



2021 Special 301 Out-of-Cycle Review of Notorious Markets
Federal Register Docket Number USTR-2020-0041 (85 FR 81263)

SUBMISSION

Thank you for considering the Alliance for Safe Online Pharmacies' (ASOP Global) comments in response to United States Trade Representative's (USTR) request for comments on the 2021 Special 301 Out-of-Cycle Review of Notorious Markets. ASOP Global is a 501(c)(4) organization that seeks to protect patient safety globally and to ensure patient access to safe and legitimate online pharmacies in accordance with applicable laws. ASOP Global is active in the United States, Canada, Latin America, Europe, India and Asia. To learn more about ASOP Global, visit www.BuySafeRx.Pharmacy.

The following comments are in response to USTR's 2021 request for comments "identify acts, policies, or practices that may form the basis of a country's identification as a Priority Foreign Country or placement on the Priority Watch List or Watch List."¹ The global rise of illegal online pharmacies, both of foreign and domestic origin, is not only a threat to intellectual property (IP) rights but is also fundamentally a public health issue. Those illegal online pharmacies engaged in IP violations are often engaged in behavior that simultaneously puts the public health at risk, including but not limited to the sale of counterfeit, falsified, substandard or unapproved medicines, and/or the sale of prescription drugs to consumers without a valid prescription or healthcare provider consultation. It is in this public health context that ASOP Global urges USTR and other government partners to take actions that will help curb the global patient safety threat caused by illegal online pharmacies.

ASOP Global appreciates USTR's efforts to address the issue of domain name registrars facilitating illegal online pharmacies in its past seven Notorious Market Reports (2014-2020). In particular, ASOP Global commends USTR for identifying domain name registrars in their 2017 and 2019 reports, including Nanjing Imperiosus Technology Co., Ltd, Hosting Concepts B.V., and Regional Network Information Center JSC. However, the latter two registrars continue to be known suppliers of domains used by illegal online pharmacies. "Safe haven" registrars like these knowingly violate the terms and conditions of their own service agreements, allowing registrants to continue to use domain names to illegally sell prescription drugs and, in some cases, controlled substances. This practice enables illegal activity to continue and places profits ahead of public health and safety.

While it is important to emphasize that a majority of registrars act responsibly and voluntarily terminate services to illegal online pharmacies, we encourage USTR to continue to send a strong message to registrars and marketplaces that turn a blind eye to, or welcome, illegal online pharmacies.

Additionally, ASOP Global is also concerned that WHOIS domain name registration data is no longer able to accurately identify who is behind individual domain names regardless of their country of origin. WHOIS data has historically been relied upon by law enforcement, government partners, and the private sector to identify and thwart criminal activity and cyber security attacks, due to an overly broad

¹ <https://www.govinfo.gov/content/pkg/FR-2020-12-15/pdf/2020-27515.pdf>

interpretation of the EU's General Data Protection Regulation by Internet Corporation for Assigned Names and Numbers (ICANN). Many domain name registries and registrars (Ry/Rr) are shutting down public access to the full range of WHOIS data, both for one-off requests and automated access. With WHOIS data now effectively unavailable, the internet is fundamentally a less safe space. This is especially troubling during the pandemic, as Americans increasingly rely on the internet to buy products, consume information, and obtain healthcare. ASOP Global strongly supports the restoration of WHOIS data transparency and participates in the Coalition for a Secure and Transparent Internet (www.secureandtransparent.org).²

BACKGROUND

While the Internet has provided immeasurable societal benefits, it has also exposed global consumers to the hazards of illegal online pharmacies and drug sellers peddling "medicines" that may be counterfeit, adulterated, misbranded, and/or unapproved. The following statistics evidence the scope of the global problem:

- At any one time there are 35,000 – 45,000 active online pharmacies, most of which are operating illegally;³
- According to the World Health Organization, the Internet is the world's largest marketplace for counterfeit drugs as 50% of the prescription medicines sold online are by websites that hide their physical address are considered substandard or falsified;
- While 6 in 10 Americans report an awareness of online pharmacies, nearly three-in-four (71%) have not experienced or heard about the risks of buying prescription medications from online pharmacies and thirty-seven percent see little inherent risk in the online purchase and only 15% believe purchasing prescription medications online is "very risky;"⁴ and
- A 2019 report by the National Association of Boards of Pharmacy⁵ states:
 - approximately 95% of online pharmacies are operating illegally – out of compliance with state and federal laws or relevant pharmacy practice standards
 - Of those websites surveyed, approximately one-third offered controlled substances and other potentially lethal drugs. Ninety-nine percent of those websites did not require a valid prescription, and 94% advertised drugs that were not FDA-approved.
- In a two-week period, there were over 45,000 tweets that promoted the purchase and non-medical use of prescription drugs through an actively marketed illegal online pharmacy (Timothy Mackey, University of California San Diego)⁶

