



Online Controlled Substances Summit

The public meeting will begin shortly

Thursday, July 25, 2024

11 am – 2 pm Eastern Time

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).





Welcome

Susan C. Winckler, RPh, Esq.

Chief Executive Officer

Reagan-Udall Foundation for the FDA

Housekeeping



Due to the meeting size, your microphone and video will remain off during the meeting.



This public meeting is being recorded. The slides, transcript, and video recording will be available on the Foundation website.



Please share your questions and comments for the speakers using the Zoom Q&A function.

Today's Agenda (Eastern Time)



11 am	Welcome
11:05 am	Introductory Remarks: FDA Commissioner Robert M. Califf
11:20 am	Session 1: Perspectives from FDA
11:40 am	Session 2: Perspectives from the Real World
12 pm	Session 3: Online Availability of Controlled Substances: A Snapshot
1 pm	Session 4: Going Beyond the Message
1:15 pm	Session 5: Perspectives from the Tech Sector
1:55 pm	Closing Remarks
2 pm	Adjourn

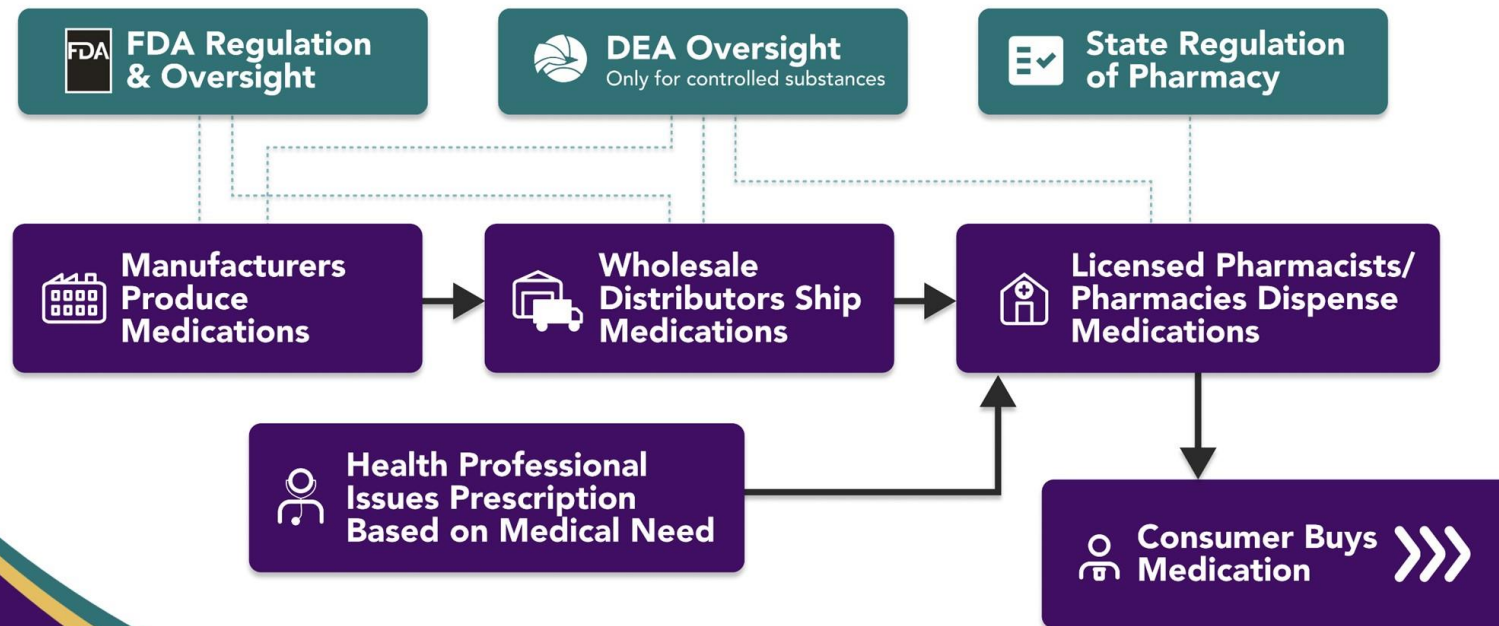


Introductory Remarks

Robert M. Califf, MD

Commissioner of Food and Drugs
U.S. Food and Drug Administration

The Legitimate Supply Chain for Prescription Medications Including Controlled Substances



Perspectives from FDA

Leigh Verbois, PhD

Director, Office of Drug Security, Integrity, and
Response

Office of Compliance

U.S. Food and Drug Administration

2024 Online Controlled Substances Summit

Protect consumers and reduce illegal online sale

Leigh Verbois, PhD

Director of Office of Drug Security, Integrity, and Response
Office of Compliance, Center for Drug Evaluation and Research

July 25, 2024

CDER Office of Compliance's Mission

To shield the public from poor-quality, unsafe, and ineffective drugs through proactive compliance strategies and risk-based enforcement actions

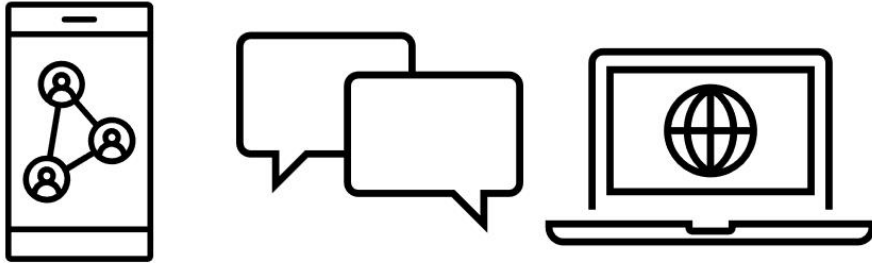


Compliance's Mission Supports FDA's Overdose Prevention Framework (OPF)

FDA's OPF consists of four overarching priorities that align with the [HHS Overdose Prevention Strategy](#) to address the overdose crisis

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

There are serious risks associated with controlled substances obtained online



Despite the tremendous health risks, continued misuse of websites and other online platforms makes it far too easy for consumers to purchase these dangerous products.

Real-Life Consequences

HEALTH

Teens are abusing Adderall bought online amid national shortage: alert

By Brooke Kato

Published April 18, 2023 | Updated April 18, 2023, 3:09 p.m. ET

NEW YORK POST

POLITICS

This is how easy it is to order deadly opioids over the internet

A Google search, a few emails, and some Bitcoin.

by Dylan Scott

Jan 24, 2018, 5:00 PM EST

Vox

EXPLAINER

Over-priced drugs are driving people to "rogue" online pharmacies — sometimes with deadly results

The high cost of medications and a lack of health care access is driving a surge in shady online pharmacy sales

By ELIZABETH HLAVINKA

salon

People buying opioids and sedatives online face deadly fakes, expert warns

National Crime Agency reveals 65 people have died from taking nitazenes, which are up to 100 times stronger than heroin

The Guardian

FDA issues warning letters

*to operators of websites unlawfully selling
unapproved and misbranded controlled
substances to U.S consumers in violation of
the Federal Food, Drug, and Cosmetic Act.*

FDA



FDA Warning Letters to Online Sites

July 22, 2024

WARNING LETTER

This is to advise you that the United States (U.S.) Food and Drug Administration (FDA) recently reviewed your website at the interstate commerce and 505(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 CFR 355(a)].

December 14, 2023

WARNING LETTER

This is to advise you that the United States (U.S.) Food and Drug Administration (FDA) recently reviewed your

November 8, 2023

WARNING LETTER

This is to advise you that the United States (U.S.) Food and Drug Administration (FDA) recently reviewed your website at the interstate commerce and 505(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 CFR 355(a)].

into
, 503(b),
3(b), and

May 22, 2023

WARNING LETTER

This is to advise you that the United States (U.S.) Food and Drug Administration (FDA) recently reviewed your

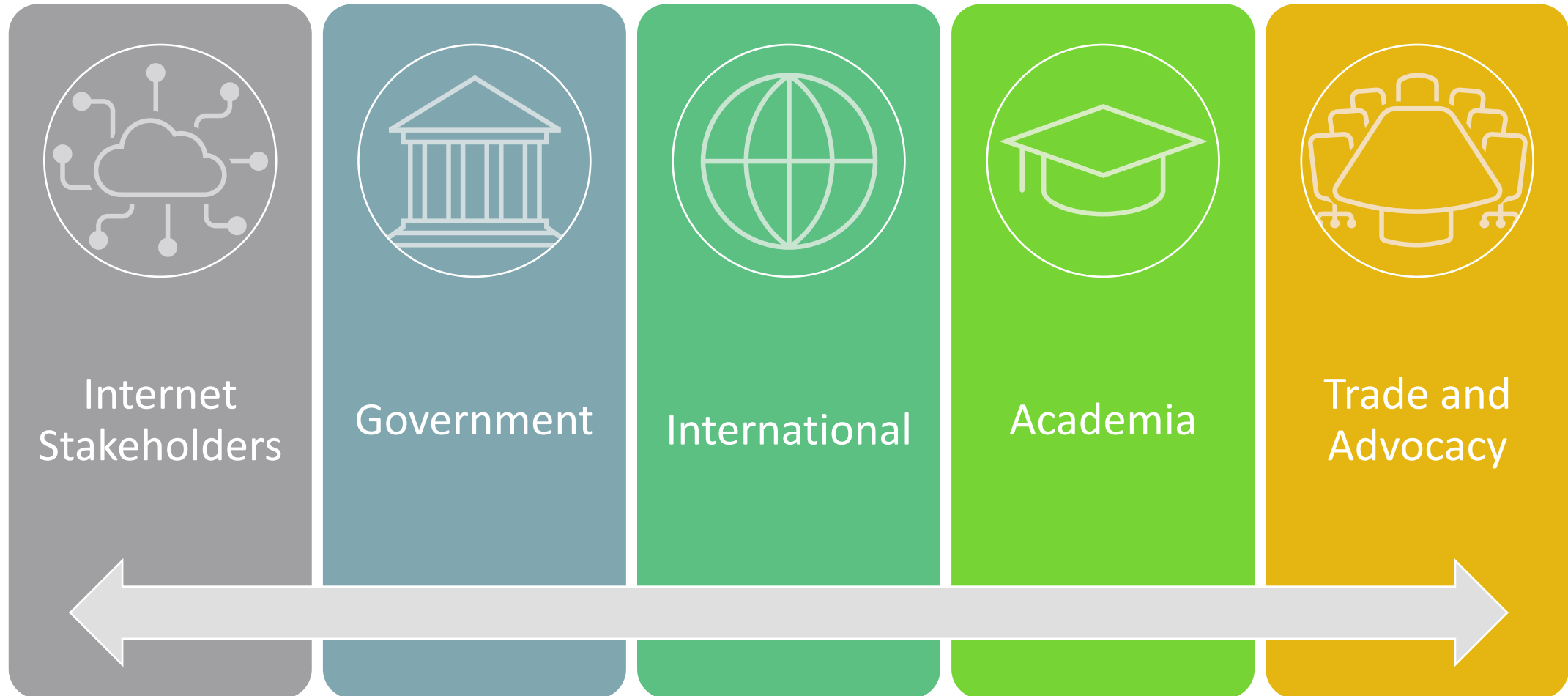
website at the interstate commerce and 505(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 CFR 355(a)].

FDA and DEA Warn Online Pharmacies Illegally Selling Adderall to Consumers

Agency Committed to Using All Available Tools to Stop Online Businesses Illegally Selling Potentially Harmful Drug Products to Consumers

April 12, 2022

Diverse Expert Perspectives from Multiple Sectors



Evolution of FDA's Online Opioid and Controlled Substances Summits

2018 Online Opioid Summit

Laid foundation for the adoption of concrete steps by stakeholders

2021 Online Opioid Summit

Expanded stakeholder participation and encouraged enhanced collaboration, in addition to addressing the evolving landscape

2024 Online CS Summit

Today...

Focused on the role of registries and registrars

2019 Online Opioid Summit

Identified four recurring themes to ensure that we were able to effectively communicate, coordinate, and collaborate through a holistic approach

2023 Online CS Summit

Collaboration is essential



Comprehensive solutions designed to change consumer behaviors and protect public health



Multi-faceted strategies that address both supply and demand



Recognition that online sale of controlled substances is a complex, evolving, and global issue

Perspectives from FDA

Dan Burke

Chief, Investigative Services Division
Office of Criminal Investigations
U.S. Food and Drug Administration

Office of Criminal Investigations



Quotes from “Pharmacists”

“[y]ou are giving too many side effects. Please remember we are trying to sell the medication and not discourage people from buying it.”

Quotes from “Pharmacists”

*You f***ing people killed my daughter [REDACTED] by sending her pain meds. without a prescription. Your company needs to be shut down. My daughter committed suicide. Think about what u r doing to young people when just care about the money u take!!!*

=====

*[message forwarded to site administrator]
just thought id tell you about this poor thing!!
She was a very regular customer- --*



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Categories

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- + Anthelmintics
- + Anti Bacterial
- + Anti Convulsants
- + Anti Depressant
- + Anti Fungal
- + Anti Viral Antibiotics & HIV
- + Antibiotics
- + Arthritis
- + Asthma & Respiratory
- + Bladder
- + Blood Pressure
- + Cancer
- + Cholesterol
- + CNS Activator & Stimulants
- + Diabetes
- + Diuretics
- + Erectile Dysfunction



Genuine Original Brand and Generic Drugs

For 10 years NpD have been
at the forefront of
providing a high quality
pharmacy service online ...

A New Style of Pharmacy with Old Fashioned Service

NpD have provided a reliable pharmacy service for our customers for nearly ten years on the internet. We are the original company that has been voted number one pharmacy many times and we offer an efficient, friendly, safe and totally reliable means of buying prescription drugs and medications online at low prices. We take quality very seriously and only supply known branded name prescription drugs and generic medications manufactured by leading pharmaceutical companies ..[See Our Complete List of Special Rx Saver Offers](#)

A well known trusted and reliable name for prescription drugs and generic medications with a brand new website and product range!

Special Offers on All Popular Medications



We provide a confidential 24
worldwide healthcare service
thousands of regular patient



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FREE SHIPPING OVER**

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- Perfumery
- Makeup & Cosmetics
- Skin & Body Care
- Men's Coloqne

Your **trusted** and **reliable** online pharmacy

TRAMADOL From \$79 Buy Now	FIORICET From \$69 Buy Now	VIAGRA From \$85 Buy Now
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- ✓ **Only FDA Approved Medications**
- ✓ **Fast FedEx Overnight Shipping**
- ✓ **Licensed USA Only Doctors**



Satisfaction Guaranteed!

Trust yesRX.com - your reliable source for FDA approved prescription medication



2024



1880





THIS DOMAIN NAME HAS BEEN SEIZED

Individuals who traffic in counterfeit drugs or controlled substances, dispense prescription drugs without a valid prescription or otherwise receive or distribute adulterated or misbranded drugs are subject to severe penalties under federal law.

Know the dangers of purchasing pharmaceuticals online.

