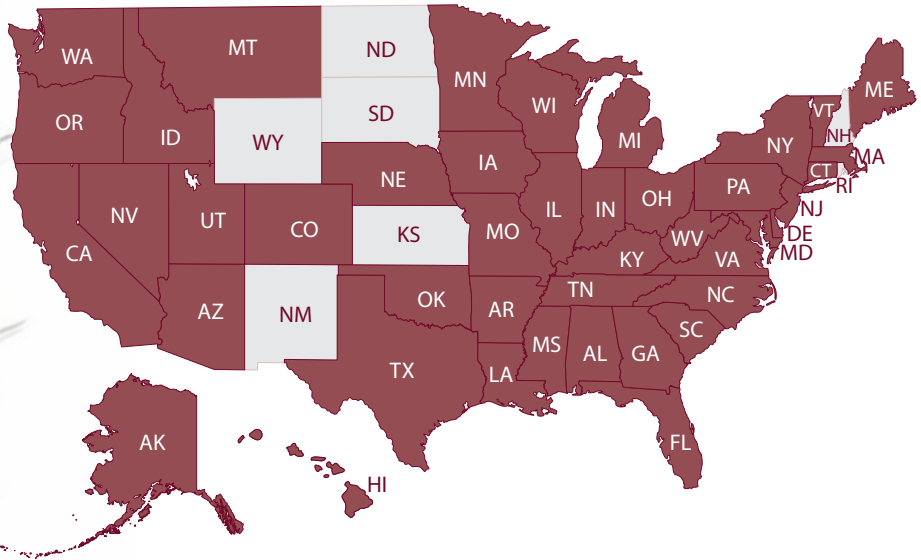


Black Market Cosmetic Injectables in the U.S., 2005 – 2013



Since 2005, at least 46 individuals in 16 states have been investigated for the purchase or sale of non-FDA approved cosmetic drugs—a variety of substances being passed off as Botox, collagen or other injected cosmetic treatments. Among those charged, 37 have pleaded guilty or been convicted in court, while the rest are still under investigation. During the same time period, 1 patient died and at least 11 others sought medical treatment for disfigurement or serious illness brought on by these black market injections.

In 2012, the FDA notified 350 medical practices in 43 states that they may have purchased counterfeit Botox and since then more than 700 doctors across all therapeutic areas have received letters warning them that they may have purchased non-FDA approved drugs.

Unlicensed distributors make a profit by selling drugs that are illegally imported, expired, stolen, damaged by bad handling or are outright counterfeits. Doctors who purchase these discounted drugs generate a profit for themselves by billing insurance, Medicare and patients at the same price they would charge for legitimate treatments. **This pursuit of profit over safety puts patients, who are unable to trust the integrity of their treatments, at tremendous risk.**

EXAMPLES OF BLACK MARKET CASES SINCE 2005



DECEMBER 2013

Missouri: Clinic manager Thomas Greg Martin charged with and pleaded guilty to 1 felony count for receiving misbranded OnabotulinumtoxinA (Botox) from an unlicensed foreign wholesaler between 2010 and 2012. Sentenced to 3 years probation in March 2014.

NOVEMBER 2013

Missouri: Dr. Erick Falconer charged with and pleaded guilty to 1 count of making false statements to federal agents after lying about how many times he purchased black market OnabotulinumtoxinA (Botox) between 2009 and 2013. Sentenced to 5 months in prison and a \$20,000 forfeiture in February 2014.

Texas: Elva Navarro arrested for practicing medicine without a license after allegedly injecting a client with liquid silicone and claiming it was Botox. The client underwent multiple surgeries and spent 17 days in intensive care. Navarro was indicted by a federal grand jury in March 2014.

OCTOBER 2013

Texas: Nohemi Gabriela Gonzalez charged with practicing medicine without a license after allegedly injecting as many as 30 victims with toxic silicon liquid rubber that she claimed was a safe cosmetic treatment. At least 1 woman was hospitalized after the treatments. Gonzalez's boss, spa owner Graciela Treviño Leon, was arrested on related charges in November 2013.

APRIL 2013

Illinois: Orthopaedic Solutions owner Christopher Carstens charged with 9 counts for distributing foreign versions of OnabotulinumtoxinA (Botox) and Juvéderm, another cosmetic drug. He allegedly sold more than \$3 million (over 5,000 units) of these drugs to healthcare professionals between 2008 and 2011. A November 2013 superseding indictment added 2 charges to

Carstens' prosecution and charged Missouri resident Christopher Tozier with 5 additional counts.

