

FDA Law Enforcers Crack Down on Illegal Botox Scammers

In November 2004, when four people became paralyzed after purportedly receiving Botox Cosmetic injections at a medical clinic in Oakland Park, Fla., the Food and Drug Administration's (FDA) Office of Criminal Investigations (OCI) was called to investigate. The four victims were hospitalized with severe botulism poisoning. The paralysis was temporary—a result of being injected with potent, unapproved botulinum toxin. The doctor who injected the toxin had passed it off as Botox Cosmetic, an FDA-approved drug to treat forehead wrinkles.



What began as one OCI investigation of a Florida medical clinic escalated into 210 investigations of health care professionals throughout the United States. As of July 2008, the work of OCI has led to 31 arrests and 29 convictions of individuals who purposely injected an unapproved, cheaper substitute toxin for FDA-approved Botox Cosmetic into nearly 1,000 unknowing patients.

Under federal law, no form of botulinum toxin may be commercially distributed for use on humans unless it has been approved by FDA. At this time, Botox Cosmetic, made by Allergan Inc. of Irvine, Calif., is the only type of botulinum toxin approved by FDA to temporarily soften the frown lines between the eyebrows. Botox Cosmetic is a sterile, purified version of the same toxin that causes botulism, a severe form of foodborne illness. In both cases, the toxin is produced by the bacterium *Clostridium botulinum*. The injectable form of sterile, purified botulinum toxin, when used in small doses, locally affects the muscles' ability to contract, smoothing out frown lines to make them nearly invisible.

Source of the Problem

OCI agents traced the fake Botox Cosmetic used in the Florida clinic to a California laboratory that sold botulinum toxin for research purposes. The agents found more of the laboratory's research product at Toxin Research International Inc. (TRI) in Tucson, Ariz. TRI was sell-

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ing the unapproved toxin to health care professionals as a cheaper alternative to Botox Cosmetic. In December 2004, OCI agents seized vials of the botulinum toxin from TRI, along with numerous marketing materials targeted to physicians.

The vials were clearly labeled, "For Research Purposes Only, Not For Human Use." Invoices and product information sheets carried the same warning. Physicians who bought the

cheaper, unapproved product from TRI increased their profits on each treatment by charging their patients the same fee as if they were using the FDA-approved Botox Cosmetic.

OCI agents arrested four individuals associated with TRI. Chad Livdahl, TRI's president, was convicted of fraud and misbranding a drug and sentenced to nine years in prison. His wife and co-owner, Zahra Karim, was sentenced to almost six years

in prison. Other co-conspirators got lesser sentences.

OCI Special Agents examined TRI shipping records to track down more than 200 health care professionals who bought the unapproved drug from TRI. "The physicians were located throughout the country, from Manhattan to Las Vegas," says Philip Walsky, Assistant Special Agent in Charge in FDA's OCI Headquarters office. "They'd learn about the drug

Sample Botox Cases Investigated by FDA's Office of Criminal Investigations

Defendant	Illegal Action	Result
Gayle Rothenberg, M.D., operator of Center for Image Enhancement, Houston	Injected more than 170 patients with unapproved drug, representing it as approved Botox Cosmetic	Indicted for mail fraud, misbranding a drug, making false statements to a federal agent; June 13, 2008, sentenced to 27 months in prison, restitution of \$98,426, fine of \$1,000
Mark E. Van Wormer, M.D., operator of GreatSkin clinic, Albuquerque, N.M.	Injected patients with unapproved drug, representing it as approved Botox Cosmetic	Indicted for fraud, misbranding a drug, tampering with documents; Dec. 14, 2007, sentenced to 1 year and 1 day in prison, restitution of \$65,265, fine of \$3,000
Albert Poet, M.D., operator of offices in Stafford Township and Montclair, N.J.	Injected patients with unapproved drug without telling patients	Indicted for mail fraud, misbranding a drug; Sept. 28, 2007, sentenced to 14 months in prison
Ivyl Wells, former M.D. and operator of Skinovative Laser Center, Boise, Idaho; surrendered medical license after charges were filed	Injected about 200 patients with unapproved drug, representing it as approved Botox Cosmetic	Indicted for mail fraud, misbranding a drug; Dec. 11, 2006, sentenced to 6 months in prison, 6 months home detention, restitution of \$88,000, fine of \$40,000, 300 hours community service
Jerome Lentini, M.D., operator of A Younger You clinics, Salem and Tigard, Ore., and his assistant, Cathryn Garcia, R.N.	Injected about 800 patients with unapproved drug, representing it as approved Botox Cosmetic	Indicted for misbranding a drug; Aug. 14, 2006, Garcia sentenced to 1 year in prison; Dec. 11, 2006, Lentini sentenced to 18 months in prison, restitution of \$330,000
Chad Livdahl and Zarah Karim, owners of Toxin Research International, Tucson, Ariz.	Sold unapproved botulinum toxin, labeled "Not for Human Use," to more than 200 physicians throughout the U.S. to use on their patients	Indicted for mail and wire fraud, misbranding a drug; Jan. 26, 2006, Livdahl sentenced to 9 years in prison, restitution of \$345,567, forfeiture of \$882,565; Karim sentenced to 5.8 years in prison, restitution of \$345,567



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Tips for Consumers Considering Botox Injections

- Botox Cosmetic is an injectable drug and should be administered by a trained, qualified health care professional.
- Know what you are being injected with. Make sure your health care professional is using only an FDA-approved product purchased within the United States. If he or she refuses to give you this information, look for another health care professional.
- Make sure the benefits and risks are fully explained to you in a patient consultation.
- Fully disclose any medical conditions you might have and medications you are taking, including vitamins and over-the-counter drugs.
- Botox Cosmetic should be administered in an appropriate setting using sterile instruments. A non-physician who is appropriately licensed and trained may perform the injections under the supervision of a qualified physician. Malls and private homes are not medical environments and may be unsanitary.

Adapted from the American Society for Aesthetic Plastic Surgery.

by going to a conference where TRI would give a spiel and demonstration to sell their product."

Many of the purchasers of the TRI product have been prosecuted. Some are serving time in federal prison and were ordered to pay restitution to their patients.

"Someone who abuses a position of trust for financial gain and subjects patients to unknown safety risks from unapproved medications will be held accountable," says Kim A. Rice, FDA Special Agent in Charge of OCI's Metro Washington Field Office. "FDA will aggressively pursue those who willfully circumvent laws that are in place to protect the consuming public."

OCI continues to investigate these cases, says Walsky.

How Patients Were Scammed

According to OCI agents, most of the health care professionals misrepresented the fake product to patients, leading them to believe they were receiving the real Botox Cosmetic. Some of the tactics they used were

- advertising in brochures, magazines, and on Web sites that they specialized in treating facial wrinkles with Botox Cosmetic
- displaying a certificate indicating they received training by the Botox Cosmetic manufacturer, when they did not
- informing patients they would be receiving Botox Cosmetic
- failing to tell patients they were getting a drug not approved for human use
- asking patients to sign a consent form indicating they would be receiving injections of FDA-approved Botox Cosmetic

e-mail subscriptions at www.fda.gov/consumer/consumerenews.html.

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American Society for Aesthetic Plastic Surgery
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