

The rise in black market aesthetic products

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The increasing availability of black market products is reshaping the practice of injectable treatments. Wendy Lewis investigates how practitioners and industry are fighting back



Liquid facelifts rank among the most popular non-surgical cosmetic procedures, but the growing demand for toxins and fillers has triggered a rise in illegal injectable products that has become a worldwide epidemic. The availability and use of fake products has emerged as a mounting problem for the aesthetic market as a whole, as doctors report that they are being inundated with offers from offshore vendors pitching cheap toxins and fillers not approved for sale in the EU or the US.

The 'black market' or 'fake market' is an illegal traffic or trade in officially controlled or scarce commodities. However, there is a distinction to be made between a black market trade that is itself an illegal act, and a situation where the goods may or may not themselves be illegal to use or trade through other legal channels. This underground market incentivises practitioners to purchase merchandise, medicine, and medical devices at very low costs and without being taxed, which in turn they sell to consumers at a lower price point as well.

The other side of this equation is that some of these products may be fakes, counterfeits, and knock-offs of patented and licensed products, which poses an even greater threat. Counterfeit products may also be contaminated, or contain the wrong ingredient or a substitute ingredient, or no active ingredient at all. They could also have the right active ingredient but at the wrong dosage. The possibilities are endless and may potentially have lethal consequences. There is an inherent global consumer safety risk when products that are not regulated are being used in such a way that governing agencies cannot monitor who is doing what to whom. In this manner, adverse events are not recorded, patient treatments may not be documented, and there is no way to track any of it.

According to the US Food and Drug Administration (FDA), the reimportation of a pharmaceutical product is illegal, as is the sale of these products, receiving these products, and administering them. Medications that are not approved by the FDA may lack necessary and required labelling to assure their appropriate and safe use¹. The FDA encourages physicians and consumers to report any suspected criminal activity to the Office of Criminal Investigations (OCI).

The sheer number of illegal fillers being marketed from unofficial vendors is confirmation that not enough is being done to identify clinics and practitioners who are buying illegal fillers and injecting patients. There are, however, some steps in place that are intended to guide consumers to protect themselves. For example, the US FDA's website contains a list of approved fillers². Major manufacturers post photographs of their products and logos, and a list of legitimate providers under the 'physician locator' section of their consumer websites. Professional medical societies like ASAPS, ASDS, AAFPRS, and others advise consumers to check the websites of state medical boards to verify that the doctors they consult with are licensed and board certified in the specialties they are claiming to be, such as dermatology or plastic surgery. But the industry as a whole agrees that much more needs to be done.

Just recently in May 2014, Aphrodite Advanced Esthetic & Skin Care Clinic received illegal imports from Gallant Pharma, which sold over \$10 million of non-FDA-approved chemotherapy and cosmetic drugs in the US. Anoushirvan Sarraf, a physician who owned the McLean, Virginia clinic, was convicted of illegal importation, receiving and delivering non-FDA-approved drugs and devices, and engaging in the unlicensed wholesale distribution of prescription drugs. He was convicted of nine felonies and four associated misdemeanours, and his office manager was convicted of one felony count of conspiracy. Sarraf faces a total maximum penalty of 87 years in prison, while his office manager faces up to 5 years in prison³.

'Products that are illegally imported may be counterfeit or the quality may have been compromised,' said Philippe Schaison, President, Allergan Medical. 'Allergan takes many steps to protect against illegal product importation of BOTOX® Cosmetic in order to ensure the safety of patients. For example, only authentic BOTOX Cosmetic vials have a sophisticated hologram image that says 'Allergan.' The authentic BOTOX Cosmetic box will also indicate if the product is packaged for use in the United States by a US license number that is located on a side panel. The US license number is also located on the product vial. In addition, authentic BOTOX Cosmetic package is stored and transported by Allergan according to rigorous specifications and standards, which is why it's critically important that healthcare professionals purchase BOTOX Cosmetic directly from Allergan or from Allergan-authorized distributors. Physicians may contact Allergan to confirm whether the distributor they intend to purchase BOTOX Cosmetic from is an authorized distributor of the company.'

Illegal versus counterfeit fillers

Although the US has the tightest regulations in the world, in other countries, regulations are not always enforced. Non-FDA approved products are considered to have less quality control. According to Facial Plastic Surgeon Jonathan Sykes, MD, in Sacramento, California, and Past President of the American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS): 'For instance, products approved in Europe only have to show efficacy and not long-term safety. The FDA process holds product approvals to a higher bar. FDA approval indicates a level of quality that is unsurpassed in any other country.'