Visit www.fda.gov/BeSafeRx for more information.

Inquiries regarding this seizure can be directed to: cyber.unit@fda.hhs.gov

Office of Criminal Investigations – U.S. Food and Drug Administration
Cybercrime Investigations Unit (CclU)

Operation SpecTor

The Joint Criminal Opioid and Darknet Enforcement (JCODE) Team and Europol's latest international operation against drug traffickers operating on the darknet.







INTERPOL



Medicines & Healthcare products
Regulatory Agency



HM Revenue
& Customs



Border Force

The screenshot shows the Incognito Market website. At the top left, a speech bubble says "Click here to quiz yourself!". In the center is a logo of a cat wearing a hat and glasses. Below the logo, the text reads "You're now Incognito" and "shopping experience reimagined". There are four buttons: "View Listings", "View Vendors", "Private Links", and "Drugs Wiki". On the right, a product listing for "OFFICIALSTATUS" is shown with a "Featured" banner. The product is "**60 CENTS** WHALES ONLY P ROMO ADDERALL DP30" priced at "1.00 USD / 1". The listing includes icons for "OfficialStatus", "stimulants", and "Ships from: United States". At the bottom, a paragraph describes the market's focus on ease of use and security.

Click here to quiz yourself!

You're now Incognito
shopping experience reimagined

[View Listings](#) [View Vendors](#)
[Private Links](#) [Drugs Wiki](#)

OFFICIALSTATUS *Featured*

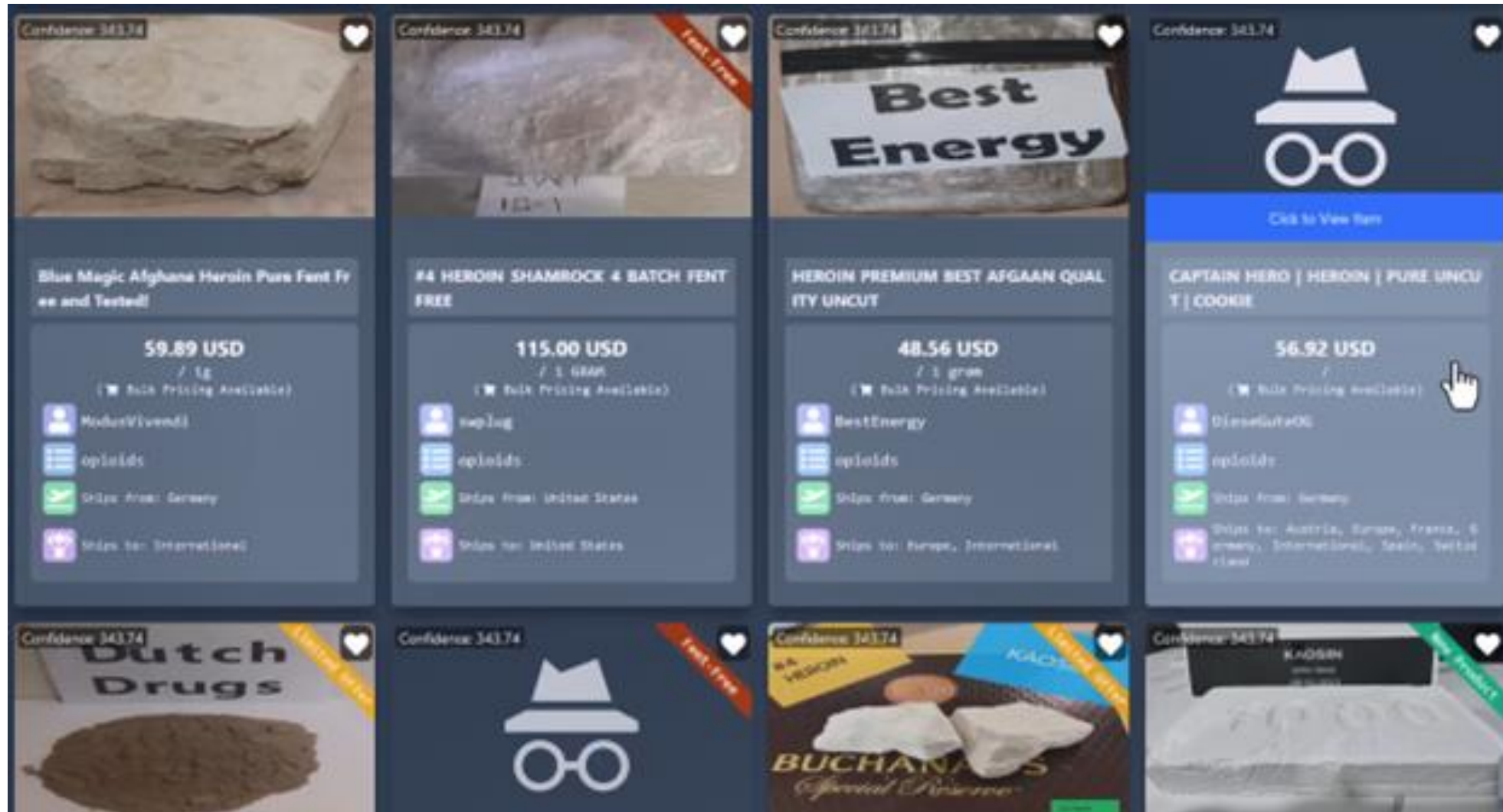
****60 CENTS** WHALES ONLY P ROMO ADDERALL DP30**

1.00 USD / 1

- OfficialStatus
- stimulants
- Ships from: United States

Incognito Market is a market with a focus on both ease of use and security. With a small, dedicated staff team and nothing useless or bloated to slow you down. Be a part of something bigger and enjoy the nice UI/UX!

An indictment is merely an allegation. All defendants are presumed innocent until proven guilty beyond a reasonable doubt in a court of law



An indictment is merely an allegation. All defendants are presumed innocent until proven guilty beyond a reasonable doubt in a court of law



An indictment is merely an allegation. All defendants are presumed innocent until proven guilty beyond a reasonable doubt in a court of law



Expecting to hear the last of us yet?

We got one final little nasty surprise for y'all.

We have accumulated a list of private messages, transaction info and order details over the years. You'll be surprised at the number of people that relied on our "auto-encrypt" functionality. And by the way, your messages and transaction IDs were never actually deleted after the "expiry"...

SURPRISE SURPRISE !!!

Anyway, if anything were to leak to law enforcement, I guess nobody never slipped up. We'll be publishing the entire dump of 557k orders and 862k crypto transaction IDs at the end of May, whether or not you and your customers' info is on that list is totally up to you. And yes...

YES, THIS IS AN EXTORTION !!!

As for the buyers, we'll be opening up a whitelist portal for them to remove their records as well in a few weeks.

Thank you all for doing business with Incognito Market

An indictment is merely an allegation. All defendants are presumed innocent until proven guilty beyond a reasonable doubt in a court of law





Perspectives from the Real World

Coreen Johnson
Young People in Recovery

COREEN JOHNSON-
YOUNG PEOPLE IN
RECOVERY, SENIOR
PROJECT
COORDINATOR



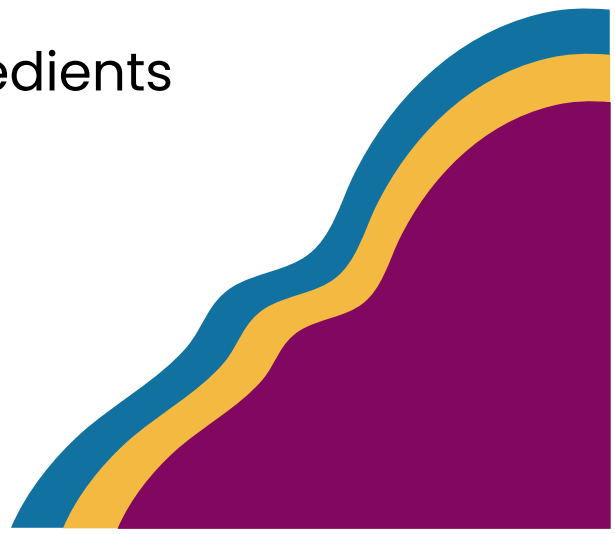
THE RISK OF PURCHASING CONTROLLED SUBSTANCES ONLINE





RISKS

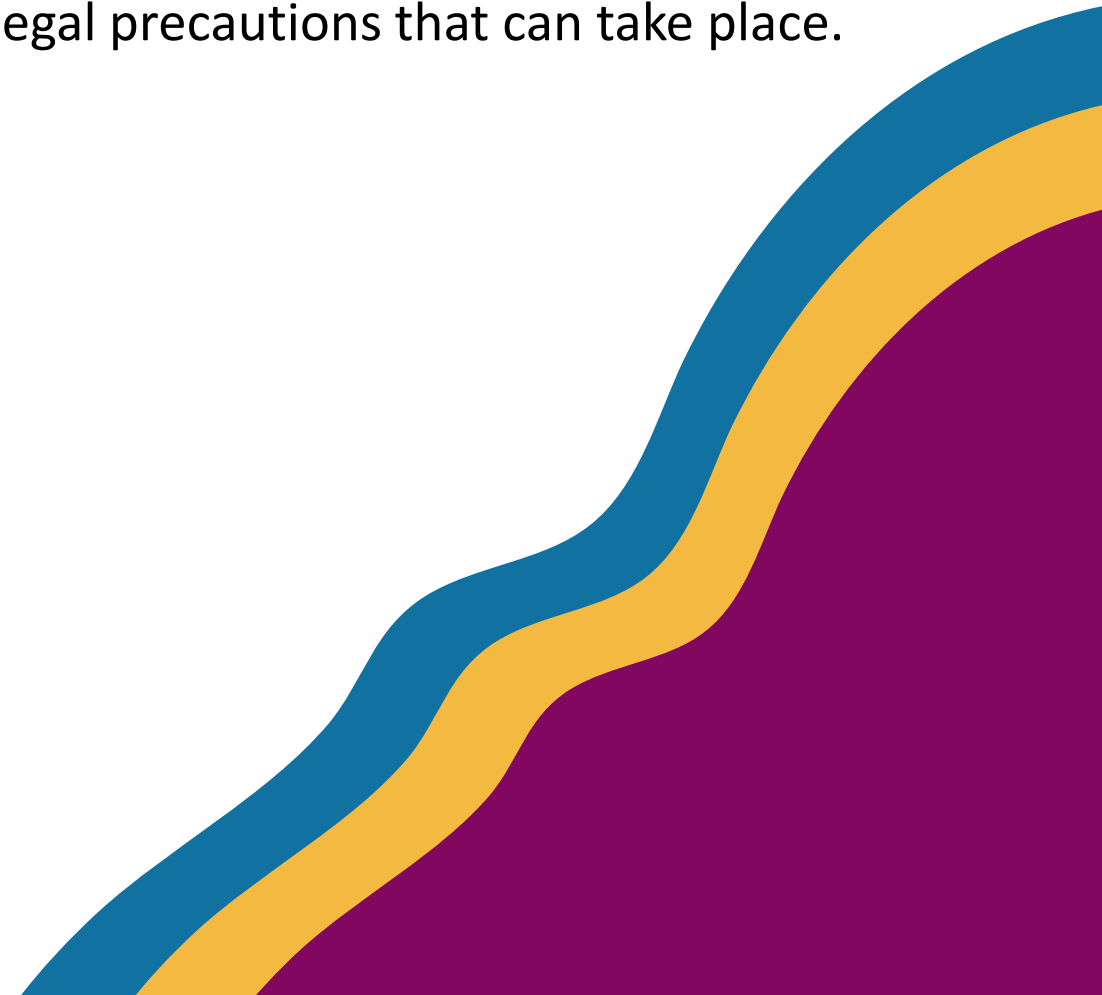
Many risks are associated with purchasing substances online.

- **Legal Consequences:** Legal Action
 - **Health Risks:** Contamination, incorrect dosage, unknown ingredients
 - **Self Harm Risks:** Infections, poisoning, addiction
 - **Safety Concerns:** Quality, Safety, Authenticity
- 

LEGAL CONSEQUENCES

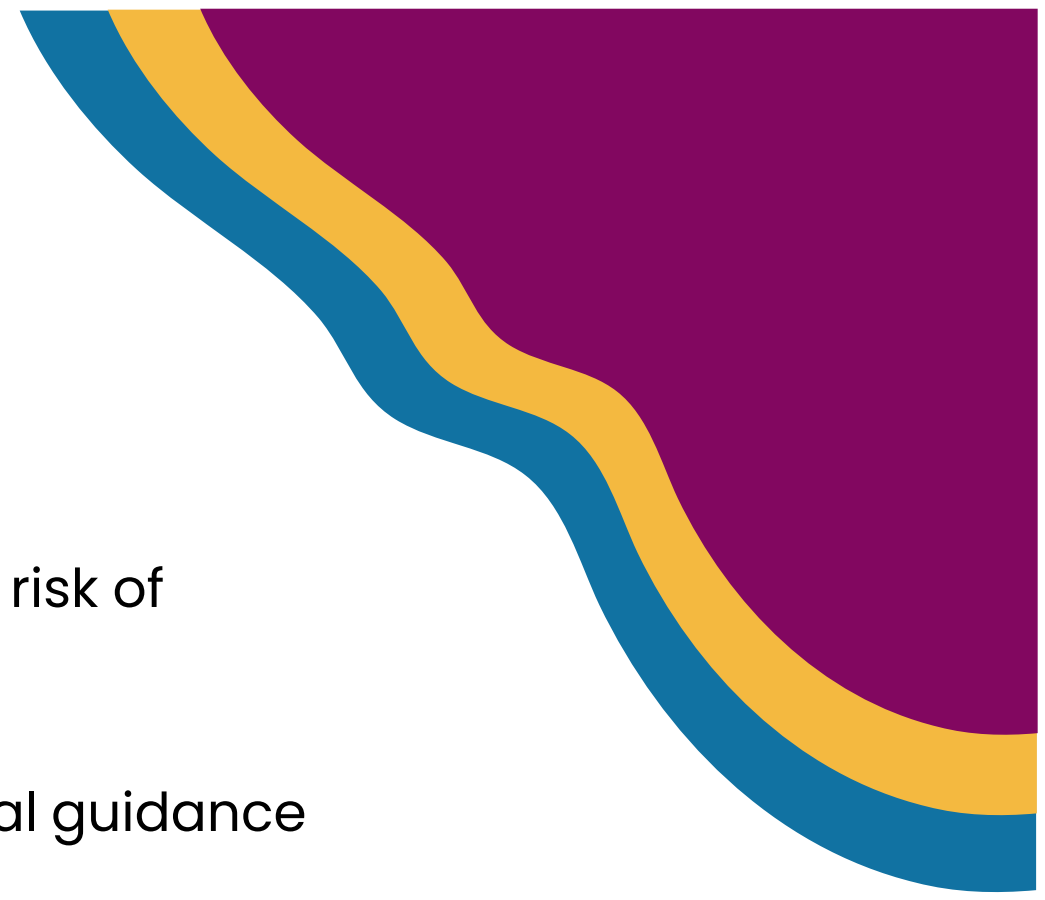
As with purchasing any illegal substances there are legal precautions that can take place.

