



Online Controlled Substances Summit

PUBLIC VIRTUAL MEETING

Meeting Summary

November 2024



FUNDING DISCLOSURE:

This activity is one part of a multi-part Foundation project related to substance use disorder. The multi-part project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an overall award of \$1,720,109 of federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit [FDA.gov](https://www.fda.gov).

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The Reagan-Udall Foundation for the FDA (Foundation) is an independent 501(c)(3) created by Congress to advance regulatory science to help the U.S. Food and Drug Administration accomplish its mission. The Foundation works to improve health and safety through stakeholder engagement and public-private partnerships that facilitate innovation, foster the use of real-world evidence, and identify modern tools and policies to keep pace with today's rapidly evolving science. www.reaganudall.org

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1. INTRODUCTION

The U.S. Food and Drug Administration’s (FDA) fifth Online Controlled Substances Summit was convened by the Reagan-Udall Foundation for the FDA on July 26, 2024. The meeting focused on identifying innovative solutions to reduce the availability of controlled substances (CS) online. The public virtual meeting featured FDA leadership, including FDA Commissioner Dr. Robert Califf, and other experts as they examined the impact and evolution of online purchases of CS. In addition to the public meeting, the Foundation convened a closed working session on July 27, 2024. The discussion included social media, internet, technology, and CS experts working collaboratively to identify immediately implementable actions and long-term strategies aimed at disrupting the trajectory of the current crisis.

This report summarizes the key themes identified from the meetings, current challenges in preventing online sales, and opportunities identified where innovative interventions exist to protect public health (Table 1). Illustrative examples of how those opportunities can be operationalized are highlighted in the callout boxes throughout the report.

TABLE 1: SUMMARY OF KEY THEMES, CURRENT CHALLENGES, AND OPPORTUNITIES FOR PUBLIC HEALTH INTERVENTIONS HIGHLIGHTED DURING THE MEETING

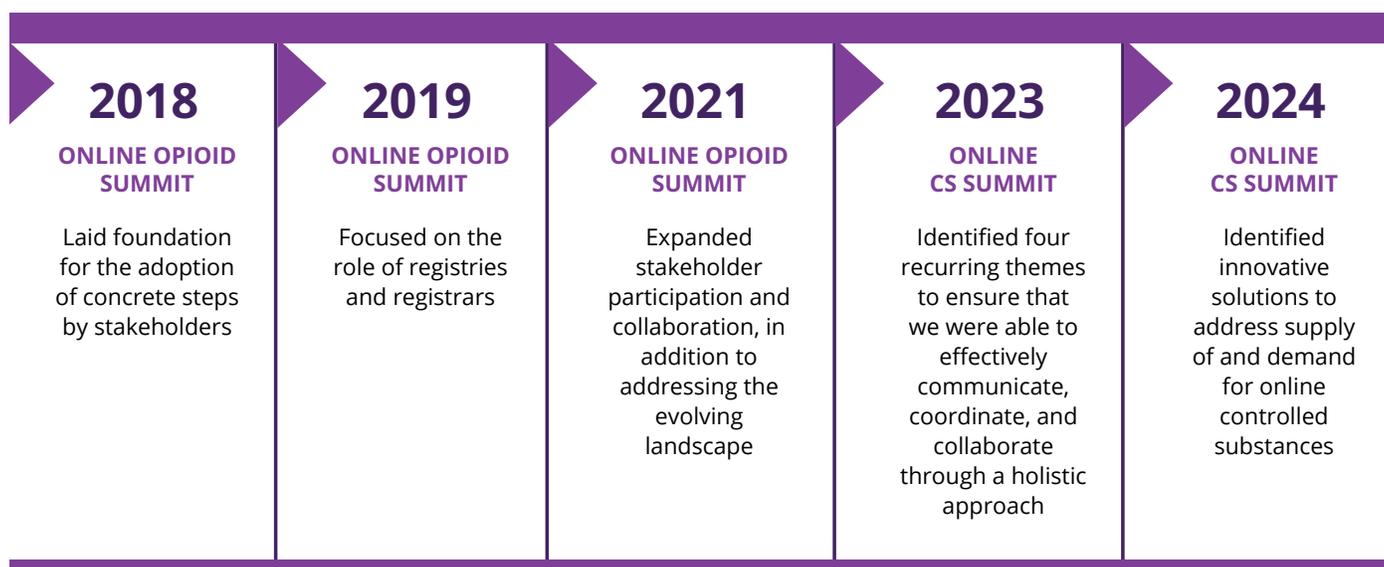
Key Themes	Current Challenges	Opportunities for Public Health Intervention
 Consumer Access	Consumers, including patients, are motivated by disparate needs for CS (medical use, self-medication, and non-medical use)	Develop tailored public health interventions that address the issue from a holistic perspective, including patient access to prescribed CS and consumer demand
 Communications	Messaging and messengers are not reaching intended audiences or having the intended impact	Identify and equip trusted messengers to amplify effective, evidence-based messages for intended audiences
 Partnerships	There is a need to establish partnerships to design and implement achievable, realistic solutions	Build partnerships across multiple platforms and organizations to foster trust, support information sharing, disseminate educational opportunities, and create effective public health interventions
 Compliance	Online demand for CS is being met by unapproved and/or counterfeit drugs, which may be unsafe or ineffective, and thus threaten public health	Empower collaborators to engage in proactive, voluntary efforts that complement FDA’s mission to protect public health

Online Controlled Substances Summits

Given the severity of this public health threat, in June 2018, then-FDA Commissioner Dr. Scott Gottlieb invited internet stakeholders, government entities, academic researchers, and advocacy groups to attend the first Online Opioid Summit. At this first Summit, stakeholders discussed collaborative strategies for taking stronger action to reduce the availability of illicit opioids online.