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But according to the US FDA, the supply chain has become increasingly complex beyond US borders in the form of counterfeiting, diversion, cargo theft, and importation of unapproved or otherwise substandard drugs or medical devices⁴.

'There is a big difference between the CE countries that are much more closed to counterfeit products in relation to a high level of legislation, and the Eastern European and Middle Eastern countries that are less closed. However, even in these countries, legislation is in progress,' said Paris Plastic Surgeon Benjamin Ascher, MD.

Many of the counterfeit products entering North America and Europe are being imported from China, India, Pakistan, and other countries in Asia, which is considered the biggest producer of counterfeit injectables and other medical products and drugs in the world. Asia remains the number one region to watch when it comes to counterfeits, not only on the filler and toxin side, but also for lasers and energy based devices. There is also a steady stream of look-alike products that claim to have the same ingredients, mechanism of action, and uses as the brand name product or market leader, but are sold under a different name, which can be confusing. Regardless of the precise method of subterfuge being used, fake products cast a wide net to include anything that is misrepresented in an effort to deceive physicians and consumers.

'There is a huge gap between Japan, Korea, Hong Kong, and Singapore, which have a higher level of regulation compared with other less restrictive countries. But legislation is in progress as well in countries like China,' said Ascher.

Faux doctors

There is not just the problem of illegal product being smuggled across our borders. Another growing predicament is the proliferation of unlicensed practitioners making their way into the US, UK, and many other countries, who are eager to get their piece of the aesthetic injectable pie at any cost.

For example, unlicensed practitioners operating in the US may include doctors trained in other countries, nurses, medical aides, and even cosmetologists, who attract patients with low fees, a willingness to use cheaper illegal fillers (most especially permanent fillers), a non-threatening atmosphere, or the convenience of not needing to make an appointment well in advance. Consumers are largely unaware of the potential consequences of being injected with unknown substances in unsanitary locations, like hotel rooms, apartments, and basement clinics.

Many illicit treatments are offered by immigrant practitioners working in the country, as well as foreign practitioners who fly in or take the train across the border to treat clients at regular intervals. In regions where there is an influx of people who received their medical training elsewhere, the practice is more commonplace. When some foreign-trained doctors get frustrated trying to pass American medical exams, they may decide to risk practicing without a license. Among the locations where this occurs, South Florida, Southern California, and Texas top the list. New York, London, and Dubai are also subject to this growing problem.

In addition to women looking for bargains, the clients for black-market treatments include transsexuals seeking to augment breasts and buttocks with large volumes of silicone. Patients may just not be able to afford to go to legitimate doctors, or they want procedures that reputable practitioners may consider too dangerous or risky, or they are looking for cheaper alternatives to brand name treatments. But that is not where it ends. Educated women of means are still attracted to the modern version of 'BOTOX® parties'. Usually one woman tells her friends that she is having someone come to her house or she is going to a hotel room to have something injected. If the friends trust her and she looks great, they may be lured into coming along for a treatment too. Patients who trust the recommendations of their friends and family are more inclined to go to unlicensed practitioners without checking on their credentials.

The explanation that consumers offer as to why they seek cosmetic treatments from amateurs is often that they believe that just because someone does not have the proper credentials in the country where they practice, he is still a doctor, so it should be safe. In some cases, consumers just do not know that they are going to an unlicensed doctor, or someone who is not trained as a doctor in any country at all. People are so anxious to have cosmetic procedures that a recommendation from a friend, colleague, manicurist or hair stylist can be deemed more important than a valid license.

Perhaps the best example of this is the incidences of failed buttock injections. According to Las Vegas Plastic Surgeon Michael Edwards, and President of the American Society for Aesthetic Plastic Surgery (ASAPS), 'Currently there is no FDA approved injectable for use in buttock augmentation procedures. We have seen numerous reports of unscrupulous providers, some with no medical training, who manage to convince patients that a substance can be injected into the buttock to achieve the desired effect. Reports have included the documentation of substances like industrial grade silicone, mixed with motor oil, concrete, or even super glue being injected into unsuspecting patients that has resulted in disfigurement and in some cases, even death.'

Some practitioners try to convince patients that silicone, medical or non-medical grade, is safe for injection into the buttock area. Edwards refutes this theory: 'Silicone is a substance that can, like any substance, be absorbed into the blood, travel to the lungs, and become fatal because it blocks oxygenation.'