- Buying controlled substances is illegal
- Potential legal action
- Criminal Charges



HEALTH RISKS

- Contamination of substances
- Overdose: Unregulated dosages increase the risk of overdose.
- Lack of Medical Oversight: Missing professional guidance on safe use.



METHODS OF PURCHASING ILLEGAL SUBSTANCES ONLINE

Dark Web Marketplaces


- Access: Requires special software like Tor to access hidden websites.
- Transactions: Typically use cryptocurrencies (e.g., Bitcoin) to maintain anonymity.
- Risks: High risk of scams, law enforcement stings, and receiving dangerous substances.






SOCIAL MEDIA

Social Media and Messaging Apps

- Platforms: Instagram, Snapchat, WhatsApp, Telegram, and other encrypted messaging apps.
 - Communication: Buyers and sellers use direct messaging to arrange deals.
 - Risks: High risk of scams, law enforcement monitoring, and exposure to dangerous substances.
- 



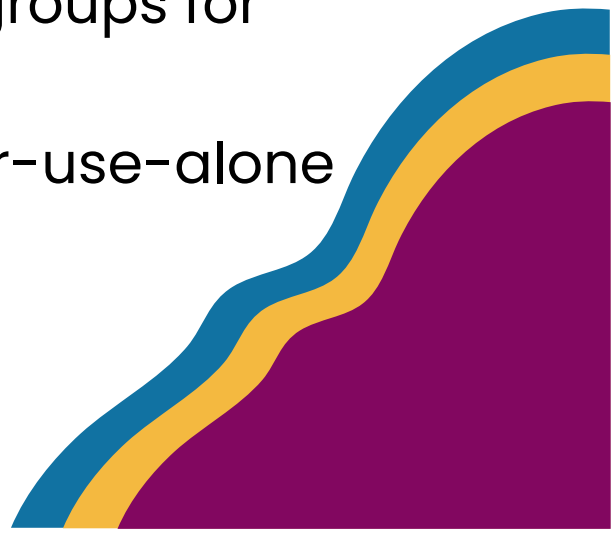
ONLINE FORUMS AND COMMUNITIES

- Platforms: Various forums, Reddit subreddits, or specialized online communities.
 - Transactions: Often move to private messaging after initial contact.
 - Risks: Similar risks of scams, legal consequences, and harmful products.
- 



SAFER ALTERNATIVES

Professional Help:

- Seek support from healthcare providers or counselors for substance-related issues.
 - Legal Channels: Use licensed pharmacies and follow legal procedures for obtaining necessary medications.
 - Support Groups: Engage with community support groups for addiction and substance misuse.
 - Use Harm Reduction approaches such as the never-use-alone hotline and ALWAYS carry NARCAN.
- 

CONTACT US



youngpeopleinrecovery.org



coreen.braden@youngpeopleinrecovery.org



Young People in Recovery



[@youngpeopleinrecovery](https://www.tiktok.com/@youngpeopleinrecovery)



Young People in Recovery



[@yngpplrecovery](https://www.instagram.com/yngpplrecovery)



Perspectives from the Real World

Chris Wilks, PhD, MPA
Health Management Associates

Online Purchasing of Controlled Substances

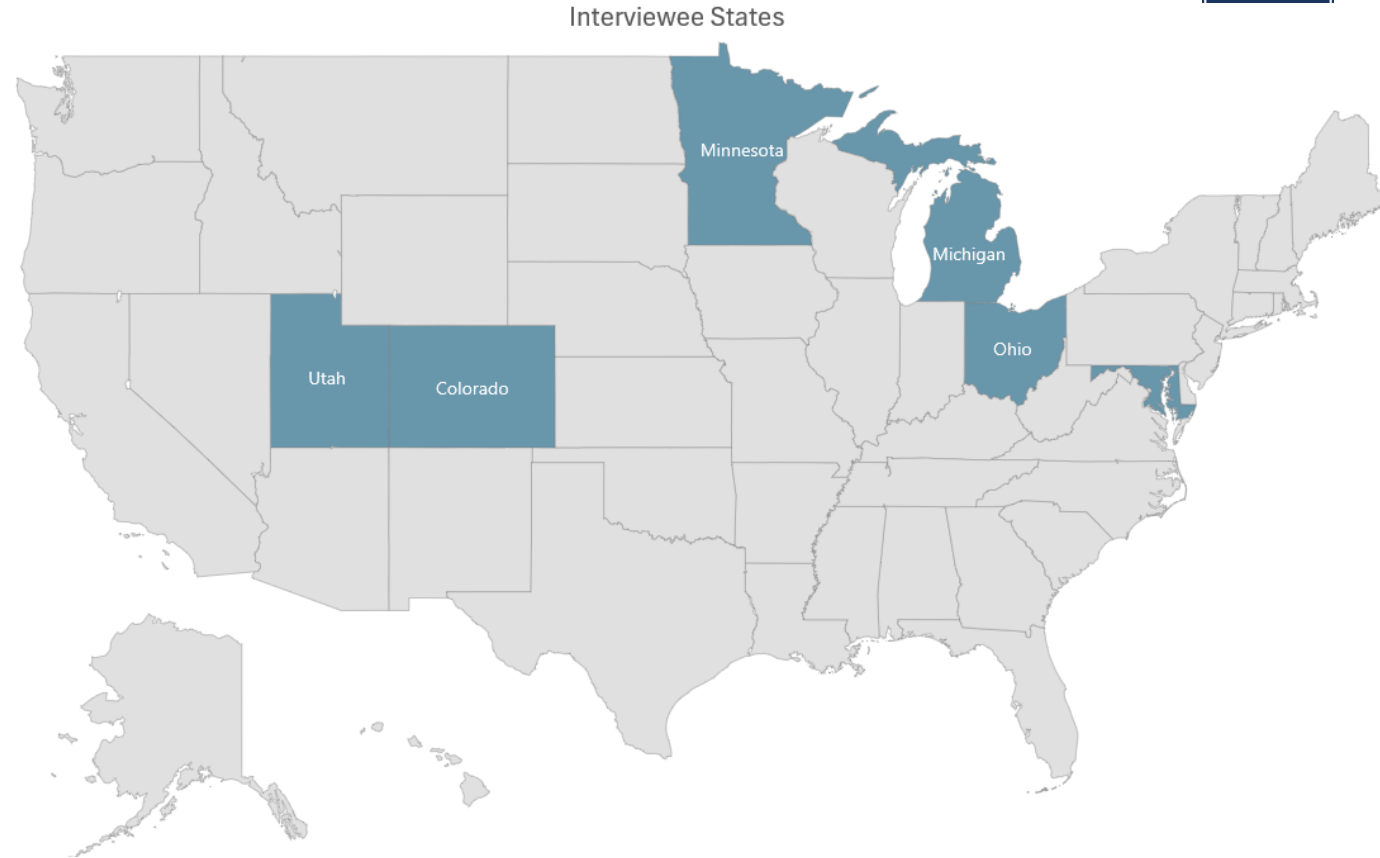
KEY INFORMANT INTERVIEWS

July 2024

LEAVITT
PARTNERS
An HMA Company

Interviews Overview

- **Who:** Professionals currently in or who used to be in related fields and people with lived experience
- **What:** Perceptions about online purchasing of controlled substances
- **When:** August 2023 to September 2023
- **Where:** Virtual and Written



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?

Harm Reduction Advocate

Professor of Criminal Justice and Students

University-based Drug Educator

Peer Recovery Specialist

Clinical Social Worker

Attorney General Staffer

Interview Topics



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 ‘sub-urbans’. [Street users] don’t go to an app.”

Motivations

Factors that Facilitate Online Purchases



“[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.”

Access

Safety Considerations



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

“Social media provides legitimacy.” “They are able to use the mechanisms to vet.”

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

Safety

Recommendations from Interviewees



“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.”

Intervention



At the Forefront of Navigating
Change in Healthcare

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Online Availability of Controlled Substances

Murray Aitken, MBA, MCom
IQVIA Institute for Human
Data Science



Online Availability of Controlled Substances: A Snapshot

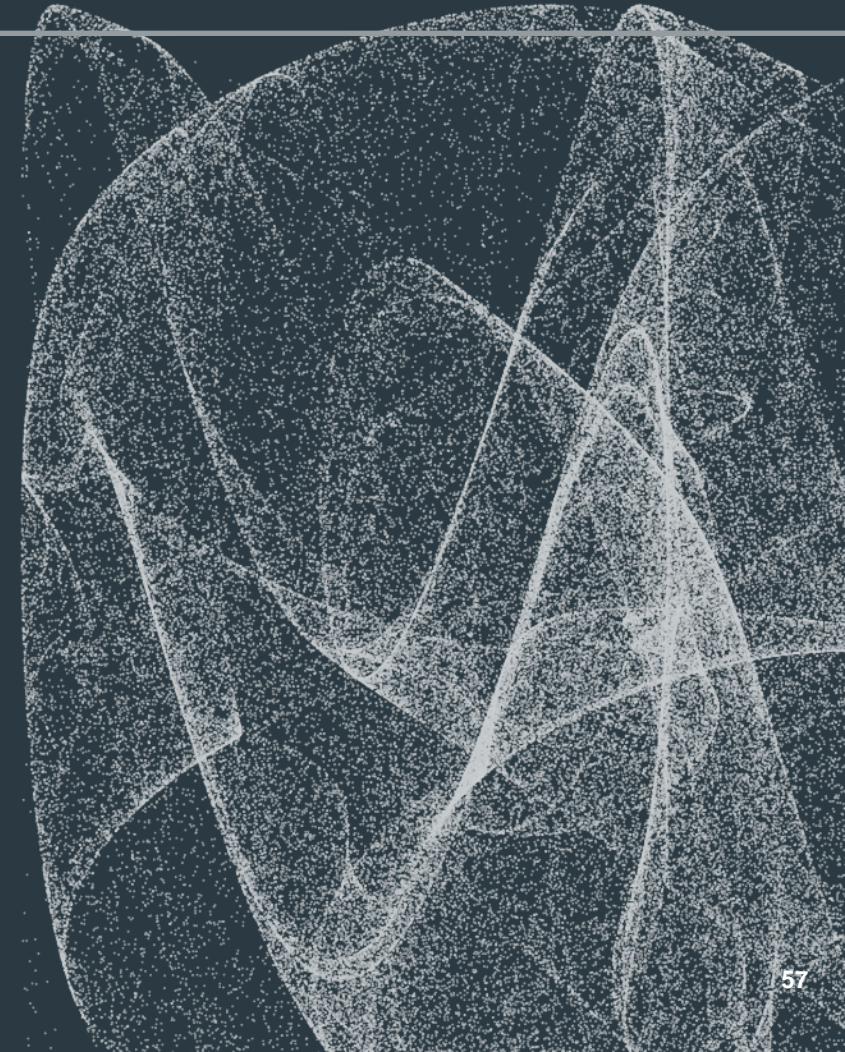
July 25, 2024

Murray Aitken, Executive Director, IQVIA Institute for Human Data Science

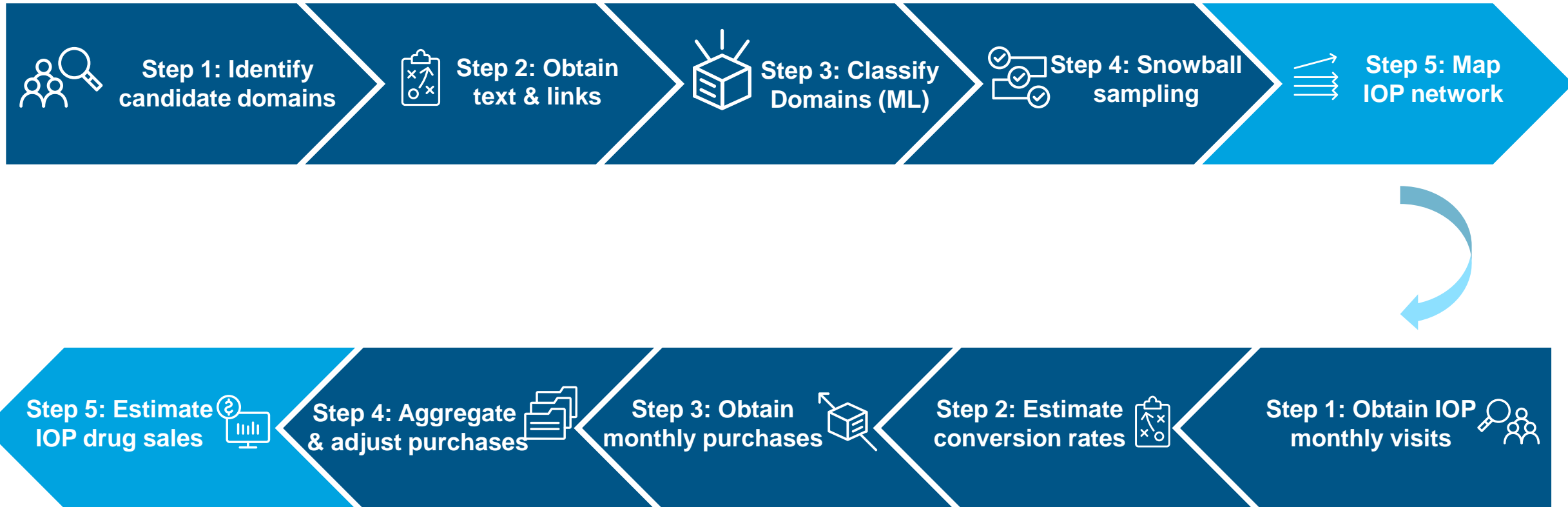
Luis Diestre, Professor IE University & CEO Translucent Datalab



