

The New York Times

Psst: Want to Buy Some Wrinkle Remover?

Restylane isn't legal here, but that isn't stopping some from using it.

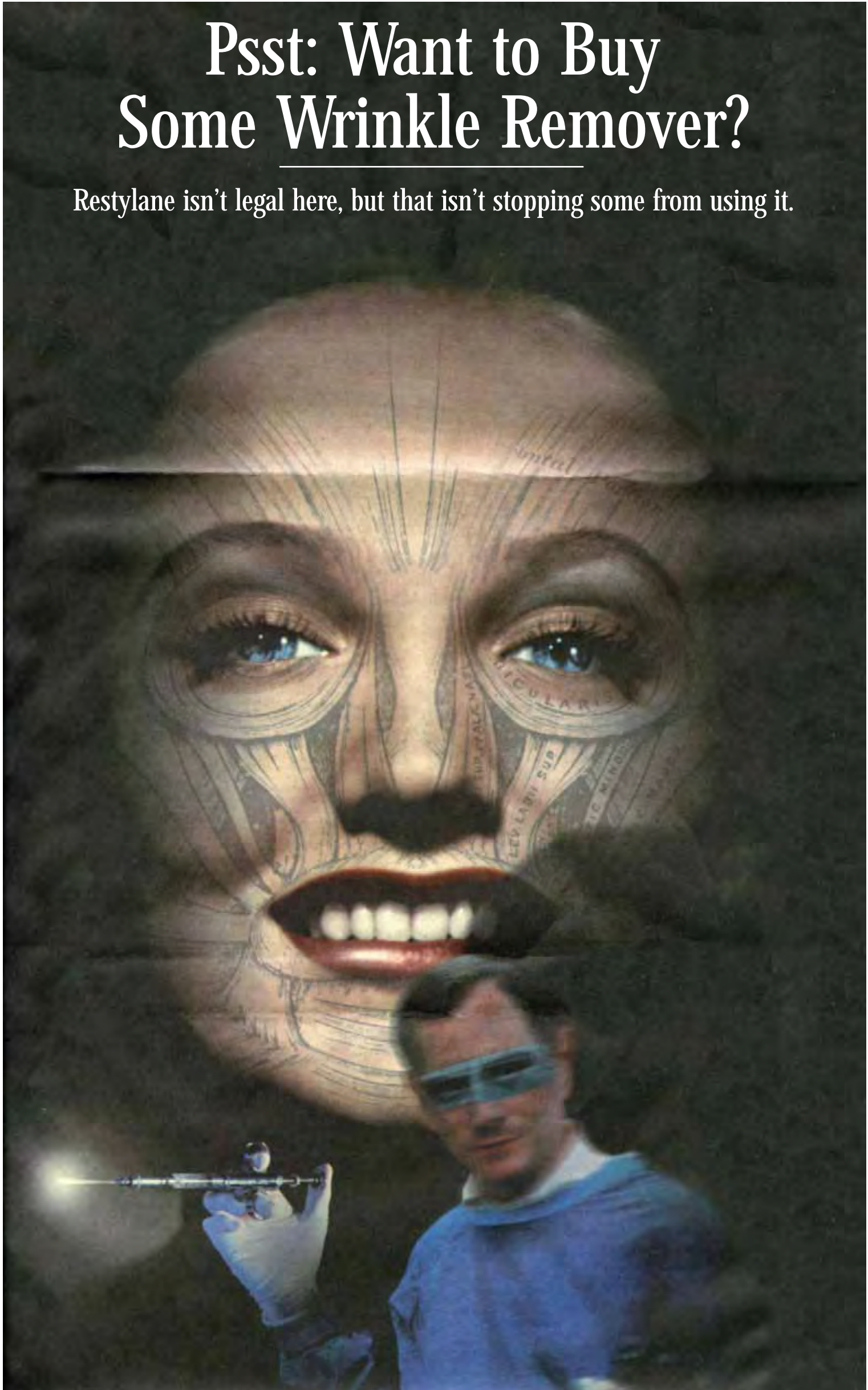


ILLUSTRATION / VIKTOR KOEN

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KEVIN VAN PAASSEN



THE CANADIAN CONNECTION: Dr. Trevor Born, a plastic surgeon who administers Restylane, the Swedish skin plumper, to patients in Toronto, where it is legal. The United States has yet to approve its use.