MARCH 2012:

Virginia: 14 people and Gallant Pharma International indicted on 17 counts for importing unapproved drugs, including black market OnabotulinumtoxinA (Botox). Between 2009 and 2013 Gallant made at least \$8.6 million by posing as a Canadian distributor selling to the American market. 9 Gallant employees have pleaded guilty. In March 2014 co-founder Talib Kahn was sentenced to 3 years in prison, 2 years of supervised release and \$3.4 million in forfeiture and restitution. 2 other employees will serve probation and pay restitution. 6 defendants await sentencing; 3 more will stand trial in 2014.

JULY 2011

Utah: Michael Lawrence O'Donnell indicted on 25 counts for distributing and diverting imported drugs. The drugs, which included black market OnabotulinumtoxinA (Botox), were sold to healthcare professionals across the U.S. Pled guilty to 1 count in July 2006. Sentenced in August 2013 to serve 1 year in prison.

MAY 2011

Florida: Diana Marcela Cardenas-Gonzalez charged with practicing medicine without a license after performing facial injections with an unknown substance that she claimed was Botox. 2 clients developed cyst-like masses that required medical treatment. Convicted of 9 felony counts and sentenced to 10 years of probation in January 2014.



BLACK MARKET CASES (cont.)

JUNE 2007

Nevada: Dr. Stephen Lee Seldon and his wife, Deborah Martinez Seldon, charged with 15 counts related to their use of black market OnabotulinumtoxinA (Botox). Between 2003 and 2005 they purchased almost \$37,000 of a version of botulinum toxin type A (acquired from Toxin Research International) that was not approved for human use. They marketed the drug as Botox, falsely claimed specialized training and altered medical records to conceal their actions. Convicted on all counts in November 2008; sentenced to 48 months and 30 months respectively, along with 3 years of supervised release and a fine of \$144,000.

MAY 2006

California: Beautician Martha Mata Vasquez charged with murder and practicing medicine without a license after a client she injected with corn oil died from an embolism. Other clients, who believed the injections were FDA-approved treatments, also required medical treatment. Pleaded guilty to 9 counts in November 2006. Sentenced to 15 years in prison in January 2007.

AUGUST 2005

Idaho: Dr. Ivyl Wells indicted on 42 counts related to treating 200 patients with black market OnabotulinumtoxinA (Botox) in 2004. He injected patients with a mixture of legitimate Botox and botulinum toxin type A (acquired from Toxin Research International) that was not approved for human use. Pleaded guilty to 5 counts in July

2006. Sentenced to 6 months in prison, 6 months home detention, 300 hours of community service and more than \$125,000 in restitution and fines in December 2006.

JULY 2005

Oregon: Dr. Jerome Lentini and Cathryn Garcia, R.N. indicted on 51 counts related to using black market OnabotulinumtoxinA (Botox). In 2003 and 2004 they injected more than 800 patients with 2 black market versions of botulinum toxin type A. They obtained the first from Toxin Research International; the other was imported from China. Garcia pleaded guilty to 1 count and was sentenced to 1 year in prison in August 2006. Lentini pleaded guilty to 1 count in March 2006. He was sentenced to 18 months in prison and \$330,000 restitution in December 2006.

FEBRUARY 2005

Arizona: Chad Livdahl and Zahra Karim, the owners of Toxin Research International, and Florida doctor Bach McComb, charged with 47 counts for selling nearly \$2 million of botulinum toxin type A that was clearly labeled as not approved for use on humans to more than 200 doctors. Livdahl and Karim pleaded guilty to 2 counts each in November 2005. The following January Livdahl was sentenced to more than \$345,000 in restitution, 9 years in prison and 3 years of supervised release. Karim was sentenced to 70 months. McComb pleaded guilty to 1 count and was sentenced to 3 years.

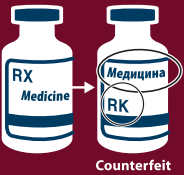


How can patients and medical practices protect themselves?



HEALTHCARE PROVIDERS: importing drugs or buying them from unlicensed distributors is illegal and dangerous to your patients. Prescription drugs should only be purchased from wholesale drug distributors licensed in the United States. **The FDA keeps a list of verification sites by state:** <http://safedr.org/fdalicense>.

In addition to sourcing medicines safely, healthcare professionals can spot therapeutic failure and educate patients about how to buy medications from safe sources. Learn more about protecting patients at http://safedr.org/healthcare_pros.



PATIENTS receiving treatments in medical offices should ask their doctors to see the medication's packaging. **Examine the product packaging for accurate labeling, good condition of the package and the language of the labeling.** All prescriptions approved for sale in the US should have product descriptions in English.

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Information current as of May 2014.



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