Since 2018, these summits have laid the groundwork for effective actions, with the 2023 event expanding focus from opioids to all CS (Figure 1). Recurring themes identified in previous Summits include collaboration, education, barriers to action, and continuity. This year's event aimed to navigate these challenges by focusing on effective communication and addressing misinformation to empower consumers to make safer choices.

FIGURE 1: EVOLUTION OF FDA'S ONLINE OPIOID AND CONTROLLED SUBSTANCES SUMMITS¹



Current Landscape

FDA Commissioner Dr. Robert Califf opened the 2024 Summit by emphasizing its focus on addressing the illegal online availability of CS, a critical priority for the Agency. He highlighted the growing threat posed by unregulated prescription drugs sold through unsafe websites and social media platforms, which increase the risk of consumers obtaining contaminated or counterfeit products, potentially laced with deadly substances like fentanyl.

¹ Verbois L, Perspectives from the FDA; July 25, 2024. <https://reaganudall.org/news-and-events/events/online-controlled-substances-summit>

Concerns were raised about the widespread misinformation related to public health and science, particularly concerning the online availability of CS. This misinformation undermines public trust and hinders informed decision-making. In response, the FDA committed to enhancing public awareness of safety risks, improving educational strategies, and communicating through trusted channels using clear and accessible language. Summit participants were urged to explore how consumers seek and interpret information about CS online and to develop strategies that lead to measurable public health improvements and build on progress made during previous summits.

Drug overdose deaths and the risky use of CS are a public health crisis. Data from the Centers for Disease Control and Prevention (CDC) show the number of predicted overdose deaths remains just under 100,000 per year, even after factoring in a roughly fourteen percent decline in predicted deaths between June 2023 and June 2024.² Opioid-related overdose deaths decreased from approximately 84,181 in 2022 to 81,083 in 2023, with a decline in deaths from synthetic opioids (primarily fentanyl), but an increase in deaths from cocaine and psychostimulants (e.g., methamphetamine).³

Addressing this issue is one of the FDA's highest priorities. In response to the opioid crisis, the FDA introduced the Overdose Prevention Framework in 2022, consisting of four key priorities:⁴

1. Supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing.
2. Encouraging harm reduction through innovation and education.
3. Advancing development of evidence-based treatments for substance use disorders.
4. Protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks.

The illegal online sale of CS, including opioids, benzodiazepines, and stimulants, presents serious health dangers to consumers of all ages. Individuals face the risk of buying counterfeit or adulterated medications. The accessibility of these substances online also increases the risks associated with their combined use.

Illegal online pharmacies (IOPs), drug dealers, and other criminals are increasingly using the internet to distribute opioids, where the risk of detection and repercussions is significantly reduced. The 2023 International Narcotics Control Board (INCB) reported an increase in online drug trafficking and illicit online pharmacies selling drugs without a prescription.⁵ Despite the tremendous health risks associated with opioids illegally sold online, the misuse of technology and online platforms continues to make it far too easy for U.S. consumers to purchase these dangerous products.

2 National Center for Health Statistics. Provisional Drug Overdose Data. Centers for Disease Control and Prevention (CDC). Published 2024. <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

3 National Center for Health Statistics. U.S. Overdose Deaths Decrease in 2023, First Time Since 2018. Centers for Disease Control and Prevention (CDC). Published May 14, 2024. https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2024/

4 U.S. Food and Drug Administration (FDA). FDA Overdose Prevention Framework. Published September 5, 2023. <https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework#:~:text=FDA>

5 International Narcotics Control Board. The Role of the Internet in Drug Trafficking and Drug Use Is Highlighted in the International Narcotics Control Board Annual Report. www.incb.org. Published March 5, 2024. <https://www.incb.org/incb/en/news/press-releases/2024/the-role-of-the-internet-in-drug-trafficking-and-drug-use-is-highlighted-in-the-international-narcotics-control-board-annual-report.html>

2. CONSUMER ACCESS

Consumers and patients may buy CS online for various reasons: for medical use based on a current or past prescription from a health care provider, for self-medication following self-diagnosis, for recreational, non-medical purposes, or for others' use (e.g., family members). Online sources for obtaining CS include IOPs, social media, communication (messaging) platforms, search engines, e-commerce websites, and the dark web⁶ (Figure 2). Examining the motivations behind choosing online sources over legal, licensed pharmacies is crucial to understanding the factors driving demand.

FIGURE 2: THE DIGITAL ECOSYSTEM⁷



⁶ The dark web is part of the World Wide Web that allows users and website owners to remain anonymous and is accessed only by using special software.

⁷ Mackey T, Going Beyond the Message: Beyond the Obvious: Developing Strategies for “Digital Prevention” of Online Controlled Substance Sales; July 25, 2024. <https://reaganudall.org/news-and-events/events/online-controlled-substances-summit>.

