

VIA ELECTRONIC DELIVERY

Friday, December 14, 2018

The Honorable Orrin Hatch

Chairman, Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510-6200

Dear Senator Hatch:

In response to your letter dated October 22, 2018 requesting information regarding the sale of counterfeit medicines via the Internet, the Alliance for Safe Online Pharmacies (ASOP Global) is pleased to provide you the attached written responses.

On behalf of our more than 40 international member and observer organizations, we are pleased to provide input with respect to the Committee's interest in illicit Internet drug sales. The constantly increasing volume of Internet users as a result of enhanced Internet accessibility, through both traditional access and mobile devices, has fast-tracked the growth and profit potential of those criminals running illicit online pharmacies. While the Internet has provided immeasurable societal benefits, it has also exposed global consumers to the hazards of illegal online pharmacies peddling "medicines" that may be counterfeit, adulterated, misbranded, and/or unapproved.

We hope to work with the Finance Committee to find additional solutions to further enhance patient safety and consumer protection online. Please do not hesitate to contact us directly with any comments or questions as we stand ready to serve as a resource to you and your office.

Respectfully,



Elizabeth Baney, JD

On behalf of the Alliance for Safe Online Pharmacies (ASOP Global)

Libby.Baney@FaegreBD.com

(202) 312-7438

1. HOW DO YOU WARN CONSUMERS ABOUT THE RISKS OF PURCHASING COUNTERFEIT MEDICINES ON E-COMMERCE WEBSITES?

Founded in 2009, the Alliance for Safe Online Pharmacies (ASOP Global)¹ is a nonprofit organization based in Washington, D.C. dedicated to addressing the public health threats posed by illegal online drug sellers and counterfeit medications. Convening more than 40 national and international partners, ASOP Global engages in the United States, Canada, Latin America, Europe, India, and Asia through activities in: (1) research, (2) education and public awareness, (3) advocacy, and (4) collaboration.

Through the traditional, legitimate supply chain, medicines are one of the most highly regulated products in the world. Online, however, there is virtually no regulation or oversight on the sale of prescription medicines. Criminals prey on patients' need for medications and make a big profit doing so. Throughout the world, criminals manufacture and sell counterfeit and unsafe prescription drugs online and through other illegitimate venues. They have no regard for the safety, efficacy, or quality of the medicines they are selling to unsuspecting patients. The counterfeit pharmaceutical drug trade exceeds that of nearly all other illicit markets –including arms and human trafficking. Illicit prescription drug sales are estimated to be between \$163 billion to \$217 billion per year.²

It is, therefore, not surprising that the Internet is the largest venue for counterfeit prescription drug sales, which also encompasses products that are misbranded or contain false or misleading claims. At any given time, there are approximately 30,000-35,000 active online pharmacy websites operating on the open web, of which approximately 96% are operating out of compliance with state and federal law and relevant pharmacy practice standards.³ Illegal online drug sellers have been found to offer counterfeit, misbranded, and unapproved prescription drugs, often without a prescription or the required pharmacy licensures.⁴ Increasing awareness of the prevalence and danger of illegal online drug sellers by patients and caregivers, healthcare providers, the judiciary, law enforcement, and policymakers, is a critical component in the fight against counterfeit medications.

Unfortunately, for an uneducated consumer, finding a safe online pharmacy website today can be like finding a needle in a haystack. With more than 600 websites launching each month⁵, ASOP Global, including our members and allies, are compelled to engage in significant efforts to help educate consumers around the risks associated with buying medicine from illegal online pharmacies and other unverified and often dangerous sources.

Over the past decade, ASOP Global has partnered with a wide array of trusted, national organizations to educate on the risks associated with illegal online drug sellers and counterfeit medications. Examples of our education and awareness activities include:

- *Ways to Save and Be Safe* campaign with Dr. Sharon Orrange of the University of Southern California and medical advisor to GoodRx⁶;

¹ <https://buysaferx.pharmacy/>

² Fighting Counterfeit Pharmaceuticals. New Defenses for an Underestimated and Growing Menace. PWC. June 2017
<https://www.strategyand.pwc.com/media/file/Fighting-counterfeit-pharmaceuticals.pdf>

³ Proposed Legislation Brings Risk of Imported Counterfeit Medications, Bypasses Regulatory Safeguards. National Association of Boards of Pharmacy. August 2017. <https://nabp.pharmacy/wp-content/uploads/2016/07/Innovations-August-2017.pdf>

⁴ https://buysaferx.pharmacy/wp-content/uploads/2018/02/NABP-Internet-Drug-Outlet-Report_February-2018.pdf

⁵ The Internet Pharmacy Market in 2016, LegitScript and the Center for Safe Internet Pharmacies, January 2016. Available at:
<http://www.safemedsonline.org/wp-content/uploads/2016/01/The-Internet-Pharmacy-Market-in-2016.pdf>

⁶ <https://buysaferx.pharmacy/buying-medicine/>

- *Your Journey to Having a Baby Starts with Safe Medicine* with RESOLVE: The National Infertility Association;⁷ and
- *Older Americans* Campaign with the National Consumers League and Center for Safe Internet Pharmacies.⁸

Through this work, ASOP Global has reached approximately 180 million patients, caretakers, and healthcare providers over the last several years. ASOP Global anticipates leading additional education campaigns and healthcare provider trainings in 2019 and beyond.

ASOP Global has also partnered with the Federation of State Medical Boards, U.S. Food and Drug Administration, University of California San Diego and LegitScript to develop a free continuing education program accredited for physicians and pharmacists. In partnership with these sixteen national organizations⁹, ASOP Global worked to leverage the data collected from over 1,000 healthcare providers that participated in the continuing education program to inform those on the front lines of healthcare delivery around the risks associated with illegal online drug sellers. Astonishingly, less than 10% of provider respondents noted that they were “very aware” that counterfeit drugs may be sold over the Internet with an even smaller percentage, only 1.4%, regularly discussing these risks with their patients.¹⁰ It is critical that both consumers and healthcare providers are given the appropriate resources to identify potentially fraudulent websites and to ensure safety and security online.

By leveraging ASOP Global’s work, our members and others are empowered to:

- Raise awareness and educate consumers;
- Engage healthcare providers through focused trainings;
- Disseminate downloadable free educational materials and tool-kits;
- Receive in-person or webinar presentations on the issue of counterfeit medicines, and illegal online drug sales; and
- Share news about the issue with their members and constituents.

Additionally, in March 2017 the ASOP Global Foundation¹¹ was established as a non-profit organization dedicated to research and education regarding the proliferation of illegal online drug sales and counterfeit medicines¹². More recently, in November 2018, the ASOP Global Foundation held its inaugural Research Symposium¹³ in Washington, DC focused on the illegal online sales of medicines. That daylong event brought together public- and private-sector stakeholders to review recent and ongoing research and discuss opportunities for collaboration to improve public health and patient safety online. Speakers included Donald Ashley, Director of FDA’s Office of Compliance, and Michael Kopcha, Director of FDA’s Office of Pharmaceutical Quality within the Center for Drug Evaluation and Research (CDER).

⁷ <https://buysaferx.pharmacy/public-awareness-campaigns/providers/fertility-information/>

⁸ <https://buysaferx.pharmacy/public-awareness-campaigns/older-americans-and-caregivers/>

⁹ <https://buysaferx.pharmacy/public-awareness-campaigns/providers/campaign-partners/>

¹⁰ <https://buysaferx.pharmacy/public-awareness-campaigns/providers/healthcare-providers-news-release-vital-role/>

¹¹ <https://asopfoundation.pharmacy/>

¹² <https://buysaferx.pharmacy/buying-medicine/>

¹³ <https://asopfoundation.pharmacy/highlights-for-2018-illegal-online-sales-of-medicine/>

a. DO YOU BELIEVE THAT CONSUMERS ARE AWARE OF AND/OR UNDERSTAND THE HEALTH AND SAFETY RISKS ASSOCIATED WITH PURCHASING MEDICINES ONLINE? IF NOT, HOW CAN WE BETTER COMMUNICATE THESE RISKS TO CONSUMERS?

Please refer to 1(b) below.

b. WHAT CHALLENGES EXIST IN INFORMING CONSUMERS OF THE RISKS ASSOCIATED WITH PURCHASING MEDICINES ONLINE?

These questions rightly call attention to the problem that the vast majority of Americans are unaware of the prevalence and dangers posed by illegal online pharmacies.

To better understand American consumers' current behaviors and perceptions of online pharmacies, ASOP Global commissioned a national polling firm to study the issue in May 2017.

ASOP Global's survey findings are highly informative and illustrate vast consumer knowledge gaps.¹⁴ These gaps create opportunities for criminals to prey – and prosper – on patients' desire for convenient, cheap medicine offered online. Top ten survey findings include:

1. The majority of Americans surveyed (72%) were either somewhat or not at all familiar with online pharmacies, and only 27% reported that they were "very familiar" with online pharmacies.
2. Despite this lack of familiarity with online pharmacies and the risk that creates for falling victim to one of the nearly 33,000 illegal online sites, one-third (1/3) of respondents had already purchased prescription drugs on the Internet for themselves or someone under their care.
3. Amongst the most worrisome findings, the survey revealed that 89% of respondents who *have* bought medicine online never discussed it with their healthcare provider. This puts patients at risk of incorrect dosing and adverse events (including drug-drug, drug-supplement, and drug-food interaction). Further, patients may unknowingly be receiving counterfeit or substandard products from online sellers and, because they fail to tell their healthcare provider, the provider may simply change treatment regimens (e.g. amending dosages, prescribe additional products, order additional testing, etc.) without realizing the true cause of the original treatment failure. This adds costs to the healthcare system, harms patients, and frustrates good clinical practice.
4. The survey revealed that consumers most likely to use online pharmacies are young, have higher incomes, purchase products online, are willing to take more risk and take more prescription drugs.
5. More than half (55%) of respondents said they have or would consider buying medication online. Of those consumers who have previously ordered medication online or are interested in doing so, levels of interest in online buying varied by product class:
 - a. 42% – for chronic on-going conditions such as blood pressure and cholesterol;
 - b. 34% – for over-the-counter medicines such as cough, cold, allergy or pain reducers;
 - c. 23% – for medicines for acute, short-term issues such as infections and insomnia; and
 - d. 21% – for specialty medications, such as for cancer treatment and hormone replacement therapy.

¹⁴ Online Pharmacy Behavior and Perception Survey Results. September 2017. https://buysaferx.pharmacy/wp-content/uploads/2017/09/us_sept2017-1.pdf

6. Less than 5% of consumers are aware of tools available to help them find safe online pharmacies, such as the National Association of Boards of Pharmacy's (NABP) .Pharmacy (dot pharmacy) Program and LegitScript's URL checker. This again is great cause for concern given the thousands of illegal pharmacy sites masquerading as legitimate sources of safe medicine.
7. When looking for an online pharmacy, one in five previous online pharmacy users said they simply typed the name of their medication into a search engine and chose a website at random, rather than ordering from a pharmacy site associated with their local pharmacy, utilizing an approved site offered by their insurance plan, or searching the list of pre-approved sites made available through NABP. This is especially concerning given that illegal online pharmacies typically appear at the top of organic search results. This is discussed further as part of our response to Question #7.
8. Americans have very little interest in using a government website to find safe online pharmacy websites. Less than 5% of survey respondents said they would use a government-sponsored list of safe online pharmacy websites, should such a list be created as was contemplated by Senator Sanders' recent drug importation legislation.¹⁵
9. Nearly one-quarter of respondents (24%) have previously considered seeking a prescription for medications approved to treat chronic pain. Notably, ASOP Global intentionally did not ask respondents whether they have considered buying opioids online, so as to not inadvertently teach people that these controlled substances are so easily available online without a prescription.
10. After learning the facts, 53% of the respondents found Canadian online pharmacies "very risky."

Additionally, research from Purdue University¹⁶ found that *even licensed pharmacists* typically cannot differentiate legitimate from illegal online pharmacies just by looking at a website. Compared to a trained pharmacist, the average consumer is all the more susceptible to illegal pharmacy websites that offer 'too good to be true' prices, claims of selling 'genuine Canadian medicines', and other tactics that put patients at risk.

Consumer Education, Online Drug Sales, and the Opioid Epidemic

Education on the dangers of illegal online pharmacies is especially important during the opioid epidemic. ASOP Global's survey found that 17% of all respondents have considered seeking a prescription for medications aimed at treating chronic pain. The number of respondents noting their seeking of a prescription for chronic pain rises to nearly one-quarter (24%) when looking strictly at those who have previously purchased prescription drugs via an online pharmacy. Consumers must also be wary that often innocuous searches and queries may lead consumers to illegal online pharmacy websites. While a consumer may be looking for credible information, such as a drug label or dosing instructions for a current or newly prescribed medication, they may instead be taken to a website that provides incorrect information or unlawful access to prescription drugs.

Moreover, in a February report issued by the National Association of Boards of Pharmacy, it is noted that the prevalence of advertisements and offers for controlled substances and illicit narcotics has continued to rise to alarming levels.¹⁷ Previous reports from NABP have found that number hovers around 10-12% of websites. In contrast, NABP's February 2018 report notes that 54% of sites surveyed offered controlled substances with 40% of those same websites offering drugs that are often counterfeited with synthetic opioids such as fentanyl. It is

¹⁵ S. 469 – The Affordable and Safe Prescription Drug Importation Act, <https://www.congress.gov/bill/115th-congress/senate-bill/469>

¹⁶ Evaluation of Pharmacists' Awareness of The Prevalence and Negative Consequences Associated With Illegal Internet Pharmacies. May 2017. https://buysaferx.pharmacy/wp-content/uploads/2017/05/CMSA_whitepaper_rphonlinelegitimacy.pdf

¹⁷ Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: February 2018. <https://nabp.pharmacy/wp-content/uploads/2018/02/Internet-Drug-Report-Feb-2018.pdf>

worth noting that 100% of those sites reviewed by NABP were operating illegally and all but two offered the sale of prescription medications without a valid prescription. At a time when more than 72,000 Americans died from an opioid-related overdose in 2017 alone, serious action must be taken to reduce the dangerous and illegal efforts by these online criminals.

2. WHAT TOOLS DO YOU PROVIDE YOUR MEMBERS WHEN A MEDICINE HAS BEEN IDENTIFIED AS A COUNTERFEIT AND IS BEING SOLD, DISTRIBUTED, AND/OR ADVERTISED ON AN E-COMMERCE WEBSITE AS GENUINE?

ASOP Global focuses its activities on (1) research, (2) patient and provider education, (3) advocacy, and (4) collaboration. As a nonprofit, ASOP Global does not have the capacity nor the mandate to perform any investigatory or law enforcement function. ASOP Global relies on – and appreciates the important work of – government law enforcement, regulatory authorities, and industry to provide tools for the detection and reporting of counterfeit medicines being sold, distributed, and/or advertised on an e-commerce website or platform. ASOP Global’s education and collaboration efforts help to steer patients and providers to these appropriate resources for the detection and reporting of counterfeit medicines including many of the resources and tools made available to consumers on our website¹⁸.

The Pharmaceutical Security Institute¹⁹, a not-for-profit membership organization dedicated to protecting the public health, sharing information on the counterfeiting of pharmaceuticals, and initiating enforcement actions through the appropriate authorities may be better-suited to answer questions related to law enforcement activities. ASOP Global partnered with the Pharmaceutical Security Institute to publish a May 2016 white paper on Law Enforcement Best Practices.²⁰

3. PLEASE DESCRIBE HOW YOU COORDINATE WITH E-COMMERCE PLATFORMS TO CURTAIL THE SALE OF COUNTERFEIT MEDICINES.

In 2016, ASOP Global ran an education campaign in collaboration with the National Consumers League and the Center for Safe Internet Pharmacies, a group comprised of e-commerce companies.²¹ This campaign reached nearly 20 million consumers and focused on educating older Americans about the dangers of counterfeit medicines and illegal online pharmacies. ASOP Global continues to collaborate with the National Consumers League on educational activities.

While not an ASOP Global initiative, we would like to take this opportunity to mention promising new collaboration involving one of our partners, the National Association of Boards of Pharmacy (NABP), and Microsoft Bing. In November 2018, Microsoft’s search engine Bing announced a voluntary partnership with the National Association of the Boards of Pharmacy (NABP) to launch a pilot program aimed at identifying illegal online drug sellers and alerting consumers of the risks associated with specific sites.²²

Starting in 2015, Bing was the first and only search engine to introduce pop-up warnings for illegal online pharmacy websites identified by the U.S. Food and Drug Administration. Now, in another major industry first, Bing will expand its consumer safety efforts by adding pop-up warnings for websites that are on [NABP’s Not](#)

¹⁸ <https://buysaferx.pharmacy/public-awareness-campaigns/consumers/>

¹⁹ www.PSI-in.org

²⁰ White Paper: Illegal Online Drug Seller Law Enforcement Best Practices (May 2016). <https://buysaferx.pharmacy/wp-content/uploads/2016/11/ASOP-Global-PSI-White-Paper-Sept.-2016.pdf>

²¹ ASOP Global campaign: <https://buysaferx.pharmacy/public-awareness-campaigns/older-americans-and-caregivers/mnr/>

²² <https://blogs.bing.com/search/2015/08/06/bing-to-warn-customers-about-the-threats-of-fake-online-pharmacies/>

[Recommend list](#). These are online drug sites that appear to be putting patients at risk by operating in violation of state and federal laws or NABP patient safety and pharmacy practice standards.

This new collaborative pilot program was announced at the [2018 ASOP Global Foundation Research Symposium](#) at the National Press Club. By partnering with NABP, Bing is leading the way in responding to Administration and Congressional calls for Internet companies to do more to address the growing problem of illegal online drug sales.

4. ONCE YOU AND/OR YOUR MEMBERS SUSPECT THAT A COUNTERFEIT MEDICINE IS BEING SOLD, DISTRIBUTED, OR ADVERTISED VIA AN E-COMMERCE PLATFORM WITHIN THE U.S. OR ABROAD, WHAT TYPES OF ACTIONS, INCLUDING THE INITIATION OF LITIGATION, DO YOU PURSUE? PLEASE PROVIDE EXAMPLES.

As mentioned above, ASOP Global focuses its activities on research, education, raising awareness, collaboration, and advocacy. ASOP Global does not engage in law enforcement or litigation activities. Our discussions with law enforcement and industry partners, however, do indicate the desire for strengthened tools to shut down illegal online drug sellers.

As a part of our efforts to address illegal online drug sales and further public health and patient safety online, ASOP Global educates about and advocates for the following:

- Voluntary actions by Internet companies (search engines, social media companies, online marketplaces, domain name registries and registrars) to protect patients from illegal online drug sellers, which may include terminating service, locking and suspending domain names, increasing the Internet visibility of verified online pharmacies, and otherwise refusing to do business with illegal online drug sellers;
- Adoption and use of the .pharmacy top-level domain (operated by the National Association of Boards of Pharmacy in collaboration with international regulatory authorities and the community) by legal pharmacies as a way to indicate that an online seller is a legitimate, law-abiding online pharmacy and a safe choice for patients;
- Boosting verified online pharmacies in organic search results;
- Delisting illegal online pharmacies from organic search results;
- Increased government oversight on the issue and enforcement against illegal drug seller websites, the Internet drug criminals behind them, and the Internet companies who facilitate them;
- ICANN enforcement against Domain Name Registrars who fail to take action against website operators who violate laws and regulations in applicable jurisdictions. These jurisdictions include (a) the jurisdiction from which the website ships drugs; and (b) the jurisdiction to which the website ships or offers to ship drugs;
- Enhanced data collection by health regulators and law enforcement authorities about (a) the number of drugs that are entering their market originating from illegal online pharmacy websites, (b) consumer behavior that contributes to use of these sites, and adverse events related to Internet drug sellers;
- Strong penalties for criminals who peddle counterfeit, falsified, substandard, adulterated or misbranded medicine via the Internet;
- Laws and policies requiring all online sales of prescription medicine to require a valid prescription that is consistent with the applicable laws in that country and applicable medical standards of care;

- Laws and policies requiring transparent and accurate disclosure of information related to any online pharmacy website, including the location, contact telephone number, and pharmacy licensure information of the dispensing pharmacy, and the website, owner/operator; and
- Laws to require transparent, publicly-accessible WHOIS domain name registration data.²³

5. DO YOU AND/OR YOUR MEMBERS PARTICIPATE IN MEDICINE VERIFICATION PROGRAMS PROVIDED BY E-COMMERCE PLATFORMS OR ANY OTHER INTERMEDIARY? WHAT FEATURES OF SUCH PROGRAMS HAVE BEEN USEFUL IN IDENTIFYING AND ELIMINATING COUNTERFEIT MEDICINES?