IOP Sales Data: Methodology

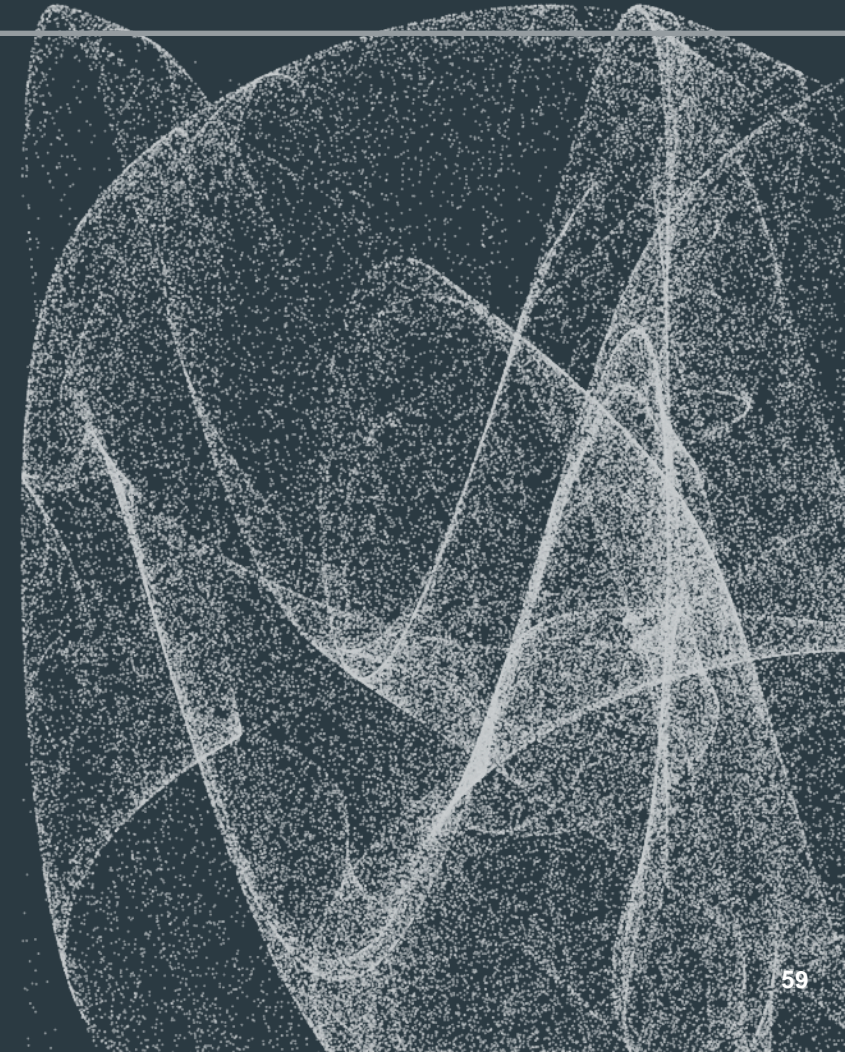


Big data techniques and multiple proprietary AI-based algorithms to: (a) map IOPs network and (b) estimate IOPs sales





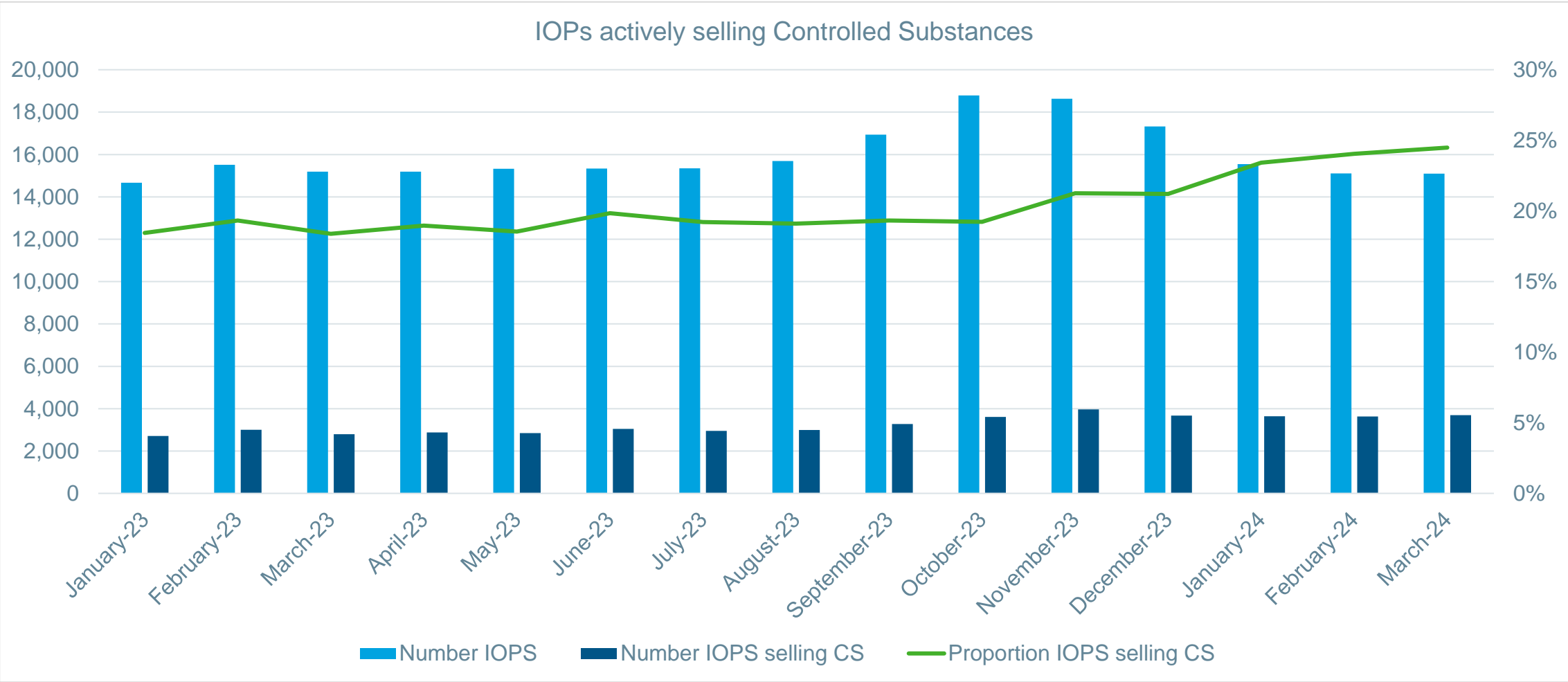
Controlled Substances sold through IOPs: Snapshot of current activity and trends



Controlled Substances: Analyzed Molecules

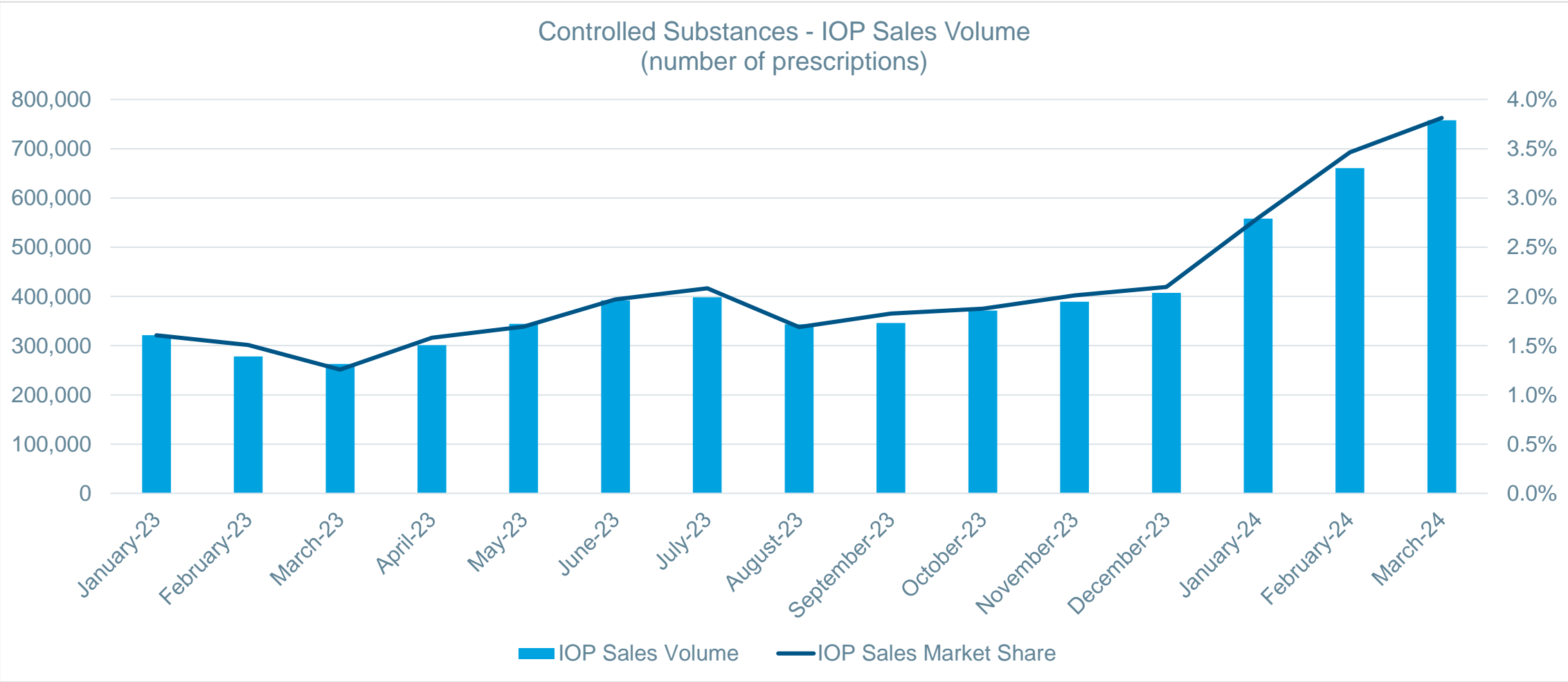
ACETAMINOPHEN-CODEINE	HYDROCODONE
ACETAMINOPHEN-HYDROCODONE	HYDROMORPHONE
ACETAMINOPHEN-OXYCODONE	KETAMINE
ALPRAZOLAM	LORAZEPAM
AMOBARBITAL	MEPERIDINE
AMPHETAMINE	METHADONE
BENZPHETAMINE	METHAMPHETAMINE
BUPRENORPHINE	METHYLPHENIDATE
CARISOPRODOL	MIDAZOLAM
CLONAZEPAM	MORPHINE
CLORAZEPATE	OPIUM
CODEINE	OXYCODONE
CODEINE-GUAIFENESIN	PENTOBARBITAL
CODEINE-PROMETHAZINE	PHENDIMETRAZINE
DIAZEPAM	SECOBARBITAL
DRONABINOL	TAPENTADOL
EZOABINE	TEMAZEPAM
FENTANYL	TESTOSTERONE
GLUTETHIMIDE	TRIAZOLAM

Controlled Substances: Availability in IOPs



About 25% of active IOPs are currently selling controlled substances

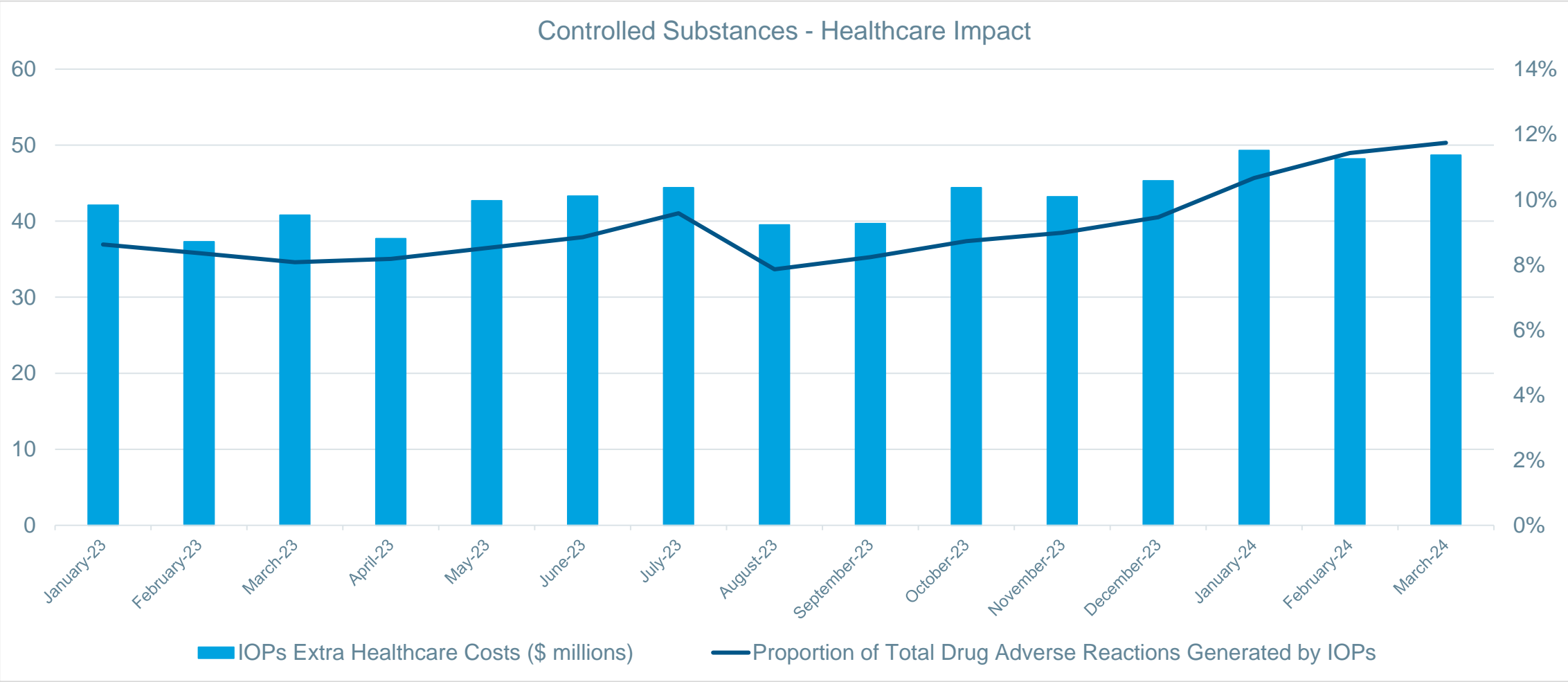
Controlled Substances: IOP Sales Volume



Sales volume through IOPs has climbed significantly recently and represent over 3.5% of volume sold through legal channels