Online Availability of CS and Consumer Motivations

“... there is no safe pharmaceutical substance sold on social media sites.”
– Mr. Sean Fearn

Representatives from IQVIA Institute for Human Data Science, Alliance for Safe Online Pharmacies (ASOP) Global Foundation, Reagan-Udall Foundation for the FDA, America’s Poison Centers, and the Drug Enforcement Administration (DEA) convened to discuss the growing issue of online drug sellers, particularly focusing on consumer perceptions and behaviors related to the online purchase of CS.

The IQVIA Institute, in collaboration with IE University in Spain and Translucent DataLab, researched the availability of CS to Americans through IOPs. Utilizing advanced analytical modeling powered by artificial intelligence, the team developed a novel methodology to map unregistered pharmacies and estimate the volume of drugs flowing through these illicit channels. Their analysis focused exclusively on e-commerce domains, excluding social media platforms and the dark web. The exact source or authenticity of the drugs involved (e.g., whether counterfeit or substandard) could not be verified.

Key findings presented include:

- From January 2023 to March 2024, an estimated 14,000 to 18,000 active IOPs were operational each month
- About 25% of these sites (3,000 to 4,000) offered one or more of 38 specific CS
- High-volume CS sold included diazepam, alprazolam, and testosterone
- The DEA’s “One Pill Can Kill” initiative, launched in September 2021, led to an 80% reduction in fentanyl sales through IOPs by February 2024 (Figure 3)



PARTNERSHIPS

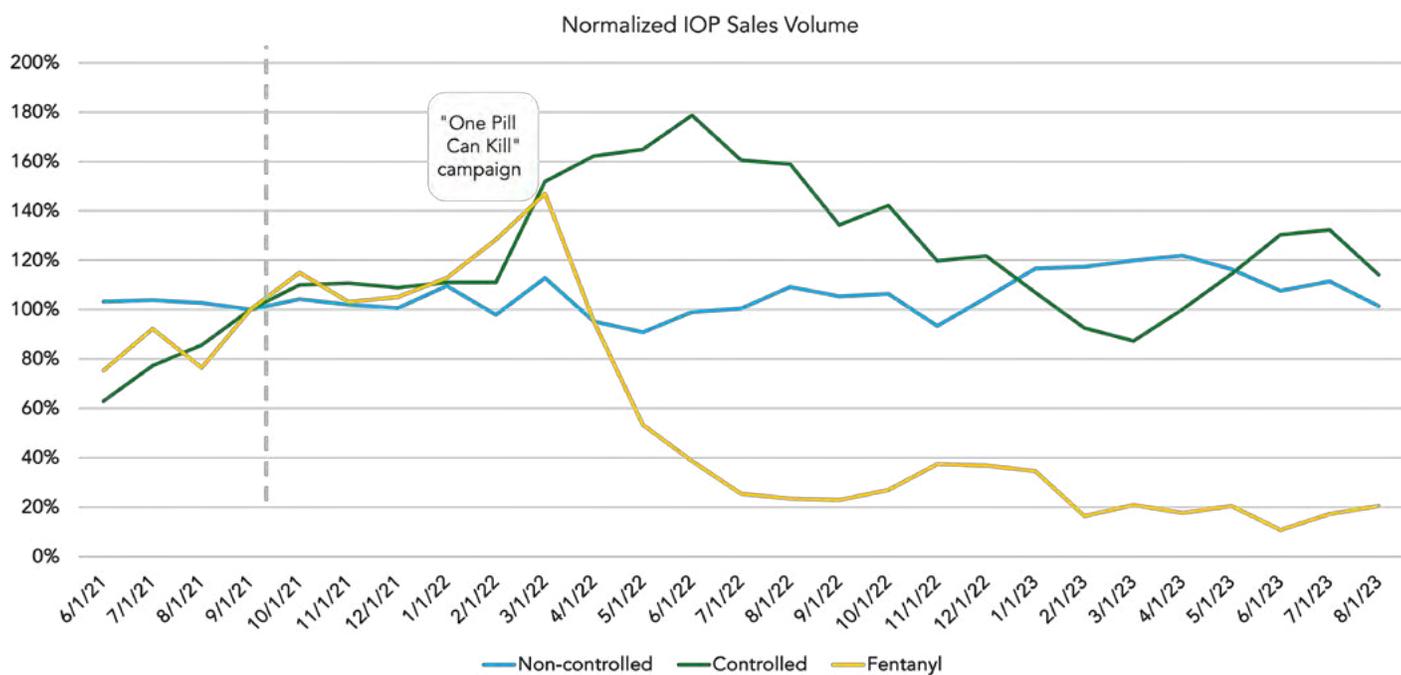
Example:

IQVIA Institute, in collaboration with IE University in Spain and Translucent DataLab, leverages modeling and analytics to monitor trends in IOPs and the impact of interventions to reduce IOP presence.

Additionally, modeling the impact on adverse drug events using the FDA’s Adverse Event Reporting System (FAERS) database, the researchers found that drugs from IOPs generated approximately eight times more adverse events compared to those from legitimate pharmacies, resulting in an estimated additional healthcare cost of USD \$40 to \$50 million per month.

The study provided a detailed snapshot of the illegal online sale of CS in the United States, highlighting a growing public health concern. The novel AI-powered methodology offered valuable insights into the scale of IOP operations, the types of CS being distributed, and the associated health and economic impacts. The researchers emphasized the critical need for continued monitoring and interventions by regulatory bodies like the FDA and DEA to disrupt these illegal activities and mitigate risks to public health.