Last Monday afternoon, a 39-year-old woman reclined on an examination table in the office of one of Manhattan's most prominent plastic surgeons. He swabbed alcohol on her cheeks, and gently pumped a syringe filled with a clear mucus-like substance. A droplet rushed to the needle's end and hung there, looking like a National Geographic photograph of a suspended Amazon raindrop.

The doctor injected a tiny amount of the goo into the deep wrinkles running from the sides of the patient's nose to the corners of her mouth. A small mound formed under the skin. Then he made more injections, until there was a string of half-dozen tiny bumps. He massaged the bumps until they flattened out the wrinkle, and presto, in about 10 minutes, with just a hint of redness, the fold of age were restored to the plumpness of youth.

The problem is, procedure was illegal (and the doctor, to protect himself, did not want to be named). The injected liquid was Restylane, a filler that functions like collagen as a skin plumper, and has been shown by a study to last twice as long, but it is not yet approved by the Food and Drug Administration for any use in human beings.

Nevertheless, for a certain cadre of pampered patients and their doctors, Restylane is the hottest new tonic in elective cosmetic surgery today, propelling doctors to buck F.D.A. regulations and ship Restylane into the United States, or have their patients bring it to them from foreign countries – typically Canada, France or Australia.

Doctors who have the drug mailed to them from abroad and who inject it into patients could be putting themselves at risk for malpractice suits, professional rebuke and, in extreme circumstances, revocation of their medical licenses, even though enforcement is unlikely, according to government agencies.

Word of mouth about Restylane is leapfrogging from lunch tables on the Upper East Side to Beverly Hills dinner parties attended by the perpetually, suspiciously young, and patient demand is only increasing. And doctors are obliging.

Calls to 61 plastic surgeons and dermatologists in Manhattan yielded 11 whose receptionists said that they would administer Restylane, at prices that ranged from \$750 to \$1,500 per treat-

ment. Several of the receptionists enthusiastically promoted its benefits with no prompting.

"Nobody will say they are using it, but believe me there are lots of little emoles bringing it into the country," said Dr. Pat Wexler, a dermatologist in Manhattan. "You go to your doctor and they will go to the cabinet and unlock it and tell you not to tell anyone. Nobody is going to admit to it."

Manufactured by Q-Med, a Swedish company, Restylane is freely available in 60 countries, including Canada and Britain, for the spackling of lines and wrinkles. Some clinical trials report that Restylane lasts longer than collagen, up to one year for the treatment of wrinkles and six months as a lip plumper.

A New York woman in her 50's said that she got her first Restylane shots about six months ago, supplied by her doctor, after hearing about the drug from fashion-industry friends, who buy a related product, Juvederm, in France and bring it home.

"Look, this stuff is in use everywhere else on the planet," said the woman, who spoke about her treatment on the condition that her name not be used because she did not want to put her doctor in legal jeopardy. "I trust my doctor," she said. "And after all the work and money we have put into my face, she is not going to put anything in it that is going to make it fall apart,"

Restylane "gives wonderful results," said Dr. Lisa Airan, a New York dermatologist whose penchant for Manolo Blahniks has landed her in the pages of several fashion magazines. She said she injected clients who brought back the substance from abroad. You can give someone a prescription and they can get it filled in Canada or give them a prescription for Juvederm and they get it filled in Paris and bring it back here." Such use, unless it is part of an approved clinical trial, is a violation of federal law, the Food, Drug and Cosmetic Act, according to an F.D.A. spokeswoman.

Restylane is a commercial name for a synthetic form of hyaluronic acid, a mucus like substance that occurs naturally in human joints and skin. According to Q-Med, the company that makes Restylane and its counterparts, Perlane and Restylane Fine Lines, patients do not need to be pre-tested for allergic reactions because the drugs are synthetic – unlike collagen, which is often derived from bovine sources

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or other collagen like fillers, some of which are derived from human cadavers.

Charla Krupp, a style contributor on the "Today" show, who has used both collagen and Restylane, said that she never felt anxious about Restylane's legal status. "It's safe in London and Paris and Canada and most of the Western world," Ms. Krupp said. "It's amazing. Why do American women have to wait so much longer?"

Dr. Michael A.C. Kane, a plastic surgeon and the author of "The Botox Book" (St. Martin's Press, 2002), believes there are dozens of dermatologists in Manhattan using Restylane. "I'd say there are about 50, and you may be able to find them, but they won't want to be found," he said.

In some instances, doctors who are not using the drug legally will ask a patient to sign a release form as protection from future lawsuits.

