

ROGUE RX ACTIVITY REPORT



The Online Sale of Opioids Continues to Put Lives at Risk

National Association of Boards of Pharmacy®

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Summary

The opioid epidemic continues to devastate the nation. According to the Centers for Disease Control and Prevention (CDC), 46 Americans die every day from overdoses involving prescription opioids. ¹ The National Safety Council reports that, in 2017, opioid overdose deaths surpassed traffic-related fatalities.² The culprit in many opioid-related overdoses is fentanyl, a potent synthetic opioid that is often used in the illicit manufacture of look-alike or falsified medicines. 3 According to regulators and enforcement authorities, the epidemic is exacerbated by the fact that prescription opioids are readily available online - generally without a prescription - from websites masquerading as pharmacies. Research performed by the National Association of Boards of Pharmacy® (NABP®) confirms the continued online availability of controlled substances (CS), including opioids. During the first half of 2019, NABP identified more than 1,500 websites operating out of compliance with pharmacy laws or patient safety standards. Nearly a third of these websites offered or facilitated the sale of opioids or other CS.

The government has worked hard to reduce the online supply of opioids but recognizes the greater need for

NABP Not Recommended List Findings

Based on website reviews conducted through June 30, 2019	
Websites included:	11,479
Websites included that offer or facilitate the sale of prescription-only drugs without a prescription:	10,388
Websites included that offer or facilitate the sale of prescription-only drugs that are clearly unauthorized for sale:	6,382
Websites included that offer or facilitate the sale of controlled substances:	1,829
This data illustrates websites selling drugs out of compliance with US stat	e and federal

drugs out of compliance with US state and federal laws or NABP standards. These sites are listed as Not Recommended. This list is searchable on NABP's patient safety website, www.safe.pharmacy. These numbers include sites that are currently active and those sites that were active at the time of review but may be inactive now for any number of reasons.

private sector action. Food and Drug Administration (FDA) has called on internet companies and domain name service providers to remove opioid sellers from social media platforms and take down websites that facilitate the illegal sale of opioids. ⁴ Likewise, members of Congress have asked that internet search engines direct users to legitimate pharmacies and disable the ability to search for illicit drugs. ⁵

In response to such prompts, internet companies – including search engines, social media, and domain name registries – have taken some steps to protect patients. However, as evidenced by recent NABP findings, CS – including opioids – are still readily available online.

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To reduce the online sale of opioids and other CS, NABP calls for additional voluntary action by internet stakeholders, including: deindexing websites of illegal drug sellers; directing users to legitimate pharmacies when they search for medicines; and reporting to law enforcement those entities that want to advertise the sale of CS via the internet platform.

Continued Online Availability of Opioids Perpetuates Public Health Crisis

Opioid Epidemic Persists:

The opioid epidemic is far from over. According to the CDC, from 2013 to 2017, the number of opioid-related overdose deaths in the United States increased 90%, from 25,052 to 47,600. ⁶ Although there was a 5% overall decline in opioid deaths between 2017 and 2018, this decline does not appear to be uniform: 18 states saw increases in overdose deaths in 2018. Among them are Delaware, Missouri, and Vermont, which experienced double-digit increases. In addition, deaths attributed to illicitly manufactured fentanyl increased by 11%.

Regulators and Enforcement Authorities Recognize the Internet's Role in the Crisis:

FDA is intensely attuned to the opioid epidemic and its impact on public health, as well as the role of illegal online drug sellers in perpetuating the crisis. "The rise in illegal sales of opioids over the internet is a critical public health concern and major focus of attention by the FDA," then-FDA Commissioner Scott Gottlieb, MD, said in an April 2, 2019 news release. "These drugs are highly addictive and can be deadly when used without a doctor's supervision." ⁷

The Department of Justice (DOJ) has also focused on the internet as a significant player in the opioid epidemic. In January 2018, DOJ announced the creation of the Joint Criminal Opioid Darknet Enforcement (J-CODE) team, which focuses on shutting down illegal online drug marketplaces. According to then-Attorney General Jeff Sessions, "The J-CODE team will help us continue to shut down the online marketplaces that drug traffickers use and ultimately that will help us reduce addiction and overdoses across the nation." ⁸

