neck; the "Botox Lip Flip" and "skin Botox," an injection of Botox into the pores to tighten and create an air-brushed look. Basically, anything you need for an Instagram Face.

"Allergan does not promote or teach off-label uses of our products," the company says in a statement to Fashionista.

HOW DO OFF-LABEL TREATMENTS START?

While the makers of substances like Botox and Juvéderm train doctors on how to administer these materials, they are legally only allowed to educate on the approved treatment areas.

When I heard this, I had a lot of questions: How do dermatologists come up with these new injectable creations, then? How do they know it's going to work? Who do they experiment on? How does it all happen??

Dr. Guanche pauses. "Hmm, how does it happen?" She eventually explains that skilled injectors have an innate knowledge of both injectables and the anatomy, and trying something new isn't the terrifying process of trial-and-error I'm imagining. "I've been injecting for 16 years," she says. "I think I've injected 9,000 syringes of Juvéderm alone and I've probably done about 25,000 injectable procedures. All day, every day I'm injecting. I think it's a natural progression."

The board-certified dermatologist — who is Olivia Culpo's go-to dermatologist, by the way — is something of an innovator in the space. Besides offering an array of common off-label procedures in her practice, she's pioneered (and trademarked) the "GuancheLift," a technique



she now independently teaches to other dermatologists. It involves injecting an off-label mix of Botox and Juvéderm around the lower face and neck and into the hairline, to "redistribute the jowls" and fake the effect of a face lift in about 30 minutes.

The idea materialized after her own consultation for a surgical face lift. The cost (\$72,000) and the recovery time (six weeks) were far from ideal. "I thought, why don't we put fillers in some of those places and see if we can get the skin to lift?" she says. She revisited anatomy texts, analyzing the risks of injecting around the temples and above the mastoid bone. She found no history of vessel occlusion — the most serious risk of fillers — in those areas. "So I tried it on myself, and I was very happy," she says. Yup, Dr. Guanche is her own "patient zero," and doesn't offer anything to clients that she hasn't first attempted on herself.

THE RISKS OF OFF-LABEL INJECTABLES

Dr. Guanche asserts that the risks of neuromodulators and fillers are pretty much the same no matter where you put them, which is true, if not a little misleading. Take vascular occlusion, for example, which is a fancy way to say "blocked blood vessel."

In rare and extreme cases, there's also the risk of blindness. This happens when blood flow to the eye is interrupted by an occlusion.

If the injector immediately notices that something doesn't seem right — say, the skin starts turning red or swelling — it can be reversed with the use of an enzyme to dissolve the filler. (Although in cases where blood flow to the eye is concerned, it is recommended for injectors to refer patients to an on-call ophthalmologist ASAP.) "Using an enzyme is also off-label, since it's not medically approved for dissolving filler — it's for opening up the tissue so antibiotics can get in better," adds Dr. Guanche.

Luckily, these outcomes are exceedingly rare. One ten-year study published in 2014 showed that only 0.05% of filler treatments resulted in vascular occlusion. Dr. Guanche says she sees "a true vessel occlusion" maybe once a month in her practice.

WHAT TO ASK BEFORE GETTING AN OFF-LABEL TREATMENT

Dermatologists agree that although the risks associated with off-label offerings are pretty rare, you can further mitigate that risk by following a few safety guidelines.

First: Please, do not get your injectables done at a medspa. And definitely don't get them done at a party. "If you're at a medspa or somebody's party, they don't necessarily have the infrastructure in place to address [complications]," Dr. Guanche says, noting that a doctor's



office should always have dissolving enzymes and other solutions on hand to treat poor outcomes ASAP.

Next, thoroughly research injectors in your area. You can learn a lot from Instagram comments and Yelp reviews, says Dr. Antunes. "Even with all of that information, I think the best thing is a face-to-face consultation," he adds. "Make sure you feel comfortable."

During the consultation, don't be hesitant to ask questions. Doctors do not legally have to disclose to you that they've never done a particular off-label injection before, or if you'd be their first — so be direct. After discussing the treatment plan, ask: Is this off-label? How often do you perform this procedure? Am I your first patient for this specific treatment? What measures do you have in place in case of complications? Oh, and you're a licensed injector, right?

"There should be warnings out there that off-label is higher-risk," Dr. Guanche says. "But when it's done in the hands of someone who's fully trained and has years and years of experience, it's less risky."

<https://fashionista.com/2019/07/off-label-injectables-botox-dangers>