FIGURE 3: TEST EFFECTIVENESS OF “ONE PILL CAN KILL” EDUCATIONAL CAMPAIGN⁸



[There is a need to] “better make the public aware that other online controlled substances or non-controlled substances may contain dangerous, unlabeled substances” – Dr. Kaitlyn Brown

Consumer Perceptions and Behaviors

To better understand the scope of online purchasing behavior, the meeting included two presentations covering work by the ASOP Global Foundation and National Association of Boards of Pharmacy (NABP) as well as the Reagan-Udall Foundation for the FDA.

⁸ Aitken M, Online Availability of Controlled Substances: A Snapshot; July 25, 2024. <https://reaganudall.org/news-and-events/events/online-controlled-substances-summit>

First, Dr. Justin Macy, representing ASOP Global Foundation and NABP, discussed the growing challenges posed by IOPs. Data from a 2023 survey of 1,500 Americans revealed alarming trends:

- An estimated 40,000 IOPs currently operate, with about 20 new illegal pharmacies launching globally each day
- Of IOPs tracked by NABP, 54% of the websites on its “Not Recommended” list sell CS
- 54% of those surveyed reported purchasing from an online pharmacy, driven primarily by cost and convenience, as well as the unavailability of medications locally
- 54% of consumers believed online pharmacies were FDA-approved or state-regulated and 44% thought prescriptions were not required when purchasing from IOPs
- 47% trust that top search engine results are verified and legitimate—this trust increased to 61% among past IOP users
- 24% had directly experienced or knew someone affected by harmful or counterfeit medications
- Despite rising adverse events, 43% believed purchasing medications online was not risky, a 12% increase from 2021

“... consumers are going to the internet and they think that 54% of all the websites that are offering care have been approved by the FDA or our members, the state regulators.” – Dr. Justin Macy

Second, Dr. Angie Hoth, representing the Reagan-Udall Foundation for the FDA, conducted a comprehensive landscape assessment to understand the online and social media purchase of CS. Findings revealed that consumers often start purchases on one platform and move to encrypted platforms to complete transactions. The majority of these consumers were under 35 years old, with access to smartphones, internet, and electronic payment methods. Motivations for purchasing included recreational use, self-medication for diagnosed or self-diagnosed conditions, weight loss from stimulant side effects, substituting prescription drugs for street drugs, and purchasing for resale to peers. The assessment also found:

- The majority of consumers (74%) recognized the risks of buying medications online without a prescription, but had low confidence in evaluating safety or legitimacy
- 71% of consumers considered the purchase of CS online without a prescription to be as risky or more risky than purchasing non-CS online
- Approximately three quarters of consumers were not confident that medications purchased online would contain the correct ingredients or dosage, or that they could identify fake medications
- Over half of the respondents were not confident that they could determine whether an online pharmacy was licensed

Despite recognizing risks and having low confidence in assessing safety, many consumers were willing to purchase CS online. Poll respondents aged 30–39 were most likely to consider purchasing CS online without a prescription and perceived less risk. Non-White respondents were more likely to consider buying medications online without a prescription, though Black respondents viewed purchasing CS online as riskier than White or Hispanic consumers. Stimulants (e.g., Adderall®) were viewed as safer to purchase online compared to other CS.

The research findings highlighted the threats to public health, emphasizing the need for improved access to medications, better education on the risks of online purchases, and enhanced measures to ensure the safety and legitimacy of online pharmaceutical sources



PARTNERSHIPS

Example:

Poison centers are also essential in detecting anomalies and responding to public health emergencies related to illicit drug use. America's Poison Centers are collaborating with the FDA and DEA to improve surveillance of falsified products. They educate specialists to recognize cases involving online-acquired drugs and facilitate information sharing between organizations.⁹

The discussion underscored the complexity of the online CS problem. Illegal activities that once occurred in person have shifted to online platforms. Continued innovation, resource focus, and public engagement are essential to protect individuals and enhance public safety.

“... we all live in a shared digital risk ecosystem, which includes social media platforms, e-commerce platforms, the internet index websites that have been discussed a lot in this meeting, communication platforms, and, of course, the dark web.” – Dr. Tim Mackey

Information sharing through expert collaboration can drive data-informed decision-making and action. Collaborative action may include, but is not limited to, data collection and evaluation, and monitoring trends in purchasing CS online.

⁹ Brown K, Online Availability of Controlled Substances: A Snapshot; July 25, 2024. <https://reaganudall.org/news-and-events/events/online-controlled-substances-summit>

Real-World Perspectives: The Risk of Purchasing Controlled Substances Online

RISKS



HEALTH RISKS

- Contamination
- Incorrect Dosage
- Unknown Ingredients

SELF-HARM RISKS

- Infections
- Poisoning
- Addiction

SAFETY CONCERNS

- Quality
- Safety
- Authenticity

LEGAL CONSEQUENCES

"As you know, we all are really just in this world, and those of us who are utilizing substances get those substances from any which direction that we can."

"Focusing on reducing stigma is going to be key to alleviating some of these harsher consequences that folks are facing when purchasing both what they feel are prescription type substances and illegal substances online."

"I think buying drugs online is really scary and it can be laced with anything. And people make up fake profiles on these online platforms that you don't really ever know who they are. You could be dealing with the police. You could be dealing with people who have ill intentions. You could be dealing with people that really are just set out to make money and you just never know."

"When we are thinking of individuals who are seeking out to buy substances online because maybe it's cheaper, maybe it's easier accessible, maybe folks, there's a little bit of shame involved and they feel a little more tucked away, so to speak. Because you're not really speaking to somebody. You're not seeking that person to person contact. You are literally just doing this in the privacy of your own home."