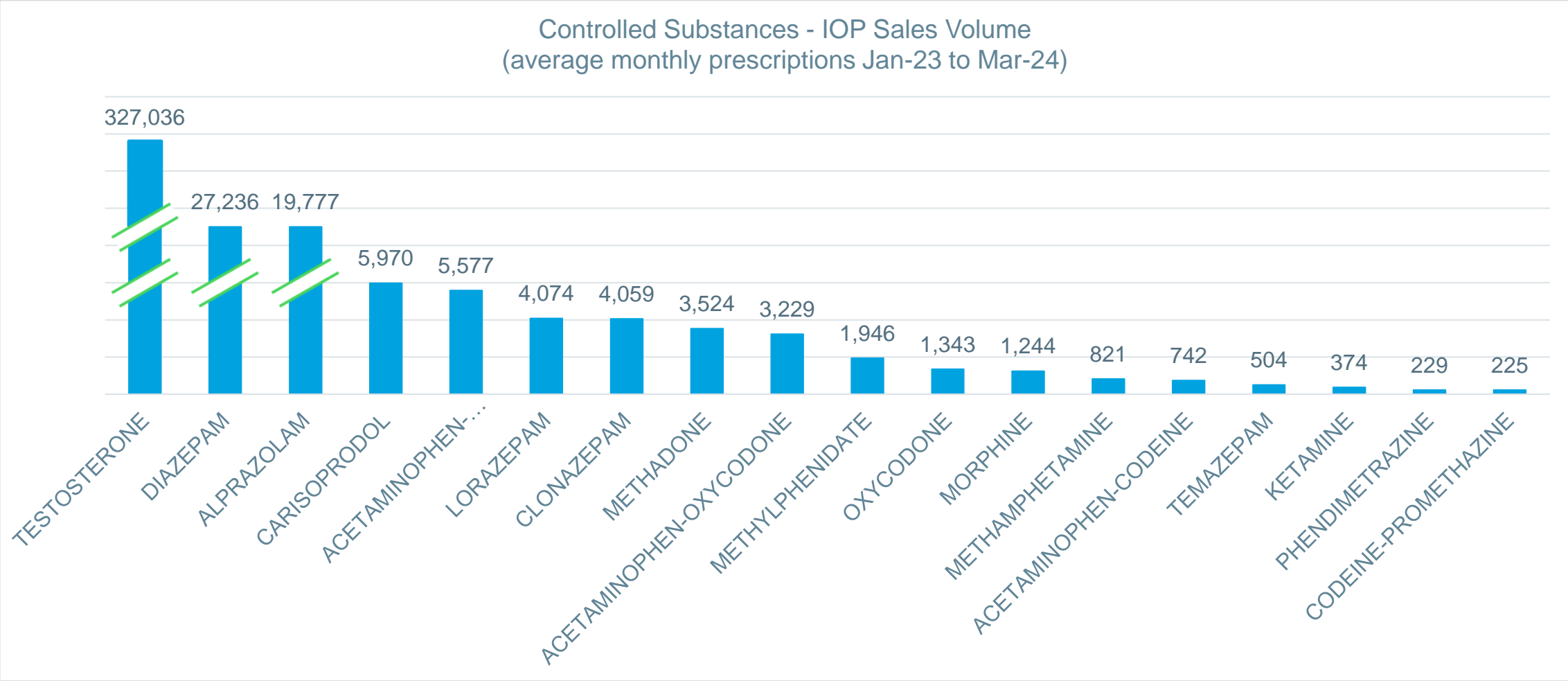
Controlled Substances: IOP Sales' Healthcare Impact

Drugs sold through IOPs generate around 8 times more adverse drug reactions



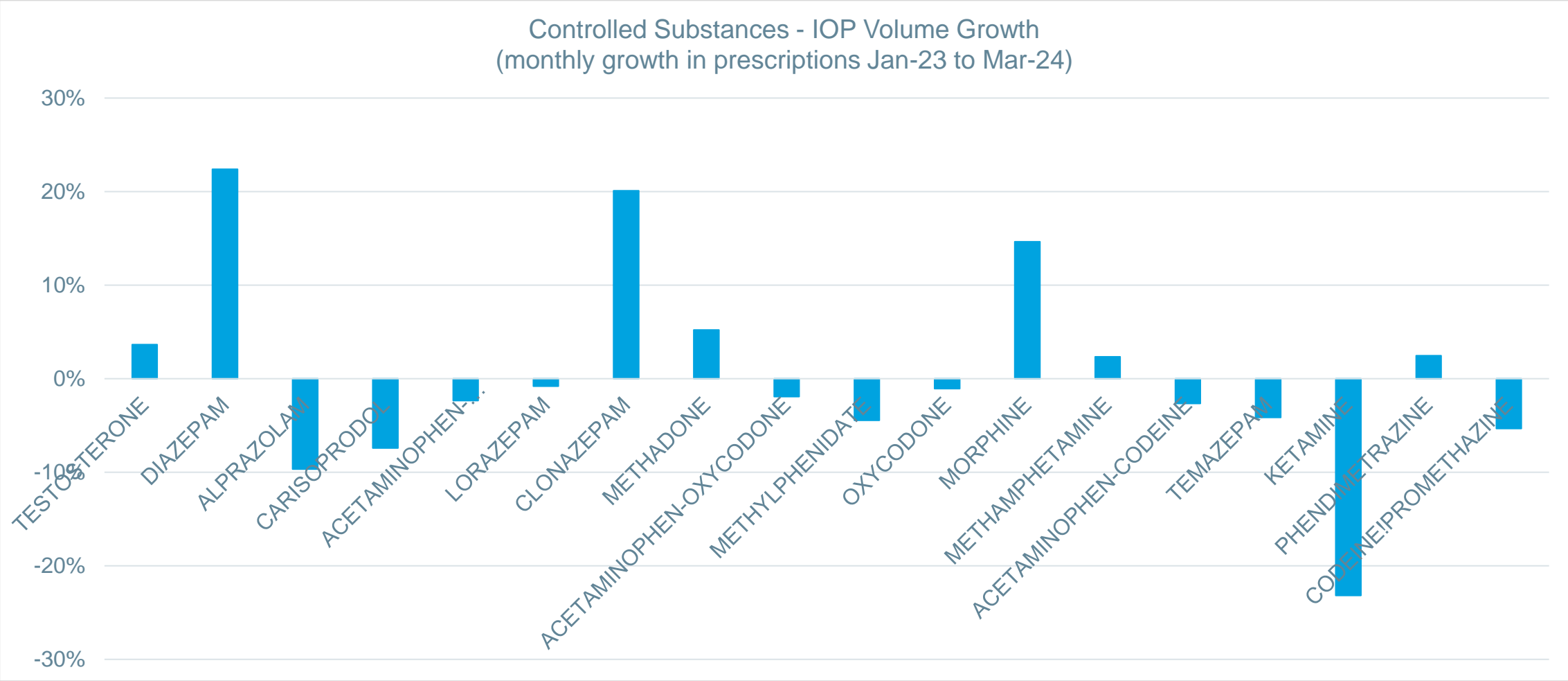
Drugs sold through IOPs are responsible for over 10% of total adverse drug reactions, which generates \$43.1M extra healthcare costs per month

Controlled Substances: Molecules IOP Sales Volume



Testosterone, Diazepam, and Alprazolam show the highest average monthly IOP sales volume

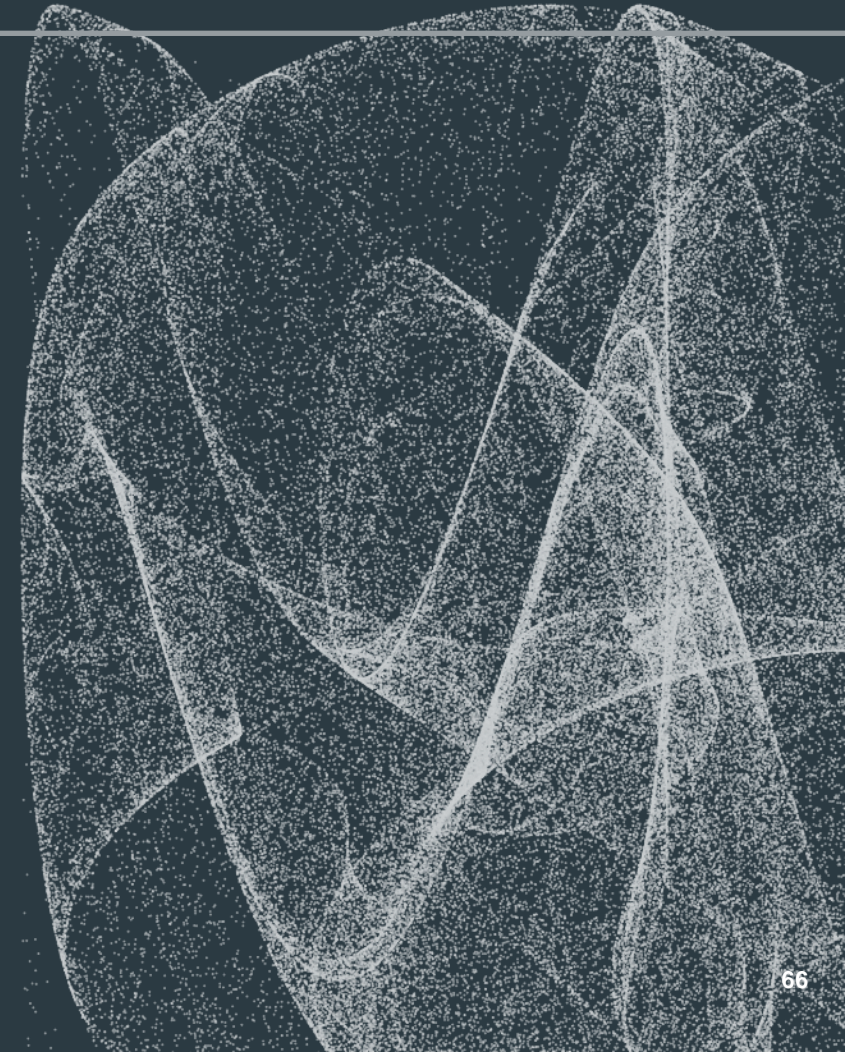
Controlled Substances: Molecules IOP Volume Growth



Monthly growth fluctuates by molecule with a notable decline in ketamine volume recorded recently

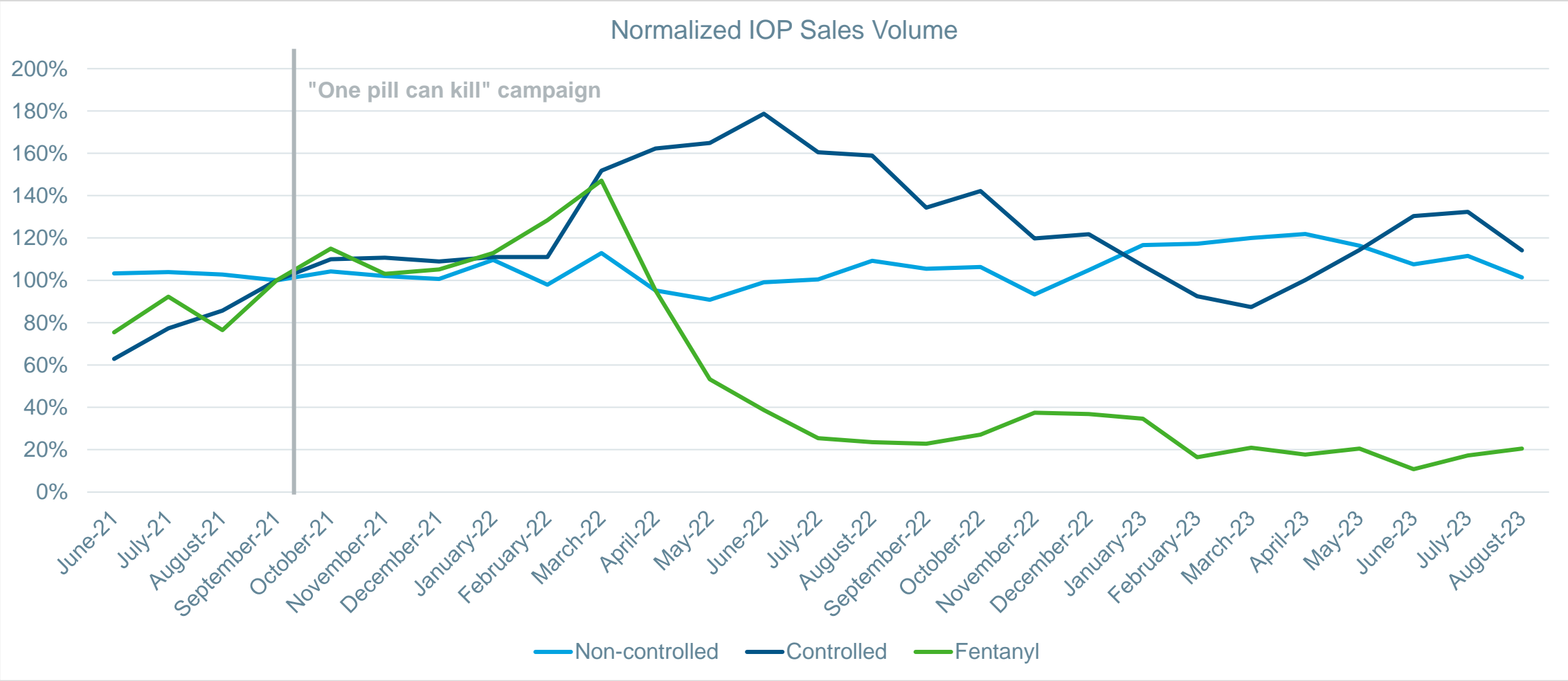


Controlled Substances sold through IOPs: Use of Data to Test Interventions



Controlled Substances: IOP Sales Data for “Demand” Solutions

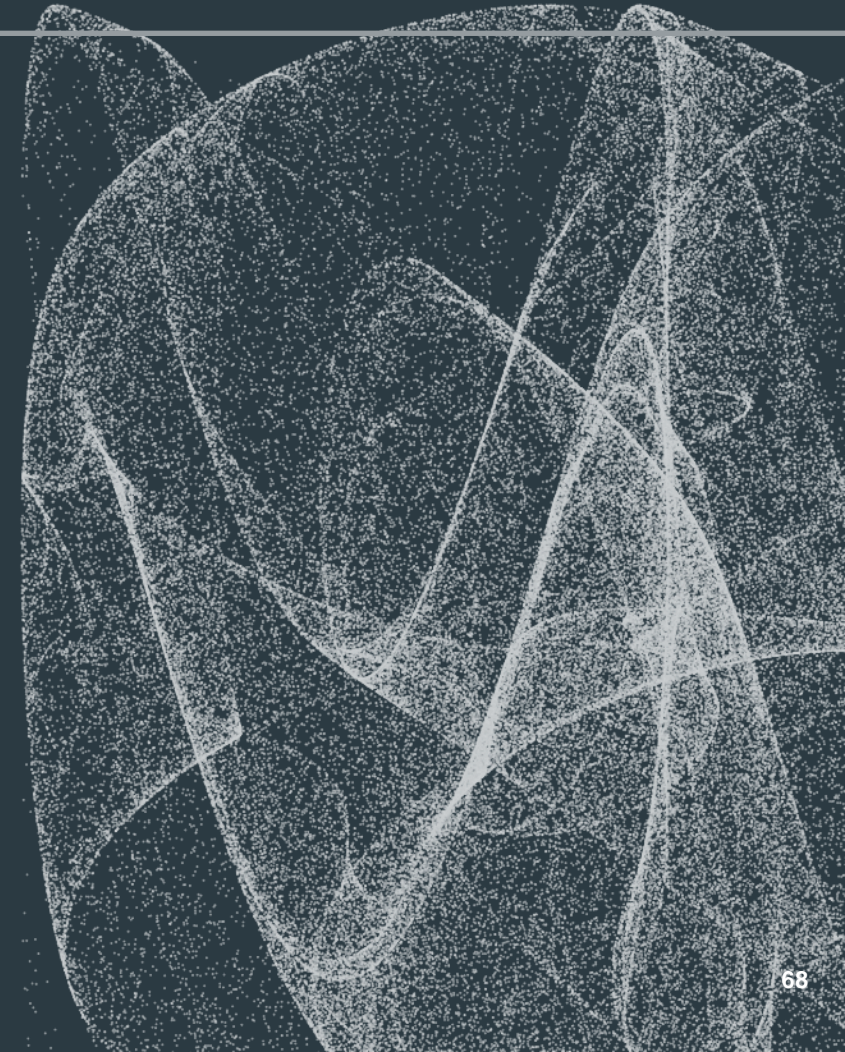
Test effectiveness of “One Pill Can Kill” educational campaign



A notable reduction of 80% (vs non-controlled) and 82% (vs other controlled) has occurred in Fentanyl IOP sales volume after 24 months



Q&A



Online Availability of Controlled Substances

Justin Macy, PharmD, JD
ASOP Global Foundation

FDA Online Controlled Substances Summit

July 25, 2024



Justin Macy, PharmD, JD
ASOP Global Foundation, Chair
NABP, Director of Innovation





ASOP Global is a nonprofit organization headquartered in Washington, D.C. with projects in the U.S., Canada, Europe, India and Asia. ASOP Global is dedicated to protecting consumers around the world, ensuring safe access to medications, and combating illegal online drug sellers and counterfeit medicines.