Likewise, the Office of National Drug Control Policy (ONDCP) noted that the internet has expanded the market

for opioids. According to the ONDCP's 21st Century Drug Trafficking: "Marketing Advisory" on Fentanyl and Other Synthetic Opioids (Tab B), "Today, fentanyl, fentanyl analogues, and other synthetic opioids are marketed to consumers in several ways, most notably via online platforms like social media and special interest online forums." ⁹

Hidden Fentanyl Involved in Many Overdose Deaths:

Fentanyl often reaches consumers by way of falsified medicines. Law enforcement authorities have seen an influx of falsified drugs where fentanyl is an adulterant. ¹⁰ Fentanyl is 50 times stronger than heroin and up to 100 times more potent than morphine, making even small amounts potentially fatal. ¹¹ Drug Enforcement Administration (DEA)



Fake oxycodone tablets made with fentanyl, as published in the DEA EI Paso Division Safety Bulletin on March 1, 2019

finds that "fentanyl in counterfeit pill form still represents a significant public health risk and law enforcement challenge." ¹²

In New York City, overdose deaths have reached record levels, and fentanyl is involved in over half of these deaths. ¹³ "Throughout New York City, we have seen a spate of cases involving tens of thousands of potentially lethal fentanyl pills masquerading as oxycodone," New York City Special Narcotics Prosecutor Bridget G. Brennan said in a news release. "Just because black market pills have the same color and design as legitimate pills, it does not mean they are safe. The ingredients and potency are all unknown, and minuscule amounts of fentanyl can cause overdose or death." In San Diego County, US Attorney Robert Brewer warned the public to be aware of pills made with fentanyl disguised as oxycodone. ¹⁴ DEA's El Paso Division issued a similar alert. ¹⁵

If someone is accustomed to taking a less potent drug, unknowingly taking a look-alike drug made with fentanyl can, and does, cause accidental overdose. These falsified drugs are often purchased online. ¹⁶

Latest NABP Findings Confirm Easy Online Access to CS:

NABP's recent findings corroborate regulator and enforcement authority assertions that illicit distributors of opioids and other CS are actively using the internet to reach customers. NABP routinely calls out those websites that endanger patient health and safety by including these domain names on its Not Recommended List ¹⁷. In the first half of 2019, NABP placed 1,543 new websites on its Not Recommended List. Of those, nearly a third (471, or 31%) offered opioids such as codeine, fentanyl, and oxycodone; or other CS, such as Adderall[®], Valium[®], and Xanax[®]. Nearly all of these websites (465, or 99%) offered CS without requiring a prescription, and 94% (441 websites) offered drugs that lacked required FDA approval. NABP research has consistently shown that 95-96% of websites selling prescription-only drugs are doing so illegally and endangering patient health.

Regulators and Stakeholders Call for Coordinated Action

Authorities Target Illegal Online Drug Sellers:

To curb the online sale of opioids and other CS, regulators and enforcement authorities have aggressively investigated and prosecuted the illegal actors behind these sales. Since September 2017, FDA has issued 25 warning letters identifying more than 450 illegally operating websites. ¹⁸ On the enforcement side, the J-CODE team has completed two operations aimed at reducing the sale of opioids: Operation Disarray and Operation SaboTor. As part of Operation SaboTor, US and international law enforcement agencies shut down 50 darknet accounts and seized 299.5 kilograms of drugs, 51 firearms, and more than \$7 million. ¹⁹

Solutions Require Action by Public and Private Entities:

While federal agencies have been actively targeting illegal online drug sellers, they have also acknowledged the need for action by private sector partners. According to FDA, "Stopping these websites from illegally offering opioids for sale will require a broad collaboration across the internet community." ²⁰

Federal legislators agree with FDA's statement. In early 2018, a group of senators wrote to Google, Microsoft, Yahoo!, and Pinterest, expressing concern about the role that these companies play in facilitating the sale of opioids.²¹ While acknowledging that these companies have compliance policies in place regarding online pharmacies, the senators urged these stakeholders to take additional steps, including: directing users to legitimate pharmacies that require a valid prescription as a condition of sale; disabling the ability to search for illicit drugs through each platform; and requiring each platform to report to law enforcement when it receives information indicating that it has been used to advertise or sell narcotics.

