Legal Backgrounder

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Penalty Disparities Frustrate Protection of Consumers from Dangerous Counterfeit and Diverted Drugs

by Sheldon Bradshaw

Though the United States drug supply chain is one of the safest in the world, its integrity is under constant threat, as unscrupulous online wholesalers and pharmacies that claim to be legal, safe, and less expensive alternatives for obtaining prescription drugs sell potentially dangerous products that have not been approved for sale in the United States by the US Food and Drug Administration (FDA). These products may be counterfeit versions of FDA-approved drugs or drugs initially purchased in a foreign country and then diverted into the United States.

Counterfeit drugs are typically ineffective, with incorrect amounts of the purported active ingredients or no active ingredients at all. They can also contain harmful ingredients, making them unsafe as well as ineffective. Diverted products—*i.e.*, drugs intended for sale in another country—often arrive in the United States after a circuitous journey from a developing country, where they were held and/or transported in unsuitable or insanitary conditions. They can also arrive well past their expiration date, with labeling in a foreign language.

A number of statutory gaps in the penalty provisions of the Food, Drug and Cosmetic Act (FDCA) pose a risk to American consumers including unequal treatment of counterfeiting and diversion, as well as differing penalties for certain types of diversion. These unreasonable gaps and disparities could be easily addressed through minor tweaks to the FDCA, changes that would benefit public health and enhance consumer confidence in the safety of their medications. Importantly, this task could be accomplished in a way that neither restricts the personal importation of drug products nor gives government prosecutors additional tools that could be used to penalize legitimate industry actors.

Enforcement Successes

For several years FDA has actively combatted the importation of counterfeit and diverted drugs. In 2012, for example, FDA learned that counterfeit copies of the cancer drug Avastin had been imported into the US. The inquiry conducted by the Agency's Office of Criminal Investigations (OCI) revealed that the counterfeit Avastin had been imported via an online Canadian pharmacy by a company whose entire business involved importing misbranded and unapproved drugs sold in foreign countries and distributing them at discounted prices to US doctors. The foreign prescription drugs distributed by the company were not the versions FDA had approved for use in the US because, among other things, the drugs' labeling information did not conform to FDA-approved labeling for the domestic versions. Even worse, laboratory analysis of the illegally imported Avastin showed that the drug did not contain *any* of the active drug ingredient, bevacizumab, that is found in legitimate versions of Avastin. When OCI began its investigation, it learned that some of the fake Avastin

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had already been shipped to US doctors for use with cancer patients. OCI's investigative work resulted in the company's owner pleading guilty to a felony and forfeiting approximately $6 million in illegal proceeds to the government. Prosecutors were able to charge this defendant with violating the FDCA's diversion rules. Had the defendant been guilty of counterfeiting only, he would not have faced stiff penalties.

Enforcement Whack-A-Mole: Botox as a Case Study

Despite such successes, many sellers remain undeterred. When one illegal importer is shut down, another steps in to fill the void. FDA's ongoing efforts to prevent the importation of both counterfeit and diverted botulinum toxin drug products, such as Botox, demonstrates these difficulties and the need for uniform penalties. A 2009 FDA pamphlet, "FDA Law Enforcers Crack Down on Illegal Botox Scammers" highlights the dangers of illegal Botox. In the pamphlet, FDA notes that OCI opened a criminal investigation in 2004 when four people became paralyzed after purportedly receiving Botox cosmetic injections at a medical clinic in Oakland Park, Florida.

Recently, on November 10, 2016, the US Attorney for the Central District of California announced that Bridget "Gigi" Goddard, the owner of a skin rejuvenation practice in Southern California, had agreed to plead guilty to a federal charge related to the illegal distribution of Botox that was not approved for use in the United States. The single criminal count to which she agreed to plead guilty—receipt and delivery of a misbranded drug—carries a penalty of up to three years in prison. 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 Botox manufactured for distribution in Turkey and other countries from Toronto-based S.B. Medical, Inc. In early 2015, after S.B. Medical ceased operations, 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 shipped from Great Britain.

As of January 2017, Doctor Medica'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 Botox. Doctor Medica even offers a referral fee to doctors—a $400 account credit when the referred doctor's orders reach $1,750.

Another internet seller, which recently changed its name from Amazon Medica to Amedicas, also offers low prices for Botox and other brand name botulinums, dermal fillers, and orthopaedics. The company falsely implies that its drugs are approved for use in the United States, touting that "[e]very vial and box of product delivered to the US travels through FDA-monitored customs channels to ensure both regulatory compliance and the most efficient delivery times for our physician clients."

Statutory Gaps and Disparities

The differing levels of jail time and fines for drug counterfeiting and diversion is one major factor in the proliferation of illegal sales and the continued viability of businesses that make such sales. The financial cost-benefit of unapproved drug sales favors the criminal sellers in two ways: 1) the size of the profits vastly outweigh the potential punishments and 2) the low penalties for counterfeiting and diversion act as a disincentive against aggressive enforcement of those laws.

Under the FDCA, for instance, though the sale or dispensing of counterfeit drugs is considered a "prohibited act," violations fall under a generalized, "catch-all" penalty provision that FDA trots out to penalize a wide range of prohibited actions and which carries light misdemeanor penalties. If one "reimports" and

sells in the US drugs manufactured domestically for sale in foreign markets, however, that act of diversion is punishable as a felony. But not all diversions are even treated equally under the FDCA. The law does not, for instance, explicitly prohibit the diversion and sale in the US of drugs that are manufactured overseas for non-US markets. That type of diversion is simply considered "misbranding" or "adulteration," punishable as a misdemeanor under the "catch-all" provision. The gaps and disparities for both diverted and counterfeit drugs are discussed in further detail below.