ASOP Global has several members that participate in active verification and monitoring programs with respect to online pharmaceutical sales. Additionally, ASOP Global has joined the *Coalition for a Secure and Transparent Internet* (www.secureandtransparent.org) in support of WHOIS data access and transparency. As discussed below, this domain name registration information is critical to identify and eliminate illegal online drug sellers offering opioids, counterfeit medicine, and other unsafe products to Americans.

LegitScript

LegitScript, a founding ASOP Global member, operates a certification program for online pharmacies, telemedicine providers and similarly situated healthcare advertisers and merchants that are either required or recognized by most of the Internet's and payment ecosystem's major providers: Google, Bing, Yahoo, Visa, Pinterest, Facebook, MasterCard and more.

National Association of Boards of Pharmacy

With 20 years of experience evaluating Internet pharmacies for compliance with pharmacy laws and practice standards, NABP launched a digital health program in 2014 to verify the legitimacy of pharmacy-related websites and e-commerce platforms selling prescription medicine to consumers. Verification includes checking for appropriate licensure and compliance with applicable laws in all jurisdictions where the seller ships medicine. The process also includes verification that the site sells only medications that are approved for use in the jurisdiction where its customers reside, and confirmation that the site has no rogue affiliations. Those applicants that are approved by NABP may register a .pharmacy domain name, signifying to the public that their website is verified as safe and legitimate.

By ensuring that all .pharmacy registrants are operating legally and sourcing medications from within the regulated supply chain, NABP's verification program provides a critical tool to help keep patients safe from rogue online pharmacies selling substandard and counterfeit medications. To date, more than half of all licensed pharmacies in the US have websites verified by NABP.

The Importance of Transparency in Verification and Monitoring Online Pharmacies

Criminals, including counterfeit medicine purveyors, operate in the shadows. An important part of both LegitScript and NABP verification standards is that they require transparency of who operates the business and websites and other key elements related both to operations and ownership.

²³ To this end, ASOP Global is a member of the Coalition for a Secure and Transparent Internet, www.secureandtransparent.org

Among the most critical requirements is one that the domain name's "WHOIS" record be accurate and available. Prior to May 2018, all that this required was to ensure that the applicant reviews the domain name's Whois record and make sure that it was accurate and not using an anonymization service (like Godaddy's "Domains By Proxy"). This accountability helped prevent cybercrime and counterfeiting by ensuring that who operates the website was public information, and also helped LegitScript and NABP to be able to identify other websites operated by the same entity.

As the Finance Committee may know, due to European privacy regulations (the General Data Privacy Regulation, or GDPR), ICANN has made the unnecessary decision that registrars will, in essence, be permitted to block WHOIS records from the public, even for commercial entities such as pharmacies and telemedicine providers. This is putting the health and safety of US residents at risk, because when cybercriminals can hide their identity this easily, they can masquerade as legitimate. Equally or more compelling, they are able to hide the ownership of the other websites they operate, which can establish a connection between the website initially in question and the cybercriminal's other activities.

While other requirements, such as pharmacy licensure, prior discipline, DEA registration and the like are very important, these are straightforward. What cybercriminals increasingly take advantage of is the anonymity that ICANN's unnecessary interpretation of the GDPR has afforded, and it is causing certification programs like LegitScript's and NABP's to be faced with challenges in keeping US residents safe from counterfeit medicines and other products.²⁴

This concern was echoed by Daniel Burke, Senior Operations Manager, Cybercrime Investigations Unit of the U.S. Food & Drug Administration in testimony before the Caucus on International Narcotics Control. During that testimony, he discussed in detail the importance of WHOIS data/domain name registration information in carrying out their investigations and addressing the opioid issue as well as the difficulty the agency is experiencing given the EU's GDPR:²⁵

“Conducting online investigations is not easy, and FDA has a narrow, but important role in combating the online sale of opioids. For good or bad, much of the Internet ecosystem, including dark nets, have adapted and changed to build in anonymity. Public information about the owner of a domain name, known as ‘whois’ data, is now often impossible to access with the implementation of the European General Data Protection Regulation (GDPR)...”

ASOP Global – along with LegitScript, NABP and eleven other organizations – participates in the *Coalition for a Secure and Transparent Internet* which is advocating for federal legislation to require publicly accessible and transparent WHOIS data.

6. WHAT OTHER SERVICES, TOOLS, PROTECTION, AND ASSISTANCE DO YOU PROVIDE YOUR MEMBERS?

As part of ASOP Global's work in research, education, advocacy, and collaboration programs, we offer the following tools and services to our members and the public at large:

- a. **International trainings in collaboration with U.S. Food and Drug Administration and other Asia-Pacific Economic Cooperation economies.** For example, in August 2018 ASOP Global joined FDA for the APEC Harmonization Center's Global Supply Chain Integrity Training in Seoul, South Korea to discuss

²⁴ See Op-Ed by NABP's CEO Carmen Catizone for more: <https://secureandtransparent.org/the-rise-and-risk-of-illicit-online-pharmacies-opinion/>

²⁵ FDA Testimony, available: <https://secureandtransparent.org/fda-cybercrimes-investigations-unit-presents-testimony-to-senate-caucus/>

regulatory harmonization, law enforcement recommendations, and consumer education best practices related to Internet drug sales.

- b. **Free educational materials** on the ASOP Global website, www.BuySafeRx.pharmacy, specifically designed to arm consumers, healthcare providers, and policymakers with easy-to-use information, fact sheets, videos, and infographics.
- c. **Ways to help consumers find safe online pharmacies** as provided by ASOP Global members LegitScript and the National Association of Boards of Pharmacy: <https://buysaferx.pharmacy/find-a-safe-online-pharmacy/>.
- d. **Provide input with regard to identification of rogue actors or promoting best practices** through submission of comments as part of the request period for the United States Trade Representative's Special 301 Out-of-Cycle Notorious Markets Report²⁶ and United States Intellectual Property Enforcement Coordinator's 2017-2019 Joint Strategic Plan²⁷.

7. IN YOUR VIEW, WHAT ARE THE CHALLENGES IN PREVENTING CONSUMERS FROM INADVERTENTLY PURCHASING COUNTERFEIT MEDICINES? WHAT STEPS SHOULD BE TAKEN TO ADDRESS THESE CHALLENGES?

When Americans buy outside of regulated supply chains, they are at grave risk of receiving an ineffective or unsafe counterfeit medicine. Indeed, counterfeit drugs comprise a growing percentage of the US drug market.²⁸ U.S. consumers are largely unaware of the dangers of purchasing counterfeit drugs from Internet pharmacies: an estimated 36 million Americans have bought drugs online without a valid prescription.²⁹ Unregulated, dangerous sources of prescription medicines – including unverified pharmacy websites, offers via social media and online marketplaces, storefront pharmacies³⁰, and local bodegas and flea markets³¹ – further exacerbates Americans' risk of receiving a counterfeit medicine coupled with the lack of consumer awareness or education around ways to report suspect medical products. No therapeutic class is impervious to counterfeiting. Prescription drugs that have been identified as counterfeit span a wide array of conditions including pain, chronic disease, antibiotics, genitourinary, mental health, and others.

Importation of foreign-sourced prescription drugs through Internet sites and other means of cross-border purchasing compounds the risk of Americans receiving counterfeit or otherwise unsafe medicines. As FDA has found, while half of imported drugs *claim to be Canadian* in origin, upwards of 85% of those drugs evaluated were from countries prescription drug evaluated were from countries *other than Canada*.³² Research conducted by the National Association of Boards of Pharmacy affirms these findings, with more than 20 years of surveillance data indicating that U.S. consumer purchases from alleged Canadian online pharmacies are rarely – if ever – the same products that domestic patients would receive.³³ In a February 2017 letter to Congress regarding prescription drug importation proposals, NABP noted:

²⁶ <https://ustr.gov/sites/default/files/files/Press/Reports/2017%20Notorious%20Markets%20List%201.11.18.pdf>

²⁷ <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/IPEC/2016jointstrategicplan.pdf>

²⁸ Blackstone EA, Fuhr JP, Pociask S. The health and economic effects of counterfeit drugs. *Am Health Drug Benefits*. 2014;7(4):216-24.

²⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4105729/>

³⁰ *IBID.*

³¹ FDA Raids Florida Stores That Consumers Use to Buy Drugs from Canada. *Kaiser Health News*. November 20, 2017. <https://khn.org/news/fda-raids-florida-stores-that-consumers-use-to-buy-drugs-from-canada/>

³² L.A. Cracks Down on Unlicensed and Counterfeit Pharmaceuticals. *Los Angeles Times*. May 9, 2018. <https://www.latimes.com/local/lanow/la-me-ln-crackdown-unlicensed-counterfeit-pharmaceuticals-20180509-story.html>

³³ <https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/1/califf-vows-not-to-lower-or-remove-fda-regulations>

³³ <https://buysaferx.pharmacy/for-the-media/about-online-pharmacies-and-canadian-pharmacy-websites/>

“To put it bluntly, sending consumers online to look for Health Canada-approved medicines is reckless, as US patients are likely to receive unapproved, substandard, and counterfeit drugs from unknown foreign sources, posing a serious risk to patient safety.”³⁴

The challenges in preventing consumers from inadvertently purchasing counterfeit medicines are:

- **The fact that simple queries for “[medicine name] online” or “buy [medicine name] online” via search engines, social media sites, and online marketplaces often yield illegal drug sellers in top results.** As discussed, illegal sites and sellers of medicine often peddle counterfeit and otherwise unapproved products. The continued ability for patients to easily find these illegal sources online makes it more likely consumers will inadvertently purchase counterfeit medicine. Moreover, the persistence of these sources in top results makes it harder for regulators, healthcare providers, and nonprofits like ASOP Global to educate consumers as Internet users have been trained to trust that their queries will lead to relevant, authoritative information.
- **The continued illegal online sale of controlled substances, which have increasingly been found to be laced with fentanyl and other deadly opioids.**³⁵ Despite the passage of the Ryan Haight Online Pharmacy Consumer Protection Act in 2008 which expressly prohibits the advertisement and sale of controlled substances on the Internet without a valid prescription, illegal online sales of these products continue to thrive. Despite this federal law, at any given time there are roughly 30,000 - 35,000 active online pharmacies operating illegally, selling prescription medicines without a prescription, operating without a license, or peddling counterfeit or otherwise illegal drugs to Americans.³⁶ Nearly 91% of first search results led users to an illegal online pharmacy selling controlled substances such as prescription opioids, often without a valid prescription.³⁷ In a two-week period, there were over 45,000 tweets that promoted the purchase and nonmedical use of prescription drugs through an actively marketed illegal online pharmacy.³⁸ Furthermore, and arguably most alarming, counterfeit drugs that have been laced with fentanyl and other synthetic opioids have been found in 43 states (as of April 2018) with deaths specifically attributed to these drugs in 22 of those states.³⁹ In fact, a recent article run in the Salt Lake Tribune notes the significant role that organized crime organizations, such as the Sinaloa Cartel, play in the manufacture, sale and distribution of counterfeit pain medications that include synthetic opioids like fentanyl and other analogues that are tens if not hundreds of times more powerful than morphine.⁴⁰
- **The lack of awareness among patients, providers, policymakers about the dangers of foreign-sourced medicines offered through foreign wholesalers and directly to consumers online as compared to the traditional and legitimate brick-and-mortar supply chain.** This includes the ability of criminals to source drugs from unknown and unregulated sources with impunity for years while putting Americans at risk, see e.g. CanadaDrugs case⁴¹, and
- **The need for increased resources to aid regulators and law enforcement as they work to thwart sophisticated criminal networks that knowingly and illegally distribute dangerous drugs, including counterfeit medicines and controlled substances.** Hundreds of thousands of packages enter the US

³⁴ <https://buysaferx.pharmacy/wp-content/uploads/2017/02/napbletter.pdf>

³⁵ <https://www.safemedicines.org/2017/09/40-states-and-counting.html>

³⁶ https://buysaferx.pharmacy/wp-content/uploads/2018/02/NABP-Internet-Drug-Outlet-Report_February-2018.pdf

³⁷ https://buysaferx.pharmacy/wp-content/uploads/2018/02/Online_Opioids_Report_Concerning_Ease_of-4.pdf

³⁸ Establishing a Link Between Prescription Drug Abuse and Illicit Online Pharmacies: Analysis of Twitter Data. December 2016

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4704982/>

³⁹ IBID.

⁴⁰ <https://www.sltrib.com/opinion/commentary/2018/12/10/commentary-utahns/>

⁴¹ Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States. The *United States Attorney's Office – District of Montana*. April 13, 2018. <https://www.justice.gov/usao-mt/pr/canadian-drug-firm-admits-selling-counterfeit-and-misbranded-prescription-drugs>

every day. The FDA is able to physically inspect less than 0.06% of packages presumed to contain drug products shipped through the International Mail Facilities every day.⁴² It can take days or weeks to get sampling results.⁴³

ASOP Global and our members and allies are dedicated to continuing to raise awareness primarily through education and research on this incredibly important public health and safety issue. It is our hope to work with our committed champions in Congress, such as this Committee, to increase resources for law enforcement and others with the intent to protect American consumers from illegal drugs sellers operating online.

Internet search engines, social media companies, and online marketplaces must also be a part of the solution.

In 2011, Google agreed to forfeit \$500 million for allowing online Canadian ‘pharmacies’ to place advertisements through its AdWords program targeting consumers in the United States, resulting in the unlawful importation of controlled and non-controlled prescription drugs into the United States.⁴⁴ The forfeiture, one of the largest ever in the United States, represented the gross revenue received by Google as a result of Canadian pharmacies advertising through Google’s AdWords program, plus gross revenue made by Canadian pharmacies from their sales to U.S. consumers.⁴⁵ Since the DOJ settlement⁴⁶, most Internet search platforms, social media and e-commerce companies prohibit illegal drug sellers from buying advertisements. These same policies do not currently apply to other areas of their platforms. As FDA Commissioner Gottlieb recently noted:

“If you’re selling a drug with the potential for abuse and misuse through an online website, you’re no longer in the business of selling widgets or books. You have a social contract to take voluntary steps to help address public health challenges.”⁴⁷

Given the magnitude of the public health crisis, there are voluntary measures that these companies could take to substantially reduce the availability of illicit opioids and counterfeit, falsified, or substandard prescription drugs online.

For example, Internet companies could:

- Modify algorithms to promote verified online pharmacies and authoritative healthcare information and treatment resources, including sites with information on the potentially fatal risks associated with opioid abuse;
 - *Google already does this for search queries involving health terms in collaboration with Mayo and Harvard Medical.*⁴⁸
- Adjust organic search results to delist or prevent optimization of non-verified websites and sellers offering illicit drugs for sale on the Internet;
- Proactively detect and remove social media posts, individual and group pages, advertisements, and other listings offering or facilitating illicit drug sales via the Internet;
- Engage in public awareness campaigns teaching consumers how to stay safe and save money; and

⁴² https://asopfoundation.pharmacy/wp-content/uploads/2018/11/Kopcha_OPQ_ASOP_FINAL.pdf

⁴³ IBID.

⁴⁴ <https://www.justice.gov/opa/pr/google-forfeits-500-million-generated-online-ads-prescription-drug-sales-canadian-online>

⁴⁵ IBID.

⁴⁶ IBID.

⁴⁷ Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to help prevent new addiction, curb abuse and overdose related to opioid products. January 2018. <https://www.prnewswire.com/news-releases/statement-from-fda-commissioner-scott-gottlieb-md-on-new-steps-to-help-prevent-new-addiction-curb-abuse-and-overdose-related-to-opioid-products-300590316.html>

⁴⁸ Google Partnership with Mayo Clinic and Harvard Medical. <https://www.mayoclinic.org/giving-to-mayo-clinic/philanthropy-in-action/features-stories/google-works-with-mayo-clinic-to-share-health-knowledge>

- Create a shared industry-wide database where companies can create “digital fingerprints” for illicit drug content and share with participating companies, building off Internet companies’ experience with terrorism content.

Notably, several Internet companies already take proactive action as related to other content found online:

- Terrorist content:⁴⁹
 - At last year’s EU Internet Forum, Facebook, Microsoft, Twitter, and YouTube declared in a joint determination to curb the spread of terrorist content online – called the Global Internet Forum to Counter Terrorism (GIFCT).
 - Under the Global Internet Forum to Counter Terrorism (GIFCT), a database became operational in the spring of 2017 that includes 13 contributing companies containing more than 88,000 hashes.
 - That database allows the Internet companies to use those hashes to identify and remove matching content—videos and images—that violate their respective policies or, in some cases, immediately take action on terrorist content.
 - GIFCT also created an online resource for smaller tech companies to seek support and feedback.
 - GIFCT created a mechanism that allows customers, regulators, users, or other interested parties to report suspect terrorist content and to receive feedback on actions taken in response to these reports.
- Health Information
 - When you search on Google for medical information⁵⁰, the content that surfaces on first-page search results has been reviewed by doctors. This includes vetted information about symptoms, treatments, and medical conditions.
- Bullying – Instagram
 - Utilization of machine learning and other technology-based tools to detect instances of bullying found in user-generated posts or comments and subsequent engagement with Instagram’s Community Operations Team for review and response.⁵¹

8. WHEN COUNTERFEIT MEDICINES HAVE BEEN IDENTIFIED, DO YOU COORDINATE WITH YOUR MEMBERS TO PREVENT THE SALE ON E-COMMERCE PLATFORMS? IF SO, PLEASE EXPLAIN.

ASOP Global focuses its activities on (1) research, (2) patient and provider education, (3) advocacy, and (4) collaboration. ASOP Global does not engage in law enforcement or investigatory activities. However, when counterfeit medicines on e-commerce platforms have been identified by appropriate law enforcement or private sector parties, ASOP Global will share the case/incident with our members and use it to educate consumers, healthcare providers, and policymakers about the dangers of illegal online drug sales and the importance of buying medicine from safe, verified sources. See examples discussed above.

⁴⁹ Senate Intelligence Committee: Response to Committee Questions for the Record. September 2018.

<https://www.intelligence.senate.gov/hearings/open-hearing-foreign-influence-operations%E2%80%99-use-social-media-platforms-company-witnesses>

⁵⁰ <https://support.google.com/websearch/answer/2364942?hl=en>

⁵¹ <https://www.cnn.com/2018/10/09/tech/instagram-anti-bullying-tools/index.html>

9. DO YOU ENGAGE WITH U.S. FEDERAL, STATE, OR LOCAL LAW ENFORCEMENT TO REMOVE COUNTERFEIT MEDICINES FROM THE STREAM OF COMMERCE AND TO CURTAIL THEIR DISTRIBUTION IN THE U.S.? IF SO, WHAT AUTHORITIES AND TYPES OF ACTIVITIES AND COORDINATION EFFORTS HAVE PROVEN SUCCESSFUL?

ASOP Global does not engage with U.S. federal, state, or local law enforcement to remove counterfeit medicines from the stream of commerce or to curtail their distribution in the U.S. ASOP Global focuses its activities on (1) research, (2) patient and provider education, (3) advocacy, and (4) collaboration.

Many of our members and allies, however, do directly collaborate with law enforcement on takedown requests directly to the sellers and notifications to Internet companies. The interaction between law enforcement and the private sector is discussed more fully in Appendix D. We also commend your attention to the work of the Pharmaceutical Security Institute.

10. DO YOU ENGAGE WITH FOREIGN GOVERNMENTS TO CURTAIL THE SALE OF COUNTERFEIT MEDICINES? IF SO, WHAT TYPES OF ACTIVITIES AND COORDINATION EFFORTS HAVE PROVEN SUCCESSFUL? WHICH HAVE NOT?

The illegal online sale of medicine is inherently a global problem as the Internet knows no jurisdictional bounds. Recognizing this, ASOP Global has undertaken projects and initiatives in the United States, Canada, Latin America, Europe, China, and India. Through this work, ASOP Global staff and member organizations engage with foreign policymakers, law enforcement and regulators to educate and share best practices related to the problem of illegal online sales of medicine.

As an example, ASOP Global recently led a delegation to meet with government officials in India to provide feedback and share best practices for ensuring safe access to prescription drugs online at a time when the Government of India is looking to authorize online sales of prescription medicines.

Also this year, ASOP Global brought together local partners under the banner of ASOP Canada to educate Canadian government officials about the risks posed by illegal online sellers of medications, and what the risks mean to the safety and security of Canadians and to patients globally.⁵²

As is true domestically, foreign governments cannot educate or enforce their way out of the growing problem of counterfeit medicine and illegal online drug sales. Rather, to have lasting impact, foreign governments need to demand increased proactive efforts by the internet companies in their jurisdictions. As discussed previously, domain name registries, registrars, search engines, online marketplaces and social media platforms have the unique ability to cut off services to illegal online drug sellers. Just as U.S. FDA has done recently, other countries' authorities should likewise call upon internet companies to take reasonable action to prevent the further distribution of dangerous counterfeit drugs and illicit opioids online.