In April 2019, FDA convened an Online Opioid Summit to bring together regulators, patient safety advocates, and industry stakeholders. In an April 2 news release regarding the summit, FDA noted that the agency is "committed to targeting these illegal sales and working with internet stakeholders to advance a proactive approach to cracking down on internet traffic in illicit drugs to address this public health emergency." ²² One summit attendee, registry services provider Neustar, concurred that the opioid crisis is exacerbated by online drug sellers. "While opioids are of course taken in the offline world," an article in Neustar's June 2019 *Safer Domains* newsletter states, "there is no question that the online distribution of opioids is a huge contributor to the current crisis." ²³

The federal government continues to call on internet stakeholders to help stem the tide of illegal online opioid sales. In August 2019, the ONDCP issued an advisory to digital platforms, which was intended to raise awareness about the "marketing and sale of illicit fentanyl via [. . .] social media, ecommerce websites, and online forums." ²⁴

Internet Stakeholders Step Up:

Recently, major internet players have begun to take action. Bing began by expanding its consumer warning banners from websites that received FDA warning letters to all websites on NABP's Not Recommended List. It then blocked all rogue online pharmacies listed on FDA's Internet Pharmacy Warning Letters site from its US search results. ²⁵ Google has similarly begun to deindex illegally operating websites named in FDA warning letters. Social media platforms, including Facebook and Instagram, have begun redirecting users looking for opioids to a government helpline. "We're committed to doing our part to help combat the opioid crisis," a Facebook spokesperson said. "This is one of a number of ways we are helping connect people with resources and communities to support them." ²⁶ Domain name registries have also taken affirmative action to combat the crisis. For instance, Neustar reported that, in response to an FDA alert, it suspended multiple .biz and .us domain names linked to the illegal sale of opioids. Then, using certain keywords related to pharmaceuticals, Neustar proactively searched for domain names in the .us Top-Level Domain (TLD). It placed illicit actors on server hold to deactivate their websites. Furthermore, Neustar took independent voluntary steps to begin policing other TLDs that it administers. Neustar's newsletter article states, "We firmly believe that both domain Registries and Registrars have an important role to play in protecting U.S. consumers from the scourge of illicit opioids by proactively taking action against websites that deliberately break the law by marketing and distributing opioids." ²⁷

Conclusion

Every half hour, another American dies as a result of an opioid-related overdose. ²⁸ Meanwhile, public health regulators and law enforcement authorities continue to grapple with this epidemic that, according to DEA, is "spreading like wildfire devastating our communities." ²⁹ NABP research supports stakeholder and regulator assertions that illegal online drug sellers fuel the flames of the opioid crisis. In the first half of 2019, NABP identified more than 1,500 active sites as Not Recommended. Nearly a third of these websites offered opioids or other CS. Of those, nearly all (99%) did not require a prescription, and 94% offered drugs illegally.

To address the opioid epidemic effectively, stakeholders must work collaboratively to approach it from multiple angles. FDA and patient safety advocates have called on internet companies to take a more active role in eliminating illegal sellers from their platforms, and some have taken steps to do so. NABP applauds the efforts of regulators, enforcement authorities, and private sector stakeholders. However, we can and must do more to halt the opioid epidemic and reverse the damage it has caused. NABP calls on internet stakeholders to take additional proactive steps, including: deindexing websites of known illegal online drug sellers; reporting to law enforcement those entities that want to advertise the sale of CS via the internet platform; and directing users to legitimate pharmacies when users search for medicines via an internet platform.

For information about NABP's Cybercrime Analysis Report, or the Association's research and reporting capabilities, please contact Policy and Communications Director Melissa Madigan via email at mmadigan@nabp.pharmacy.

Resources

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Mission Statement of the National Association of Boards of Pharmacy

NABP Mission Statement

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Vision Statement

Innovating and collaborating today for a safer public health tomorrow.

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