Educating consumers

According to Oculoplastic Surgeon Steven Fagien in Boca Raton, Florida, 'The biggest problem relates to the fact that a significant number of these patients have no idea about what product had been injected and more often enter into these situations thinking that these are 'good deals' with regard to price and convenience. These patients fail to understand that the product can be as important as the injector yet they will become victim to poor technique and lack of adequate sterility as well as products that are not approved and are comprised of substances that can be harmful as well as likely to cause long-term problems. Some of these filling agents are more likely to cause reactions (granulomas) or prone to infection that can be related to lack of adequate hygiene but also to ingredients that are more likely to become infected.'

When these sorts of complications arise, patients will see another doctor when the treating injector fails to remedy the situation, and the new doctor has no idea how to best treat the problem mostly because they do not know the composition of the product and/or how to manage the complication.'

London based Plastic Surgeon Rajiv Grover, and President of the British Association of Aesthetic Plastic Surgeons (BAAPS), explains that there are two elements to this problem. 'First is the issue that patients do not always ask what is being injected into them. This stems from their trust of the practitioner, but especially with fillers it is essential they ask this. Second is the lack of scrutiny some practitioners give to sourcing their products and choosing not only a good tried and tested product but also purchasing from a trusted source. Clearly the patient's interests should always come before the possible slight increase in profit from choosing a cheaper product or buying from an unreliable source.'

It should also be noted that it is technically unlawful for a practitioner to tell patients that he or she is using BOTOX from Allergan (Irvine, CA) or Restylane® from Galderma (Uppsala, Sweden), when he is actually using another brand or product entirely.

Jim Hartman, Vice President of Merz Aesthetics, recognises that this is an ongoing problem that isn't going to go away overnight. 'Wherever there is opportunity, people are going to try to get around the system. From Merz' perspective, we have to first of all make sure we are aligned with physicians—people should only buy from reputable companies, and reliable sources. Unless you can definitively certify that it is real product from the real company, you're flying in the wind. From a corporate responsibility, we take it very seriously and constantly troll the waters. From our customers and field sales force, we are looking for agitators in the system. In the US, we have sent cease and desist letters to crack down on operations that were illegally importing product into the US. We have consistently been stepping up our efforts to take action against the parties who are doing this. We owe it to our physician practices to keep patients safe.'

Risks of fake injectables

The risks associated with unlicensed fillers range from dangerous reactions to outdated or ineffective products. The most frequent side-effects are lumps and bumps, asymmetries, and disproportionate facial features. More serious consequences, ranging from infection to death, have also occurred.

Physicians all over the world report that they are seeing an increase in the number of patients coming in for corrections from injections that have gone wrong. 'The dominant problems we are seeing are foreign body granulomas and infections, and epidermal injuries from lasers,' said Ascher.

Complications run the gamut from infections, extrusions, chronic inflammation, to more severe consequences including death from illegal injections of permanent substances such as PMMA performed by non-physicians and/or unlicensed physicians.

According to Paris based Cosmetic Doctor Nelly Gauthier, 'With the counterfeit fillers being imported illegally into Europe and the do-it-yourself injectables being sold direct to consumers over the Internet, we are heading towards catastrophic scenarios like death, illnesses, and patients with distorted faces. This can backfire on every aspect of beauty, not only the medical aesthetics market.'

'The only way to fight the safety and beauty issues at stake here is to have mass-media information/education, showcasing the numerous accidents that have already happened and showering warnings in the media. I do not believe it is possible to eradicate it entirely, but information can downsize its spread,' she said.

'Another problem with counterfeit products is that doctors deny it, so, when you have a problem they pretend it was from a legal filler. The only way to prove it is with a biopsy. Biopsies might leave the patient with permanent scars, so this is seldom accepted. I have treated many granulomas where the injector claimed it was a legal filler, but I am positive that it was not,' Gauthier added.

Dermatologist Hassan Galadari in the UAE has also seen his share of adverse events. 'I have seen many complications during my time in the US, especially from products that have been injected from South American origins and not only in the face, but the body. I have seen patients who have had filler 'parties,' where I was told that a person, the injector, would come in, mixing ingredients in a pot, filling up a syringe and then injecting it in the face, breast, and even buttocks. Not only do these products contain many unapproved and dangerous ingredients, the problem is that it is done under completely unsterile environments, which in itself is a disaster.'

He continued: 'These patients cite expense as the major driving force behind their behavior, but again, you pay for your service. Such complications can be more expensive and detrimental to the person's health than simply being injected by a trained medical practitioner.'