11. IF YOU AND/OR YOUR MEMBER BECOMES AWARE OF COUNTERFEIT MEDICINES SOLD VIA AN E-COMMERCE PLATFORM, WHAT, IF ANY, ACTION CAN YOU TAKE TO PREVENT THE SALE OF THE GOOD?

⁵² <https://buysaferx.pharmacy/canada/>

ASOP Global focuses its activities on (1) research, (2) patient and provider education, (3) advocacy, and (4) collaboration. As discussed above, when ASOP Global becomes aware of counterfeit medicines sold on e-commerce platforms through appropriate law enforcement or private sector parties, ASOP Global seeks to share the case/incident with our members and will use it to educate consumers, healthcare providers, and policymakers about the dangers of illegal online drug sales and the importance of buying medicine from safe, verified sources.

12. IF THERE ARE ANY OTHER PIECES OF INFORMATION, DETAILS, OR DATA YOU FEEL WOULD BE HELPFUL TO THE COMMITTEE, WE RESPECTFULLY REQUEST THAT YOU SUBMIT THEM AS PART OF YOUR ANSWERS AS WELL.

ASOP Global, including our Board and 40 plus national and international members, have substantial experience with the dangers of drug importation and counterfeit medicines. While we appreciate policymaker efforts to find ways to increase patient access to safe, affordable prescription medicines, ASOP Global is concerned by some policymakers' interests in using drug importation as a means to lower drug prices. At a time when the U.S. Government and federal regulators are working to implement the next phase of the Drug Supply Chain Security Act (DSCSA; PL 113-54)⁵³, these efforts come directly in conflict with those targeting the legitimate supply chain. Provisions within the DSCSA do not impact safety or quality of medications purchased via the Internet.

As rational economic actors, drug counterfeiters are known to regularly market the highest cost, hardest to get, and most in-demand products because that is where there is American demand. For examples refer to the following cases: counterfeit Avastin case⁵⁴; FDA press release on counterfeit Botox⁵⁵; FDA crackdown on fake "Ebola cures" sold online⁵⁶; FDA warning of fraudulent and unapproved flu products⁵⁷; and FDA warning of illegal erectile dysfunction products⁵⁸. We could expect additional proliferation of drug counterfeiting should the U.S. Government authorize drug importation of high cost and/or high demand prescription medicines. Such importation would, at best, force Americans to rely on foreign governments to regulate and police the pharmaceutical supply chain that operates outside of U.S. jurisdiction. There is also an intrinsic risk that the number of Americans exposed to counterfeit medicines would continue to grow concurrent with those comfortable doing so. This casts an increasingly large shadow – and places an incalculable risk – around online drug sales from foreign countries for which these foreign medications and counterfeit drugs are generally indistinguishable.

Lifesaving medicines are also subject to counterfeiting by criminals. In July, the website for CanadaDrugs.com was shut down after settling a case with the Department of Justice and paying a \$34 million fine for selling and importing counterfeit cancer drugs and other unapproved pharmaceuticals into the United States. For additional examples of patient harms and recent law enforcement actions, please see Appendix A and B, respectively.

U.S. consumers buying medications from alleged 'Canadian online pharmacies' rarely, if ever, receive the same regulator-approved products provided to Canadian consumers. Indeed, FDA has found that 85% of the drugs being promoted as "Canadian" came from 27 other countries around the globe, including India, Costa Rica and Vanuatu. Just as online criminals currently pass themselves off as "Canadian", allowing even a limited legal

⁵³ <https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/>

⁵⁴ <https://www.fda.gov/ICECI/CriminalInvestigations/ucm605139.htm>

⁵⁵ <https://www.fda.gov/drugs/drugsafety/ucm443217.htm>

⁵⁶ <https://www.npr.org/sections/health-shots/2014/10/23/358318848/fda-cracks-down-on-fake-ebola-cures-sold-online>

⁵⁷ <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm599223.htm>

⁵⁸ <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048386.htm>

means of importation would no doubt cause criminals to likewise pass themselves off as falling within that exception.

Further, importation of prescription drugs could undermine the significant efforts of local, state and federal stakeholders in combatting the prescription drug abuse epidemic. At a time when more than 72,000 individuals are dying each year from an opioid-related overdose, importation puts patients at greater risk of receiving dangerous counterfeit or otherwise illegal medicine.

If the US Government authorizes drug importation, we should anticipate increased proliferation of drug counterfeiting – especially for high cost and/or high demand medicines. The government already struggles to stop unsafe medicine from entering the country through International Mail Facilities (IMFs). Increasing the volume of drugs from other countries would stress an already overburdened safety system.

Importation would make America reliant on foreign governments to regulate and police the pharmaceutical supply chain outside the U.S., while implying to consumers that it is safe to buy any medicine from foreign sources. Research shows the opposite to be true. Drugs made in places like India and China – often sold under the guise of being from Canada – can be manufactured in unsafe conditions; contain too much, too little, or no active ingredients; and/or may be made using dangerous and sometimes deadly substances, including fentanyl and other poisons.^{59,60}

ASOP Global looks forward to discussing our views with this Committee, other Congressional offices, and the Administration. We share their goal of increasing patient access to safe, affordable medicine and welcome the opportunity to provide data and insights into why importation is not the solution to high drug prices.

⁵⁹ <https://buysaferx.pharmacy/public-awareness-campaigns/canadian-online-pharmacies/faqs/>

⁶⁰ <https://buysaferx.pharmacy/for-the-media/key-data-about-controlled-substances-sold-online/>

Appendix A

EXAMPLES OF PATIENTS HARMED BY MEDICATIONS PURCHASED ONLINE

These are just a few illustrations, in chronological order, of the serious and growing global problem of illegal online drug sellers.

1. On February 12, 2001, U.S. citizen Ryan Haight died from adverse reactions to painkillers that he purchased over the Internet. He was only required to fill out a questionnaire that was “examined” by a doctor who had never met him.¹
2. On December 17, 2006, Craig Schmidt, a 30-year-old plastics salesman, purchased Xanax (an anxiety drug) and Ultram (a painkiller) from an online drug seller without seeing or speaking to the doctor that prescribed the medications. After taking the drugs, he nearly died and has been left permanently impaired with brain damage that inhibits him from driving or even walking without stumbling.²
3. Marcia Bergeron, a Canadian resident and US citizen, died in 2006 from heavy metal poisoning caused by the contaminated prescription medications she had purchased from an illicit online pharmacy. Otherwise healthy, the coroner determined that Bergeron died of cardiac arrhythmia caused by metal toxicity from counterfeit medication. According to the coroner, the website where Marcia bought her medicines looked reputable as did the box of pills, but the drugs were actually shipped from overseas and had high levels of lead, titanium, and arsenic, which caused her death.³
4. On May 22, 2008, a man from Wichita, Kansas died from an accidental overdose of muscle relaxants he received from an online pharmacy. He obtained these drugs without ever visiting a doctor. The man's wife described her husband as "an addict ----and that the Internet sites that sold him the drugs were his pushers."⁴
5. Steven Kovacs was a 22-year old aspiring psychologist in New York when he started buying medication online after first being prescribed Adderall, used to treat attention-deficit hyperactivity disorder, and Xanax, used to treat anxiety. Steven died of a prescription drug overdose on July 8, 2009 after mixing, Adderall, Xanax and OxyContin.⁵
6. In January of 2010, 150 patients were admitted to hospitals in Singapore after taking counterfeit Tadalafil and herbal preparations that claimed to cure erectile dysfunction. Seven (7) of the patients

¹ “Experimentation Turns Deadly for One Teenager,” Washington Post (October 21, 2003): available at <http://www.washingtonpost.com/wp-dyn/content/article/2007/06/28/AR2007062801395.html?noredirect=on>

² “Online Extra: The Deadly Side Effects of Net Pharmacies” Bloomberg Businessweek (December 18, 2006); available at <http://www.businessweek.com/stories/2006-12-17/online-extra-the-deadly-side-effects-of-net-pharmacies>

³ “Counterfeit Pills Bought Online Leads to Death, Coroner Confirms,” The Times Colonist (July 6, 2007); available at <http://www.canada.com/victoriatimescolonist/news/story.html?id=05142ca2-9796-4868-bf42-76e939915fa5&k=29039>. This medicine was contaminated with significantly high levels of metal.

⁴ “Widow: My Husband Died from Online Drugs” CNN (May 22, 2008); available at <http://www.cnn.com/2008/HEALTH/05/21/online.drugs/index.html?iref=allsearch>. This drug was misused and abused. The medicine was purchased online without a doctor’s visit or a prescription.

⁵ “Mom, Schumer urge Web Pharmacy Crackdown,” Newsday, United States (July 10, 2011); available at <http://www.newsday.com/long-island/mom-schumer-urge-web-pharmacy-crackdown-1.3016581>. This medicine was obtained without a prescription and was abused because online prescription drugs were easily accessible.

were comatose and four (4) subsequently died from the online drugs which contained powerful ingredients used to treat diabetes.⁶¹⁶

7. On June 3, 2011, an emergency room doctor from Texas suffered a stroke from ingesting counterfeit Alli from *www.2daydietsshopping.com*. The counterfeit Alli was produced using the controlled substance sibutramine, rather than the approved ingredient orlistat, and then shipped to the US for redistribution. Two individuals operated the site. The first is a Chinese citizen who has been sentenced to 7 years in federal prison, \$504,815.39 in restitution to victims, and deportation following his sentence. The second US citizen received 3-years' probation.⁷
8. On April 4, 2012, a mother and son in Los Angeles were looking for cold medication. They purchased and fell victim to a counterfeit drug "vitamin injection." The victim's heart rate increased rapidly, experienced severe headaches, dramatic weight loss, fainting and numbness in lips. The victim was eventually hospitalized.⁸
9. On April 23, 2013, Sarah Houston, a 23-year old medical student in the United Kingdom obsessed with her weight, purchased DNP, a deadly diet pill, through an online drug seller. The pill, sold as a weight loss aid through many illicit online pharmacies, is actually a pesticide with lethal consequences to humans. Ms. Houston died the day after a bout of breathlessness, icteric sclera and hyperthermia, symptoms she had previously experienced.⁹
10. In November 2014, Aidan Karpenko, 19, was found dead just hours after taking a single Etizolam pill that was purchased by his friend on the Internet. Etizolam is a medication used to treat anxiety, insomnia and panic attacks. The drug is not licensed or regulated in the UK; however, it is licensed in Japan and India.¹⁰
11. On January 3, 2015, Kelly Best, a 19-year-old man, died after taking counterfeit OxyContin that contained a high dose of a different drug. Best is the third person in Saskatoon to be killed by the pills within 6 months according to Canadian police.¹¹
12. Emily-Sue Thomas, 18, became violently ill after taking a weight-loss pill that she purchased online. Thomas said she became interested in the drug after viewing an advertisement on her Facebook page claiming that the drug was popular with celebrities.¹⁴

⁶ "Counterfeit Internet Drugs Pose Significant Risks and Discourage Vital Health Checks," Science Daily (January 20, 2010).

<http://www.sciencedaily.com/releases/2010/01/100120085348.htm>. This contaminated medicine, claimed to cure erectile dysfunction contained a powerful drug used to treat diabetes.

⁷ "June 3, 2011: Chinese National Sentenced to Federal Prison for Trafficking Counterfeit Pharmaceutical Weight Loss Drug" U.S. Department of Justice (June 3, 2011); available at <http://www.fda.gov/ICECI/CriminalInvestigations/ucm257912.htm>. This medicine was contaminated with significantly high levels of metal. The patient suffered a stroke after ingesting the medication.

⁸ "Cracking Down on Counterfeit Drugs" San Diego Union-Tribune (April 4, 2012); available at <http://www.utsandiego.com/news/2012/apr/04/cracking-down-counterfeit-drugs/?page=1#article>. This medicine was contaminated.

⁹ "Banned slimming drug kills medical student: Coroner attacks online dealers who target the vulnerable" The Daily Mail, United Kingdom (April 22, 2013); available at <http://www.dailymail.co.uk/health/article-2312986/Sarah-Houston-Banned-slimming-drug-DNP-kills-medical-student-coroner-attacks-online-dealers-target-vulnerable.html>. This medicine was misused. The patient took both anti-depressants and a pill marketed as a weight loss aid containing lethal ingredients.

¹⁰ "'One pill can kill' warning after death of popular Chesterfield teen" Derbyshire Times (November 27, 2014); available at

<http://www.derbyshiretimes.co.uk/news/grassroots/one-pill-can-kill-warning-after-death-of-popular-chesterfield-teen-1-6973111>.

¹¹ "Counterfeit OxyContin claims another life in Canada" Securing Industry (January 12, 2015); available at

<http://www.securindustry.com/pharmaceuticals/counterfeit-oxycontin-claims-another-life-in-canada/s40/a2233/#.VoBtZVJmo-x>.

¹⁴ "Health professionals urge the public to steer clear of 'dangerous' online slimming pills" Wales Online (March 26, 2015); available at <http://www.walesonline.co.uk/news/health/health-professionals-urge-public-steer-8926003>.

13. On April 12, 2015, Eloise Parry died after consuming “diet pills” that she purchased over the Internet. The police are investigating the case and believe the pills contain the highly toxic substance, dinitrophenol or DNP.¹³
14. Michael Thompson, a Nova Scotia man, died on March 18, 2015, of an accidental overdose. Thompson was addicted to prescription drugs and his family received an alarming package in the mail just two days after his death. The envelope was from reChem Labs and contained what they thought was the drug equivalent to Ativan, an anti-anxiety medicine. After analysis, it was found to be Etizolam, a drug 10 times more potent than Valium. Etizolam is not approved for sale in either the U.S. or Canada.¹²
15. David Connell, 21, died after taking too much etizolam, which is approved in Japan and India but banned for human use in most of Europe. Mr. Connell had bought the drug online from a Scottish company for £43 a few days before his death, after researching tips to help anxiety on the Internet. After his body was discovered, police found a clear bag labeled ‘etizolam: reagent only. Not for human consumption’ in his bin, along with a blue, granular substance around his body. The drug is up to ten times more powerful than diazepam.¹⁵
16. In February 2017, 21-year-old Bethany Shipsey died after consuming 2,4-dinitrophenol (DNP), an industrial strength pesticide, that was purchased from an online site.¹⁶
17. Over a two-week period in late 2017, the Senate Homeland Security and Governmental Affairs Permanent Subcommittee on Investigations was able to identify seven confirmed synthetic opioid-related deaths that were linked back to online sellers of illicit narcotics. The report outlines the death of a 49-year-old Ohio resident that purchased roughly \$2,500 of synthetic opioids from an online seller over a 10-month period, receiving eighteen packages in total. The cause of death for this Ohioan, according to the autopsy report, was “acute fentanyl intoxication.” In addition, a Michigan man sent \$400 to an online seller in late 2016 and received several packages believed to be synthetic opioids. According to the report, just one day later, this individual died of an accidental overdose of multiple drugs, including a fentanyl analogue.¹⁷
18. On March 28, 2018, 34-year-old Brian Parker and 30-year-old Victoria Koleski of Long Island City, New York pled guilty to their roles in distributing synthetic opioids that resulted in the death of a customer in Madison, Wisconsin. These substances were purchased through two of Parker’s online companies, Unbeatablechems and RC Powders.¹⁸
19. On April 11, 2018, documented Lakeside (CA) gang member Uriah Odish was indicted by a federal grand jury for selling fentanyl that led to the death of a 25-year-old La Mesa woman. Odish is the fourth person since January to be charged in the Southern District of California with Distribution of Fentanyl Resulting in Death.¹⁹

¹³ “Warnings after student ‘diet-pills’ death” Yahoo! News (April 21, 2015); available at <https://uk.news.yahoo.com/warnings-student-diet-pills-death-092436702.html#RFWMuwe>.

¹² “Research chemicals’ making their way into illicit drug markets, police say” Yahoo! News (October 1, 2015); available at <https://ca.news.yahoo.com/research-chemicals-making-way-illicit-090000428.html>.

¹⁵ First Class’ Student Died After Taking Anti-Depressants Bought Online to Combat Exam Stress (January 22, 2016); available at <https://www.mirror.co.uk/news/uk-news/first-class-student-died-after-7223588>.

¹⁶ “Much-Loved Daughter Bethany Shipsey Overdoses on Online Diet Pills (January 8, 2018); available at <https://www.birminghammail.co.uk/news/midlands-news/much-loved-daughter-bethany-shipsey-14127508>.

¹⁷ Combatting the Opioid Crisis: Exploiting Vulnerabilities in International Mail – Staff Report (January 2018); available at <http://www.hsgac.senate.gov/download/psi-report-combatting-the-opioid-crisis>.

¹⁸ DOJ Press Release: “New York Man Admits Distributing Synthetic Drug Leading to Overdose Death” (March 28, 2018); available at <https://www.justice.gov/usao-nj/pr/new-york-man-admits-distributing-synthetic-drug-leading-overdose-death>

¹⁹ DOJ Press Release: “Lakeside Gang Member Indicted in Fentanyl Overdose Death” (April 11, 2018); available at <https://www.justice.gov/usao-sdca/pr/lakeside-gang-member-indicted-fentanyl-overdose-death>

20. On April 25, 2018, 32 individuals were charged with participating in a fentanyl trafficking conspiracy that caused death. Sergio Martinez of Lawrence, Massachusetts, one of the conspiracy's leaders, was charged with aiding and abetting a distribution of fentanyl that resulted in death.²⁰
21. On May 21, 2018, Vincent Koh, M.D., and his wife and office manager Milly Koh of Poughkeepsie, New York, were sentenced for delivering misbranded and foreign oncology drugs to their patients. The couple purchased the unapproved drugs from a foreign source with improper labeling and administered them to cancer patients.²¹
22. On July 13, 2018, CanadaDrugs.com is scheduled to shut down after investigators found that the site was selling two counterfeit cancer drugs with no active ingredient.²²
23. Two people in Akron, Ohio fatally overdosed on Acetyl fentanyl purchased through one of the Zheng drug trafficking organization's many online companies. Two Chinese nationals were charged for running the global drug trafficking ring and importing controlled substances into the United States.²³
24. 200,000 people die every year from counterfeit or substandard anti-malarial drugs, 160,000 of which are from sub-Saharan Africa. Many of these fake medicines originate in India or China.²⁴
25. It was determined that a man responsible for distributing opioids that resulted in several overdose deaths in northeastern Ohio in 2016 had ordered the drugs from a Chinese website and was redistributing them from one of his online companies.²⁵

²⁰ DOJ Press Release: "Members of Fentanyl Trafficking Conspiracy Charged with Drug Distribution Resulting in Death, Money Laundering, and Firearms Offenses" (July 13, 2018) available at <https://www.justice.gov/usao-nh/pr/members-fentanyl-trafficking-conspiracy-charged-drug-distribution-resulting-death-money>

²¹ DOJ Press Release: "Oncologist and Office Manager Sentenced in Connection with Administering Unapproved, Foreign Drugs" (May 21, 2018) available at <https://www.justice.gov/usao-ndny/pr/oncologist-and-office-manager-sentenced-connection-administering-unapproved-foreign>

²² ABC11.com: "I-Team: Online Pharmacy Shutting Down After Selling Fake Cancer Drugs," (July 9, 2018) available at <https://abc11.com/health/i-team-online-pharmacy-shutting-down-after-selling-fake-cancer-drugs/3733321/>

²³ DOJ Press Release: "Two Chinese Nationals Charged With Operating Global Opioid and Drug Manufacturing Conspiracy Resulting in Deaths" (August 22, 2018) available at <https://www.justice.gov/opa/pr/two-chinese-nationals-charged-operating-global-opioid-and-drug-manufacturing-conspiracy>

²⁴ TheConversation.com: "Fake drugs are one reason malaria still kills so many," (April 24, 2018) available at <https://theconversation.com/fake-drugs-are-one-reason-malaria-still-kills-so-many-92712>

²⁵ VOANews.com: "Chinese Businessman Pleads Guilty of Importing Opioids," (August 7, 2018) available at <https://www.voanews.com/a/chinese-businessman-bin-wang-pleads-guilty-to-importing-opioids/4517815.html>

Appendix B

RECENT LAW ENFORCEMENT ACTION

These are just a few illustrations, in chronological order, of law enforcement action against those illegally selling, purchasing or distributing opioids in the last six months.