ASOP Global Foundation is a charitable 501(c)(3) nonprofit, established in 2017 to further ASOP Global's mission by supporting education programs that inform patients and healthcare providers of the public health risks of illegal online drug sellers and funding research to investigate innovative solutions to make the internet safer for patients



About NABP

Mission

The National Association of Boards of Pharmacy (NABP) is the independent, international, and impartial Association that assists its member boards in protecting the public health.

Vision

Innovating and collaborating today for a safer public health tomorrow.

NABP is governed by our [Executive Committee](#), which consists of 4 officers and 8 members. We support and work with our [members](#) to protect the public health. Our members consist of the 50 United States state boards of pharmacy, as well as the boards in District of Columbia, Guam, Puerto Rico, the Virgin Islands, and 10 Canadian provinces. The boards of pharmacy are divided into [8 geographical districts](#) to better consider important regional issues and communicate with regional boards. Our [Constitution and Bylaws](#) direct our operations and activities allowing us to follow our guiding principles.

Online “Pharmacy” 101

40,000

websites that have been found selling prescription medicines online without a license and failing to comply with pharmacy practice standards

95%

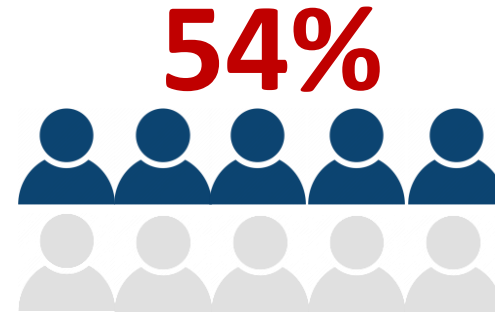
Of these websites sell prescription-only medicines **without a valid prescription**

54%

Of these websites **sell controlled substances**, including codeine and oxycodone

20

Number of **illegal online pharmacy websites** that go live globally *every day*



Americans that have previously purchased medications from an **online pharmacy** for themselves or someone in their care

85%

Currently use an online pharmacy to fill one or more medications

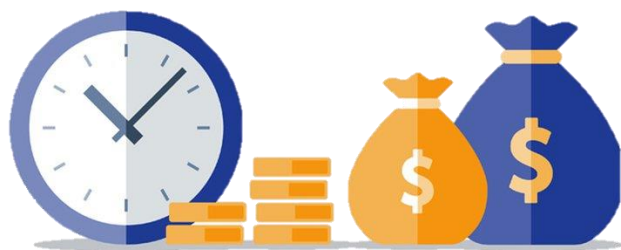
61%

Currently use online pharmacies to **purchase most, if not all, of their medications**

71%

First started using online pharmacies in the **last 1-3 years**

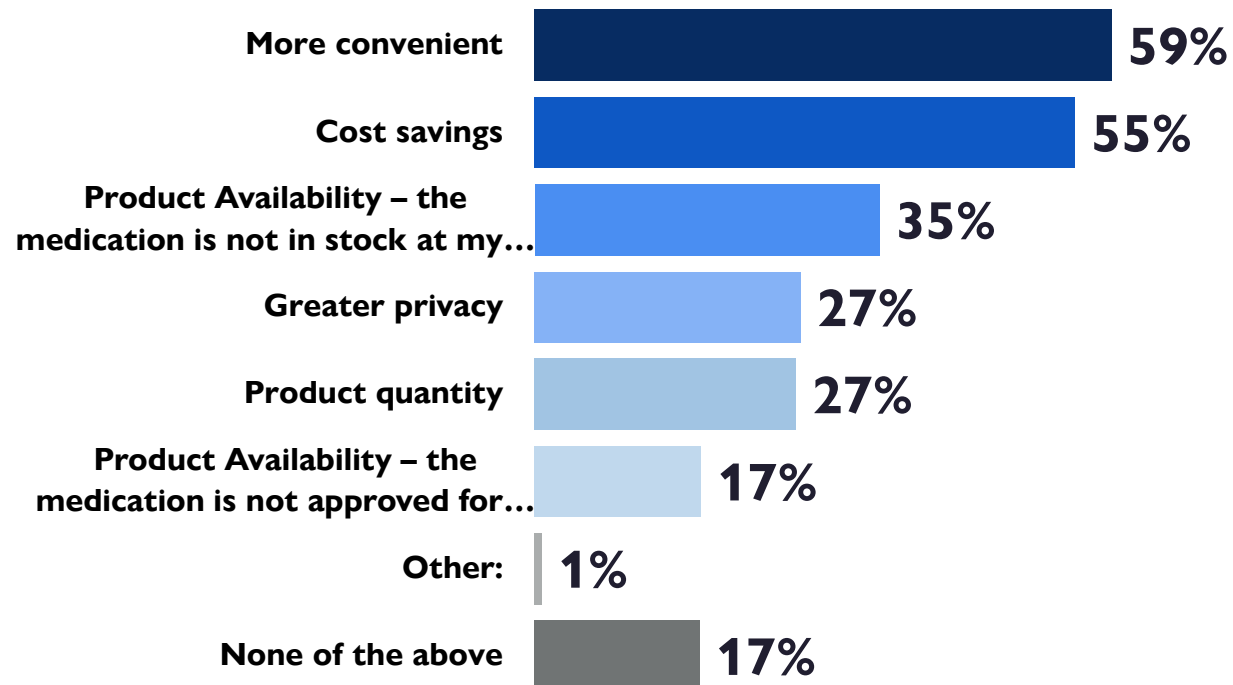
Why Americans Buy Online



Convenience and cost-savings remain the most frequently cited reasons Americans have or would use online pharmacies



Have you or would you purchase prescription medications from an online pharmacy because of... Select all that apply



Telehealth Visits and Prescriptions for Mental Health Disorders Rose Significantly during the PHE

- According to an IQVIA study, from 2019 to 2021, **telehealth visits for Attention Deficit/Hyperactivity Disorder (ADHD) rose 21% and 28% for anxiety.**
- This led to a **9.4% increase in prescriptions for ADHD treatments.**
- 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.**
- Prescriptions for mental health disorders also increased 7.6% in 2020 and another 5.5 % in 2021.**

Exhibit 4: Share of diagnosis visits in office vs. telehealth for selected diseases, 2019–2021

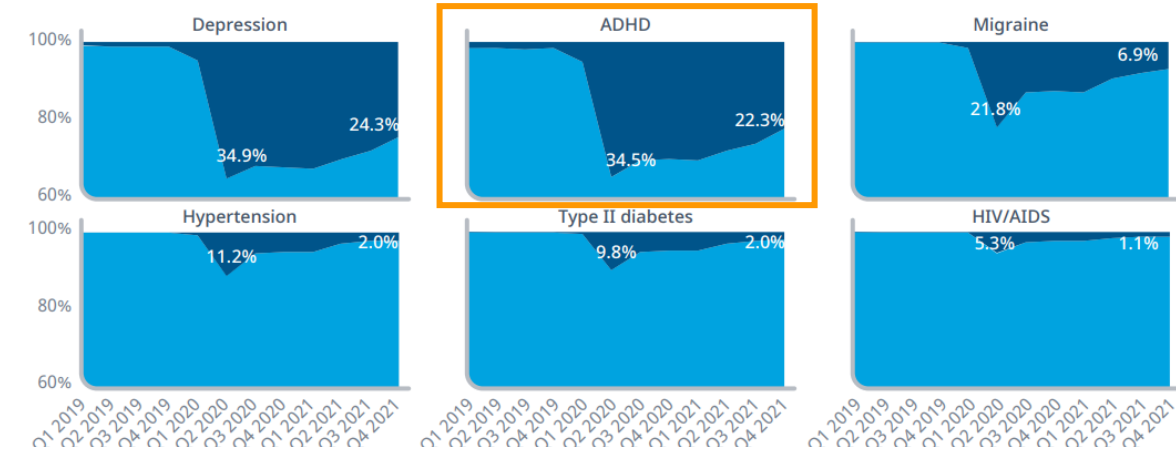
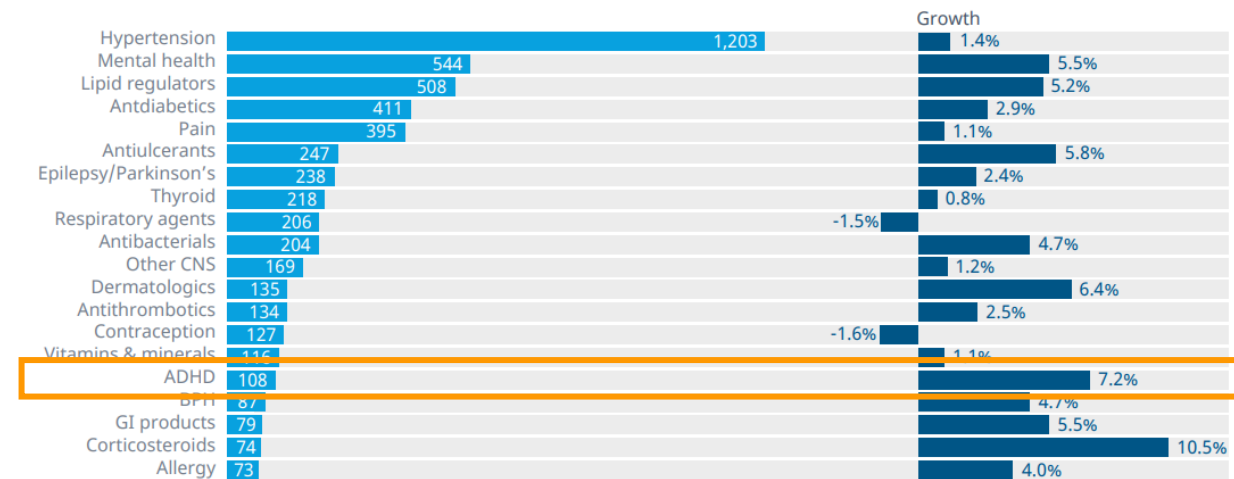


Exhibit 13: Adjusted dispensed prescriptions 2021 and % growth from 2020



Source: IQVIA National Prescription Audit, Dec 2021; IQVIA Institute, Mar 2022.

CDC Warns of Stimulant Medication Disruptions and Counterfeit Risks

On June 13, the [CDC Health Alert Network](#) released a statement outlining potential disruptions to prescription stimulant medications, specifically ADHD medication.

- “On June 13, 2024, the U.S. Department of Justice announced a federal health care fraud [indictment](#) against a large subscription-based telehealth company”
- “A disruption involving this large telehealth company could impact as many as 30,000 to 50,000 patients ages 18 years and older across all 50 U.S. states.”

Disrupted Access to Prescription Stimulant Medications Could Increase Risk of Injury and Overdose

[Print](#)



Distributed via the CDC Health Alert Network

June 13, 2024, 1:00 PM ET

CDCHAN-00510


Summary

The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to inform public health officials, clinicians, and affected patients, their families, and caregivers about potential disrupted access to care among individuals taking prescription stimulant medications and possible increased risks for injury and overdose. On June 13, 2024, the U.S. Department of Justice announced a federal health care fraud [indictment](#) against a large subscription-based telehealth company that provides attention-deficit/hyperactivity disorder (ADHD) treatment to patients ages 18 years and older across the United States. Patients who rely on prescription stimulant medications to treat their ADHD and have been using this or other similar subscription-based telehealth platforms could experience a disruption to their treatment and disrupted access to care. A disruption involving this large telehealth company could impact as many as 30,000 to 50,000 patients ages 18 years and older across all 50 U.S. states.

Mental Health and Controlled Substances


- Mental health telemedicine start-ups offer online prescribing for controlled substances (eg, Adderall®, Ritalin®, Xanax®)
- Subscription models
- Social media advertising (eg, Instagram, TikTok)
- Complaints surface about advertising, prescribing practices, and access to professional care
- Investigations: Congressional, DEA, DOJ, and FTC





TikTok is enabling predatory ADHD advertisers to target young users

WRITTEN BY [OLIVIA LITTLE](#)
RESEARCH CONTRIBUTIONS FROM [GIDEON TAAFFE](#), [KAYLA GOGARTY](#) & [ABBIE RICHARDS](#)
PUBLISHED 02/08/22 11:52 AM EST



FIERCE
Healthcare

HEALTH TECH

Cerebral under federal investigation for possible violations of controlled substances law

By **Heather Landi**
May 7, 2022 04:09pm

[Cerebral](#) [Behavioral Health](#) [U.S. Department of Justice](#)
[subpoena](#)

Businessweek | Feature

ADHD Drugs Are Convenient To Get Online. Maybe Too Convenient

Backed by SoftBank and promoted by Simone Biles, Cerebral has built the fastest-growing online mental health business. Former employees say the rapid expansion comes at the expense of patient care.

By [Polly Mosendz](#) and [Caleb Melby](#) +Follow

March 11, 2022 at 2:00 AM PST

Updated on March 11, 2022 at 5:15 PM PST

FTC Launches Investigation Into Telehealth Startup Cerebral

The probe, which comes a month after the virtual mental healthcare provider received a grand jury subpoena, will examine whether it used deceptive business practices.



Source: Getty Images



By **Anuja Vaidya**



June 15, 2022 - The Federal Trade Commission is investigating telemental health startup Cerebral, according to a letter obtained by the [Wall Street Journal](#).

THE WALL STREET JOURNAL

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WSJ NEWS EXCLUSIVE | HEALTH

Walmart, CVS Pharmacies Have Blocked or Delayed Telehealth Adderall Prescriptions

Cerebral and Done Health have at times struggled to fill prescriptions



Walmart said it has blocked some clinicians working for Done Health to prevent pharmacists in the retail giant's stores from filling prescriptions.
PHOTO: RYAN DAVID BROWN FOR THE WALL STREET JOURNAL

By [Rolf Winkler](#) [Follow](#) and [Sarah Nassauer](#) [Follow](#)
Updated April 27, 2022 4:01 pm ET

◆ WSJ NEWS EXCLUSIVE

Cerebral Treated a 17-Year-Old Without His Parents' Consent. They Found Out the Day He Died.