Perspectives from the Real World

Purchasing CS online poses significant risks, including legal consequences, health hazards from contamination, incorrect dosages, and unknown ingredients. While online platforms and social media offer anonymity, which makes buying substances online appealing, this also heightens the risks of scams, law enforcement intervention, and overdose. For example, consumers may purchase what they believe is a prescription stimulant, benzodiazepine, or other CS from an IOP, website, or social media, but the formulation is in fact an illegally produced pressed pill made to look like the prescription medication. In that case, people risk taking a medication which can contain other ingredients or an incorrect dose. In other cases, people may be purchasing a product laced with additional substances they are not aware of, such as fentanyl, and could be at risk for an opioid overdose. Specific real-world experiences are highlighted in the callout boxes.

As highlighted by speakers, motivations for online purchases include recreational use, difficulty obtaining prescriptions, and the desire for secrecy. Key facilitators included the convenience of online transactions, generational comfort with technology, and a multi-platform approach that hindered tracking. Encryption and coded language (like icons and emojis) added layers of concealment. Safety perceptions varied: some buyers disregard risks, others feel falsely reassured by social media connections, and some lack awareness of dangers like fentanyl contamination. Recommended interventions included addressing misinformation, focusing on patient education, promoting harm reduction, and guiding buyers to safer, legal options.

3. COMMUNICATIONS

Messaging regarding the dangers of purchasing CS online is not reaching the intended audiences or having the intended impact. Despite awareness of potential risks, consumers continue to purchase CS through websites and social media.

A 2023 study, presented by Erin Stack from Comagine Health, sought to understand awareness, beliefs, and behaviors held by teens and young adults related to fentanyl and counterfeit pills.¹⁰ Researchers surveyed 897 young people (ages 15 to 25) and conducted interviews with 21 individuals. The study focused on where young people currently receive information, who they trust to provide this information, and how they prefer information to be shared.

Most young people obtained information from the internet, friends, and acquaintances. Only 3% used government sources for information on fentanyl and counterfeit pills. Young people expressed a desire to receive information from healthcare providers and state health authorities, with these sources moving to the top of the list when asked who they trust most. Teachers and parents were also seen as trusted sources. Social media and government entities were the least preferred sources, although there is potential to use social media as a platform for disseminating information from trusted sources. Participants shared their preferences for message content (Table 2) and delivery (Table 3), calling for messaging that avoided stigmatizing drug use and promoted a supportive, community-focused approach.

TABLE 2. INFORMATION NEEDS AND CONTENT PREFERENCES¹¹

Participants shared that they were interested in education including:

- What forms fentanyl comes in and what it could be mixed into
- The short-term and long-term effects of fentanyl on the body
- Statistics on overdose rates and fentanyl prevalence
- Overdose response training
- Debunking common misconceptions

10 Stack E, Going Beyond the Message: Insights From Young People About Trusted Messengers & Communication Strategies for Fentanyl and Pill Use Prevention; July 25, 2024. <https://reaganudall.org/news-and-events/events/online-controlled-substances-summit>

11 Ibid

TABLE 3. INFORMATION FORMAT¹²

Participants shared that messaging could come in the form of:

- Short-content media: Instagram Reels, TikTok, or Facebook
- Billboards with advertising: Fentanyl facts and statistics, naloxone access

They recommended content that was:

- Tailored to youth populations
- Quick and easy to digest
- Nonjudgmental
- Harm reduction focused rather than abstinence based

The study highlighted that young people were eager for accurate and trustworthy information about fentanyl and counterfeit pills. They preferred receiving this information from healthcare providers and state health authorities via social media in a format that is quick, nonjudgmental, and focused on harm reduction. Collaboration among public health, healthcare, and social media platforms was encouraged to effectively develop and deliver these messages.

“... participants shared frequently that they wanted to hear from healthcare experts, specifically people working directly with people with substance use disorder and people with lived and living experience of drug use.” – Ms. Erin Stack



COMMUNICATIONS

Example:

Public Good Projects: Trusted Messenger Program¹³– a program to strengthen health systems and defend against the continued erosion of trust in health information and intervention.

Collaborative efforts can focus on enhancing communication, education, and outreach to key audiences through trusted messengers. Identifying and empowering these messengers will help deliver impactful, evidence-based messages effectively to the intended audiences.

¹² Ibid

¹³ Public Goods Project. Trusted Messenger Program. [Publicgoodprojects.org](https://www.publicgoodprojects.org/). Published 2018. Accessed October 1, 2024.

4. PARTNERSHIPS

This Summit highlighted the urgent need for strategic, multi-sectoral collaboration to combat the illegal sale of CS online. Bringing together stakeholders from across the internet ecosystem, government, international bodies, academia, and advocacy groups, the summit served as a platform to collate evidence and develop actionable solutions aimed at disrupting current trends in the online availability of CS.



PARTNERSHIPS

Example:

The 21st Century Cures Act Trusted Exchanged Framework and Common Agreement creates “a nationwide policy and infrastructure backbone to ease information sharing across health record networks and other health IT systems. Using data exchange to improve public health.”¹⁴

The challenge of unsafe distribution of CS online is driven by increased consumer demand, exponential growth in tech innovation (i.e., the online technologies and capabilities available to individuals), and consumer misconceptions. Disrupting current trends requires comprehensive solutions designed to change consumer behaviors and protect public health by addressing both the supply and demand sides of the issue.

