Cosmetic Practitioners Take Huge Risks Purchasing and Administering Illegal Botulinum Toxin Drug Products

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In their article "Importing Injectables" in the September 2014 issue of the *Journal of Drugs in Dermatology*, Dr. Kenneth Beer and Karen Rothschild highlighted the possible harm to patients and practitioners from the use of unapproved botulinum toxin products – eg, Botox, Dysport, Xeomin, and Myobloc – and other cosmetic prescription drug products purchased from foreign or unlicensed suppliers.[1] In the intervening years, the accuracy of their critique has been repeatedly demonstrated, as the dangers to patients' health, as well as to cosmetic practitioners' liberty, has only increased.

Not surprisingly, given the countries from which the unapproved cosmetic products are frequently sourced, a significant percentage are counterfeit and/or misbranded or adulterated and their use is a violation of federal law, possibly subjecting the practitioner to criminal sanctions, fines, loss of a medical license, and malpractice liability. More importantly, the use of these products puts patients at risk and, for this reason alone, the FDA's Office of Criminal Investigations ("OCI") is actively seeking to identify, warn, and, in some cases, prosecute practitioners who purchase or administer counterfeit and/or misbranded or adulterated drugs that have been illegally imported into the United States.

The significant dangers posed by the importation of unapproved drug products have also recently caught Congress' attention. Just last month (August of 2017), Congress passed (and the President has pledged to sign) legislation that significantly increases the penalties associated with illegally imported drug products. As a result of these revisions to the Food, Drug & Cosmetic Act ("FD&C Act"), healthcare practitioners who knowingly make, sell, or dispense (or hold for sale or dispensing) illegally imported botulinum toxin drug products may now be imprisoned for up to ten years and fined up to $250,000. Under federal law, healthcare practitioners may also be subject to forfeiture (of property) and disgorgement (of past revenues) for selling and dispensing illegally imported botulinum toxin drug products.

Real Criminal of Orange County

Bridget "Gigi" Goddard, the owner of a skin rejuvenation practice in Southern California, was outwardly extremely successful. Her medical spa's clients included stars of the hit TV show "Real Housewives of Orange County" and she even appeared on the cover of a local magazine. What her clients didn't know, however, is that she was risking their health by purchasing (and then injecting them with) unapproved botulinum toxin products from overseas internet sellers.

On November 10, 2016, the U.S. Attorney for the Central District of California announced that Goddard had agreed to plead guilty to a federal charge – receipt and delivery of a misbranded drug – which carries a penalty of up to three years in prison. According to the United States Department of Justice, Goddard was caught knowingly misleading an FDA undercover agent as to whether the botulinum toxin that she offered to inject into the FDA agent was approved for use in the United States. In the guilty plea announcement, the Special Agent in Charge of the FDA's Office of Criminal Investigations said, "When criminals attempt to distribute unapproved drugs in the U.S. marketplace, they put the public's health at risk. Our office will continue to pursue and bring to justice those who would jeopardize the health and safety of the public."

Siren Song of the Internet Sellers

Goddard admitted that, over the course of several years, she ordered Botox over the internet from Canadian companies that specialized in selling unapproved drugs to customers in the United States. Until late 2014, she purchased from Toronto-based S.B. Medical, Inc., Botox manufactured for distribution in Turkey and other countries. In early 2015, after S.B. Medical ceased operations because of an FDA criminal investigation, Goddard began purchasing Botox from Doctor Medica based in Vancouver, Canada, and from at least one other internet seller. The Botox from Doctor Medica was manufactured for distribution in Europe and was shipped from Great Britain.

Since it is specifically named in Goddard's plea agreement, Doctor Medica is clearly operating on borrowed time. Yet, as of early March 2017, the company's website was still offering "healthcare professionals worldwide" dozens of "brand name medical injectables to alleviate osteoarthritis symptoms, reduce signs of aging, and enhance beauty," including botulinum toxin products. Doctor Medica is even so brazen as to offer a referral fee to doctors – a $400 account credit when the referred doctor's orders reach $1,750.

Another internet seller, Amazon Medica, offers low prices for brand name botulinums, dermal fillers and orthopaedics. The company falsely implies that its drugs are approved for use in the United States, touting that "Every vial and box of product delivered to the U.S. travels through FDA-monitored customs channels to ensure both regulatory compliance and the most efficient delivery times for our physician clients." Amazon

Medica, if its location and principals can ever be located, is also probably on borrowed time: on November 10, 2016, Allergan (the manufacturer of Botox) filed suit against Amazon Medica, alleging that "Amazon Medica is a rogue and unlicensed foreign criminal entity that illegally advertises, imports, sells, and ships prescription medicines to unwitting doctors in the United States. These doctors, in turn, inject the unlawfully obtained, adulterated, and potentially unsafe prescription medicines into unknowing and unsuspecting patients. Amazon Medica misleads these doctors and endangers patient safety in the pursuit of unearned financial profit." Allergan is seeking to locate Amazon Medica and identify its principals through litigation discovery. Case proceedings could ultimately reveal U.S. doctors who have purchased illegally from Amazon Medica.

