

Alliance for Safe Online Pharmacies (ASOP Global) Comments Docket No. DEA-407

Friday, March 31, 2023

Thank you for considering the [Alliance for Safe Online Pharmacies](#) (ASOP Global) comments in response to the Drug Enforcement Agency's (DEA) Proposed Rule for Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (Docket No. DEA-407).

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 Alliance for Safe Online Pharmacies (ASOP) Global commends the DEA for easing restrictions and embracing a more flexible approach to telehealth prescribing of controlled substances than those established by the Ryan Haight Act (RHA). Numerous studies showed that patients took advantage of state and federal waiver authorities that allowed greater access to telehealth during the pandemic. When delivered by responsible, appropriately licensed healthcare providers, telehealth can be a powerful tool for improving patient adherence and outcomes, particularly for mental health and substance use disorders. ASOP Global appreciates DEA's steadfast efforts to balance public safety through maintaining select RHA provisions and ensuring that patients continue to be able to access the treatments they depend on via telehealth. When enacted, the RHA played a critical role in safeguarding Americans from illegal online pharmacies that might otherwise have become Internet versions of the brick-and-mortar pill mills that fomented the opioid crisis. ASOP Global agrees that controlled substances should only be prescribed by an appropriately licensed, DEA-registered healthcare provider and dispensed by State-licensed pharmacies.

However, there are many other factors that make the decision DEA faces today significantly more complex and higher stakes than the one faced in 2008 when virtual prescribing of controlled substances was prohibited in all but a handful of exceptions. ASOP Global has studied and documented illegal online drug sales since 2009 and knows that despite DEA restrictions, illegal online pharmacies continued to offer controlled substances. We also know that patients buy from unknown, unlicensed internet drug sellers for reasons of cost, convenience, and access to care. In response to the proposed reinstatement of restrictions on telemedicine controlled substance prescribing on May 11th, we fear that many Americans will lose access to appropriate medical treatments that include controlled substance prescriptions and consequently will turn to illegal online sources for controlled substances they can no longer access through their telemedicine-only provider and U.S. licensed pharmacies. As a result, many will likely receive counterfeit or substandard products, putting their health at serious risk. Thus, the primary purpose of our comments is to call the DEA's attention to this foreseeable public health crisis and emphasize the importance of educating the public and addressing the threats imposed by illegal online drug sellers.

Limiting Access to Appropriately Licensed Healthcare Providers Will Restrict Access to Safe Sources of FDA-Approved Medications and Drive Americans to Dangerous, Illegal Online Sources

When the RHA was enacted in 2008, telehealth was not mainstream, and only a few states authorized practitioners to provide telehealth services. Thus, most healthcare providers and patients had not yet become

accustomed to the convenience and ease of access virtual healthcare has provided. As these services became more readily available during the pandemic, telehealth usage surged, and the virtual delivery of healthcare services and products is now entrenched in everyday life for many Americans. This is particularly true for mental health care, which saw a dramatic and sustained increase in use throughout the pandemic. According to a study conducted by IQVIA, from 2019 to 2021, telehealth visits rose 21% for Attention Deficit/Hyperactivity Disorder (ADHD), 28% for anxiety, and 21% for depression.¹ Not surprisingly, this led to a 7.6% increase in prescriptions filled for mental health disorders in 2020 and another 5.5 % in 2021. This doesn't include prescriptions for ADHD treatments, which reportedly rose 9.4% from 2019 to 2022. A separate report from Trilliant Health also found that prescriptions for Adderall® for people ages 22 to 44 increased by 15% between 2020 and 2021.

Illegal Drug Sellers Respond Quickly to Demand

Illegal online drug sellers are aware of the ramifications that the DEA's rule will have on demand and they're already prepared to meet it. For years, illegal drug sellers have been peddling counterfeit copies of common controlled substances such as Percocet®, Xanax®, and Oxycodone®, mimicking the physical characteristics of their legitimate counterparts with alarming precision. Sadly, far too many Americans have unknowingly taken these counterfeit pills without any suspicion that instead of an FDA-approved medication, they were receiving highly addictive and often lethal doses of illicit substances, including methamphetamine and fentanyl². In recent years, these same drug dealers have also responded to the increasing demand for ADHD medication. In August 2021, a Michigan man was found in possession of over 15,000 fake Adderall® pills containing methamphetamine³. In March 2022, a Rhode Island man was found in possession of 665,728 methamphetamine-laced counterfeit Adderall® pills, which is thus far the single largest seizure of its kind in the country⁴. A recent study published by UCLA also confirmed that counterfeit Oxycodone®, Percocet®, and Adderall® pills containing fentanyl, heroin, and methamphetamine are already readily accessible without a prescription at brick-and-mortar pharmacies across the border in Mexico⁵. As has been the case with counterfeit Percocet®, Xanax®, and Oxycodone®, it won't be long before counterfeit Adderall® becomes commonplace in illegal online pharmacies and on social media.