Research showed multiple platforms were being misused (i.e., violating user agreements) to complete CS purchases online. Strategies for developing digital prevention measures to curb online CS sales require a “whole of internet” approach inclusive of the entire digital ecosystem (Figure 2). This approach calls for proactive risk mitigation strategies by the internet ecosystem, sharing intelligence across platforms, and consistent enforcement. Strategies include dynamic tracking of changes in seller behavior, a universal blacklist for noncompliant drug sellers (i.e., those who fail to adhere to laws and regulations), and the importance of platform responsibility even when transactions occur off-platform. There is also a need to move towards creative and substantive solutions tailored to different digital platforms, as well as targeted interventions based on understanding why and how users interact with noncompliant drug sellers.

It is important to develop digital prevention measures that are as effective as the methods used by noncompliant drug sellers. This includes replacing harmful content with health promotion and harm reduction messages, particularly on social media where young people are most active. It is also critical that this messaging is nonjudgmental, focused on harm reduction, and delivered through trusted sources.

¹⁴ Kolman S. Using Data Exchange to Improve Public Health. National Conference of State Legislatures. Published June 30, 2022. <https://www.ncsl.org/state-legislatures-news/details/using-data-exchange-to-improve-public-health>



PARTNERSHIPS

Example:

Project Lantern¹⁵ – a cross-platform signal sharing program about activity and accounts that violate child safety policies; allows companies to work collaboratively in order to enhance detection of potential threats.

Representatives from the social media sector of the digital ecosystem acknowledged the need for broader collaboration across other sectors, such as search engines and payment systems, to address challenging topics like the opioid crisis. The conversation highlighted the efforts of Snapchat and Meta in combating drug misuse on their platforms.

Snapchat emphasized creating a safe and enjoyable environment by limiting interactions to real friends and proactively combating drug sales using technology like machine learning. They provide educational resources through initiatives like the “Heads Up” portal, and they work closely with law enforcement to remove drug-related content and bad actors from their platform.



COMMUNICATIONS

Example:

TikTok Safety Center¹⁶ and Suicide Support¹⁷ – search terms prompt redirection to the safety center providing education and connections to support services.

Meta has strengthened its community standards to remove content promoting illicit drug sales and focuses on detecting and preventing such content through advanced technologies. They collaborate with organizations like Mobilize Recovery and the Partnership to End Addiction to provide educational resources and support recovery efforts. Meta also works closely with law enforcement to address illegal activities on their platforms.

“... there is a lot of intersection between the work that Meta is doing and the work that Snap’s [Snapchat] doing, which is great. That’s what we want to see. The platforms banding together to do the right thing, to leverage our respective resources to make an impact.” – Ms. Amanda Plisner

15 Tech Coalition. Announcing Lantern: The First Child Safety Cross-Platform Signal Sharing Program. Technologycoalition.org. Published November 7, 2023. Accessed October 1, 2024. <https://www.technologycoalition.org/newsroom/announcing-lantern>
16 TikTok. Safety Center. Tiktok.com. Published 2024. Accessed October 1, 2024. https://www.tiktok.com/safety/en?sc_version=2024
17 TikTok. You’re Not Alone. Tiktok.com. Published 2024. Accessed October 1, 2024. <https://www.tiktok.com/search/user?q=suicide&t=1727741442867>

Both companies stressed the importance of collaboration across industries, government, and communities to combat the opioid crisis, and amplified their work in establishing the Alliance to Prevent Drug Harms (Prevent Alliance), a public-private partnership aimed at sharing strategies to fight drug-related harms online.¹⁸ The discussion concluded with an acknowledgment of the ongoing challenges posed by evolving online drug sales tactics and the need for continued vigilance and collaboration. Collaborative action requires using a holistic approach to develop interventions across multiple platforms to discourage and disrupt the purchase of CS online.



PARTNERSHIPS

Example:

Tech Against Trafficking¹⁹ – practical approaches to countering cross-platform exploitation of online services for drug trafficking.

18 United States Mission to the United Nations. Ambassador Linda Thomas-Greenfield Launches Alliance to Prevent Drug Harms in Collaboration with United Nations and Tech Industry. Published July 11, 2024. Accessed September 26, 2024. <https://usun.usmission.gov/ambassador-linda-thomas-greenfield-launches-alliance-to-prevent-drug-harms-in-collaboration-with-united-nations-and-tech-industry/>

19 International Narcotics Control Board (INCB). Tech against Trafficking: Practical Approaches to Countering Cross-platform Exploitation of Online Services. Incb.org. Published March 5, 2024. Accessed October 1, 2024. https://www.incb.org/incb/en/news/news_2024/tech-against-trafficking_-_practical-approaches-to-countering-cross-platform-exploitation-of-online-services.html

5. COMPLIANCE

The FDA, through the Center for Drug Evaluation and Research (CDER) and its Office of Compliance, aims to protect consumers from poor quality, unsafe, and ineffective drugs. One key focus is the online availability of CS, which poses serious health risks due to unregulated and potentially dangerous drugs. Online demand for CS is being met by unapproved and/or counterfeit drugs, which may be unsafe or ineffective, and thus threaten public health.