1. On June 19, 2018, a Texas woman pleaded guilty to one count of possessing a controlled substance with the intent to distribute and one count of receiving a misbranded drug in interstate commerce. Vanesa Gonzales was one of the owners of X2Zero, a store selling dietary supplements and through stores located in Corpus Christi.¹
2. On June 20, 2018, a Shelton, Connecticut resident was arrested on several charges including illegally distributing counterfeit medicine after he was identified as the source of Xanax pills containing fentanyl that contributed to an overdose death.²
3. In July 2018, CanadaDrugs.com was ordered to forfeit \$29,000,000 of the proceeds of their counterfeit drug operation, where online buyers were shipped bottles of pills with no instructions, labeling, or active ingredients. The Chief Executive Officer was sentenced to pay a fine of \$250,000 and five years of probation with the first six months in home confinement.³
4. In July 2018, a Long Beach man who led an operation that sold bulk amounts of counterfeit opioids was sentenced to 26 years in state prison. Gary Resnik, 33, was discovered manufacturing counterfeit pills to look like Vicodin and OxyContin using acetylfentanyl in a homemade lab.⁴
5. On July 13, 2018, it was announced that Gary Davis, also known as “Libertas,” was extradited from the Republic of Ireland to the United States to be tried for his involvement with the “Silk Road,” a secret online marketplace for purchasing illegal drugs, hacking services and other criminal activity. Davis was an administrator for the site and received a weekly salary for his work from June to October 2013.⁵
6. On July 16, 2018, a Baltimore drug dealer was sentenced for conspiracy to distribute heroin and fentanyl. Thomas Merrick, age 37, arranged for the importation of narcotics from Mexico and distributed the substances through the Baltimore area.⁷
7. On July 17, 2018, it was announced that an Illinois man and a Florida man were sentenced for delivery of misbranded drugs. Paul Leix, 36, of Bloomingdale, Illinois, and Thomas Keightly, 35, of Palm Beach

¹ “Vitamin Shop Owner Guilt of Selling Misbranded Drugs and Controlled Substance,” U.S. Department of Justice, (June 18, 2018); available at <https://www.justice.gov/usao-sdtx/pr/vitamin-shop-owner-guilty-selling-misbranded-drugs-and-controlled-substance-0>

² “Shelton Man Charged with Distributing Counterfeit Drugs,” U.S. Department of Justice, (June 20, 2018); available at <https://www.justice.gov/usao-ct/pr/shelton-man-charged-distributing-counterfeit-drugs>

³ “I-Team: Online Pharmacy Shutting Down After Selling Fake Cancer Drugs,” ABC11, (July 9, 2018); available at <https://abc11.com/health/i-team-online-pharmacy-shutting-down-after-selling-fake-cancer-drugs/3733321/>.

⁴ “Long Beach Drug-Ring Leader Who Made Thousands of Opioid Pills Using Illegal Drug From China is Sentenced to 26 Years,” KTLA, (July 10, 2018); available at <https://ktla.com/2018/07/10/long-beach-drug-ring-leader-who-made-thousands-of-opioid-pills-using-illegal-drug-from-china-is-sentenced-to-26-years/>.

⁵ “Manhattan U.S. Attorney Announces Extradition of Irish Man Who Helped Run the ‘Silk Road’ Website,” U.S. Department of Justice, (July 13, 2018); available at <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-extradition-irish-man-who-helped-run-silk-road-website>.

⁷ “Baltimore Drug Dealer Sentenced to Over 11 Years in Federal Prison,” U.S. Department of Justice, (July 16, 2018); available at <http://www.fda.gov/ICECI/CriminalInvestigations/ucm257912.htm>.

Gardens (FL), were involved in a business called L&P Trading which used the Internet to market and distribute peptides and other bodybuilding chemicals that were not approved for human consumption.⁸

8. On July 19, 2018, a Wise, Virginia resident pleaded guilty to one count of using a communications facility to unlawfully import fentanyl and fentanyl analogues. Kristofer Rucinski, 35, was charged after Customs and Border Patrol officers intercepted a package intended for Rucinski that had been shipped from China. Rucinski used Bitcoin to pay for the drugs.⁹
9. On July 31, 2018, three residents of British Columbia, Canada and the company they operated were sentenced in federal court in Pittsburgh on charges of conspiring to distribute wholesale quantities of misbranded prescription drugs made for the foreign market and money laundering. Quantum Solutions, SRL, purchased prescription drugs made for foreign markets and sold wholesale quantities to three pharmacists in western Pennsylvania.¹⁰
10. In August 2018, five people from New York were charged for their role in illicitly selling drugs online following a year-long national investigation targeting vendors selling illicit drugs on the Internet. The five New York residents were all members of a conspiracy to distribute a controlled substance after investigators found a variety of pills, pill presses, and powders. The defendants were linked to online marketplaces and the use of cryptocurrency.¹¹
11. On August 3, 2018, the U.S. Drug Enforcement Administration announced the indictment of a man found with counterfeit Adderall pills that were made with methamphetamine. Gino Carl von Eckstein was indicted for possession with intent to distribute after he was found possessing over 1,000 grams of methamphetamine. Agents discovered pills, pill presses, punches and dies in the man's San Leandro home.¹⁴
12. On August 7, 2018, two California men were indicted for distributing counterfeit oxycodone pills made with fentanyl. Alfredo Sanchez and Saybyn Borges sold approximately 7,500 counterfeit oxycodone pills that had been contaminated with fentanyl between May 3, 2018 and June 7, 2018. A confidential source who purchased a glass jar of pills from Sanchez and Borges overdosed after ingesting three pills.¹³
13. A Euclid, Ohio man pleaded guilty to distributing fentanyl that he ordered from China and sold domestically, including to an undercover FBI agent. Antonin Austin, 28, sold various types of fentanyl analogues and other opioids on the dark web. Austin purchased the fentanyl from a Chinese distributor and shipped his product to buyers through the U.S. Postal Service.¹²

⁸ "Illinois Man and Florida Man Sentenced for Delivery of Misbranded Drugs," U.S. Department of Justice (July 17, 2018); available at <https://www.justice.gov/usao-mdpa/pr/illinois-man-and-florida-man-sentenced-delivery-misbranded-drugs>

⁹ "Wise Resident Pleads Guilty to Opioid Importation Related Charges," U.S. Department of Justice, (July 19, 2018); available at <https://www.justice.gov/usao-wdva/pr/wise-resident-pleads-guilty-opioid-importation-related-charges>.

¹⁰ "Three Canadians and their Company Sentenced for Wholesale Distribution of Misbranded Prescription Drugs and Money Laundering," U.S. Department of Justice (July 31, 2018); available at <https://www.justice.gov/usao-wdpa/pr/three-canadians-and-their-company-sentenced-wholesale-distribution-misbranded>

¹¹ "New York Residents Charged After Being Found with Over 12 Kilos of Counterfeit Xanax Pills," The Partnership for Safe Medicines (August 9, 2018); available at <https://www.safemedicines.org/2018/08/new-york-residents-charged-after-being-found-with-over-12-kilos-of-counterfeit-xanax-pills.html>.

¹⁴ "Euclid Man Pleaded Guilty to Distribution of Fentanyl that He Ordered From China and Sold Domestically," U.S. Department of Justice (August 13, 2018); available at <https://www.justice.gov/usao-ndoh/pr/euclid-man-pleaded-guilty-distribution-fentanyl-he-ordered-china-and-sold-domestically>

¹³ "DOJ Indicts Two in Northern California Who Distributed Counterfeit Pills Made with Fentanyl," The Partnership for Safe Medicines, (August 7, 2018); available at <https://www.safemedicines.org/2018/08/doj-indicts-two-in-northern-california-who-distributed-counterfeit-pills-made-with-fentanyl.html>.

¹² "Research chemicals' making their way into illicit drug markets, police say" Yahoo! News (October 1, 2015); available at <https://ca.news.yahoo.com/research-chemicals-making-way-illicit-09000428.html>.

14. On August 15, 2018, a Jacksonville, Florida man pleaded guilty to his role in a scheme with two Nixa, Missouri men to market all-natural male enhancement supplements that contained Sildenafil, the active ingredient found in Viagra. Michael Schindele owned and operated Executive Image International, a website that sold dietary supplements and failed to properly label the active ingredients.¹⁵
15. On August 22, 2018, Attorney General Jeff Sessions announced the unsealing of a 43-count indictment in federal court in Cleveland, which charged two Chinese citizens with manufacturing and shipping deadly fentanyl analogues and various other drugs to 25 countries and 27 states. This criminal activity directly led to two fatal overdoses in Akron, Ohio. The pair operated numerous online companies to manufacture and distribute the controlled substances across the globe.¹⁶
16. In August 2018, a New York man was scheduled to appear in court on eight counts of distributing and possessing with intent to distribute synthetic cannabinoids, fentanyl, and oxycodone. Shadab Chowdhury, 26, of Brooklyn, New York distributed these substances over three websites, two email accounts, and text messages.¹⁷
17. On September 20, 2018, a Houston physician and the owner of a pain management clinic were each sentenced to 420 months in prison for their roles in running a pill mill that provided tens of thousands of unlawful prescriptions for millions of doses of opioids and other controlled substances.¹⁸
18. On October 2, 2018, two Baltimore County men pleaded guilty to a money laundering conspiracy, admitting that they used a home to manufacture counterfeit Xanax and then sell the drug through the dark web.¹⁹
19. On October 9, 2018, a Frenchman who used the alias “Oxymonster,” was sentenced on charges of conspiracy to distribute drugs and money laundering for his role as a “senior moderator” on the dark web narcotics dealing site, Dream Market.²⁰
20. On October 12, 2018, the District Court of the Eastern District of Tennessee unsealed a 32-count indictment charging four individuals and seven companies in a \$1 billion health care fraud scheme. Defendants were charged with a variety of crimes, including health care fraud, mail fraud, and introducing misbranded drugs into interstate commerce.²¹

¹⁵ “Florida Man Pleads Guilty to Scheme to Market Dietary Supplements,” U.S. Department of Justice (August 15, 2018); available at <https://www.justice.gov/usao-wdmo/pr/florida-man-pleads-guilty-scheme-market-dietary-supplements>

¹⁶ “Two Chinese Nationals Charged with Operating Global Opioid and Drug Manufacturing Conspiracy Resulting in Deaths,” U.S. Department of Justice (August 22, 2018); available at <https://www.justice.gov/opa/pr/two-chinese-nationals-charged-operating-global-opioid-and-drug-manufacturing-conspiracy>

¹⁷ “Brooklyn, New York, Man Charged With Distributing Synthetic Drugs, Fentanyl, and Oxycodone Over the Internet,” U.S. Department of Justice (August 24, 2018); available at <https://www.justice.gov/usao-nj/pr/brooklyn-new-york-man-charged-distributing-synthetic-drugs-fentanyl-and-oxycodone-over>.

¹⁸ “Houston Physician and a Pain Management Clinic Owner Each Sentenced to 35 Years in Prison for Running Pill Mill That Provided Unlawful Prescriptions for Millions of Doses of Opioids and Other Controlled Substances,” U.S. Department of Justice, (September 20, 2018); available at <https://www.justice.gov/opa/pr/houston-physician-and-pain-management-clinic-owner-each-sentenced-35-years-prison-running>

¹⁹ “2 Maryland Men Plead Guilty in Multimillion-Dollar Drug Case Involving Dark Web,” WBLA, (December 2, 2018); available at <https://www.wbalt.com/article/2-maryland-men-plead-guilty-in-multimillion-dollar-drug-case-involving-dark-web/23571824>

²⁰ “Oxymonster,” wearing a long beard, sentenced to 20 years for drug deals on dark web,” Miami Herald, (October 9, 2018) available at <https://www.miamiherald.com/news/local/article219698010.html>

²¹ “Four Men and Seven Companies Indicted for Billion-Dollar Telemedicine Fraud Conspiracy, Telemedicine Company and CEO Plead Guilty in Two Fraud Schemes,” U.S. Department of Justice (October 15, 2018) available at <https://www.justice.gov/opa/pr/four-men-and-seven-companies-indicted-billion-dollar-telemedicine-fraud-conspiracy>

21. On October 18, 2018, a Michigan man was sentenced to 18 months in prison for ordering what he believed to be a hallucinogenic drug online and shipping the drugs to a friend in Iowa, who died of a fentanyl overdose.²²
22. On Friday, October 19, the last of four defendants was sentenced for his role in a narcotics importation and distribution ring, operating in Miami-Dade and Osceola Counties, which sold an analogue of the powerful opioid fentanyl, as well as n-ethylpentylone.²⁴
23. On October 22, 2018, eight New Orleans, Louisiana-area defendants pleaded guilty for their participation in a conspiracy to obtain oxycodone through fraud by using fake prescriptions. Six of the defendants also pleaded guilty for a scheme to distribute oxycodone on the black market.²³
24. On October 23, 2018, it was announced that a federal jury in Pocatello (ID) convicted a man for conspiracy to import anabolic steroids, importation of anabolic steroids, and possession with intent to distribute anabolic steroids. Travis M. Newbold, 47, was found to be helping trans-ship packages for a China-based anabolic steroid supplier.²⁵
25. In October 2018, the Food and Drug Administration launched Operation Pangea XI in collaboration with international regulatory and law enforcement agencies, which will target 465 illegally-operating websites selling potentially dangerous medication. The multi-agency operation is part of a prolonged strategy to identify and take down illegally operating online pharmacies.²⁶
26. On November 13, 2018, an Akron, Ohio man was sentenced to nearly 10 years in prison on charges of possession with the intent to distribute 500 grams of methoxyacetylfentanyl, a fentanyl analogue shipped from China.²⁷
27. On November 19, 2018, a Chinese national who had been living in Massachusetts was sentenced to almost six years in prison for distributing opioids and other drugs that had been shipped from China. Bin Wang, 43, operated online companies Cambridge Chemicals, Wonda Science and other companies from a warehouse in Woburn.²⁸
28. On November 20, 2018, a Rochester, New York resident pleaded guilty to two counts of smuggling goods into the United States after Customs and Border Protection officers intercepted two packages containing thousands of counterfeit Viagra and Cialis pills that had been shipped from Hong Kong.²⁹

²² "Michigan Man Gets 18 Months for Drug Death of Woman in Iowa," AP News, (October 18, 2018) available at <https://apnews.com/dc2f6452e4ed45fb98fbdcdb01645cee>

²⁴ "Eight New Orleans-Area Defendants Plead Guilty to Scheme to Possess Oxycodone by Fraud; Six of the Eight Also Plead Guilty to Scheme to Possess with Intent to Distribute Oxycodone on the Black Market," U.S. Department of Justice, (October 22, 2018) available at: <https://www.justice.gov/opa/pr/eight-new-orleans-area-defendants-plead-guilty-scheme-possess-oxycodone-fraud-six-eight-also>

²³ "Eight New Orleans-Area Defendants Plead Guilty to Scheme to Possess Oxycodone by Fraud; Six of the Eight Also Plead Guilty to Scheme to Possess with Intent to Distribute Oxycodone on the Black Market," U.S. Department of Justice, (October 22, 2018) available at <https://www.justice.gov/opa/pr/eight-new-orleans-area-defendants-plead-guilty-scheme-possess-oxycodone-fraud-six-eight-also>

²⁵ "Federal Jury Convicts Pocatello Man on Anabolic Steroid Charges," U.S. Department of Justice, (October 23, 2018) available at <https://www.justice.gov/usao-id/pr/federal-jury-convicts-pocatello-man-anabolic-steroid-charges>

²⁶ "FDA Launches Global Operation to Crack Down on Websites Selling Illegal, Potentially Dangerous Drugs; Including Opioids," U.S. Food and Drug Administration (October 23, 2018) available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624070.htm>

²⁷ "Akron Man Sentenced to Nearly 10 Years in Prison After Ordering 500 Grams of a Fentanyl Analogue from China," U.S. Department of Justice, (November 13, 2018) available at: <https://www.justice.gov/usao-ndoh/pr/akron-man-sentenced-nearly-10-years-prison-after-ordering-500-grams-fentanyl-analogue>

²⁸ "Chinese National Sentenced to Nearly Six Years in Prison for Distributing Opioids and Other Drugs That Were Shipped From China to the U.S. and Ultimately to Ohio," U.S. Department of Justice, (November 19, 2018), available at: <https://www.justice.gov/usao-ndoh/pr/chinese-national-sentenced-nearly-six-years-prison-distributing-opioids-and-other-drugs>

²⁹ "Rochester Man Pleads Guilty to Smuggling Counterfeit Cialis and Viagra into the United States," U.S. Department of Justice, (November 20, 2018), available at: <https://www.justice.gov/usao-wdny/pr/rochester-man-pleads-guilty-smuggling-counterfeit-cialis-and-viagra-united-states>

29. On November 21, 2018, a Sugarloaf, Pennsylvania man was indicted on charges of unlawfully importing controlled substances after importing Tramadol from India, Germany, Singapore, and Switzerland.³⁰
30. On November 28, 2018, two Southern California residents were arrested in connection with a long-running scheme to smuggle falsified dietary supplement ingredients into the United States from China. Defendants attempted to deceive the FDA and Customs and Border Protection investigators by mislabeling certain stimulants in the substances.³¹
31. On November 29, 2018, two Rancho Cordova residents were indicted on charges of conspiracy to distribute and possess with intent to distribute marijuana and psilocybin mushrooms. The pair operated their drug distribution through social media platforms including Instagram and Snapchat and sold large quantities under the company name “Fine Cali Herb.”³²

³⁰ “Luzerne County Man Indicted for Unlawfully Importing Controlled Substances,” U.S. Department of Justice, (November 21, 2018), available at; <https://www.justice.gov/usao-mdpa/pr/luzerne-county-man-indicted-unlawfully-importing-controlled-substances>

³¹ “Dietary Supplement Ingredient Importers Arrested in Connection with Large-Scale Smuggling and Money Laundering Scheme,” U.S. Department of Justice, (November 29, 2018), available at; <https://www.justice.gov/usao-cdca/pr/dietary-supplement-ingredient-importers-arrested-connection-large-scale-smuggling-and>

³² “Rancho Cordova Pair Indicted for Selling Narcotics Through Social Media Accounts and Receiving Payment in Bitcoin,” U.S. Department of Justice, (November 29, 2018), available at; <https://www.justice.gov/usao-edca/pr/rancho-cordova-pair-indicted-selling-narcotics-through-social-media-accounts-and>

Appendix C

List of Recent Published Academic Journals Regarding Illegal Online Drug Sellers

- Anderson A, Mackey TK, Attaran A, Liang BA. Mapping of Health Communication and Education Strategies Addressing the Public Health Dangers of Illicit Online Pharmacies. *J. Health Commun.* 2016;21(4):397-407.
- Guerra C, Mackey TK. U.S. Criminal and Civil Prosecutions Associated with Illicit Online Pharmacies: Legal Analysis and Global Implications. *Medicines Access @ Point of Care.* 2017;1(1):e104-e118.
- Hertig JB, Anderson C, Marwitz K, Harrell M. Evaluating Attitudes Towards legalizing Canadian Online Pharmacies After Opioid Epidemic Messaging Statements. Purdue University College of Pharmacy. 2017. Available at: https://asopfoundation.pharmacy/wp-content/uploads/2017/12/ASOP-Opioid-White-Paper_Final.pdf
- Hertig JB, Anderson C, Scott C, Marwitz K, Walters K, and Wasynczuk J. Evaluation of Risk Perception Associated with Online Pharmacies. Purdue University College of Pharmacy. 2017, Available at: <https://asopfoundation.pharmacy/wp-content/uploads/2017/08/ASOP-White-Paper-Final.pdf>
- Hertig JB, Sebahar N. Evaluation of Pharmacists' Awareness of the Prevalence and Negative Consequences Associated With Illegal Internet Pharmacies. Purdue University College of Pharmacy Center for Medication Safety Advancement. 2017. Available at: https://buysaferx.pharmacy/wp-content/uploads/2017/05/CMSA_whitepaper_rphonlinelegitimacy.pdf
- Kalyanam J, Katsuki T, Lanckriet G, Mackey TK. Exploring Trends of Nonmedical use of Prescription Drugs and Polydrug Abuse in the Twittersphere Using Unsupervised Machine Learning. *Addict Behav.* 2017;65:289-295.
- Kalyanam J, Mackey T. Detection and Characterization of Illegal Marketing and Promotion of Prescription Drug Abuse on Twitter. *NIPS 2017 Workshop on Machine Learning for Health (ML4H).* 2017; <https://arxiv.org/abs/1712.00507>
- Kalyanam J, Mackey TK. A Review of Digital Surveillance Methods and Approaches to Combat Prescription Drug Abuse. *Curr Addict Rep.* 2017;4(4):397-409.
- Katsuki T, Mackey TK, Cuomo RE. Digital surveillance of prescription drug abuse: An accessible methodology for collecting and analyzing twitter NUPM data. *Annals of Global Health:* 2016; 82(3):590 [published conference abstract].
- Katsuki T[^], Mackey TK[^], Cuomo RE. Establishing a Link Between Prescription Drug Abuse and Illicit Online Pharmacies: Analysis of Twitter Data. *J Med Internet Res.* 2015;17(12):e280.
- Mackey TK, Aung P, Liang BA. Illicit Internet Availability of Drugs Subject to Recall and Patient Safety Consequences. *Int J. Clin Pharm.* 2015;37(6):1076-1085
- Mackey TK, Kalyanam J, Katsuki T, Lanckriet G. Twitter-Based Detection of Illegal Online Sale of Prescription Opioid. *Am J. Pub Health.* 2017;107:1910-1915.
- Mackey TK, Kalyanam J. Detection of Illicit Online Sales of Fentanyl via Twitter. *F1000.* 2017;6:1937.
- Mackey TK, Nayyar G. A Review of Existing and Emerging Digital Technologies to Combat the Global Fake Medicines Trade. *Expert Opin Drug Saf.* 2017;16(5):587-602.
- Mackey TK, Nayyar G. Digital Danger: A Review of the Global Public Health, Patient Safety and Cybersecurity Threats Posed by Illicit Online Pharmacies. *Br Med Bull.* 2016; 118(1):110-126.