Telehealth startup didn't use software to flag minors, according to employees and documents; company says it complies with state rules and the case is an outlier

By [Khadeeja Safdar](#) [Follow](#) / Photographs by [Whitney Curtis](#) for *The Wall Street Journal*

Sept. 29, 2022 12:01 am ET

Many Americans Assume Online “Pharmacies” are Safe, Verified, and Regulated



- **54%** of Americans falsely believe **ALL WEBSITES** offering healthcare services/prescription medications to Americans **have been approved by the FDA or state regulators.**

- *68% of those with online pharmacy experience share this same misconception*



- **44%** of Americans falsely believe that **online pharmacies do not need a prescription** from a healthcare provider

- *53% of those with online pharmacy experience share this same misconception*



- **47%** of Americans falsely believe that **only safe, verified websites selling prescription medications appear on the first page of search engine results**

- *61% of those with online pharmacy experience share this same misconception*

Increased Online “Pharmacy” Use is Leading to Increased Harms

- **24%** of those who have used an online pharmacy report having previously been exposed to **harmful, counterfeit, or substandard medication** they purchased online
 - A 7-percentage-point increase from 2021



- **43%** of Americans describe purchasing medicines online as either **“Not too risky”** or **“Not risk at all”**
 - 12% Increase from 2021



Bad Meds Kill Real People

DANNY
TREJO

BENNY
NICKS

DEBORAH
SULLIVAN

MICHAEL
MCCARTHY

TONY
SCHARKO

BAD MEDS



THE STORY OF A FAKE

SOMETIMES IT'S HARD TO SPOT A FAKE. LIKE THIS MOVIE POSTER. IT'S NOT A MOVIE POSTER FOR A NEW DANNY TREJO MOVIE. IT'S NOT EVEN A MOVIE POSTER AT ALL. IN FACT, IT'S ACTUALLY A PSA TO TELL YOU THAT COUNTERFEIT MEDICATION IS AFFECTING YOUR COMMUNITY, AND THE BEST WAY TO STOP IT IS TO **VERIFY BEFORE YOU BUY AT SAFE.PHARMACY.**

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Watch the PSA



Verify Before you Buy

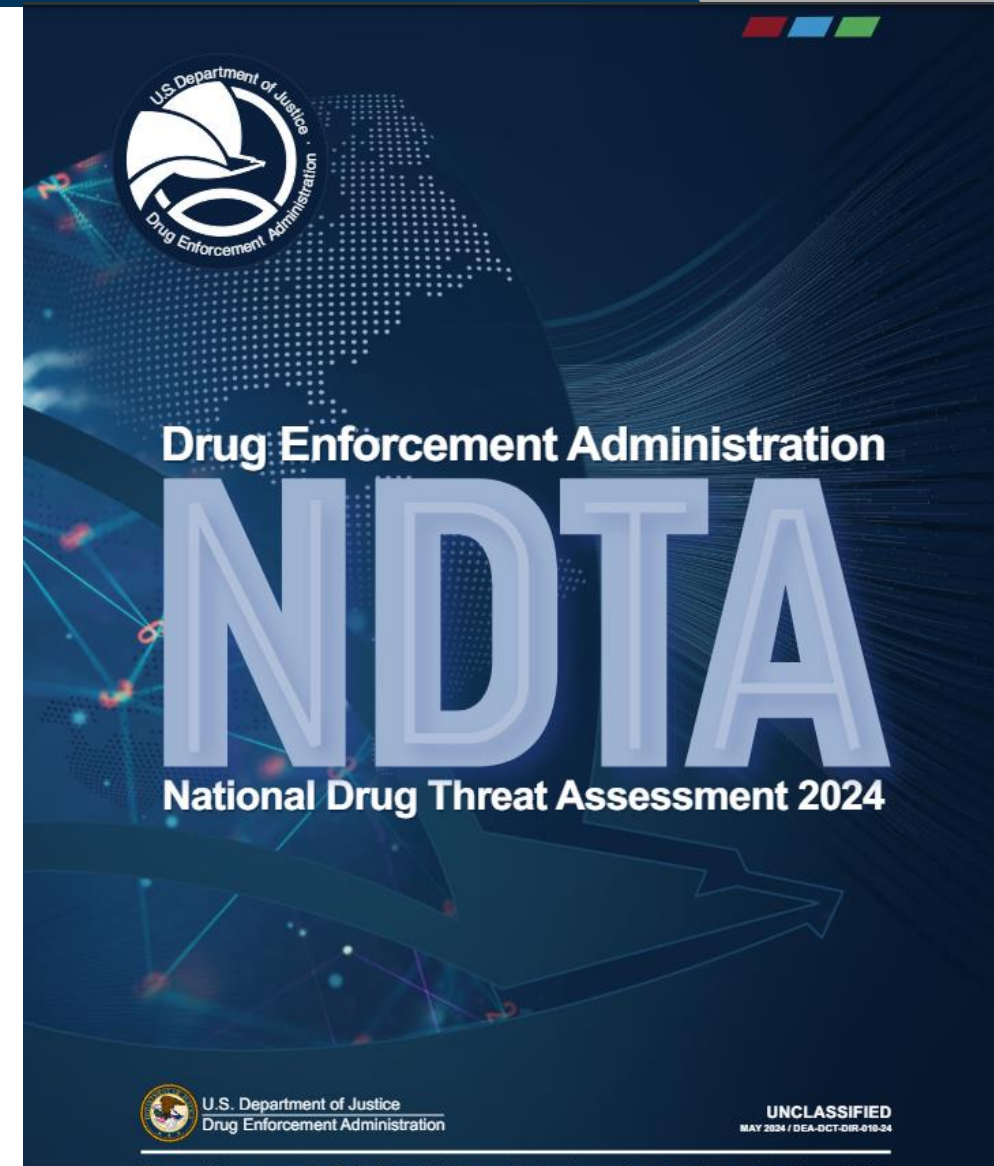


@StopBadMeds

DEA Finds Messaging and Social Media Platforms Used for Opioid Sales and Recruitment

In DEA's [2024 National Drug Threat Assessment](#) (NDTA), released in May, it noted **cartels utilizing encrypted and open messaging applications, as well as social media platforms, to attract customers and advertise and sell illicit opioids. These platforms have also been found to be used as recruitment channels for couriers and dealers.**

This report comes a few weeks after DEA Administrator Anne Milgram's remarks at a House hearing, emphasizing her agency's concerns of cartels counterfeiting medications and selling them on social media and the need for social media platforms to adopt a "zero tolerance policy."



Eventbrite Promoted Illegal Opioid Sales to People Searching for Addiction Recovery Help

A WIRED investigation found thousands of Eventbrite posts selling escort services and drugs like Xanax and oxycodone—some of which the company recommended alongside addiction recovery events.

Real lives have been lost. Illegal digital drug sellers exploit platforms.

PHOTO-ILLUSTRATION: JACQUI VANLIER; GETTY IMAGES

SPECIAL REPORT

Inside Snapchat's Teen Opioid Crisis

Law-enforcement sources and grieving families allege that the social media giant Snapchat has helped fuel a teen-overdose epidemic across the country. Now, their parents are fighting back

BY PAUL SOLOTAROFF

Illustration by Justin Metz

JUN 16, 2024 8:02 PM



Surgeon General Calls for Warning Labels on Social Media Platforms

Dr. Vivek Murthy said he would urge Congress to require a warning that social media use can harm teenagers' mental health.

▶ Listen to this article · 7:04 min [Learn more](#)

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💬 1428



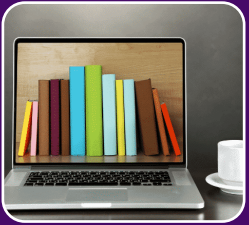
Online Availability of Controlled Substances

Angie Hoth, PharmD, MPH

Reagan-Udall Foundation for the FDA

Research Snapshot

Research Strategy



Preliminary Research

- Literature search
- Social media evaluation
- Interviews with thought leaders



Consumer Input

- Online polls – consumer perceptions & knowledge
- Listening sessions – consumer motivation & behaviors

Research Questions

1

- What is the landscape?

2

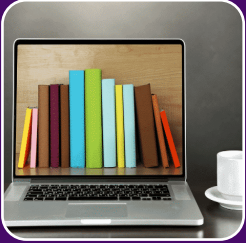
- Who is purchasing controlled substances (CS) online?

3

- What motivates people to purchase online or via social media & what steps are taken to obtain CS?

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Research Strategy



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- Literature search
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Key Findings: Social Media Evaluation, Online Polls & Listening Sessions

Social Media

Landscape

Open Market

- Controlled substances (CS) are being exchanged & purchased
- Social media (SM) as the primary communication tool

User-friendly Features

- Data encryption, disappearing posts & ease of creating new accounts

Inter-platform Strategy

- Begin transactions on one platform then move purchases to a secondary encrypted platform

Consumers

Demographics

- Younger age
- Social & economic stability

User Status

- Recreational/social, experimental or 1st time users
- Individuals who had previous legitimate reasons to access the substance

Motivations

- Recreation
- Self-medication
- Weight loss
- Step-down from illicit drugs
- Redistribution



Online Polls

The majority of respondents recognized the risks of buying medication online or without a current prescription, but this was paired with low confidence in their ability to evaluate a medication or online environments' safety or legitimacy.

RISK

74% Somewhat/very risky to buy medication without a current prescription*

71% Risky/much more risky to buy CS without a current prescription*



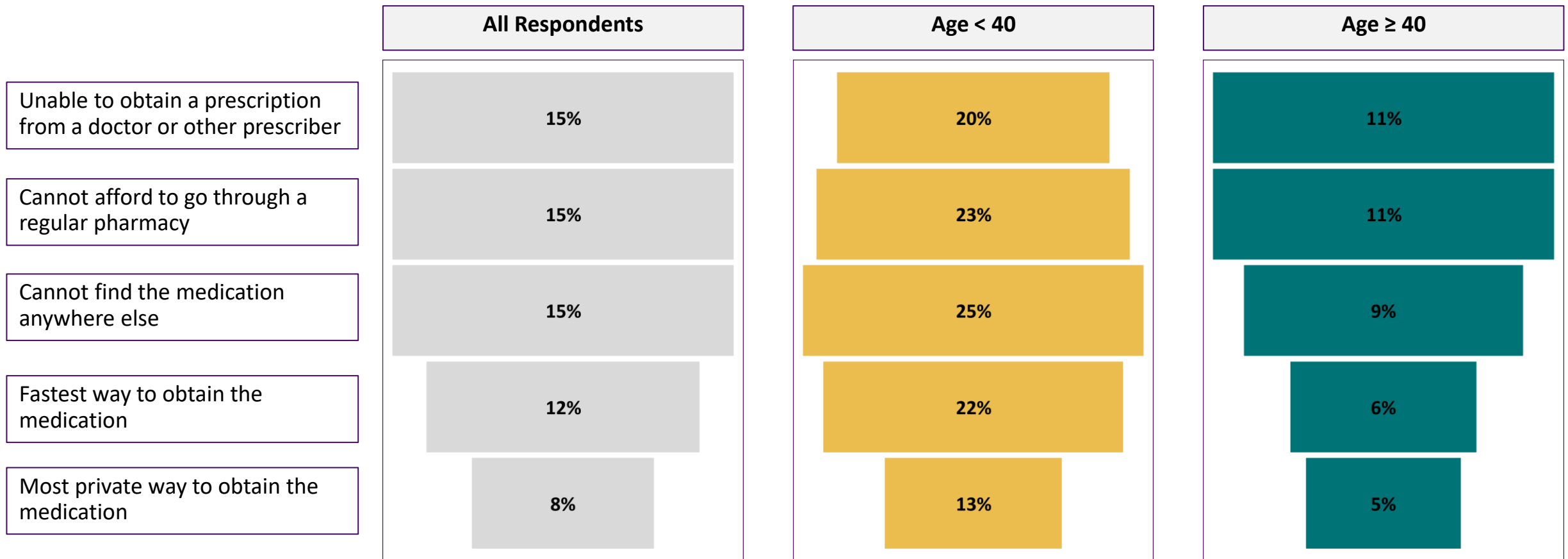
CONFIDENCE

75% NOT confident – safe, contain the right ingredients, contain the right amount of medication^

68% NOT confident – could tell if a medication purchased online is fake^

60% NOT confident – online pharmacy is licensed^

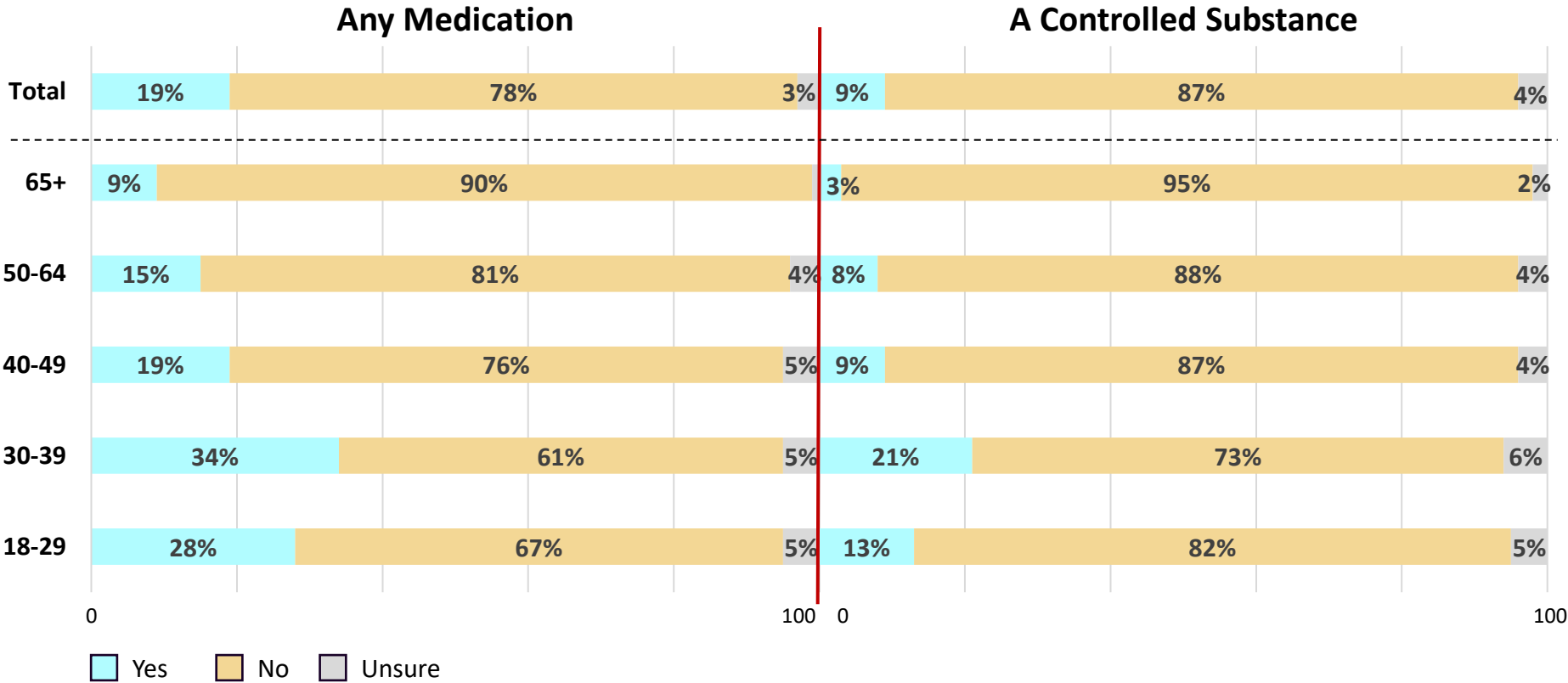
Purchasing a controlled substance online even if the source is not trusted