FDA Cracking Down on Doctors and Illegal Distributors

The FDA, as part of its efforts to combat importation of unapproved drugs, has for several years gone after purveyors of unapproved botulinum toxin products. On August 7, 2013, the FDA's OCI announced that eleven people had been charged in a case involving Gallant Pharma International Inc., an unlicensed company accused of distributing misbranded prescription drugs, including injectable cosmetic drug products. A physician who owned an esthetic and skin care clinic in Virginia (as well as his office manager) was convicted at trial for partnering with Gallant in exchange for a deeply discounted price on non-FDA approved cosmetic drugs and devices. The physician used these cosmetic drugs and devices at his practice without the patients' knowledge or consent. He also provided Gallant with his medical license to enable Gallant to order non-FDA approved chemotherapy and cosmetic drugs from around the world, and allowed those drugs to be smuggled into the United States, addressed to his clinic. Many of the shipments involved "cold-chain" drugs subject to strict temperature controls (which were not followed by the conspirators), and the use of those drugs posed serious potential harm to patients throughout the U.S.

More recently, DOJ announced on June 16, 2017 that (following an FDA investigation) the owner of Midwest Medical Aesthetics Center Inc., Kathleen Stegman, had been charged with obtaining Botox and Dysport from foreign sources. If convicted she faces up to three years in federal prison (under the older, more lenient, penalty provisions in the FD&C Act that, as noted above, have now been significantly enhanced). And, on June 19, 2017, six Canadian men associated with CanadaDrugs.com (and affiliated companies) were arrested under the Extradition Act. DOJ and FDA have accused the men of illegally importing $78 million worth of unapproved drug products into the U.S.

FDA Letters to Doctors

Following a trend noted in Dr. Beer and Ms. Rothchild's 2014 article, the FDA continues to issue thousands of letters – *publicly identifying recipients* – to doctors purchasing unapproved botulinum toxin products and other products from illegal distributors. On April 1, 2015, the FDA sent more than 300 letters to medical practices that purchased from Gallant Pharma. On March 21, 2016, the FDA issued more than 1,300 letters to medical practices that purchased unapproved prescription drugs and/or injectable devices from TC Medical (aka SB Medical – one of Bridget Goddard's Botox sellers). And, on March 30, 2016, the FDA sent approximately 100 letters to medical practices that had purchased from TC Medical and had also purchased from a different unlicensed distributor previously (and had previously received one of the FDA letters). The FDA singled out one of the doctors for previously receiving FDA letters for purchasing from two other illegal distributors

Receiving one of these FDA letters is not a good thing for doctors. Doctors who receive the letters could become the target of a criminal investigation, especially doctors who receive FDA letters for purchasing from more than one illegal distributor (eg, doctors listed in an FDA document titled "repeat offenders"). Further, receiving such an FDA letter makes it markedly more difficult for the doctor to plead ignorance of the law with respect to future purchases of unapproved products. Being publicly identified by the FDA also puts the doctor's professional reputation at risk – particularly if local newspapers report on the matter – and exposes practitioners to medical board disciplinary actions, including possible loss of their medical licenses (eg, for violating federal law by purchasing and administering misbranded or adulterated drugs).

Malpractice Liability

When doctors buy misbranded, non-FDA-approved or adulterated drugs from overseas distributors it is illegal, and threatens the health of their patients. These drugs:

- May contain harmful ingredients;
- May be ineffective, containing incorrect amounts of active ingredients or no active ingredient at all;
- May cause adverse health events;
- May be expired; or
- May have been produced, stored and imported under insanitary or incorrect conditions.

If the patient suffers an adverse event from one of these counterfeit or diverted drugs, the doctor should not expect his malpractice carrier to provide any assistance: malpractice policies typically exclude liability arising from criminal acts (eg, administering botulinum toxins not approved for use in the United States).

Caveat Emptor

Buying counterfeit or misbranded botulinum toxin products (or other prescription drugs) from illegal internet sellers or unlicensed distributors puts practitioners (and their patients) at serious risk. The question isn't whether, but when, the FDA, medical licensing boards, and the public will find out about these purchases. When the FDA shuts down an illegal seller, it typically looks for the seller's customer list and will reach out to those persons. Practitioners who are purchasing from overseas internet sellers or other unapproved distributors should immediately stop doing so. These practitioners, especially if they have received an FDA letter regarding purchases of unapproved prescription drugs, should also talk to their lawyers.

Disclosure

Sheldon Bradshaw currently represents Allergan, Inc.

References

1. Beer, K, Rothschild K. Importing injectables. *J Drugs Dermatol.* 2014;13:9:1156.

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