- Mackey TK. Opioids and the Internet: Convergence of Technology and Policy Issues to Address the Illicit Online Sales of Opioids. *Health Services Insights*. 2018;in press.
- Mackey TK[^], Kalyanam J[^], Klugman J, Kuzmenko E, Gupta R. Solution to Detect, Classify, and Report Illicit Online Marketing and Sales of Controlled Substances via Twitter: Using Machine Learning and Web Forensics to Combat Digital Opioid Access. *J Med Internet Res*. 2018;20(4):e10029.

Appendix D

Illegal Online Drug Seller Law Enforcement Best Practices White Paper by ASOP Global and the Pharmaceutical Security Institute

Available at:

<https://buysaferx.pharmacy/wp-content/uploads/2016/11/ASOP-Global-PSI-White-Paper-Sept.-2016.pdf>

White Paper: Illegal Online Drug Seller Law Enforcement Best Practices



Presented by
The Alliance for Safe Online Pharmacies-Global
and the Pharmaceutical Security Institute

ASOP
GLOBAL

ALLIANCE FOR
SAFE ONLINE
PHARMACIES

May 2016



White Paper: Illegal Online Drug Seller Law Enforcement Best Practices

*Presented by the Alliance for Safe Online Pharmacies-Global
and the Pharmaceutical Security Institute*

CONTENTS

Introduction	2
Background and Context.....	3
Executive Summary	4
Law Enforcement Best Practices.....	6
A. United States	6
1. Federal Activities.....	6
a) Suggested Enforcement Mechanisms/Improvements	7
b) Model Investigations and Prosecutions.....	9
c) Information Sharing and Collaboration.....	12
2. State and Local Activities	13
B. Europe.....	15
1. European Union Activities.....	15
a) Model Investigations and Prosecutions.....	16
b) Information Sharing and Collaboration.....	17
2. Council of Europe Activities	18
a) Council of Europe/European Directorate for Quality of Medicines.	18
b) Medicrimes	18
3. Country-Specific Activities	19
a) Investigations and Prosecutions.....	19
b) Information Sharing and Collaboration.....	22
C. Asia.....	23
1. Regional Law Enforcement Activities	23
a) Model Investigations and Prosecutions.....	24
b) Information Sharing and Collaboration.....	24
2. Country-Specific Activities	25
a) China	25
b) Japan	26
Raising Awareness.....	28
Conclusion.....	29
Appendix: High-Level Checklist of Best Practices.....	30
A. Best Practices for Governments.....	30

Introduction

Illegal online drug sellers constitute a global threat to public health. In order to assist law enforcement in combating these criminal enterprises, the Alliance for Safe Online Pharmacies (ASOP Global) and the Pharmaceutical Security Institute (PSI) have compiled a list of best practices and exemplars. Included within are suggestions on how best to utilize existing enforcement mechanisms, as well as ideas that could allow for more successful enforcement efforts moving forward.

Background and Context

Illegal online drug sellers plague the Internet and endanger patients globally. The constantly increasing volume of Internet users as a result of enhanced Internet accessibility, through both traditional access and mobile devices, has fast-tracked the growth and profit potential of those criminals running illicit online pharmacies.

The criminals running illegal online pharmacies are selling substandard, spurious, falsely labeled, falsified and counterfeit (SSFFC) medicines. For this White Paper, we use several terms to describe the SSFFC medicines sold online by drug sellers including “unapproved,” “misbranded” and “counterfeit” since some countries discussed herein have specific statutory definitions. Substandard, spurious, falsely labeled, falsified, counterfeit, unapproved and misbranded medicines have much in common as they mislead patients as to their true source, manufacturer and content, place patient health and safety at risk because they may be manufactured in unlicensed, unregulated and uninspected sites, frequently under unsanitary and unsafe conditions and CANNOT guarantee the ingredients or contents of the product.

Enabling prescription drug abuse with medications such as pain killers has been a lucrative part of the illegal online drug sellers’ profitability; however, lifestyle and life-saving drugs have also become top targets. Finally, adding to this flourishing global public health threat is the sheer lack of centralized governance over the Internet.

At any one time there are roughly 35,000 – 50,000 active online drug sellers,¹ and only 3% of these comply with applicable laws.² While consumers in the United States and the European Union are the primary targets of this crime—due to widespread access to high-speed Internet and the large demand for pharmaceutical products—patients in every market are at risk. Illegal online drug sellers peddle medicine globally without regard to national laws and safety standards. These international criminal operations evade law enforcement and complicate private sector operations. According to the U.S. Government Accountability Office (GAO):

At any one time there are roughly 35,000 – 50,000 active online drug sellers, and only 3% of these comply with applicable laws.

Rogue Internet pharmacies are often complex, global operations, and federal agencies face substantial challenges investigating and prosecuting those involved. According to federal agency officials, piecing together rogue Internet pharmacy operations can be difficult because they may be composed of thousands of related websites, and operators take steps to disguise their identities. Officials also face challenges investigating and prosecuting operators because they are often located abroad in countries that are unable or unwilling to aid U.S. agencies. The Department of Justice (DOJ) may not prosecute such cases due to competing priorities, the complexity of these operations, and challenges related to bringing charges under some federal laws.³

Given the complexity of online drug seller crime, stakeholders may ask: a) What does work; b) are there best practices for governments and private sector organizations that should be shared? This paper addresses these questions and provides guidance to U.S. and international stakeholders interested in enforcement of illegal online drug sellers by identifying specific and concrete actions that government leaders and law enforcement can take to protect patient safety online.

1. Be Careful Where You Click, NEEDYMEDS (Oct. 2, 2013), <http://blog.needymeds.org/2013/10/02/be-careful-where-you-click/>.

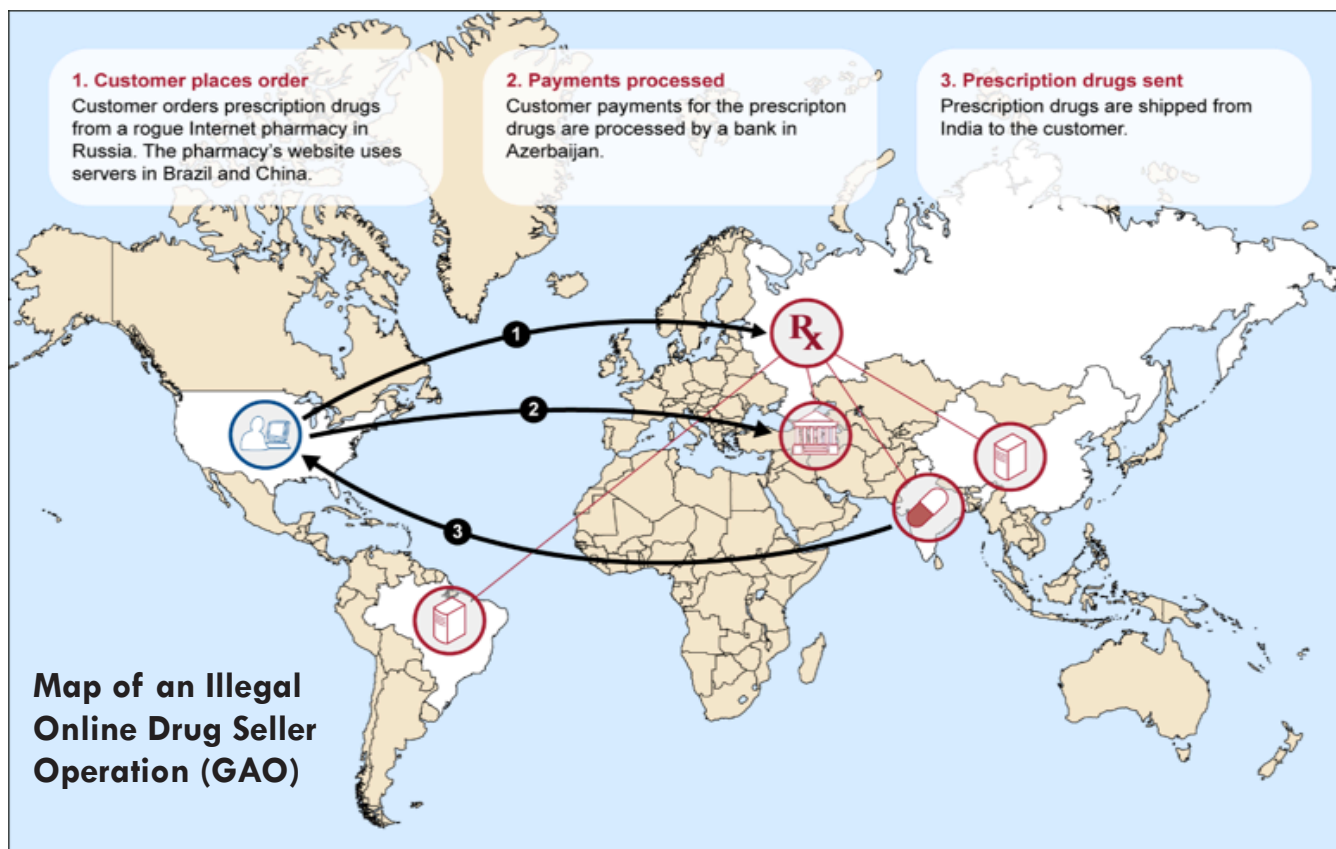
2. See NABP, INTERNET DRUG OUTLET IDENTIFICATION PROGRAM: PROGRESS REPORT FOR STATE AND FEDERAL REGULATORS: JULY 2013 (July 2013), available at http://awarerx.s3.amazonaws.com/system/redactor_assets/documents/237/NABP_Internet_Drug_Outlet_Report_July2013.pdf.

3. GAO, INTERNET PHARMACIES: FEDERAL AGENCIES AND STATES FACE CHALLENGES COMBATING ROGUE SITES, PARTICULARLY THOSE ABROAD (July 8, 2013) [hereinafter GAO REPORT], available at <http://www.gao.gov/assets/660/655751.pdf>.

Executive Summary

Illegal online drug sellers operate on a global scale. Their criminal networks often extend across multiple continents, frustrating potential investigations and enforcement actions along the way. In order to counter this growing problem, law enforcement officials must utilize all of the resources at their disposal, both domestically and internationally.

Enforcement actions are generally more successful when the resources and expertise of multiple agencies are brought together. This is true at both the national and international levels. To understand why coordinated actions are necessary, see the following figure detailing the reach and complexity of an illegal online drug seller's network:



Source: Christian Kreibich © 2011 Institute of Electrical and Electronics Engineers (data); Map Resources (map).

Several recent law enforcement actions discussed below illustrate how coordinated actions can be leveraged to combat these illegal schemes. However, coordination among law enforcement is not enough. It takes substantial time and resources to engage in these types of operations. It also requires cooperation from the private sector, namely Internet commerce companies. Internet companies—manufacturers, advertising providers, registrars and registries, and payment networks and shippers stand at the proverbial chokepoints of the illegal online drug market and are thus uniquely equipped to combat the problem. These companies can quickly shut down trade at any number of points along the illegal supply chain, often more efficiently and completely than law enforcement could hope to do alone. This White Paper demonstrates that both public and private sector efforts are required to combat this threat through the identification of global best practices.

Law Enforcement Best Practices

A. United States

Illegal online drug sellers violate a host of U.S. federal and state laws, but law enforcement efforts are often hindered by lack of prosecutions initiated. Investigations can prove difficult and resource-intensive due to the complexities of the criminal operations and the multi-jurisdictional coordination they require. When cases are successfully prosecuted to conviction, inadequate penalties serve as poor deterrents and may allow offenders to return to their lucrative schemes within a few years.

1. Federal Activities

Illegal online drug sellers violate several federal laws, but investigations and enforcement often prove complicated. There is no single U.S. federal agency tasked with combating illegal online drug seller activity. Instead, several agencies must coordinate their distinct roles to initiate and execute a successful investigation. These enforcement agencies include the Food and Drug Administration (FDA); the Drug Enforcement Administration (DEA); Department of Homeland Security (DHS) comprised of the U.S. Customs and Border Protection (CBP) and Homeland Security Investigations (HSI); the U.S. Postal Inspection Service (U.S. PIS); Internal Revenue Service (IRS); the Federal Trade Commission (FTC); and the Federal Bureau of Investigation (FBI). Each agency serves its own role:

- **FDA.** Under the Food, Drug and Cosmetic Act (FDCA), the FDA is responsible for ensuring the safety and effectiveness of prescription drugs. Drugs that are unapproved, misbranded, adulterated or counterfeit are subject to FDA enforcement. The FDA's Office of Criminal Investigations (OCI) has the primary responsibility for criminal investigations pertaining to threats against FDA-regulated products.
- **DEA.** The DEA is responsible for enforcing the Controlled Substances Act, which regulates the possession, manufacture, distribution and dispensing of controlled substances, and the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, which regulates the online distribution of controlled substances.
- **CBP.** The CBP is responsible for enforcing laws regulating importation of goods into the U.S. CBP's role includes the seizure and destruction of prescription drugs that are unapproved, misbranded, or counterfeit. The CBP often coordinates with the FDA to conduct inspections of products seeking entry at the U.S. border.
- **HSI.** HSI operates the National Intellectual Property Rights Coordination Center (IPR Center) and is responsible for investigating violations of customs and trade laws, including trafficking in counterfeit and smuggled goods.
- **U.S.PIS.** U.S.PIS investigates misuse of the U.S. Postal Service. It provides the CBP with information about suspicious mail packages entering the U.S, including those that may contain drugs.
- **IRS.** The IRS investigates money laundering, a crime that often plays an important role in illegal online drug operations.
- **FTC.** The FTC investigates websites that make false or misleading statements, including statements about how an online drug seller collects or uses its customers' medical information. The FTC also investigates violations of the CAN-SPAM Act of 2003, which regulates certain unsolicited commercial email messages. These messages have the primary purpose of advertising or promoting commercial products.

- **FBI.** The FBI investigates online drug sellers if they present a clear public health or safety threat, or if their activities defraud health care benefit programs.⁴

Suggested Enforcement Mechanisms/Improvements

In exploring ways to combat the illegitimate online supply chain, several factors must be considered. First, this problem is global. The criminal networks are global; the supply channels and distribution networks are global; and the websites targeting the United States are largely foreign-based. Addressing this problem requires international cooperation on enforcement, appropriate harmonization of regulations and diplomatic leadership and cooperation within major international bodies. Second, most criminals view trafficking in counterfeit drugs as a low-risk, high-return proposition.⁵ Facing relatively small fines and short prison sentences, many criminals are not deterred by the risk of getting caught.⁶ Third, law enforcement agencies attempting to allocate their limited resources often do not prioritize drug counterfeiting commensurate with the grave public safety risks it imposes.⁷ This, in turn, further dilutes the deterrent effect of existing laws.

Recognizing these three factors, below are some recommendations for U.S. law enforcement best practices:

- **Use Current Authority**

The U.S. is fortunate to have a series of existing local and national laws that prohibit many of the activities that drive prescription drug counterfeiting or diversion schemes. The following non-exhaustive list provides examples of federal and state laws that have been used to prosecute illegal online drug sellers:

- 18 U.S.C. § 2320(a)(4) – Criminalizes trafficking in counterfeit prescription drugs
- 18 U.S.C. § 371 – Conspiracy
- 18 U.S.C. § 1341 – Mail fraud.
- 18 U.S.C. § 1349 – Attempt and conspiracy
- 18 U.S.C. § 1343 – Wire fraud.
- 18 U.S.C. § 545 – Smuggling.
- 18 U.S.C. § 1956 – Money laundering.
- 21 U.S.C. §§ 829-831 - Bans the sale of a controlled substance online without registration with the Drug Enforcement Agency and prior in-person medical evaluation, among other conditions.
- 21 U.S.C. § 351 – Part of the Federal Food, Drug and Cosmetic Act regarding adulterated medicines.
- 21 U.S.C. § 352 – Part of the Federal Food, Drug and Cosmetic Act regarding misbranded medicines.
- 21 U.S.C. § 846 - Part of the Controlled Substances Act which makes it illegal to distribute or dispense controlled substances over the Internet.

The criminal networks are global; the supply channels and distribution networks are global; and the websites targeting the United States are largely foreign-based.

While not an exhaustive list, these laws in particular have been effective authorities for U.S. law enforcement officials in combatting illegal online drug seller crime.

- **Increase Prosecutions to Strengthen Deterrence**

Law enforcement investigations and the resultant prosecutions can have a strong deterrent effect on current and would-be criminals. This impacts both the operators of the rogue drug sites and the sites' potential customers. While current prosecutions are few and far between, significant changes in rates of illegal

4. GAO REPORT, *supra* note 3, at 5-9

5. The Economic Impact of Counterfeiting, OECD, 18.

6. *Id.*

7. The Economic Impact of Counterfeiting, OECD, 7.

online drug sellers will be made through initiating more cases, increasing seizures and incurring stronger penalties. For example, the Pharmaceutical Security Institute (PSI) conducted an interview of a convicted internet operator at a recent general assembly. The convict, having served his time, readily admitted that he avoided selling medicines which were scheduled under the Controlled Substance Act, because he wanted to avoid attracting the attention of the DEA. Furthermore, he was concerned about the possibility of a twenty year sentence compared to the penalty associated with the sale of non-controlled substances. For more information on the specific prosecutions, as outlined in this white paper, please contact us and we will do our best to put you in contact with the appropriate individual.

- **Penalties for Violations of the FDCA**

Federal prosecutors often charge illegal online drug sellers with violations of the 18 U.S.C. § 545 (smuggling), § 1341 (mail fraud), and § 1956 (money laundering), as these crimes are subject to penalties of up to 20 to 30 years in jail, or fines ranging from \$500,000 to \$1 million, or both.⁸ Prosecutors reportedly feel obligated to bring charges under these offenses—which are often more difficult to prove than FDCA violations—because the penalties available for misbranding and counterfeiting violations of the FDCA are, as the GAO notes, “relatively light.”⁹ Misbranding and counterfeiting can result in up to three years in jail and/or a \$10,000 fine, significantly less than the penalty for mail fraud noted above.

To supplement these weak penalties, prosecutors will sometimes tack on a charge under the Alternative Fines Act (18 U.S.C. § 3571). This general statute allows for assessment of a \$250,000 fine for all felony violations,¹⁰ including FDCA felonies. Alternatively, prosecutors can seek a fine of “twice the gross gain” derived by any individual defendant.¹¹

Multiple parties interviewed, including law enforcement officials and pharmacy and pharmaceutical company representatives, expressed their concern that misbranding and counterfeiting offenses aren’t punished more severely, especially for complex Internet drug seller cases. The time it takes for law enforcement to build a case could be greater than the criminal penalty that would be imposed, even if the criminal were found guilty. This creates a disincentive to law enforcement and prosecutors, who are reportedly reluctant to bring counterfeiting cases unless they can charge and prove other crimes.

- **Expand Authority for Civil Seizure of Criminal Proceeds from Illegal Online Drug Sellers**

Stakeholders also noted that, unlike other law enforcement agencies, FDA’s Office of Criminal Investigations (OCI) does not have the authority to civilly seize assets. This is especially troubling in cases involving illegal online drug sellers who make millions of U.S. dollars peddling misbranded, substandard, adulterated, or diverted medicine (in addition to sales of proven counterfeit medicines). Other U.S. law enforcement agencies can civilly seize assets, giving them additional tools and incentive to pursue tough cases.

- **Increase U.S. Customs and Border Protection Program to Deter Criminals**

The U.S. Customs and Border Protection (CBP) currently sends warning letters to most illegal importers whose shipments are seized. However, this simple admonishment is not a strong enough measure to deter criminals. Stakeholders interviewed recommended that law enforcement should work to identify all suspects (i.e., importers), investigate them, and prosecute them for their illegal actions related to illicit shipments of medicines. Letting these criminals off with a warning conveys the inaccurate message that such violations are not serious. Increased investigations, coupled with prosecutions of illegal actors, will serve as reminders to other illegal importers that the U.S. Government views illegal importation of counterfeit and unapproved medicines as serious criminal activity.