Recognizing the complexity and global nature of online CS sales, the FDA employs a multidisciplinary approach to tackle this public health threat. The FDA has issued warning letters to operators of websites unlawfully selling unapproved and misbranded CS such as stimulants, tramadol, and oxycodone. While prevention, education, research, monitoring, and treatment are crucial, enforcement also plays a vital role in protecting public health. Protecting consumers and holding those who threaten public health by profiting from illegal activity accountable are part of the government's overall strategy to combat this problem.



COMPLIANCE

Example: FDA In Brief: FDA Continues Efforts to Curb Illegal Availability of Unapproved Opioids Online – nearly 30 websites illegally selling opioids were shut down as a result of a 120-day pilot project between the FDA, the National Telecommunications and Information Administration (NTIA) and domain name registries.²⁰

Example: Operation Wild Web led to the arrest of 275 individuals, 224 convictions, as well as the seizure of drug counterfeiting tools, counterfeit drugs, and over \$59 million in virtual currencies and other assets.²¹

Example: Operation SpecTor – an international operation to disrupt darknet trafficking of fentanyl and opioids that led to 288 arrests, 64 kg of fentanyl or fentanyl-laced narcotics, and \$53.4 million in cash and virtual currencies.²²

20 U.S. Food and Drug Administration. FDA Continues Efforts to Curb Availability of Unapproved Opioids. www.FDA.gov. Published 2021. Accessed November 13, 2024. <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-continues-efforts-curb-illegal-availability-unapproved-opioids-online>

21 Burk D, Perspectives from the FDA; July 25, 2024. <https://reaganudall.org/news-and-events/events/online-controlled-substances-summit>

22 U.S. Department of Justice Office of Public Affairs. Largest International Operation against Darknet Trafficking of Fentanyl and Opioids Results in Record Arrests and Seizures. www.justice.gov. Published May 2, 2023. Accessed October 25, 2024. <https://www.justice.gov/opa/pr/largest-international-operation-against-darknet-trafficking-fentanyl-and-opioids-results>

Legal online pharmacies are regulated by state pharmacy boards and are required to verify prescriptions before dispensing medications. In the U.S., NABP provides the Verified Internet Pharmacy Practice Sites (VIPPS) accreditation to online pharmacies that meet stringent criteria.²³ Still, challenges exist in monitoring the vast number of pharmacies operating online, and current legal tools and investigative resources remain inadequate to ensure that online pharmacies are operating legally.

The problem of IOPs persists due to criminals' creative tactics, increased consumer reliance on online services, and the complexity of regulating cross-jurisdictional activities. Cybercriminals have become more sophisticated, using technologies like cryptocurrency, dynamic IP addressing, cloud computing, darknets, and encryption to evade detection. IOP networks are decentralized and often globally operated, making enforcement efforts more complex. Technological advancements used to promote secure computing are also exploited by online sellers.

For these reasons and more, it is necessary for all parties in the internet ecosystem to develop strategic voluntary compliance plans that proactively incorporate other stakeholders to prevent harm. The FDA and the Office of Criminal Investigations (OCI) remain vigilant in identifying emerging threats and taking appropriate action when warranted, and stand ready to be partners in these efforts.

6. SUMMARY AND CALL TO ACTION

As online availability and demand for CS continue to escalate, collaboration is essential. Throughout the Summit, diverse perspectives were shared on the risks, motivations, and challenges associated with purchasing CS online. Addressing this complex issue requires a collective response that tackles both the supply and demand sides of the problem. Collective actions resulting from the Summit would help prevent overdoses, reduce deaths, and alter the course of the opioid crisis through innovation and cooperative efforts.

Key discussions emphasized the importance of matching the right messages with appropriate messengers, leveraging digital prevention strategies, and fostering critical partnerships between public and private stakeholders. A consistent theme was the necessity of a coordinated, multi-sectoral approach to effectively reduce the availability of CS online.

The Summit concluded with a strong call to action: simply warning consumers is not enough. Continued collaboration and innovation among public and private stakeholders are essential to develop and implement effective strategies to address this pressing public health concern.

²³ National Association of Boards of Pharmacy (NABP). Digital Pharmacy Accreditation. <https://nabp.pharmacy/>. <https://nabp.pharmacy/programs/accreditations/digital-pharmacy/>

Interviews

- People with lived experience and professionals who work(ed) with them

Sample Questions

- How do people purchase controlled substances without a prescription?
- Describe motivation individuals may have for purchasing controlled substances through social media platforms.
- Who may be purchasing controlled substances via apps?

Interview Topics

- Motivations
- Safety
- Access
- Intervention



Interviewees highlighted several motivations for purchasing controlled substances online, including recreational use, the need for drugs previously prescribed, and the desire for secrecy and anonymity.

Factors that facilitate online purchases include the ease and convenience of online transactions, generational familiarity with technology, and the multi-platform process that makes tracking difficult. Encryption and the use of alternate language (e.g., icons) further obscure illegal transactions.

Safety considerations vary among different groups of buyers. Some are unconcerned about the risks, while others feel falsely secure due to the perceived legitimacy of social media connections. Others are unaware of the risks, such as fentanyl contamination.

Suggested interventions: correcting misinformation, educating both buyers and sellers, centering efforts on patient education, increasing harm reduction campaigns, and guiding buyers toward safer, legitimate options.

Wilks C, Online Purchasing of Controlled Substances; July 25, 2024. <https://reaganudall.org/news-and-events/events/online-controlled-substances-summit>

Real-World Perspectives: Online Purchasing of Controlled Substances



Motivations

Possible Motivations for Purchasing Online

"There are people who are partying, who can use and go on with their lives."

