

Prevalence of Rogue Online Pharmacies Pushes Regulators to Raise Awareness, Continue the Fight Against Counterfeits



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The proliferation of rogue online drug outlets and the increase of counterfeits entering the United States drug supply chain continue to threaten public health. Drug products sent by such sites also exacerbate the opioid epidemic, which has led governors in several states, including Alaska, Arizona, Florida, Maryland, and Virginia, to declare statewide public health emergencies. With as many as 34,000 illegal online pharmacies active at any moment and more and more consumers turning to the internet for less expensive drugs or to avoid doctors’ appointments, efforts to reduce patient harm from this global threat have been at the forefront for regulators – both in the US and Canada.

Uncovering False Canadian Claims

While a consumer may order medicine from what appears to be an online Canadian pharmacy, the product delivered may not be what the consumer ordered. Such rogue online drug outlets market themselves as Canadian internet pharmacies, but sell medications that do not come from Canada and are not approved to sell in Canada or the US.

Health Canada, the federal department responsible for Canadians’ public health, seized almost 5,500 packages of counterfeit drugs, mostly for sexual enhancement (eg, fake Viagra®), on their way into the country between April 2016 and March 2017. Within one week last year, \$2.5 million worth of counterfeit pharmaceuticals – mainly for erectile dysfunction – were seized by Health Canada at the border, reports the National Post in the June 12, 2017 article “Canada fights influx of fake Viagra, as erectile dysfunction creates ‘perfect storm’ for counterfeiters.” These drugs are commonly bought from online drug outlets or social media sites because people do not want to go to their doctors. Pfizer’s North American Director of Global Security, Brian Donnelly, told the National Post, “The problem is significant,” and “I think most people believe that they’re getting something . . . that is approved by Health Canada or approved by [Food and Drug Administration (FDA)].”

Additionally, wholesale quantities of counterfeit prescription drugs entering the US is a growing problem for regulators and law enforcement. For example, US federal prosecutors have accused Kristjan Thorkelson, *CanadaDrugs.com*, and affiliated companies and associates in the United Kingdom and Barbados of illegally importing and selling \$78 million worth of unapproved new drugs, misbranded drugs, and counterfeit drugs to American doctors between 2009 and 2012. Thorkelson is the president and founder of *CanadaDrugs.com*, a Winnipeg-based company.

According to court documents obtained by *CBCNews Manitoba*, Canada Drugs allegedly bought its inventory from questionable sources and sold fake versions of the drugs Altuzan® and Avastin® to US doctors. The fake Avastin was found to contain cornstarch and acetone, and no active ingredients. In addition, Canada Drugs’ UK affiliate, River East Supplies, is accused of falsifying customs documents to hide the product. Further, River East Supplies and several US companies are accused of not keeping

the medications at the cold temperatures required to keep them safe.

Trafficking Opioids Directly to Consumers

Online sales of prescription opioids also continue to be a problem, and have become more alarming with the distribution of dangerous synthetic drugs, such as fentanyl and carfentanil, into the US via international mail. Alliance for Safe Online Pharmacies – Global Executive Director Libby Baney notes that the websites selling these products exploit a global postal system incapable of sufficiently screening the materials within its shipments.

Drugs bought online from the dark web have allowed synthetic opioids, such as fentanyl – the fastest-growing cause of overdoses nationwide – to be delivered to consumers in small packages by mail. Enough fentanyl to get approximately 50,000 people high can fit into a standard first-class envelope, in contrast to heroin and prescription drugs, which are bulky. Although authorities took down Silk Road – the online black market where buyers anonymously used special browsers and bought illegal drugs using virtual currencies like Bitcoin – since 2013, countless dark web markets have emerged, making synthetic opioids readily available to consumers. AlphaBay, the leading dark web market, was recently shut down and seized by the US Department of Justice for selling deadly drugs and other harmful goods for over two years. The investigation revealed that numerous vendors sold fentanyl and heroin, and several overdose deaths across the country have been attributed to purchases on the site.

In yet another scheme, fake prescription drugs made from fentanyl were distributed in Utah and throughout the US to customers who had ordered pills via the dark web. On May 31, 2017, six individuals, including the alleged ringleader, Aaron Shamo, were indicted for their involvement. These individuals purchased pill presses, dyes and stamps to mark pills to match those of legitimate pharmaceutical drugs, and inert pill ingredients, such as binding agents

and colors. Some bulk ingredients were purchased legally and others, such as fentanyl and alprazolam, were imported into the US illegally, including from China. Court documents indicate the enterprise sold hundreds of thousands of pills.

STOP Act

One effort to address such scenarios at the source is bipartisan legislation aimed at stopping dangerous synthetic drugs from being shipped into the US. The Synthetics Trafficking and Overdose Prevention Act (S.372) would require shipments from foreign countries arriving through the postal system to be subject to review by US Customs and Border Protection (CBP), and would require advance electronic information (eg, whom and where it is coming from, who it is going to, and what is in it) before the shipments enter the US.

Registrar-Level Solutions

A February 2017 report released by KnujOn.com, LLC, an independent online abuse handler and internet policy research organization, scrutinized several US registries' and registrars' responses to complaints of domains trafficking opioids online. More than 300 domains selling opioids were analyzed in the report, and approximately 50 different internet companies were contacted directly.

When contacted about internet domains that were promoting illegal activity (eg,

trafficking opioids), numerous US registries and registrars did not investigate, suspend, and/or report the illegal activity to law enforcement. The report, which is available at knujon.com/onlineopioidsUSfeb2017.pdf, further discusses which US-based registry companies had the most opioid domains and which registrars should be considered rogue.

NABP has been addressing the increasing prevalence of rogue online pharmacies at the registry level with the .Pharmacy Verified Websites Program. Part of the Association's motive for launching the .Pharmacy Program was to keep the .pharmacy domain out of the hands of a third party that may turn a blind eye to illegal activities.

As the registry operator for the .pharmacy domain, NABP is committed to ensuring that all businesses seeking a .pharmacy domain for their websites have been verified and hold applicable licenses in the jurisdictions where they are based and where they do business. These sites undergo continual monitoring and must apply for renewal of their domain registrations annually. In addition, NABP thoroughly vets the registrars that service .pharmacy registrants and continually monitors these registrars to ensure that they are adhering to the terms and conditions they agreed to when they became a .pharmacy registrar. ■