8. Id.

9. Id. at 22.

10. 18 U.S.C. § 3571(b)(3).

11. Id. § 3571(d).

- **Increase Cooperation with Internet Commerce Companies, including Registrars, Search Engines, and Payment Processors**

Internet commerce companies—including search engines, domain name registrars and registries, payment processors, and shippers—serve as critical chokepoints, all providing potential opportunities to cut off the illegal online drug trade and the funds that keeps these illegal sellers in business. Law enforcement officials should collaborate with these companies to complement their own enforcement activities. For example, members of the nonprofit Center for Safe Internet Pharmacies (www.safemedsonline.org) have partnered with law enforcement in the U.S. and abroad, through INTERPOL, to share data on illegal online drug sellers as part of Operation Pangea. For many years, PSI has participated in the planning of the Pangea operations, served as a single point of contact for the manufacturers and a de-confliction center for the pharmaceutical security directors. This type of voluntary collaboration and data sharing should be encouraged and expanded.¹²

Model Investigations and Prosecutions

The following case studies are illustrative of the types of successes that can be obtained using existing resources. They are offered as helpful strategic examples.

(1) Emedoutlet.com

A recent case showing some of the above methods in action was the shutdown of emedoutlet.com and the arrests of its operators.

In June 2014, four members of a family that spanned India and North America were indicted in U.S. federal court for working together to sell counterfeit drugs online.¹³ Brothers Javed Sunesra, 36, of Live Oak, Florida and Zuned Sunesra, 34, of West Mumbai, India were indicted on 17 counterfeit drug charges, as were their mother, Bismilla Sunesra, 59, of Sidney Point, India, and their cousin, Taimur Khan, 32, of Vancouver, Canada.¹⁴ The family members were accused of running emedoutlet.com and dozens of related websites from 2005 through 2014. These websites advertised and sold Indian-made versions of prescription drugs like Viagra, Xenical, Celebrex, Soma, Cymbalta, and Cialis that were not FDA-approved.¹⁵

Over the course of its existence, emedoutlet.com and its affiliate sites sold millions of dollars worth of unapproved prescription drugs to 40,000 customers worldwide.¹⁶ The criminal enterprise employed at least 30 people, and investigators found evidence of monthly gross sales of \$400,000.¹⁷ The websites dispensed drugs without asking for a prescription and claimed that they were selling the “same compatible brand name in generic strength prescription products you would find in your neighborhood pharmacy,”¹⁸ but laboratory tests confirmed that the drugs were not the same as comparable U.S. medications.

12. For more details, see *infra* Part VII.

13. Family That Ran Online Medicine Website Indicted in Federal Court in Pittsburgh, Pittsburgh Post-Gazette (Aug. 18, 2014), <http://www.post-gazette.com/news/health/2014/08/18/Family-that-ran-online-medicine-website-indicted-in-federal-court-in-pittsburgh/stories/201408180142>.

14. *Id.*

15. *Id.*

16. *Id.*

17. 4 Family Members Accused of Running Fake Online Pharmacy Network Operating in Florida, Canada and India, P'SHIP FOR SAFE MEDS. (Sep. 3, 2014), <http://www.safemedicines.org/2014/09/4-family-members-accused-of-running-fake-online-pharmacy-network-operating-in-florida-canada-and-ind-9-2-14.html>.

18. *Id.*

On July 15, 2014, Taimur Khan was arrested at Los Angeles International Airport as he attempted to enter the United States.¹⁹ Zuned Sunesra was later arrested in Florida in August 2014. As of September 2014, Javed and Bismilla Sunesra remained at-large in India.²⁰

On September 12, 2014, Khan pleaded guilty to charges of conspiracy, money laundering, wire fraud, and mail fraud.²¹ Khan had joined the Sunesras' conspiracy in early 2012 and continued to work with them until late 2013. At the time he joined, the Sunesras were having difficulty securing a payment processing system through which to conduct their illegal business. Needing a payment processor to allow consumers to purchase drugs with MasterCard and Visa, Khan set up a fake payment website called mygiftgard.biz. The site was designed to appear as if users were purchasing retailer gift cards, but in actuality, the charges went directly to illegal drug sales. In circumventing the payment processor restrictions to allow for the online purchase of illegal drugs, Khan committed the crimes of wire and mail fraud.²²

The funds collected from "gift card" sales were transmitted to Khan's account in Canada. From there, he wired the proceeds—minus his own "commission"—to the Sunesra brothers' accounts at the State Bank of Mauritius.²³ This is yet another example of how illegal online drug sales operate on a global scale.

The U.S. Department of Justice credits the investigation leading to Khan's successful prosecution to the enforcement arms of the FDA and the IRS.²⁴ Khan's sentencing is scheduled for later in 2015. For his crimes, he faces up to 20 years in prison and a \$250,000 fine.

In January 2015, federal law enforcement took a further step to cut off the crime ring's assets. A motion was filed to seize three condo units in Palm Beach County, Florida that were owned by Javed and Zuned Sunesra.²⁵

(2) Costa Rican Online "Pharmacy"

On September 12, 2014, Marla Ahlgrimm, 59, a Wisconsin pharmacist and Balbir Bhogal, 67, a Nevada pharmacologist were arraigned in New York federal court. The two were charged with conspiring to supply "at least four million misbranded and counterfeit pharmaceuticals to an illegal Internet pharmacy based in Costa Rica that catered to U.S. customers."²⁶

From June 2007 through May 2010, Ahlgrimm and Bhogal allegedly arranged for the manufacture in India of millions of illegal tablets. These included controlled substances, such as alprazolam and phentermine, and prescription drugs, such as

19. Canadian National Pleads Guilty to Illegally Importing Prescription Drugs into the United States, U.S.D.O.J.: U.S. Attorney's Office – W. Pa. (Sep. 12, 2014), http://www.justice.gov/usao/paw/news/2014/2014_september/2014_09_12_01.html.

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

25. Federal Authorities Move to Seize Three Condos from Accused Drug and Money Launderers, S. FLA. BUS. J. (Jan. 22, 2015), <http://www.bizjournals.com/southflorida/news/2015/01/22/federal-authorities-move-to-seize-three-condos.html>.

26. Wisconsin Pharmacist and Nevada Pharmacologist Charged with Smuggling Counterfeit Pharmaceuticals Using a Costa Rican Internet Pharmacy, DOJ: OFF. PUB. AFF. (Sep. 12, 2014), <http://www.justice.gov/opa/pr/wisconsin-pharmacist-and-nevada-pharmacologist-charged-smuggling-counterfeit-pharmaceuticals>.

carisoprodol and counterfeit Viagra.²⁷ Despite not holding an importer's license from the DEA, the defendants arranged for and facilitated the importation of the drugs into the United States.²⁸

The drugs then went to supply an illegal Internet pharmacy based in Costa Rica that catered to U.S. customers.²⁹ These illegal online drug sellers used call centers and websites based outside of the U.S., but filled their orders from inside the country. In doing so, non-licensed individuals were employed to bottle, label, and drop-ship the drugs.³⁰ Further emphasized the global transactions in play, payments within the operation involved wire transfers from Costa Rica to the U.S. and then from the U.S. to India.³¹ The charges brought include importing and distributing controlled substances and misbranding drugs, trafficking in counterfeit drugs, mail and wire fraud, smuggling, and money laundering.³²

The case was investigated jointly by the FBI, FDA's Office of Criminal Investigations (FDA-OCI), and Homeland Security Investigations (HSI).³³ The FBI, through informants, collected statements and e-mails from the defendants that helped tie the fake drugs to companies, banks, addresses, and Internet accounts associated with Ahlgrimm and Bhogal.³⁴ For example, emails from Ahlgrimm showed that she had provided one such informant—a licensed Internet pharmacy—with codes needed to deposit money into an account she controlled.³⁵ The defendants were originally charged in 2010, but the charges were dropped. The 2014 indictments essentially reinstate the same charges.³⁶

(3) Google Settlements

In August 2011, Google paid \$500 million to settle charges with the U.S. Department of Justice for knowingly allowing Canadian pharmacies to target AdWords advertisements at United States consumers, thereby facilitating the unlawful importation of prescription drugs into the U.S.³⁷ The agreed-upon forfeiture amount represented the gross revenue Google received from Canadian pharmacies through its AdWords program, plus all revenue those pharmacies themselves made from their sales to U.S. consumers.³⁸ In addition, the non-prosecution agreement laid out numerous compliance and reporting requirements for Google to adhere to.³⁹ Google, clearly reformed by that time, had already instituted many of the required certification and monitoring programs that are now considered industry standards.⁴⁰

27. Id.

28. Id.

29. Id.

30. Id.

31. Id.

32. Id.

33. Id.

34. 'Unimaginable': Charges Against Renowned Pharmacist Shock Colleagues, WIS. ST. J. (Sep. 11, 2010), http://host.madison.com/news/local/crime_and_courts/unimaginable-charges-against-renowned-pharmacist-shock-colleagues/article_f1e70ebe-bdba-11df-b919-001cc-4c002e0.html.

35. Id.

36. Counterfeit Drug Importation Charges Reinstated Against Prominent Wisconsin Pharmacist, P'SHIP FOR SAFE MEDS. (Oct. 14, 2014), <http://www.safemedicines.org/2014/10/counterfeit-drug-importation-charges-reinstated-against-prominent-wisconsin-pharmacist-10-15-14.html>.

37. Google Forfeits \$500 Million Generated by Online Ads & Prescription Drug Sales by Canadian Online Pharmacies, U.S. Dep't of Justice (Aug. 24, 2011), <http://www.justice.gov/opa/pr/google-forfeits-500-million-generated-online-ads-prescription-drug-sales-canadian-online>.

38. Id.

39. Id.

40. See Google Non-Prosecution Agreement, paras. 7-8, <http://s3.amazonaws.com/s3.documentcloud.org/documents/1109253/aug-2011-google-non-prosecution-agreement.pdf>.

Shortly after the 2011 settlement with the government, Google was sued by its shareholders over the same issue. The matter settled in 2014, with Google agreeing to spend \$250 million on an internal program to disrupt illegal online drug sellers.⁴¹ Under the settlement, the company will allocate \$50 million a year to the program for at least five years. Google also agreed to work with legitimate pharmacies to counter marketing from rogue sellers, and to improve the visibility of content about prescription drug abuse.⁴²

(4) Shipping Companies (UPS and FedEx)

In March 2013, UPS paid \$40 million to settle a federal criminal probe with the U.S. Department of Justice.⁴³ The charges stemmed from UPS facilitating the unlawful distribution of illegal online drug shipments, with the \$40 million forfeiture representing the fees UPS had collected from illegal online drug sellers.⁴⁴ As part of its non-prosecution agreement, UPS agreed to implement a compliance program featuring the best practices above, many of which it had already voluntarily adopted in the interim, as Google had done in its settlement.⁴⁵

UPS's settlement was meant to serve as a warning and a guide to other shippers. As then FDA-OCI Director John Roth said, "[t]he FDA is hopeful that the positive actions taken by UPS in this case will send a message to other shipping firms to put public health and safety above profits."⁴⁶ In 2014, FedEx was indicted on similar charges, having allegedly earned \$820 million from illegal online drug shippers.⁴⁷ If convicted, it could face fines of double that amount.⁴⁸ That case is pending in San Francisco.

Information Sharing and Collaboration

U.S. federal agencies collaborate domestically, as well as engaging with international law enforcement actions.

The most prominent example of such international action is Operation Pangea, an annual INTERPOL-led crackdown on illegal online drug sellers. In June 2015, Operation Pangea VIII resulted in 156 arrests and the seizure of an estimated \$81 million in potentially dangerous medicines.⁴⁹ In addition, Pangea VIII resulted in the takedown of more than 2,140 websites involved in illegal online drug sales and medical devices, including two websites linked to the potential lethal, illicit diet drug DNP. At least 550 ads were removed from social media platforms and 429 investigations were launched.⁵⁰ Pangea VIII was the largest global operation

Operation Pangea VIII resulted in 156 arrests and the seizure of an estimated \$81 million in potentially dangerous medicines. A record 20.7 million illicit medicines were seized.

41. U.S. Judge Says Google Settlement over Pharma Ads Is Fair, Reuters (Oct. 29, 2014), <http://www.reuters.com/article/2014/10/29/google-pharmaceuticals-settlement-idU.S.L1N0SO1E020141029>.

42. Id.

43. UPS Pays \$40M to End Online Pharmacies Probe, U.S.A TODAY (Mar. 29, 2013), <http://www.usatoday.com/story/money/business/2013/03/29/ups-pays-40m-to-end-online-pharmacies-probe/2035647/>.

44. Id.

45. UPS Agrees to Forfeit \$40 Million in Payments from Illicit Online Pharmacies for Shipping Services, DEP'T OF JUSTICE: U.S.AO-NDCA (Mar. 28, 2013), <http://www.justice.gov/usao-ndca/pr/ups-agrees-forfeit-40-million-payments-illicit-online-pharmacies-shipping-services>.

46. UPS Pays \$40M to End Online Pharmacies Probe, supra note 43.

47. FedEx Pleads Not Guilty to Online Pharmacy Charges, CNBC (July 29, 2014), <http://www.cnbc.com/id/101875934#>.

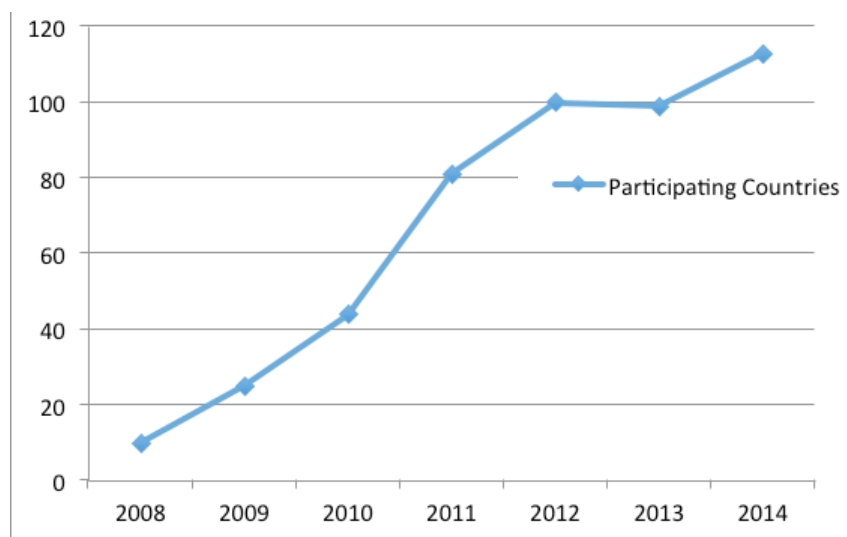
48. Id.

49. Operation Pangea, INTERPOL: <http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea>

50. Id.

targeting fake medicines with 236 agencies in 115 countries coordinating their efforts. A record 20.7 million illicit medicines were seized. These included cancer, erectile dysfunction and blood pressure medicines and nutritional supplements. Having begun as a one-day operation put forth by the MHRA to target medicines sold illegally in 2004, and since its broader inception globally in 2008, Operation Pangea has grown substantially.⁵¹ The U.S. also collaborates internationally on operations targeting websites that generally sell counterfeit goods, including counterfeit medicines. These crimes are often connected to the operations of illegal online drug sellers. For example, in December 2014, the U.S. National Intellectual Property Rights Coordination Center (IPR Center) joined with Europol in carrying out Project In Our Sites (IOS) Transatlantic V. Through this collaborative effort—executed along with 25 law enforcement agencies from 19 countries—292 total domain names were seized, including those engaged in illegal pharmaceutical sales.⁵² Since its launch in June 2010, Project In Our Sites has targeted and seized thousands of websites and domains that distribute counterfeit and pirated goods over the Internet. While illegal online drug sales are more appropriately addressed through public health regulation, intellectual property enforcement offers an additional point of attack for law enforcement.

Countries Participating in Operation Pangea, By Year



Additionally, the U.S. Government engages in transatlantic cooperation with the European Union via the Transatlantic Economic Council (TEC). Through the Transatlantic Intellectual Property Rights (IPR) Working Group, the U.S. Trade Representative's Office engages the EU delegation on intellectual property matters, including the online sale of counterfeit pharmaceuticals. The IPR Working Group offers another important mechanism by which governments may harmonize actions and coordinate transatlantic initiatives to help address the global threat of illegal online drug sellers. In June 2016, Operation Pangea IX took action against over 4,400 websites that illegally sold unapproved and counterfeit medications to unassuming US consumers. Of those websites, 110 were found to sell DNP, a product never approved by the FDA, as a weight loss drug. In the past, DNP has been linked to multiple deaths.⁵³

State and Local Activities

At least 29 states have laws in place addressing Internet pharmacy practice – some of them stating their purpose in the law's name. Delaware, for instance, enacted its Safe Internet Pharmacy Act in 2008 based on the determination that unlicensed online drug sellers pose a significant public safety risk, and that previously existing laws did not sufficiently deter this activity.

51. Id.

52. 292 Internet Domain Names Seized for Selling Counterfeit Products, EUROPOL (Dec. 1, 2014), <http://www.europol.europa.eu/content/292-Internet-domain-names-seized-selling-counterfeit-products>.

53. <http://www.europol.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm505921.htm>.

According to the 2016 National Association of Boards of Pharmacy (NABP) Survey of Pharmacy Law, two-thirds (19) of the 29 states that address Internet pharmacy practice currently recognize Verified Internet Pharmacy Practice Sites® (VIPPS®) accreditation as meeting certain requirements for Internet pharmacies operating in those states. The National Association of Boards of Pharmacy® (NABP®) established the VIPPS accreditation program in 1999 to verify and help patients identify safe and legitimate Internet pharmacies. NABP is a 112-year-old organization that supports the state boards of pharmacy in protecting public health.

Several states including Arkansas, District of Columbia, Indiana, Iowa, Kentucky, Montana, Nevada, North Carolina, Vermont, and Virginia require VIPPS or other state board of pharmacy-approved accreditation for any pharmacy to sell, dispense, distribute, or deliver any prescription drug to any consumer in that state if any part of the transaction was conducted through an Internet site. Other states such as Nebraska and South Carolina recognize VIPPS in their laws but do not require it.

States including Arkansas, Iowa, and Nevada have specific language requiring the sale of prescription medications via the Internet to follow the same state and federal laws as any legitimate pharmacy, including appropriate licensure. Some states – Arkansas, Florida, Illinois, Iowa, Missouri, Nevada, and Utah among them – require a special permit, certification, license, or registration for the operation of an Internet pharmacy.

Many states, including Alabama, Arizona, Arkansas, Colorado, Delaware, Iowa, Kansas, Louisiana, Missouri, New Mexico, Texas, and Wyoming, specifically prohibit dispensing a prescription drug if the order was issued on the basis of an Internet-based questionnaire or consultation without a valid preexisting patient-practitioner. Some states including Arkansas and Iowa also explicitly prohibit Internet pharmacies from waiving any liability to which the pharmacy otherwise is subject under the law for the selling, dispensing, or delivering prescription drugs. Some states – Delaware and Nevada among them – consider violations of their Internet pharmacy laws to be a felony and assess fines of up to \$100,000 for each violation of the Act.

As an extension of its VIPPS accreditation program, NABP launched the .Pharmacy Top-Level Domain (TLD) Program in late 2014 as a new and better way to address the problem of illegal online drug sellers and to provide a safe online community where consumers can find legitimate Internet pharmacies and other pharmacy-related services and information. (dot) Pharmacy is a secure and trustworthy TLD where consumers around the globe can be sure the medications and they buy online are safe. Unlike most TLDs that are open to anyone, the .pharmacy TLD is granted only to website operators that meet standards for safe and legitimate practice. Additionally, unlike seals of approval and verification sites, the .pharmacy extension in the URL reveals at a glance that the site has been vetted and found to be safe and legitimate. The .pharmacy TLD is available only to select pharmacy community members that have been thoroughly vetted and have demonstrated a commitment to patient safety.

.Pharmacy is a secure and trustworthy TLD where consumers around the globe can be sure the medications and they buy online are safe.

Despite the global scale of the problem, state and local enforcement activities can help in the fight against illegal online drug sellers by using existing authorities and leveraging their bully pulpits to draw attention to the public health threat. The following are ways in which state attorneys general can leverage their positions to better protect the public health:

1. Use their authority under the Ryan Haight Act (21 C.F.R. 1300, 1301, 1304, 1306) to shut down illegal online drug sellers that peddle controlled substances to patients across the country.⁵⁴
2. Pursue so-called “storefront pharmacies” for violations of state pharmacy law. These brick-and-mortar sellers—that are no more than physical fronts for illegal online drug sellers—are popping up across the country, often in locations with elderly populations.⁵⁵

54. See Vermont News: The Ryan Haight Online Pharmacy Consumer Protection Act, NABP (Sept. 3, 2009), <http://www.nabp.net/news/vermont-news-the-ryan-haight-online-pharmacy-consumer-protection-act>.