In many instances, bungled filler treatments do not get reported because doctors have no way of knowing exactly what material has been injected, and patients typically have no idea themselves. Sykes has also seen some problems from non-FDA approved fillers, but notes that the occurrence is under-reported because patients are often unaware that the product is not FDA approved. 'Physicians should use only FDA products to ensure maximum safety and efficacy to not possibly jeopardise their license. I saw a patient who had a substance injected into her lower eyelids abroad that resulted in chronic oedema of the lower eyelids. To correct the problem, the product would have to be cut out, which can cause a secondary deformity,' he said.

DIY fillers

According to Grover, 'A new and even more worrying twist is on the rise in so called DIY facial rejuvenation, where products are bought online for self administration. Clearly the public should be advised to leave the administration of treatment to qualified healthcare professionals. The medical device manufacturers and toxin producers are looking into this problem very seriously with redesign of packaging to make fakery as difficult as forging a fifty pound note.'

Gauthier agrees. 'As for the do-it-yourself, or have anyone-do-it-to-you, I have so far only seen bad BOTOX around the eye because the patient said, 'I couldn't do my forehead well'.'

Note that at least in the US, only FDA-approved fillers may be sold to licensed healthcare practitioners and should be used under their supervision. The FDA has not approved any dermal filler devices for self-injection, and of course, that also goes for toxins, which are considered drugs.

Yet, the website listed under the name pmma.com that claims to be the '#1 Dermal Fillers Store since 2008,' openly promotes non-regulated products. They also maintain an active Facebook page with deals and specials, and a video of a doctor (or not) promoting their great deals (facebook.com/dermalfillers). Among the many 'hooks' on the site that contain a number of misspelled words and incomplete sentences is: 'Are you looking for the great results you have come to expect from high profile products like Radiesse, Artefill, Restylane and Sculptra? Our products contain the same API in an enhanced formula. Higher quality products at a fraction of the cost, shipped discreetly to your door.' The site also lures customers in by offering free samples, gift cards and free shipping within Europe, the US, and Canada. With two locations in Milton Keynes, UK, and Bridgeport, Connecticut, pmma.com claims to have 6000 medspas, clinics, skin care professionals, and individual practitioners as customers worldwide. To the untrained eye, it would appear to be no different than any beauty site selling creams and cosmetics, and nowhere does it state that the site is restricted to healthcare practitioners only. There have been attempts made by some big industry players to shut this site down, although unsuccessfully so far.

Product police

How can the industry police the rampant influx of products in the market that are finding their way into clinics?

'It's not the industry's job to be the quality control vehicle. That is the job first of the FDA and next of physicians. Physicians will make those decisions by examining the best evidence available to help them make good decisions on which products to use, and whether they are safe and efficacious for patients,' said Sykes.

According to Fagien, it's a very difficult dilemma. 'The industry does best when a large push is undertaken to educate the consumer about these sorts of practices and how to avoid them.'

Galadari adds that the problem resides mainly in whether these fillers have a safety track record or not. 'Some fillers have been around for many years abroad and have been used internationally with good success in addition to a great safety profile. Others have not, and cause problems such as granulomas, abscess formation to infection. Unfortunately, just by

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‘While the FDA has been successful in weeding out the bad apples, the stringent rules have been an obstacle to having genuinely good products from getting into the US without it being cost prohibitive. Think of how long Juvéderm® VOLUMA took to be approved. Many other good and safe products are not making it and the doctor is forced to use ingenious techniques to ‘dilute’ certain fillers in certain areas for example, a practice which in itself is not FDA approved,’ Galadari continued.

It is clearly challenging for companies to keep up with which doctors are bringing products into their clinics that are illegal or counterfeit. ‘You cannot just walk into a doctor’s office and demand to see his ‘stash.’ It is important

for them, however, to report known cases to the authorities,’ he said.

It’s also far too easy to get product into the country adds Galadari, ‘I have brought some samples in my suitcase to show at a meeting and was not stopped, so you can imagine how easy it would be for professional smugglers. When these materials are brought in, complications are bound to happen. If there is a rise in complications, there will be more stringent regulations by the FDA that may impede genuinely safe and good products from coming into the US. We have to draw a line between safety and innovation. Too many rules simply defeats that, and in the end, the patients are the ones who are on the losing end,’ he said.

According to Ascher, ‘The new European Directive 93/42/EEC will bring more regulation to the EU market. IMCAS, along with many scientific societies in our field, would like to promote referenced clinical studies on the evidence based medicine (EBM) standard, before any CE approval is granted.’

Counterfeiting is a losing proposition for practitioners and consumers alike. There are steep penalties and even jail time being handed out in many countries for those who get caught participating in this practice, and to their employees, as well. It also leads to greater uncertainty in the marketplace, and more consumer fear and apprehension. Consumers should be reminded that something that seems cheap can end up costing them dearly in the end.