² <https://buysaferx.pharmacy/wp-content/uploads/2021/01/ASOP-NTIA-WHOIS-Statement-1.6.21.pdf>

³ <https://asopfoundation.pharmacy/consumers/>

⁴ <https://buysaferx.pharmacy/wp-content/uploads/2020/10/ASOP-Global-Survey-Press-Release-October-2020.pdf>

⁵ <https://nabp.pharmacy/wp-content/uploads/2019/11/Rogue-Rx-Activity-Report-2019.pdf>

⁶ https://www.researchgate.net/publication/287106089_Establishing_a_Link_Between_Prescription_Drug_Abuse_and_Illicit_Online_Pharmacies_Analysis_of_Twitter_Data

The Department of Homeland Security's [January 2020 report Combating Trafficking in Counterfeit and Pirated Goods](#) underscores the importance of mitigating the risk posed by illegal online drug sellers and counterfeit prescription drugs.⁷ The report highlights that 97% of the United States' seized drugs were manufactured in places such as China, India, and Singapore and further details significant concerns around patient health and safety related to counterfeit and otherwise dangerous products online. As the report notes, counterfeit drugs are found in all therapeutic categories, especially those in high demand and/or with the prospect of significant profits such as insulins, chemotherapy, and specialty medicines.

COVID-19 HAS MADE MATTERS WORSE

The COVID-19 pandemic has served as an opportunity for criminals to prey on consumer fear and profit from peddling misinformation. Countless warning letters by the FDA and FTC regarding pandemic-related frauds have been issued highlighting the reckless disregard that some have in foregoing safety for profit.^{8,9}

The findings of a [2020 study by the National Association of Boards of Pharmacy](#)¹⁰ only confirms the above:

- Most active websites have clear ties to known criminal networks or their affiliates;
- Some newly created COVID-specific websites redirect users to established rogue network sites;
- Many domain names, both active and inactive, are clustered on “safe haven” registrars – a practice common among sophisticated internet pharmacy cybercriminals; and
- The domain name registration information for almost all identified websites is anonymized, making it difficult for enforcement agencies to investigate these criminals.

Supply Chain Security & Drug Importation

FDA's research¹¹ has shown that upwards of 85% of drugs claiming to be from Canada actually come from other countries. ASOP Global and our partners have identified that these so-called “Canadian” pharmacies operating on the internet are actually selling medications from countries like India, Hong Kong, and Singapore.¹² Unfortunately, the proliferation of “Canadian” pharmacies targeting American consumers will only grow in the coming months and years as policymakers in Washington, DC, continue to erroneously espouse the unrealistic cost-savings benefits of purchasing drugs from Canada.

Specifically, in 2020, the Trump Administration's Drug Importation Final Rule compromises patient safety by wrongly telling consumers that Canadian drugs will be safe and affordable. In reality, drug importation compromises the closed and highly regulated U.S. drug supply chain. News of the Trump

⁷ https://www.dhs.gov/sites/default/files/publications/20_0124_plcy_counterfeit-pirated-goods-report_01.pdf

⁸ <https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products>

⁹ <https://www.ftc.gov/coronavirus/enforcement/warning-letters>

¹⁰ <https://nabp.pharmacy/wp-content/uploads/2020/05/Rogue-Rx-Activity-Report-May-2020-1.pdf>

¹¹ <https://www.raps.org/regulatory-focus%e2%84%a2/news-articles/2016/1/califf-vows-not-to-lower-or-remove-fda-regulations>

¹² https://nabp.pharmacy/wp-content/uploads/2016/08/Internet-Drug-Outlet-Report-August-2017.pdf?utm_source=news-release&utm_medium=wire&utm_campaign=IDOI&utm_content=canada

Administration's action is likely to drive American and Canadian patients to unknowingly access counterfeit, substandard or unapproved medicines online, put a further strain on the pharmaceutical supply chain and place consumers at risk for considerable harm. As published, the rule is reckless and does nothing to protect patients from the thousands of illegal online drug sellers masquerading as "Canadian pharmacies," close these illicit internet markets or hold domain name registrars and registries accountable. These fake websites take advantage of patients to push illegal opioids and fraudulent COVID-19 products.