55. See Pharmacy Discount Shops Pose New Dangers for Consumers, NABP (July 9, 2014), <http://www.nabp.net/news/pharmacy-discount-shops-pose-new-dangers-for-consumers>

3. Use the bully pulpit to spread the word to consumers, including examples by linking to the ASOP Global consumer resource page (<http://safeonlinex.com/public-awareness/>), which provides videos, fact sheets, and helps consumers find safe sources of medicines.
4. Encourage increased enforcement actions and increased training for state law enforcement officers on counterfeit medicines. As the state's chief law enforcement officer, each attorney general has the power to change State priorities, devote resources, and direct enforcement divisions to focus on online pharmacy and counterfeit medicines crimes.
5. Engage directly with Internet commerce companies like domain name registrars, advertising providers and shippers doing business in the state to encourage the companies to take steps to prevent the use of their platforms by illegal online drug sellers. For example, domain name registrars could be encouraged to lock and suspend the domain names of illegal online drug sellers, and search engines could be encouraged to disable auto-complete results that yield illegal online drug sellers in the page results.

B. Europe

European Union Activities

At any one time, there are approximately 30,000 websites selling medicines targeting the European Union.⁵⁶ A 2014 survey found that 18% of European respondents have purchased medicines online,⁵⁷ and 62% of the medicines purchased online are fake or substandard.⁵⁸ As discussed below on page 33, various EU Member States have statutory provisions in place to address the threat of illegal online drug sellers and the sale and supply of medicines “at a distance”. Nonetheless, the transnational nature of this crime means countries need to, and regularly have, coordinate their efforts and work together to combat the threat.

Fortunately, the European Commission is aware of the threat posed by illegal online drug sellers and other supply chain lapses and has taken action to help protect patients. In July 2011, the Commission published the Falsified Medicines Directive (FMD).⁵⁹ Specific to online sales, the FMD instituted a “Common Logo” requirement. This provision calls for the establishment of a Common Logo at a minimum, yet recognizable throughout the EU, which “shall be clearly displayed on websites offering medicinal products for sale at a distance to the public.”⁶⁰ All Member States must implement the common logo requirement by July 1, 2015.⁶¹ The Common Logo will be issued by each Member State based on a list of legitimate Internet drug sellers and must include penalties for noncompliance. Internet sellers of both prescription and non-prescription medicines must register with the relevant competent authority in the Member State where business is based to be included on the national list of legal online drug sellers.



EU Common Logo (UK Version)

56. ASOP EU, FALSIFIED MEDICINES COSTING THE EARTH (2013), available at www.asop.eu/new-report-falsified-medicines-costing-the-earth.download.

57. Only 20% of Europeans Associate Counterfeiting with Medicines, ASOP EU (May 15, 2014), <http://asop.eu/europe-survey-on-counterfeiting>.

58. EAASM, THE COUNTERFEITING SUPERHIGHWAY (2008), available at <http://www.eaasm.eu/index.php?clD=21&cType=document&download=1>.

59. *Id.* at Art. 85c(3).

60. *Id.* at Art. 85c(3).

61. See Commission Implementing Regulation (EU) No. 699/2014, available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_184_R_0004&from=EN.

The Common Logo is intended to enable consumers to readily identify legitimate online pharmacies and other sellers. Clicking on the Common Logo will link the user to the applicable national regulatory authority's website, which will in turn provide a list of approved online pharmacies. A user who clicks through and finds that the seller's website is not listed among those approved—or that the link directs anywhere but to the appropriate regulatory authority's website—will thus be warned away from purchasing. If the website houses a legitimate online pharmacy supplier, the user will find the seller's site listed on the national registry and thus can feel confident that the site is operating legally.

Implementation of the Common Logo by EU Member States is only one part of the equation. Law enforcement must also be prepared to enforce against illegal actors who may feign legitimacy by faking the Common Logo or those who are not registered nor do they display the Common Logo. Europol and its partner organizations therefore play a significant role in combating illegal online drug sellers in the EU. Because the operations of online criminals are rarely confined to a single country, Europol's unique ability to organize and unite various national law enforcement agencies around their remit of IP rights enforcement is crucial. Below are examples of successful European operations and collaborations that should be emulated, as well as suggestions that could improve effectiveness.

Model Investigations and Prosecutions

Europol and Eurojust, the EU's judicial cooperation unit, are uniquely equipped to address the international problem of illegal online drug sales. Criminal operations often extend well beyond the borders of a single Member State, limiting the ability of national law enforcement agencies alone to fight them. This is true where Internet crime is concerned. A recent example case shows how wide an illegal online drug ring can span, and why the coordinating functions of Europol and Eurojust are needed to ensure law enforcement success, especially in relation to intellectual property and trademark offenses.

On September 1, 2014, Europol announced that it had dismantled a vast European ring of illegal online drug sales.⁶² Through cooperation with law enforcement in Austria, Belgium, Cyprus, France, Hungary, Slovakia, Spain, and the United Kingdom, authorities seized several million fake pills valued at €10 million (\$14 million U.S.). Another €7.5 million was seized from various bank accounts, and 12 people were arrested. According to Europol, “[t]he counterfeit medicines targeted by this operation [were] imported into the European Union from Asia and contain incorrect dosages and ingredients which pose a serious health hazard.”⁶³

The crime ring was centered in Vienna, Austria, where the leader of the fake drug scam was arrested.⁶⁴ Austrian police began investigating the scam in 2012, when a package of medication that was sent to Spain was returned for having insufficient postage. The sender had used the mailing address of a genuine Austrian pharmacy in lieu of his actual address. When the package was returned to the legitimate pharmacy's address as undelivered, the pharmacy brought it to the attention of authorities. Since the investigation began, more than 300,000 pills with an estimated value of €2 million were seized in Austria alone, representing only one-fifth of the total transactions that are thought to have occurred there.⁶⁵

The crime ring extended into the UK, where authorities identified more than €12 million in transactions involving counterfeit and unlicensed medicines over the two

62. International Law Enforcement Action Against Fake Medicines, Europol (Sept. 1, 2014), <https://www.europol.europa.eu/content/international-law-enforcement-action-against-fake-medicines>.

63. Id.

64. Insufficient Postage Leads to Bust of Fake Drugs, Daily Mail (Sept. 1, 2014), <http://www.dailymail.co.uk/wires/ap/article-2739954/Insufficient-postage-leads-bust-fake-drugs.html>.

65. International Law Enforcement Action Against Fake Medicines, supra note 63.

66. Id.

year investigation.⁶⁶ Two Londoners were arrested who are believed to have laundered money through a local charity as part of the Europe-wide operation.⁶⁷ Payments were taken from victims from as far as Australia in exchange for counterfeit impotency, slimming, and anti-smoking pills that were sold on more than 400 websites since March 2012.⁶⁸ In France, payments totaling €9 million were identified as having been processed over three years.⁶⁹ In Spain, counterfeit goods worth more than €1.5 million were seized and three people were arrested.⁷⁰ Hungarian authorities, and others, conducted similar investigations.⁷¹

The involvement of Europol and Eurojust proved key to coordinating and carrying out this united effort. After Spanish authorities provided Europol with intelligence from a criminal case that offered leads connected to further investigations in Austria, France, and the UK, Eurojust organized a meeting of the relevant national authorities and established a joint investigation team (JIT).⁷² The September 2014 joint operations were then coordinated from Eurojust headquarters, while Europol deployed a mobile office for real-time analysis and sent experts to assist national and local police agencies.⁷³ This type of large-scale enforcement would have been impossible without coordination from the EU-wide level.

Law enforcement agencies at the Member State and local levels recognize the dangers posed by illegal online drug sellers and appreciate the need for this type of coordinated effort. Austria's Minister of the Interior, Johanna Mikl-Leitner, called the bust "the greatest blow against the trade in counterfeit medicines Europe-wide."⁷⁴ Detective Chief Superintendent Tom Manson—of London's Metropolitan Police Service Specialist, Organised and Economic Crime Command—said:

[The] operation with our counterparts in Austria and Europol has been about taking down a highly organised crime group who make an incredible amount of money by selling potentially harmful drugs to unsuspecting members of the public, some of whom are in the UK. These so-called medicines are peddled on very professional looking websites which feature convincing medical advice, but the people behind them have no medical training.⁷⁵

Similarly, those interviewed for this paper expressed their praise for recent international investigations, with one noting that "we never would have seen such action a few years back." As in the example case, those interviewed noted their concern over organized crime's presence in this area and encouraged further coordinated efforts to combat it.

Information Sharing and Collaboration

Complementing its own coordinated efforts among EU Member States, Europol collaborates in wider takedown efforts with international law enforcement, especially in relation to intellectual property infringement.

67. London Pair Arrested as Met Police Uncovers Plot to Flood Market with Millions of Fake Medicines, International Business Times (Sept. 2, 2014), <http://www.ibtimes.co.uk/london-pair-arrested-met-police-uncovers-plot-flood-market-millions-fake-medicines-1463639>.

68. Id.

69. International Law Enforcement Action Against Fake Medicines, supra note 63.

70. Id.

71. Id.

72. Id.

73. Id.

74. Insufficient Postage Leads to Bust of Fake Drugs, supra note 65.

75. London Pair Arrested as Met Police Uncovers Plot to Flood Market with Millions of Fake Medicines, supra note 68.

Collaborative enforcement initiatives like Operation Pangea and Operation In Our Sites (see page 15 above for details on these projects) are important efforts, and those interviewed were aware of the publicity surrounding such efforts, although their purpose of serving as an actual deterrent to such crime has yet to be determined. Many interviewed noted that Operation Pangea “highlights the problem”—helping with consumer awareness and public health benefits—and forces law enforcement agencies across the world to engage on these crucial public health issues which they might “otherwise ignore.” At the same time, many are quick to caution that the problem of illegal online drug sellers can never be stopped through occasional policing. A number of representatives interviewed from the pharmacy and pharmaceutical sectors expressed the view that, while Pangea is a good idea on paper, it is a commercial operation run for maximum exposure. What are truly needed, then, are sustained yearlong efforts to ensure the short-term gains from such operations do not dissipate as agencies’ collective focuses turn elsewhere. While all acknowledge the budgetary and manpower limitations that law enforcement agencies face, stakeholders interviewed nonetheless would encourage more frequent efforts like Pangea and In Our Sites to further protect patient safety. This is true not only in the EU but for all economies.

In addition to cross-agency collaboration, it is important for agencies like Europol to engage in information sharing with the private sector. For example, operations like Pangea and In Our Sites produced a wealth of data that industry security experts could use to great avail. Informing manufacturers that drugs purporting to be their product(s) were seized—and from where—would significantly enhance industry’s ability to locate and stop potential counterfeiters and online drug sellers. These communications could go a long way in helping to fight the problem. Please note, that while this does cover a portion of the online pharmacy marketplace, the majority of medicines sold illegally online are not counterfeit nor falsified.

Council of European Activities

Council of Europe/European Directorate for Quality of Medicines

The Council of Europe (CoE) published the Medicrime Convention in 2010 that establishes a framework for international cooperation in the fight against the counterfeiting of medical products (pharmaceuticals, medical devices, etc.) and related crimes. With its 47 member states, the Council of Europe, based in Strasbourg (France), covers virtually the entire European continent. Established on May 5, 1949 by 10 founder states, the Council of Europe aims to promote a common democratic and legal area in Europe, organized around the European Convention on Human Rights and other reference texts on protection of the individual.

The EDQM, a partial agreement under the Council of Europe, co-ordinates a practical work program to protect public health from the dangers of counterfeiting of medicines (including medical devices and veterinary medicines) and related crimes through risk management and prevention, and improved co-operation between member states and other stakeholders in Europe and beyond. EDQM also collaborates with national and international organizations in efforts to combat counterfeit medical products and similar crimes. Signatory states and some observer states may make use of the expertise and working results coordinated by the Council of Europe and its EDQM to support the follow-up of the Convention.

The Medicrime Convention

The Medicrime Convention was established in 2010 and opened for signature in 2011 by the Council of Europe (CoE) and establishes a framework for international cooperation in the fight against the counterfeiting of medical products (pharmaceuticals, medical devices, etc.) and related crimes. It is the first international treaty to establish the manufacturing and supply of falsified/counterfeit medical products as a criminal offence, and also makes it illegal to falsify documents relating to medicines (including medical devices and veterinary medicines), manufacture and supply drug products without authorization. To date, 24 countries have signed the Convention and five (5) have now ratified it—meaning they consent to be legally bound by the terms of the treaty—and this triggers its implementation.

The Medicrime Convention is aimed at remedying the situation that counterfeiting of medicines can be handled differently from a legal perspective between countries both in the CoE region and elsewhere. It is not concerned with intellectual property infringements, but defines counterfeit as products with a “false representation as regards identity and/or source.” Medicrime offers a legal framework for world-wide cooperation to combat the counterfeiting of medical products and similar crimes involving threats to public health. Medicrime also requires parties to set up single points of contact within the health authorities, police and customs to exchange information and provide assistance for the operational management of cases at national level. Each country’s points of contact will ensure international cooperation with their counterparts in other countries. This cooperation represents an asset for effective implementation and monitoring of the Convention.

The Medicrime Convention text clarifies the definition of counterfeiting of medical products and similar crimes at international level. This form of crime is primarily international and the Medicrime Convention remedies the lack of a specific international legal instrument in this field. Counterfeiting (falsifying) of medical products that have not received an EU-approved ‘Marketing Authorization’ and similar offences are considered crimes. Hitherto, they were treated merely as violations of intellectual property rights (manufacture of products resembling genuine products). The Medicrime Convention makes counterfeiting and other IP crimes criminal offences. Individuals or organizations manufacturing or distributing counterfeit products will be regarded as criminals seeking a quick profit to the detriment of the health and lives of patients and will be tried accordingly. Persons suffering adverse physical or psychological effects as a result of using a counterfeit medical product or a medical product deriving from a similar crime may be recognized as victims.

Country-Specific Activities

Despite the well-documented importance of EU-level efforts, much still depends on law enforcement in the individual Member States. The section below will examine specific examples of investigations, prosecutions, information sharing and collaboration by EU Member States, especially in instances of IP infringement.

Investigations and Prosecutions

Law enforcement efforts and successes among the EU’s 28 Member States are varied. Some countries’ agencies deserve praise for taking a tough stand against illegal online drug sellers, while others could improve their efforts.

- **Belgian Customs**

Belgium’s Customs office offers a good example of how taking tough action and collaborating with industry can lead to success.

In recent years, Belgian Customs has enhanced its efforts to combat illegal online drug sellers. The agency accomplishes this through its Cyber Squad, which works to close offending websites in a streamlined manner. Here’s how it works:

1. Pharmaceutical manufacturers submit complaints of counterfeiting to Customs on a good faith basis.
2. Customs reviews the complaints and, typically, takes action. Indeed, when a manufacturer’s representative comes forward with allegations that a website is selling counterfeit medicines, Customs typically takes them at their word, on a good faith basis.
3. Customs proceeds to obtain a court order. This process can take as short as a “couple weeks” to as long as two months, according to one Belgian official.
4. Once the court order has been issued, Customs then takes it to the domain name registry DNS Belgium, which is the registry for .be domains, or to EURid, the registry for .eu domains.
5. The domain name registry then takes down the offending website within 24 hours.

Belgian Customs monitors two top-level domains: .be and .eu. In cases where a .eu domain has been registered under a false name (e.g., “John Doe”), an administrative procedure can be implemented that will result in a takedown in just “hours,” according to a Belgian official.

There are a few factors that allow for such efficiency in these processes.

1. First, Customs accepts pharmaceutical companies’ allegations as true. By placing the incentives upon the pharmaceutical companies—as they are in the best position to distinguish their own products from fakes found in test buys—this acceptance of good faith reports made by pharmaceutical industry experts facilitates a faster enforcement timeline;
2. Belgium has special magistrates who are well-versed in computer laws and can readily comprehend the issues when presented with a request for a court order; and
3. Belgian Customs has special relationships with the relevant domain name registries, EURid and DNS Belgium. Customs has an agreement with EURid through which it is able to fast-track administrative takedowns. Customs also has jurisdiction over DNS Belgium, who is likely to be more willing to comply with enforcement requests and can be compelled to comply with a Belgian court order.

Belgian Customs has also engaged in a special arrangement with one pharmaceutical manufacturer, through which the company sends a list of new problem websites that have appeared every six months. Customs finds this method to be mutually beneficial, and encourages other pharmaceutical companies to consider setting up similar arrangements in the future. As a Customs representative noted, it is “entirely worthwhile in the long run” to just “take a couple hours” to build a list of illegal websites and send it to the Customs office.

- **Opportunities to Strengthen Country Laws in Europe**

Despite the great work done by some EU Member States on the issue of counterfeit pharmaceuticals and online drug sellers—like that of Belgium—regulatory gaps exist within Europe as they do elsewhere. European countries outside of the EU with weak laws complicate, and can even forestall, international law enforcement efforts against illegal online drug sellers. For example, the EU Member State of Cyprus was noted by commenters due to its “lax banking laws,” which allow criminals to transfer illicit funds with impunity. This can greatly frustrate the “follow the money” law enforcement tactic that is often cited as essential for law enforcement success.

Additionally, those interviewed commented about a few countries that are not part of the European Union body but which, due to their geographic proximity to EU Member States, threaten the safety of EU citizens and patients worldwide as part of the global supply chain. A few examples are below:

- **Russia:** Those interviewed pointed to Russia as a source of much of the world’s pharmaceutical crime. One commenter noted that Russian “crime bosses” are often protected by the government so long as their crimes are not committed on Russian soil and do not target Russian citizens.
- **Turkey:** Turkey was cited as a problem country by many stakeholders interviewed. One commenter noted that there is a “major diversion problem” in Turkey that has led to illegal shipments reaching EU Member States and the United States.

- **Opportunities in India**

India is another major source of Internet pharmacy crime. In a recent publication by ASSOCHAM, the Associated Chambers of Commerce of India, it is estimated that fake medicines account for \$4.25 billion of the total domestic medication market estimated between \$14-17 billion. Further, studies have found that these counterfeit, IP-infringing, medications could account for upwards of 25% of the total market throughout India.⁷⁶

76. Fake drugs in India may cross US \$10 billion in next three years: ASSOCHAM; elets eHealth. <http://ehealth.eletsonline.com/2014/07/fake-drugs-in-india-may-cross-us-10-billion-in-next-three-years-assochem/>

Another key role for law enforcement is to raise awareness in the governments of the source countries by providing them with evidence and intelligence on offending products. This should include identifying exporters/shippers and the manufacturers whose products are being exported in violation of that countries law; regardless of method, mail, sea and air freight. This activity, directed at the EU and US entities, fuels the illegal internet supply capability.

Turkey has long been identified by law enforcement, drug regulators and the pharmaceutical industry as a problem country with many Turkish market products, i.e. products which are manufactured specifically for the Turkish market, being found outside Turkey. This is largely due as a result of diversion from the Turkish market itself. Diverted Turkish market medicines have helped to fuel illegal online drugs sellers' sales and supplies. Over the last 10 years or more, individual packs of diverted Turkish market medicines have been found all over the world. Often, this widespread distribution is the result of an online purchase from an illegal online pharmacy or from bulk quantities imported and distributed by unsuspecting or complicit wholesalers operating in other parts of the world. During that time, law enforcement agencies in Turkey have been particularly proactive against counterfeiters of medicines and distributors of counterfeit medicines by conducting long term, successful operations, arrests and convictions. But the issue of diverted medicine had not been addressed.

On September 25, 2014, PSI organized a seminar in Ankara on counterfeit and diverted medicines. The seminar was attended by senior representatives from the Turkish Ministry of Health, police and customs as well as representatives from the U.S. FDA-OCI, United Kingdom MHRA, as well as PSI Members' security representatives. The issue of diversion was discussed in great depth.

On November 20, 2014, the Head of the Turkish Ministry of Health (MOH)'s Medicines and Medical Devices Agency, Dr. Saim Kerman, issued a circular setting out details of new measures aimed at preventing export - 'diversion'. The new measures came into effect on December 3, 2014.

The last 2 paragraphs of an official translation of the Circular read:

As such, export of medicinal products that were manufactured for our country and approved for import serve only as a detriment to market availability, thus leading to significant problems with drug supplies as well as putting public health at risk.

In this respect, and with public health and services in mind, our Administration finds exporting medicinal products, which were imported in the first place for national use, to be highly objectionable, and is determined to take all necessary measures in order to ensure market availability, including systemic blocking of such actions.