This wouldn't be the first-time counterfeiters have moved quickly to ramp up production of popular medicines in a rapidly changing health care environment. In the early 2000s, the threat of a possible avian flu (H5N1) prompted high demand for oseltamivir (Tamiflu). Within weeks, US Customs and Border Protection (CBP) seized more than 50 shipments of fake Tamiflu containing no active ingredient.⁶ Shortages of popular antineoplastic agents from 2012 – 2016 also led to a surge in falsified oncology medications ranking fifth in the most commonly falsified drug category among the reports received by the Pharmaceutical Security Institute in 2016.⁷ Analyses of

¹ IQVIA Institute. "The use of medicines in the US 2022: usage and spending trends and outlook to 2026." Published April 21, 2022. Accessed March 21, 2023. <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022>

² Partnership for Safe Medicines (PSM). "All 50 States Have Reported Deadly Counterfeit Pills Made with Fentanyl." Published October 2020. Accessed March 21, 2023. <https://www.safemedicines.org/wp-content/uploads/2019/09/2020-Oct-50state-42dead-1.pdf>

³ "West Michigan Man Sentenced To 23 Years in Prison for Illegally Possessing Firearms And Intending To Sell Fake Adderall Pills." United States Attorney's Office, Western District of Michigan, Department of Justice. Published June 28, 2022. Accessed March 21, 2023. https://www.justice.gov/Usao-wdmi/pr/2022_0628_Wilson

⁴ "Cumberland Man to Plead Guilty in Largest Meth-Laced Pill Seizure." United States Attorney's Office, District of Rhode Island, Department of Justice. Published September 19, 2022. Accessed March 21, 2023. <https://www.justice.gov/usao-ri/pr/cumberland-man-plead-guilty-largest-meth-laced-pill-seizure>

⁵ Friedman, Joseph et al. "Fentanyl, Heroin, and Methamphetamine-Based Counterfeit Pills Sold at Tourist-Oriented Pharmacies in Mexico: An Ethnographic and Drug Checking Study." medRxiv : the preprint server for health sciences 2023.01.27.23285123. 28 Jan. 2023, doi:10.1101/2023.01.27.23285123. Preprint.

⁶ "US agents seize shipments of fake Tamiflu." University of Minnesota Center for Infectious Disease Research and Policy (CIDRAP). Published December 20, 2005. Accessed March 21, 2023. <https://www.cidrap.umn.edu/avian-influenza-bird-flu/us-agents-seize-shipments-fake-tamiflu>

⁷ Venhuis, Bastiaan J et al. "Oncology drugs in the crosshairs of pharmaceutical crime." *The Lancet. Oncology* vol. 19,4 (2018):

the online marketplace at the time confirmed that all of the oncology medications affected by these shortages were available without a prescription from illegal online pharmacies and the number of websites offering these medications increased over time.⁸

DEA's Unique Ability to Protect Consumers from Harmful Medication Sold Online

The DEA is uniquely positioned to help mitigate the health risk patients will face in the wake of reinstating restrictions on prescribing of controlled substances by telemedicine consultations. In the interest of patient safety, we encourage DEA to partner with patient safety organizations such as ASOP Global and local law enforcement to proactively warn Americans about the public health threats of buying from unverified sources online. ASOP Global and its members have a long history of educating patients and healthcare providers on the risks of illegal online pharmacies and how to stay safe. A recent example of our work is the [Bad Meds campaign](#), launched in 2022 in collaboration with the National Association of Boards of Pharmacy, the Los Angeles County Sheriff's Department, the LAPD, the U.S. Dept. of Homeland Security & Investigations, and Crimestoppers. The campaign's public service announcement features actor Danny Trejo and provides resources through its website to educate consumers about the dangers of buying from illicit and online sources. We welcome the opportunity to partner with DEA on a similar nationwide campaign.

Lastly, we encourage the DEA to support policy solutions that will address the root of the problem - the lack of accountability of online stakeholders. Up to 95% of online pharmacies are not compliant with US law and over 50% sell controlled substances⁹. These criminal actors refuse to abide by the rules that are designed to foster legitimate activity on the internet, and instead help to create an atmosphere of lawlessness that adversely puts the health of millions of Americans in danger. Yet they remain prevalent because these internet entities fail to enforce their own terms and conditions that prohibit illegal activity. We look forward to the day that state and federal laws address the source of today's public health threats without restricting patient access care.

Respectfully,

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⁸ Fittler, András et al. "A challenge for healthcare but just another opportunity for illegitimate online sellers: Dubious market of shortage oncology drugs." *PloS one* vol. 13,8 e0203185. 28 Aug. 2018, doi:10.1371/journal.pone.0203185

⁹ National Association of Boards of Pharmacy (NABP). "Rogue RX Activity Report – Disrupting Illegal Online Pharmacies: Lock-and-Suspend as a Tool to Protect Patients." Published 2022. Accessed March 21, 2023. <https://nabp.pharmacy/wp-content/uploads/2022/10/Rogue-Rx-Activity-Report-Disrupting-Illegal-Online-Pharmacies-2022.pdf>