ASOP Global opposes the new Trump Administration's Importation Final Rule as it introduces new health risks to the system that directly contradict more than 20 years of science-based leadership at the FDA. ASOP Global urges USTR and other government partners to be especially diligent to recognize and avoid policies that will directly or indirectly send American patients to illegal domestic or global online pharmacies. Further, ASOP Global requests that USTR consider how other countries will take advantage of this misguided American policy with the sole purpose of profiting from selling illicit drugs to Americans online.

THE IMPORTANCE OF DOMAIN NAME REGISTRARS

In the virtual space of the Internet, there is no door for police to break down or warehouse to raid. Instead, law enforcement officials who wish to shut down illegal online pharmacies must engage in an often long back-and-forth process with the courts and the domain name's registrar. In the interim, criminals operate with ostensive impunity – selling more and more illegitimate and dangerous, if not potentially deadly, drugs to consumers – unless and until registrars, the entities that license the domain names, step in. As explained below, registrars have both the ability and authority to help stop the problem of illegal online pharmacies.

In 2019, LegitScript, an organization that voluntarily reports rogue online pharmacies to the registrars that sponsor these domain names, issued 63 notifications comprising 7,083 domain names.¹³ This complimentary notification service helps registrars take action against illicit operators and helps prevent the public from buying potentially unsafe drugs. In the same year, LegitScript had 6,149 domain names that they counted as "enforced," meaning that the registrar suspended the domain name after LegitScript sent a notification. These enforced domain names include some whose notifications were issued in 2018. Per LegitScript, in May of 2019, Epik was notified of 481 websites that were identified as rogue pharmacy sites; however, as of January 2021, 60% of those websites are still online and still registered with Epik. Of the 190 sites taken offline, 72 were allowed to transfer to another registrar. Most of these domains appear to be affiliated with PharmacyXL, a rogue pharmacy network. In May of 2020, CJSC was notified of 357 websites that were partaking in illegal online drug sales, and only 29 sites were taken offline. As of January 2021, CJSC, according to LegitScript, has 900 online rogue internet pharmacies in its portfolio. These statistics are worrisome as it appears registrars and registries do not take the necessary steps—even when warned—to shut down illegal and dangerous activity happening on sponsored domain names. As such, ASOP Global supports policies that will stop registries and registrars from facilitating online crime – and profiting from it – by requiring them to immediately

¹³ <https://www.legitscript.com/blog/2020/01/legitscript-helps-shut-down-6149-rogue-internet-pharmacies-in-2019/>

lock and suspend any domain name used to facilitate the illegal sale of drugs or any coronavirus and other public health scams.¹⁴

FOREIGN ILLEGAL ONLINE PHARMACIES FACILITATE THE SALE OF COUNTERFEIT, SUBSTANDARD, AND UNREGISTERED PHARMACEUTICALS

A major challenge in combating the illegal sale of counterfeit, substandard, and unregistered medicines abroad is the unfettered operation of foreign online pharmacies.

India

Online marketplaces based in India continue to generate substantial trade in illegal medicines as well. ASOP Global applauded USTR for placing Indiamart.com on the Notorious Markets List in 2018; however, Indiamart (www.indiamart.com) continues to allow the selling of illicit drugs, disclaiming any associated legal liability in its terms and conditions:

“Users(s) hereby undertake that they shall solely be responsible and shall bear all the liabilities in respect of selling prescription medicines and/or drugs mentioned in any of the Schedules of the Drug Rules without a prescription issued by a registered medical practitioner and in accordance with the conditions laid down in such rules. In the event of breach of such condition, Indiamart shall not be liable and responsible in any manner whatsoever.”

As an international seller, Indiamart has been repeatedly notified that it facilitates the delivery of large quantities of substandard, unregistered, and falsified pharmaceuticals to unknowing patients worldwide, violating the health and safety regulations of numerous foreign jurisdictions, without any discernable effect on its practices.

China

In 2019, ASOP Global and LegitScript developed a report titled “[The Chinese Internet Pharmacy Market Threat Assessment](#),” which examines the overall landscape of the illicit internet pharmacy market in China, where it is illegal to sell prescription drug products online.¹⁵ A comprehensive analysis of LegitScript’s review found that 17% of websites surveyed were operating illegally in offering prescription drugs or controlled substances. In total, 57% of online drug sellers are operating illegally with respect to Chinese law and regulation when including legitimate online pharmacies that only sell OTC products online in the total. The 26 searches for life-saving medicines returned a total of 2,261 results. Of those 18% were illicit results, and 59% of the illicit results were for illicit internet pharmacies. The 10 searches for controlled substances returned a total of 877 results. Of those, 15% are illicit results and 46% of the illicit results are for illicit internet pharmacies. None of the websites selling controlled substances required a prescription.