At a meeting with PSI on December 3, 2014, the Turkish Ministry of Health (MoH) reported that the new measures had been introduced based upon the findings of recent research and monitoring they had undertaken. The measures also follow from representations made at the PSI seminar in September, as well as during subsequent visits and dialogue between senior Turkish MoH officials and PSI. Further relevant points discussed include: brokers in Turkey cannot buy from pharmacies any longer; pharmacies, if they have excess or surplus product, must return them only to the licensed warehouse they obtained them from; and the opportunity to export medicines by Turkish companies under the old system ceased as of midnight on the day of the meeting, December 3, 2014.

The key is that the imported products were intended for the Turkish market and include products that were assembled as well as manufactured in Turkey using imported materials. It does not apply to the export of medicines that were produced in Turkey for elsewhere, however, the exporter has to obtain a license for that process. Before such a license is granted the MoH will check the availability of that medicine in Turkey and the level of demand by the Turkish population.

PSI and its members, the U.S. FDA OCI and the MHRA, are working with the MoH and are providing the MoH with details of suspected diverted Turkish medicines found in other parts of the world. Each pack of Turkish market medicine carries a unique data matrix code. The MoH is then researching the history of each pack with the intent to identify the offending diverters in Turkey.

Information Sharing and Collaboration

Individual Member States can greatly improve their law enforcement capabilities through collaboration with one another. The Fakeshare initiative, led by the Italian Medicines Agency (AIFA), with involvement from a large group of EU and non-EU stakeholders, offers a fine example of this.

Fakeshare is a European Union-funded project whose aim is to ensure coordination in investigating and prosecuting crimes involving medicinal products, pharmaceutical counterfeiters and illegal online drug sellers.⁷⁷ Fakeshare's main partners are EU drug regulatory agencies (DRAs):

- Italian Medicines Agency – Agenzia Italiana del Farmaco (AIFA), Italy;
- National Authority for Medicines and Health Products – Autoridade nacional do Medicamento e Produtos de Saúde (INFARMED), Portugal;
- Spanish Agency for Medicines and Health Products – Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Spain; and
- The Universities of Rome “La Sapienza” – Psychology and Trento – Criminology, Italy.
- The Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom.

The associate partners of Fakeshare are enforcement authorities, like the Commodities and Health Unit of the Italian police (Comando dei carabinieri per la tutela della salute, Nucleo Antisofisticazioni e Sanità – NAS) and the Pharmaceutical Security Institute (PSI, United Kingdom). Other partners involved are professionals from industry/DRAs, such as the European Federation of Pharmaceutical Industries & Associations (EFPIA, Belgium), RMSHMR, the National Agency for Medicines of the Public Health Institute (Agencia Nacional de Medicamentos del Instituto de Salud Pública – ANAMED, Chile), and also IT experts like LegitScript (U.S.). Finally, ASOP offers additional support to the Fakeshare initiative.

Fakeshare focuses on information sharing between authorities. To that end, the Fakeshare project aims at:

- ensuring coordination in investigation activities and polices forces initiatives;
- targeting the illegal web distribution of medicines;
- sharing information between countries with similar scenarios; and
- allowing the development of coordinated initiatives (e.g., investigation, campaigning, training) against the illegal distribution of medicines, with the goal of optimizing the use of resources in activities developed at the national and international levels.

The goal of these information sharing initiatives is to “create a common scientific ground for investigation and communication activities against dangerous web sites.”⁷⁸

77. Fake drugs in India may cross US \$10 billion in next three years: ASSOCHAM; elets eHealth. <http://ehealth.eletsonline.com/2014/07/fake-drugs-in-india-may-cross-us-10-billion-in-next-three-years-assochem/>

78. Id.

C. Asia

Regional Law Enforcement Activities

According to the Pharmaceutical Security Institute (PSI) statistics, the “Asia Region” has been linked to the largest number of incidents for the past ten years and continues to stand out as a major region for pharmaceutical crime. Through close interactions with law enforcement agencies, there has been an increased understanding of this particular crime problem in many Asian countries. Also evident, enforcement actions have been stepped up against online pharmaceutical crime to include taking down the rogue Internet sites with complementary efforts at increasing public awareness. Authorities in China have conducted several nationwide enforcement operations with positive results during the past few years. In the Philippines, authorities have also stepped up enforcement actions. Each year, there is a week designated as the “National Consciousness Week against Counterfeit Medicines” to raise the awareness of the enforcement agencies and the general public.

Eleven Asian countries participated in the Storm V operation in 2014. They seized 4,701,789 units and 3,454 kg of pharmaceutical products.

Despite these positive developments, concerns remain in the following areas:

1. *Inadequate training opportunities prevent the development of Internet crime expertise.* Police officers and detectives view the investigation of online pharmaceutical crimes as being quite different from their traditional investigations. Thus, there is an increased need for specific training seminars for the police. PSI, along with its members, has facilitated the development of successful operations that have been built on training exercises designed to tackle online pharmaceutical crime.
2. *Low priority due to the perception that this is only an economic crime and not a public safety issue.* Often due to a low priority, authorities in some Asian countries have not sought training in this area. Accordingly, they have little understanding of the techniques used in the conduct of online investigations. This is often evident in countries where there are no specialized Internet investigation teams to handle these cases. In this fashion, the cycle of low priority – limited understanding of health risk – and no training - continues.
3. *Lack of effective collaboration among the law enforcement agencies and pharmaceutical industry.* The collaboration among the public and private sectors is ineffective in some countries. Key areas needing attention include case referrals, information sharing and the examination of suspect medicines. Fortunately, new efforts launched in the region have helped to improve the capability of the enforcement officers as they gain a better understanding of the problem from the pharmaceutical manufacturers’ security departments’ presentations and discussions.

Interpol’s Operation Storm V and national training on the investigation of online pharmaceutical crime is notable activity positively impacting Asia. Operation Storm is an ongoing, multinational Interpol program developed to address the counterfeit medicines problem in Southeast Asia by promoting collaboration among the enforcement agencies in Asian countries. During the time that Operation Storm runs, the participating countries engage in a focused enforcement operation.

This year, with a view to improving their capability to conduct online pharmaceutical crime investigation, Interpol also conducted trainings in online investigation of pharmaceutical crimes in the region. PSI members supported the training with specialized briefings while PSI explained the nature of support that could be provided. Eleven Asian countries participated in the Storm V operation in 2014. They seized 4,701,789 units and 3,454 kg of pharmaceutical products valued at USD \$3,168,692. Actions were taken against 29 websites while 56 arrests were made.

Model Investigations and Prosecutions

In the fight against global Internet sales of counterfeit, illegally diverted and stolen medicines, the pharmaceutical companies play an important role. They provide critical information in support of multinational investigations. By promoting international cooperation, a vital element in dismantling transnational criminal groups, pharmaceutical companies can help to expedite cases of this nature.

The Philippine authorities have taken steps to combat counterfeit medicine activities and worked closely with the pharmaceutical companies. The take-down of a call center in the Philippines in 2012 is an excellent example of the collaboration between the law enforcement agencies and the pharmaceutical industry which provided substantial information in that matter.

PSI member company investigators tracked the activities of the online pharmacies and determined that these criminals were turning to call centers to facilitate the online sales of prescription drugs. Continuing their inquiry, a call center was detected in Cebu, Philippines. This call center employed 200 agents to call patients in the U.S., U.K. and Australia, encouraging them to refill orders for medicines.

Acting on this information, the Philippines authority raided the call center in July 2012. Instead of finding computers where incriminating data was stored, they discovered that all sales data was strategically stored in Google's virtual storage, which was beyond the immediate reach of local law enforcement. With the assistance of U.S. Immigration and Customs Enforcement (ICE), Google agreed to "freeze" the data, ensuring its availability to enhance evidence and investigation. A follow-up investigation linked the call center to approximately 70 online pharmacies worldwide. In this example, close collaboration between international enforcement agencies, pharmaceutical company security teams and the search engine staff disrupted the online sales of counterfeit medicines.

One person interviewed noted that some enforcement authorities have enacted a useful strategy to stamp out illegal drug sellers. Once an illegal website has been identified, the relevant authorities will collaborate to locate the physical location of the illicit goods. Then, on the same day that the offending website is taken down, the warehouse is also raided, "removing all the links in the chain." These actions, taken in tandem, help to cripple the criminal enterprise, making it "increasingly difficult to re-establish the operation."

Information Sharing and Collaboration

The Asia-Pacific Economic Cooperation (APEC) was established in 1989 to promote free trade and economic growth in the Asia-Pacific region. APEC's 21 member economies engage in meetings and collaborative processes that support sustainable growth in the region. Due to its collaborative structure, APEC offers an ideal forum for information sharing on how best to combat illegal online sellers. Through the APEC Life Sciences Innovation Forum (LSIF) and the LSIF Regulatory Harmonization Steering Committee (RHSC), APEC recently established the Internet Sales Working Group to focus specifically on the problem on illegal online drug sales. This Working Group is chaired by Health Canada and USFDA and includes APEC member economy regulator and industry representatives.

In late 2013, the APEC Internet Sales Working Group developed a survey, titled APEC Survey: Internet Sales of Medicinal Products. The survey was sent to each of the APEC economies to help identify issues related to Internet sales of medicines and strategies to address these issues. Ten APEC economies responded in spring 2014, six of which are located in Asia (Indonesia, Japan, Papua New Guinea, Philippines, Singapore and Thailand). Responses to the survey show that some of these nations have taken steps to fight back against illegal online drug sellers. For example, Indonesia, Philippines, and Singapore have all participated in INTERPOL's Operation Pangea, and a few economies are engaged in developing laws and rules regulating the sale of medicines online.

In addition, the APEC RHSC Internet Sale Working Group conducted a training program on combating illegal Internet drug websites during an APEC Senior Official Meeting in Cebu, Philippines, August 26–27, 2015. Nineteen (19) APEC economies participated in this two-day workshop focused on developing an APEC Toolkit on combatting illegal online drug sales. Once the tool kit is finalized, additional APEC activities are anticipated during 2016 for APEC economies to work together implementing the Toolkit. The Toolkit has now been finalized, pending endorsement from RHSC and LSIF. Future additional APEC activities are anticipated for APEC economies to work together implementing the Toolkit.

Country-Specific Activities

Asian nations have begun to recognize the threat posed by illegal online drug sellers, and some have started to take action. Two distinct approaches are detailed below. First, China shows how targeted domestic crackdowns can have noticeable positive effects. Second, Japan's approach illustrates a novel attempt to combat illegal online drug sellers at the registrar level.

China

China offers a recent example of the types of targeted domestic crackdowns that should be emulated by other nations. Since 2013, the Chinese government has initiated numerous efforts to crack down on illegal online drug sellers:

- In February 2013, the China Food and Drug Administration (CFDA) entered into a strategic partnership with Baidu, China's largest search engine. CFDA gave Baidu access to its database of approved drugs and Internet OTC pharmacy registrations, allowing Baidu to provide detailed information and warning messages to consumers. Subsequently, other search engines received similar access to help combat illegal online drug sales.
- In July 2013, the China's Ministry of Public Security launched "Operation Cloud," a half-year campaign focused on illegal online drug sales. On December 14, 2013, the Ministry announced the results of that crackdown: over 400 criminal networks were taken down, over 140 rogue Internet pharmacies were shut down, and over 1,300 arrests were made.
- Also in July 2013, the CFDA initiated its own half-year campaign, "Two Strikes, Two Setups." The interagency operation was intended to combat the illegal manufacture and sale of drugs, including illegal online sales. CFDA worked with other government departments to crack down on illegal online drug sellers, including the State Internet Information Office, the Ministry of Industry and Information Technology (MIIT), the Ministry of Public Safety, and the State Administration for Industry and Commerce.

These targeted actions resulted in the following concrete successes, including:

By the end of September 2013, the CFDA had identified more than 2,000 online drug sellers operating illegally in China. As a result of these findings, arrests were made, 194 illegal domestic websites were shut down by MIIT, and 609 foreign websites were reported to the relevant countries for enforcement. Additionally, in January 2014, ten CFDA-certified Internet OTC pharmacies were suspended due to unlawful prescription drug sales.

China's efforts in this area are laudable, and the May 2015 ASOP China Internet Drug Study finds that these efforts have indeed proven effective in reducing access to illegal online drug sellers.⁷⁹ By focusing their combined resources on the problem, Chinese law enforcement agencies have made great headway. Enforcement efforts must continue, however, as online drug sellers continue to proliferate in and outside of China.

While China has seen some recent success in enforcement, regulatory gaps remain a concern. Many stakeholders interviewed expressed concern about China's ability to truly curb its illegal drug market. In particular, those interviewed pointed to the rash of counterfeit manufacturing industries that exist within the country. These tensions—strong enforcement against illegal online drug sellers operating in China on the one hand, and weaker regulations and IP protections for medicines on the other—need to be reconciled, or else patients both within and outside of China remain at risk.

Japan

In order to more nimbly combat illicit online drug sellers at the source, the Japanese government has taken a unique step. In 2014, Japan's Ministry of Health, Labour and Welfare signed an agreement with LegitScript (www.legitscript.com), a global leader in rogue Internet pharmacy threat assessment, compliance, risk analysis, and enforcement,⁸⁰ to help monitor and shut down rogue drug sellers targeting Japan.⁸¹ As discussed below and as part of this agreement Japan, designated LegitScript as its "authority" for online pharmacy enforcement,⁸² a heretofore unprecedented move.

Under the Internet Corporation for Assigned Names and Numbers (ICANN)'s 2013 Registrar Accreditation Agreement (RAA), complaints of illegal web activity are submitted through one of two paths. Complaints lodged by everyday Internet users fall under Section 3.18.1 of the RAA.⁸³ That section simply requires that the registrar "take reasonable and prompt steps to investigate" and "respond appropriately,"⁸⁴ setting no specific timeline for such response. Governmental authorities (of jurisdictions in which the registrar maintains a physical office), on the other hand, are authorized to submit complaints under Section 3.18.2. Under this section, "registrars are required to establish and maintain a dedicated abuse point of contact, including a dedicated email address and telephone number that is monitored 24 hours a day, seven days a week, to receive reports of Illegal Activity."⁸⁵ Furthermore, registrars have a heightened requirement to respond to Section 3.18.2 complaints within 24 hours.⁸⁶ The enhanced Section 3.18.2 requirements, in essence, force registrars to take abuse complaints more seriously.

However, Section 3.18.2 authority is not exclusively limited to governmental agencies. The provision also allows for a "national or territorial government" to designate this power to other entities that may operate on its behalf.⁸⁷ Japan's Ministry of Health, Labour and Welfare has now formally done so with respect to LegitScript, making LegitScript "the first entity in the world to be granted a Section 3.18.2 designation."⁸⁸

Together, Japan and LegitScript can now act far more nimbly to monitor and take action against any illicit online drug sellers whose domains are housed by registrars with Japanese offices. Registrars are obliged to respond to

79. ASOP Global Report on the Chinese Rogue Internet Pharmacy Market (March 2015): <http://safeonlineix.com/2015/02/23/asop-and-legitscript-issue-report-on-chinese-rogue-Internet-pharmacy-market/>

80. Disclosure: LegitScript is a Board Member of ASOP Global

81. John Horton, LegitScript Signs Agreement with Japanese Ministry of Health, Labor and Welfare, LegitScript (Sep. 2, 2014), <http://blog.legitscript.com/2014/09/legitscript-signs-agreement-japanese-ministry-health-labor-welfare/>.

82. See Letter from Haruo Akagawa, Director, Compliance & Narcotics Div., Ministry of Health, Labour & Welfare, to Fadi Chehade, President & CEO, ICANN (Aug. 28, 2014), available at http://www.legitscript.com/download/Japan_MHLW_Letter_to_ICANN.pdf.

83. 2013 Registrar Accreditation Agreement, ICANN (June 27, 2013), <http://www.icann.org/en/system/files/files/approved-with-specs-27jun13-en.pdf> [hereinafter 2013 RAA].

84. Id. § 3.18.1.

85. Id. § 3.18.2.

86. See id.

87. Id.

88. Horton, *supra* note 81.

LegitScript's reports of illegal activity within 24 hours and "take necessary and appropriate actions."⁸⁹ If they fail to do so, they will have breached the RAA and are then subject to sanctions from ICANN. For example, Singapore-based registrar IP Mirror, which has a Tokyo office, recently received an ICANN contract-breach notice for its failure to respond timely to LegitScript's 3.18.2 complaint.⁹⁰

Japan, by taking this novel step, has ensured that its citizens' health will be vigilantly protected by a company with the knowledge and expertise to identify illegal online drug sellers.

Japan's Customs services have made significant progress over the past three years in disrupting the flow of illegal medicines into Japan. By 2015, they were involved in over 1,000 actions against over 88,000 drugs illegally imported versus 736 actions involving some 43,000 drugs in 2013.⁹¹

89. 2013 RAA, *supra* note 83.

90. See Kevin Murphy, .health Backer Has Cop-Like Takedown Powers for All gTLDs in Japan, DOMAININCITE (Dec. 8, 2014), <http://domainincite.com/17758-health-backer-has-cop-like-takedown-powers-for-all-gtlds-in-japan>.

91. http://www.mof.go.jp/customs_tariff/trade/safe_society/chiteki/cy2015/20160304c.htm

Raising Awareness

Law enforcement has a clear role in preventing and detecting serious crime. There are many organized crime groups involved in the illegal sale and supply of drugs online, a serious crime that generates huge profits for those involved. Much of the profit is ploughed back into the same crime or used to fund other serious criminal activities. Money laundering, on a large scale, is a byproduct of this crime. Investigative leads and sources can come from the public or the industry, e.g. 'whistleblowers', pharmacists, health care professionals, etc.

Increasing the awareness of the public, the judiciary, law enforcement, government and many more stakeholders is a key component in the fight against illegal online drug sellers. Law enforcement agencies have a role to play in such awareness raising. This can be achieved by using their local or national media correspondents to publish warnings in newspapers, websites and social media about the dangers of buying drugs online, reports of cases, particularly those where people have suffered as a result, as well as sentences in the event of a successful prosecution. The International Federation of Pharmaceutical Manufacturers and Associations, IFPMA, (<http://www.ifpma.org>) coordinates a multi-stakeholder awareness campaign called 'Fight the Fakes'. The Pharmaceutical Security Institute and the Alliance for Safe Online Pharmacies are members of this campaign (www.fightthefakes.org). Fight the Fakes was launched in January 2014 and there are 20 partner organizations which include wholesalers, pharmacists, mobile app services, healthcare professionals, disease-specific organizations, research-institutes, product-development partnerships, foundations, coalitions for consumer protection, non-profits and the private sector.

Since its inception, 'Fight the Fakes' has made significant progress in a field that was in dire need of such improvement. There are now over 100 website resources in addition to almost 13,000 mentions of [#FightTheFakes/#fakemeds](https://twitter.com/FightTheFakes) on Twitter. Additionally, this campaign has led to the sharing of more resources and personal stories from patients and family members affected by fake medicines.

Conclusion

Illegal online drug sellers operate on a global scale and global responses are needed to combat them. These criminal enterprises can only be stamped out by sustained, coordinated efforts at the international level, for which public and private sector initiatives and efficiencies may vary.

Law enforcement officials should seek to emulate the successful prosecutions detailed above. Where regulatory gaps exist, policymakers must take action to pass tougher laws that better address the problem. And in many instances, concurrent assistance by private sector entities serve to greatly benefit the patients in removing dangerous, if not deadly, medications off of the Internet. Illegal online drug sales will not dissipate on their own, so ignoring the issue is no solution at all. All stakeholders must recognize the grave public health threat that exists and take actions within their power to protect patients from illegal online drug sellers.

We would like to thank the following stakeholders who were consulted for this paper (hyperlinked):

- [Alliance for Safe Online Pharmacies \(ASOP Global\) Members and Observers](#)
- [Asia Pacific Economic Cooperation Internet Sales Working Group Members](#)
- [Administratie der Douane en Accijnzen; Belgium](#)
- [U.S. Food and Drug Administration](#)
- [United Kingdom Medicines and Healthcare Products Regulatory Agency](#)
- [Pharmaceutical Security Institute Staff and Members](#)

Appendix:

High-Level Checklist of Best Practices

Best Practices for Governments

- ✓ Collaborate with foreign governments and law enforcement
- ✓ Use current authority
- ✓ Increase cooperation with Internet commerce companies and payment processors
- ✓ Increase prosecutions to strengthen deterrence
- ✓ Increase penalties for violations of laws and regulations
- ✓ Provide authority for civil seizure of criminal proceeds from illegal online drug sellers
- ✓ Prioritize the issue of illegal online drug sellers in your jurisdiction through work with federal, state and local enforcement officials
- ✓ Collaborate with enforcement groups that are able to track geo coordinates, ports, and mail facilities (track these, and watch for offenders)
- ✓ Maintain or increase cooperation with industries corporate security professionals