Diversion

Many of the products sold in the United States by unscrupulous online pharmacies and wholesalers are drugs that were intended for sale in foreign markets. Such drugs are usually not FDA approved, may contain inadequate labeling, and may be expired. There is a widespread belief, perhaps because many of the online pharmacies purport to be operating out of Canada, that the drugs were originally intended for sale in Canada and simply shipped into the United States from our neighbor to the north. The reality is often very different. Based on their labels, diverted drugs are frequently intended for sale in developing countries and their lengthy and convoluted journey to the United States can result in their being held and/or transported under unsuitable or insanitary conditions. This is particularly true for drugs that must be held and transported under precise temperature conditions, like Botox.

Currently, drugs that are manufactured domestically and exported for sale in foreign markets may not be reimported by anyone other than the drug's manufacturer.[1] Such a violation is governed by § 333(b) of the FDCA. That provision imposes a penalty of not more than 10 years in prison, a fine of $250,000, or both, for committing specific acts. Section 333(b) prohibited acts include, among other activities, the sale of drug samples, the sale, trade, or purchase of coupons, and the *reimportation of drugs manufactured in the US but intended for foreign markets*.

Felony treatment of this type of diversion must be compared, however, to the differing treatment of another type of diversion. The FDCA does *not* explicitly prohibit the importation into the US of drugs manufactured *in foreign facilities* and intended for sale in foreign markets. The sale of such drugs is commonly considered an introduction of misbranded or adulterated drugs. This general prohibition is only subject to minor misdemeanor penalties. Given that such drugs have the potential to be equally, if not more dangerous or ineffective than those manufactured in the US for foreign markets, the disproportionately light penalty framework makes little sense.

Counterfeiting

The sale or dispensing of counterfeit drugs[2] is currently prohibited under § 331(i)(3) of the FDCA, which states "[t]he doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug" is prohibited.[3] While this language effectively prohibits much of the problematic activity conducted by the online pharmacies and wholesalers, the potential

[1] While this prohibition technically applies to reimportation of drugs by an individual for personal use, the FDCA requires FDA to "focus enforcement on cases in which the importation by an individual poses a significant threat to public health" and to "exercise discretion to permit individuals to make such importations" where the importation is for personal use, and the prescription drug or device does not appear to present an unreasonable risk to the individual. 21 U.S.C. § 384(j)(1).

[2] The FDCA defines "counterfeit drug" as "a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer or distributor." 21 U.S.C. § 321(g)(2).

[3] 21 U.S.C. § 331(i)(3).

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penalties for violation of this provision are woefully limited. Section 333(a) provides that committing any prohibited act under § 331 is punishable by not more than one year's imprisonment, a fine of $1,000, or both. This relatively minor punishment can be contrasted with the much harsher felony provisions available for diversion of drugs that are produced in the US for the foreign marketplace, as described above.

The disparity between counterfeiting penalties and foreign-market-intended drug diversion is difficult to justify (and, based on the FDCA's legislative history, does not appear to have been intentional). Counterfeiting's potential for harm to the public health is extraordinarily high, as demonstrated above in the discussion of bogus Avastin and Botox. There is little risk that higher penalties or increased law enforcement will ensnare innocent actors, as long as the laws focus on those entities that sell fake drugs, and not on those who deliver or purchase them. Furthermore, drug counterfeiting is an international problem, inspired in large part by low criminal penalties and enforcement apathy in other countries.[4] The US has encouraged those nations and the World Health Organization to increase anti-counterfeiting efforts. Maintaining such a leadership role, however, will be difficult as long as the punishment for counterfeiting in the US is different than that for diversion.

Conclusion

The disparities in penalties for drug counterfeiting and diversion can be cured with simple changes to the FDCA. While one method of addressing the issue could involve increasing the penalties on the "catch-all" provision, this approach would be misguided. Giving more power to governmental prosecutors to hammer industry actors for the broad range of actions covered by the "catch-all" penalty provision would overcriminalize the FDCA and is far too broad a solution. The cure would be worse than the disease. Instead, the solution should focus solely on penalizing drug counterfeiting and diversion and should direct FDA's authority toward appropriately combating the commercial importation of dangerous products.

In order to equalize the penalties for diversion of drugs manufactured in the US and for diversion of those manufactured overseas, language can be added to FDCA § 381(d)(1) to include within its prohibition the diversion into the US of drugs manufactured outside the US and intended to be marketed outside the US. That would subject such diversion to the same penalties applied to those that divert drugs back into the US that were exported from the US to a foreign market. To equalize the penalties for drug counterfeiting and diversion, a brief provision can be added to the part of the FDCA that governs counterfeiting, § 331(i)(3), that allows for the same punishment for violation of the part that governs diversion, § 333(b).

The integrity of the drug supply chain in the United States is an ongoing concern that FDA frequently monitors. Despite successes in preventing potentially dangerous or ineffective drugs from reaching consumers, sales of illegal products continue, due to the potential profits that can be made. Perhaps by closing gaps in the FDCA's penalty structure, the criminal penalties from importing the dangerous product will outweigh the perceived financial benefits for bad actors, thereby protecting American consumers and strengthening the supply chain.

[4] *See, e.g.*, Alexandra Ossola, *The Fake Drug Industry Is Exploding, and We Can't Do Anything About It*, NEWSWEEK, Sept. 25, 2015, *available at* http://www.newsweek.com/2015/09/25/fake-drug-industry-exploding-and-we-cant-do-anything-about-it-373088.html.

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