The Chinese government and private sector have made significant efforts to combat illegal online drug sales, but additional efforts may be taken to ensure compliance with relevant laws and practice guidelines.

¹⁴ <https://buysaferx.pharmacy/wp-content/uploads/2020/05/ASOP-Global-Lock-and-Suspend-Fact-Sheet-FINAL14.pdf>

¹⁵ www.safemedicines.org/wp-content/uploads/2019/10/The-Chinese-Internet-Pharmacy-Market-2019.pdf

Based on the data LegitScript collected for this report, the top two registrars in China used by the illicit internet pharmacies are Alibaba/HiChina and Xin Net.

LegitScript's research for this report also identified websites promoting medical tourism to India for more affordable treatments. These websites further offer to connect patients with doctors in India through telemedicine and to deliver prescription medication to Chinese patients from a partnering licensed Indian pharmacy. Currently, there is no regulation regarding telemedicine conducted internationally.

Chinese illicit drug sellers are unique in that they rely heavily on third-party platforms, such as WeChat, to complete transactions instead of processing the orders directly through their own websites. LegitScript predicts that the trend of illicit online drug sales over smartphone-based apps will continue. Enforcement efforts must evolve to respond to the illegal market's utilization of technology and social media

REGISTRAR ACCOUNTABILITY RECOMMENDATIONS

Rogue Internet registrars that knowingly facilitate illegal online pharmacies epitomize the types of notorious markets that USTR admirably seeks to combat, and they should be clearly branded as such. To that end, ASOP Global has provided in previous comment letters figures on rogue registrars hosting illegal online pharmacies.¹⁶ Unlike the majority of the registrar community, these offenders are non-responsive to abuse notifications and consistently refuse to cut off services to rogue internet pharmacies regardless severity of the infraction. ASOP Global urges USTR to support specific, no-cost and common-sense policy measures to hold offenders accountable.

Federal policies to combat the facilitation of rogue internet pharmacies include:

- Make WHOIS data transparent and require registries and registrars to routinely confirm domain name registration information and make registration data accessible.
- Require domain name registrars to immediately lock and suspend any domain name used to facilitate the illegal sale of prescription drugs or any coronavirus/public health scams upon notification by a trusted notifier.
- Encourage the enforcement of terms & conditions to prohibit domains from being used for illegal activity, including illegal online drug sales in the jurisdiction where the consumer is located.

The Alliance for Safe Online Pharmacies Commitment

[The Alliance for Safe Online Pharmacies](#) (ASOP Global) launched in 2009 to combat illegal online pharmacies and counterfeit medicines and fight to make the internet safer for patients worldwide through research, education, advocacy and collaboration. Arguably, the internet is now more relevant to patient access to care than ever before and has been jumpstarted by regulatory flexibility associated with the COVID-19 pandemic.

As demand for legitimate telemedicine, online pharmacy and lower cost "Canadian" drugs continues to grow, so will the potential profits for illegal online drug sellers taking advantage of American consumers.

¹⁶ <https://buysaferx.pharmacy/?s=USTR>

Data demonstrates a continued reliance on the internet for healthcare services and products, driven primarily by cost, convenience and access to care. A growing number of patients are utilizing online pharmacies while unaware of the risks and harms associated with such use. Momentum is building for structural and policy reforms to increase accountability for internet ecosystem actors – there are downstream effects on the global illicit drug trade.

As USTR engages in policy processes in the coming months, we request that you think about the public health consequences of criminals' peddling medicines online illegally. While there are countless foreign actors targeting and intentionally misleading—and even harming—American patients, it's important to note that there are domestic policy options that can protect consumers. These policies include but are not limited to: enacting targeted reforms of Section 230 of the Communications Decency Act, allowing for WHOIS data transparency, ensuring Registrar/registry accountability, and revering drug importation policies. Should you have any questions related to these policies, the sale of illicit drugs online, or how foreign marketplaces are infiltrating the American drug supply chain illegally, please contact ASOP Global Board Chair John Hertig at jhertig@butler.edu or ASOP Global Senior Advisor Libby Baney at Libby.Baney@FaegreDrinker.com.

Regards,



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