Only doctors using Restylane as part of a clinical study are using it legally, said Sharon Snyder, a spokeswoman for the F.D.A., which has the drug under review. "But otherwise, it is not an approved product. If they are shipping it into the country and using it, that is not within our guidelines."

Nevertheless, it seems doubtful that any government agency is going to go after doctors or patients who use Restylane. In theory, the New York State Department of Health could reprimand a doctor or, at the remote edges of possibility, act to suspend his or her medical license, according to Kristine Smith, a department spokeswoman, but in practice the likelihood is remote. "It is not just a matter of someone saying, 'Hey I heard this doctor is using a medicine not approved by the F.D.A.,'" Ms. Smith said. "Can we prove the doctor was negligent or incompetent? Would other experts in the field consider the care to be substandard?"

The status of Restylane differs from that of Botox, the wrinkle-erasing toxin, which prior to its approval by the F.D.A. last year for cosmetic use was allowed as a treatment for neuromuscular disorders. Doctors who used Botox as an "off label" treatment to soften wrinkles were not violating any laws or F.D.A. guidelines.

Demand for Restylane in the United States started percolating in 1998, when Canada approved its use. Now, according to some doctors, interest has reached feverish levels.

"They ask about it every week," said Dr. Rod J. Rohrich, the president-elect of the American Society of Plastic surgeons and the chairman of plastic surgery at the University of Texas Southwestern Medical Center in Dallas. "There is a big, big demand for it."

Dr. Michelle Copeland, a plastic surgeon and the author of "Change Your Looks, Change Your Life: Qhix fixes and Cosmetic Surgery Solutions for Looking Younger, Feeling Healthier and Living Better" (Harper Resource, 2002), said that her patients are champing at the bit to try Restylane.

"They hear one of their friends say they tired it and say, Hey, she looks good," Dr. Copeland said. "It is just another thing we have in our armamentarium. The fact that is non-animal is attractive, and it seems more natural and flows really nicely."

That said, she normally does not use drugs that are not F.D.A., approved on patients. "If we do, we open ourselves up to the malpractice," she said. "But there are a lot of doctors who will do it."

Many doctors are annoyed by what they see as foot-dragging by the F.D.A. "The F.D.A. in this case is being a bit overcautious because Restylane has been used in so many countries and so many good places like Canada," Dr. Rohrich said.

"People are tired of collagen," Dr. Rohrich added. "It has minimum effects and requires multiple injections,"

Dr. Steven Teitelbaum, a plastic surgeon in Los Angeles, said that he does not use Restylane because he finds that the scalpel is more effective than wrinkle fillers, but added that Restylane can bring in a fast income, which makes it attractive to doctors.

"Look, dermatologists are not making a living doing mole checks because the insurance company pays them \$13.75 for each one," he said., Restylane, he said, is an immediate cash infusion for the doctor.

Approval may come soon. Restylane is under consideration by the F.D.A., according to Q-Med, and has been undergoing medical trials. Medicis, the Arizona company that last week bought the right to distribute the products in this country, expects approval of Restylane as early as this July. The F.D.A. said it does not comment on the timetable for drugs under review.

There are downsides to Restylane, however, including the fact that it is not supplemented with any kind of anaesthetic, so the pain of injections if often howl-inducing. (Certain brands of collagen, by contrast, are augmented with lidocaine, which numbs the treatment area as it is injected.) Doctors can apply an anaesthetic to numb the pain.

Nor is Restylane entirely free of complications. Dr. Trevor Born, a plastic surgeon in Toronto who administers it, said that he has heard of some adverse reactions.

"There have been reactions, such as patients who develop draining cysts," he said. "But in the 3,001 I have treated, I had one patient who had some redness for about three weeks and that was it."

Dr. Arthur Caplan, the director of the Centre for Bioethics at the University of Pennsylvania, said that he was disturbed that any doctor in this country would use Restylane without government approval.

Remember silicone, he said, which was also a harmless substance that could not interfere with the body's natural processes, and then came under fire for causing health problems. (The ultimate safety of silicone is a subject of continuing controversy.)

"The thing to think about it is that If you are wealthy enough to get your wrinkles stuffed, you might want to be smart enough to ask your doctor, 'Is this safe? Why hasn't it been approved yet?'" he said.

But in New York, where the gotta-have-it, gotta-buy-it mentality reigns, patients are too needy.

"We have fat, collage, and now we have this," Dr. Wexler said. "I can tell you that for now, Restylane is on everybody's lips."

She paused and added: "And in everybody's lips."



BEAUTY IN A BOX: The product, ready for injection.