"People are typically pursuing the same drug they were prescribed."

"The people in question here are likely 'suburbans.' [Street users] don't go to an app."



Access

Online Access Incentives

"[Buyers] don't have to have therapy. There are all these hoops you have to jump through – financial or social [to get therapy]."

"Social media is the way kids are interacting so it's the way they are going to interact around drugs."

"Rare that there is a transaction happening entirely on one Platform."



Safety

Safety Considerations

"There are some people who are absolutely unaware of the risks. They are unable to protect themselves because of the easy access."

"People who are involved in addiction are concerned about the drugs, but they are never concerned about the danger."

"There are some people who are absolutely unaware of the risks. They are unable to protect themselves because of the easy access."



Interventions

Areas for Intervention

"Even in the illicit market there is a lot of peer miseducation."

"The person selling may not know what they are selling. They got a reasonable bulk purchase on the darknet."

"Always center and focus on the patient/client." "Educate them so that they are more equipped."



APPENDIX A: Resources

Resources Provided in Presentations

Mobilize Recovery	https://www.mobilizerecovery.org/
NABP Safe Pharmacy	https://safe.pharmacy/
Never Use Alone	https://neverusealone.com/ 877-696-1996
One Pill Can Kill	https://www.dea.gov/onepill
Partnership to End Addiction	https://drugfree.org/
SAMHSA National Helpline	1-800-662-HELP (4357) or 1-800-487-4889 (TDD)
Song for Charlie	https://www.songforcharlie.org/
Take Back Day	https://www.dea.gov/takebackday
Young People in Recovery	https://youngpeopleinrecovery.org

Research Presented

ASOP Global Foundation. **Americans' Perception and Use of Online Pharmacies. ASOP Foundation 2023 Consumer Survey.** 2023. <https://asopfoundation.pharmacy/wp-content/uploads/2023/12/ASOP-Foundation-Consumer-Behavior-Survey-Key-Findings-2023.pdf>

Colorado Department of Law, S-3 Research. **Social Media, Fentanyl & Illegal Drug Sales: A Report from the Colorado Department of Law.** Vol § 24-31-116, C.R.S.; 2022. Accessed September 25, 2024. <https://coag.gov/app/uploads/2023/03/Colorado-AG-Report-Social-Media-Fentanyl-Illegal-Drug-Sales.pdf>

IQVIA. **Assessing the Impact of Illegal Online Pharmacies in the U.S.** Published April 25, 2023. <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-impact-of-illegal-online-pharmacies-in-the-us>

LaForge K, Stack E, Shin S, et. al. **Knowledge, attitudes, and behaviors related to the fentanyl-adulterated drug supply among people who use drugs in Oregon.** J Subst Abuse Treat. 2022;141:108849. <https://doi.org/10.1016/j.jsat.2022.108849>

APPENDIX B: Agenda

Online Controlled Substances Summit

Public Session

Thursday, July 25, 2024

11 am to 2 pm (Eastern), Zoom Virtual Platform

AGENDA

Moderator: Susan C. Winckler, RPh, Esq.

- 11 am **Welcome**
Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA
- 11:05 am **Introductory Remarks**
Robert M. Califf, MD, Commissioner of Food and Drugs, FDA
- 11:20 am **Session 1: Perspectives from the FDA**
Presenters:
- ▶ Leigh Verbois, PhD, Director, Office of Drug Security, Integrity, and Response, Office of Compliance, Center for Drug Evaluation and Research, FDA
 - ▶ Dan Burke, Chief, Investigative Services Division, Office of Criminal Investigations, FDA
- 11:40 am **Session 2: Perspectives from the Real World**
Presenters:
- ▶ Coreen Johnson, Senior Project Coordinator, Young People in Recovery
 - ▶ Chris Wilks, PhD, MPA, Senior Consultant, Health Management Associates
- 12 pm **Session 3: Online Availability of Controlled Substances: A Snapshot**
Presenters:
- ▶ Murray Aitken, MBA, MCom, Executive Director, IQVIA Institute for Human Data Science
 - ▶ Justin Macy, PharmD, JD, Chair of Alliance for Safe Online Pharmacies (ASOP) Global Foundation
 - ▶ Angie Hoth, PharmD, MPH, Research Consultant, Reagan-Udall Foundation for the FDA
- Reactor Panelists:*
- ▶ Kaitlyn Brown, PharmD, DABAT, Clinical Managing Director, America's Poison Centers
 - ▶ Sean Fearn, Chief, Community Outreach & Prevention Support, Office of Public Affairs, Drug Enforcement Administration

1 pm

Session 4: Going Beyond the Message

Presenters:

- ▶ Tim Mackey, MAS, PhD, Professor, University of California, San Diego
- ▶ Erin Stack, MS, Director of Research and Evaluation, Comagine Health

1:15 pm

Session 5: Perspectives from the Tech Sector

Panelists:

- ▶ Megan Jones Bell, PsyD, Clinical Director for Consumer and Mental Health, Google
- ▶ Amanda Plisner, JD, Senior Manager, Proactive Trust and Safety Operations, Snap Inc.
- ▶ Ernest Voyard, JD, Director, Public Policy, Meta

1:55 pm

Closing Remarks

Marta Sokolowska, PhD, Deputy Center Director,
Substance Use and Behavioral Health,
Center for Drug Evaluation and Research, FDA

2pm

Adjourn