Age is the strongest driver of behavior & perceptions of risk

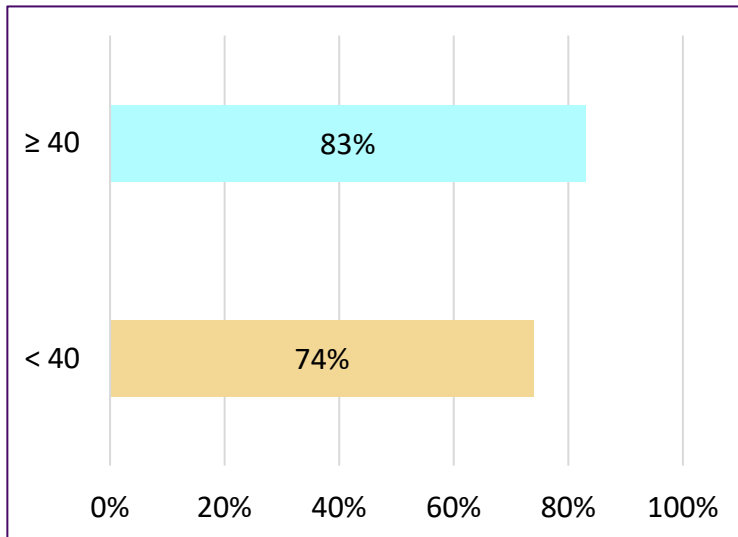


Ever bought or thought about buying online:

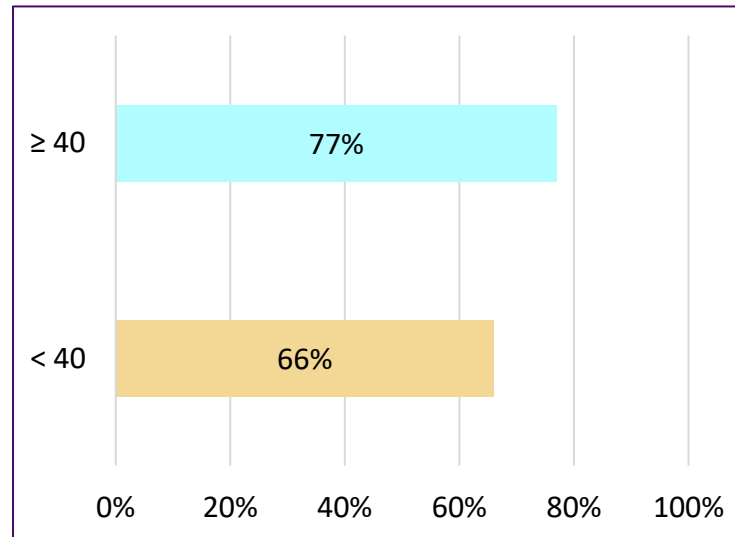


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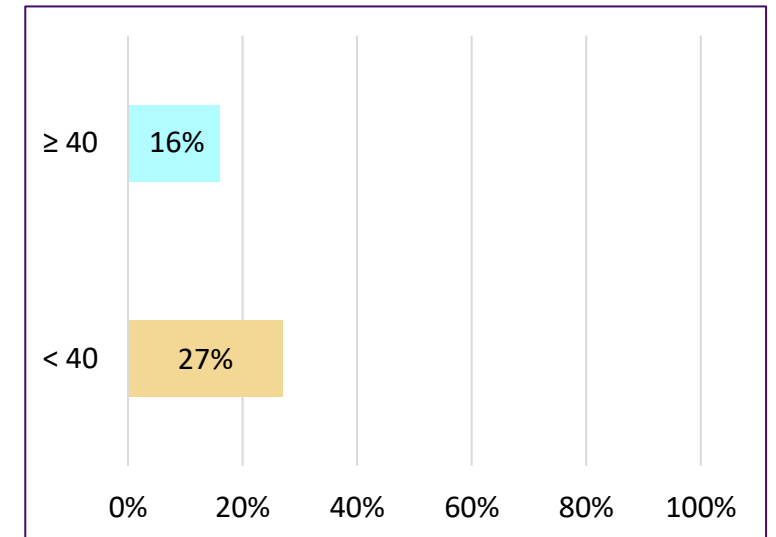
Buying any medication online*
is **risky** according to



Buying a controlled substance
online* is **more risky** according to



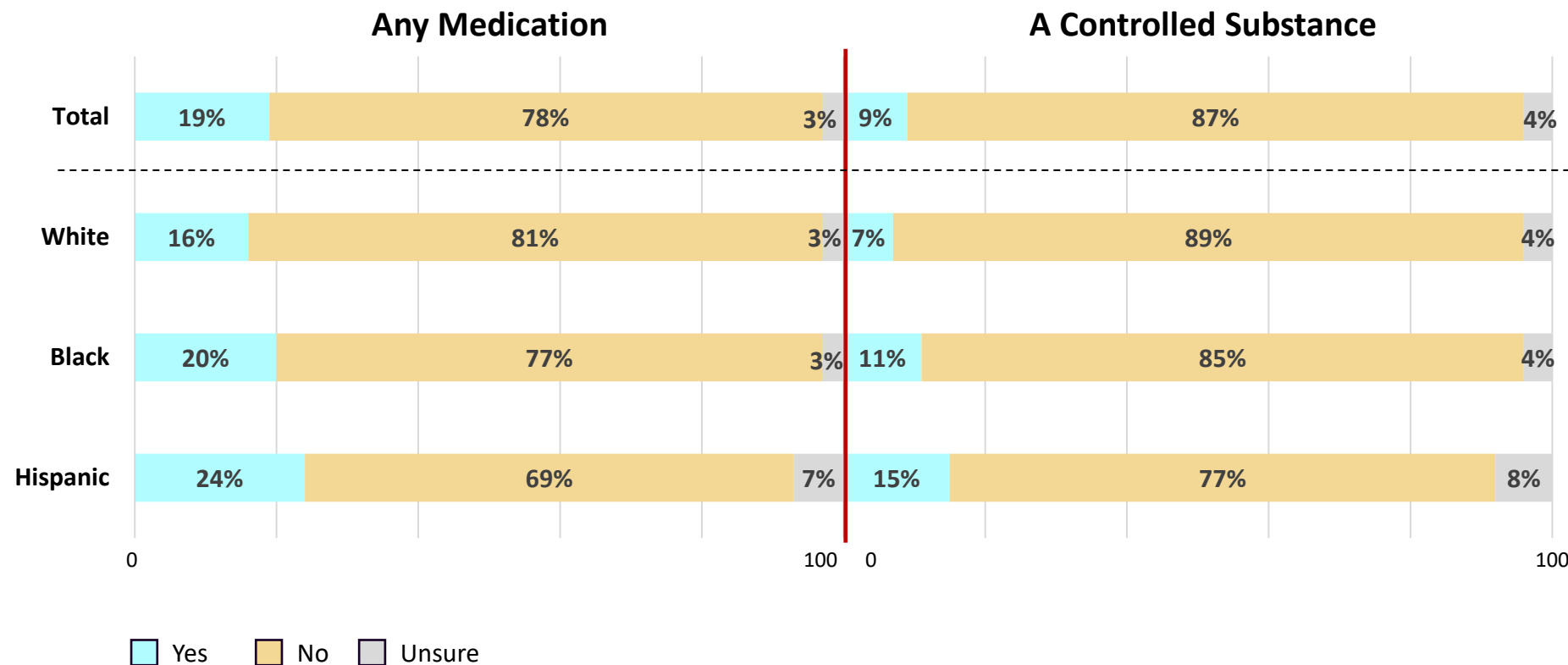
Buying a controlled substance
online* is **neither more nor
less risky** according to



*without a current prescription

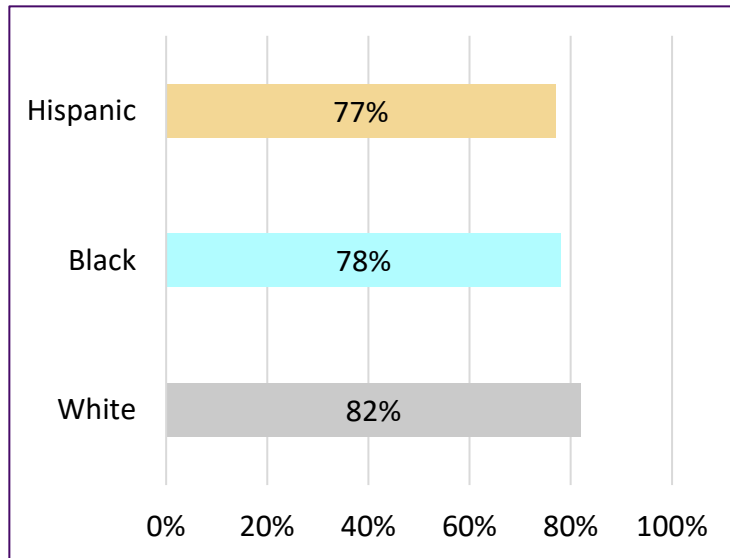
Race/ethnicity also impacts behavior and perceptions of risk

Ever bought or thought about buying online:

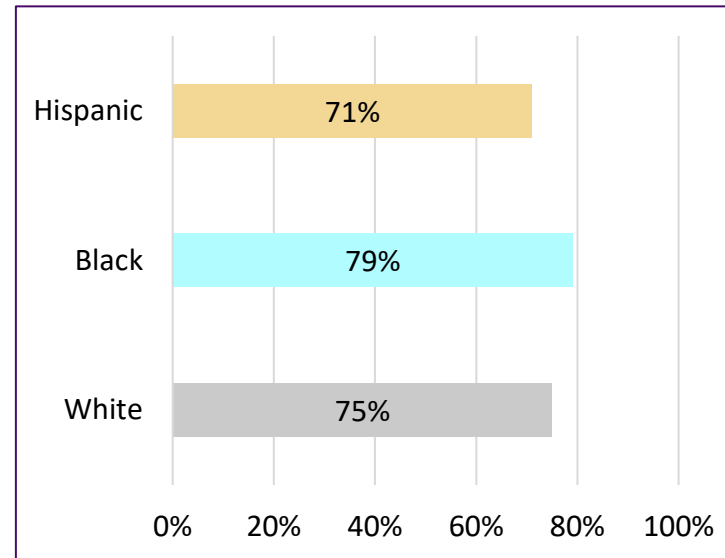


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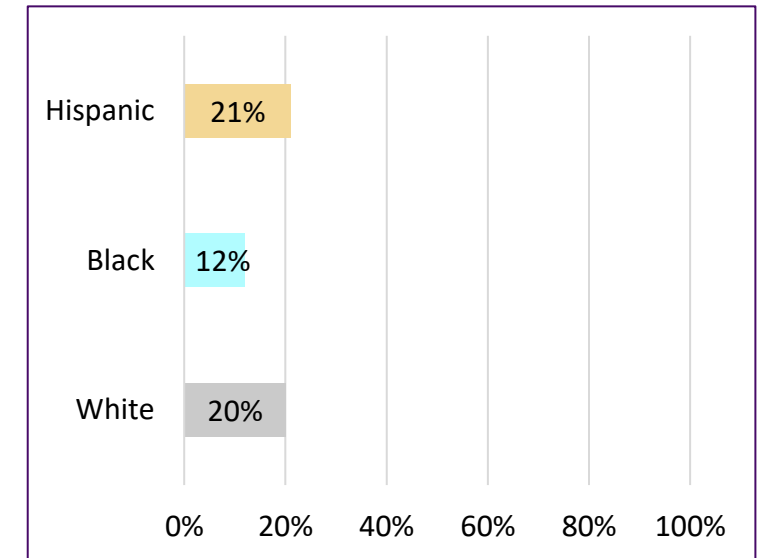
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Buying a controlled substance online* is **neither more nor less risky** according to

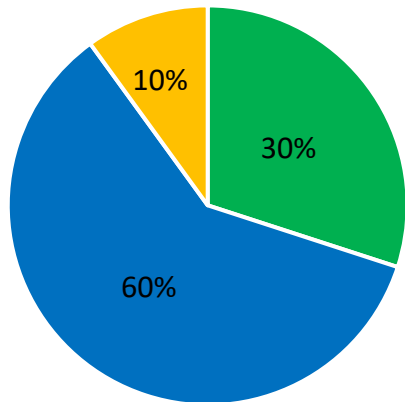


*without a current prescription

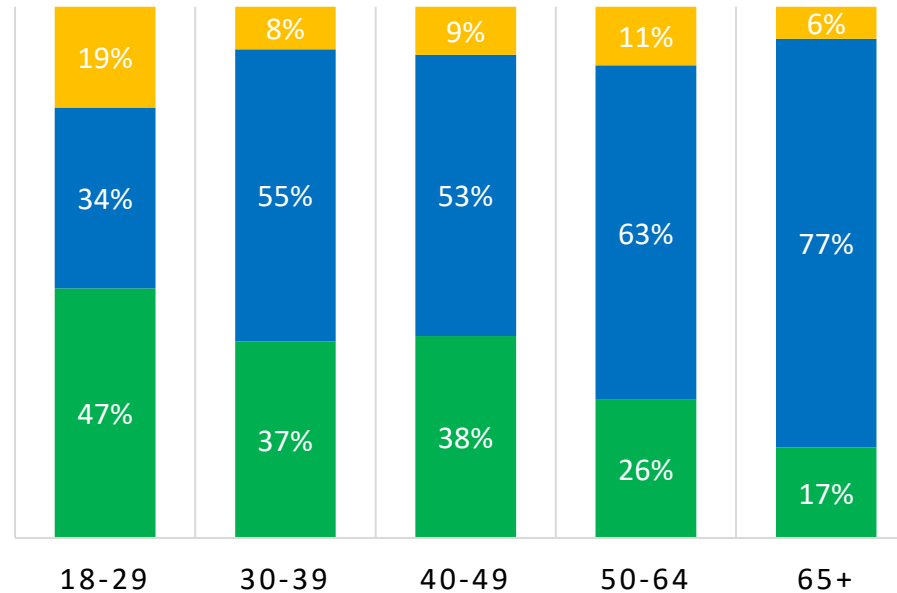
Age & race/ethnicity impact confidence in judgement

How confident are you that you could tell if an online pharmacy is licensed?

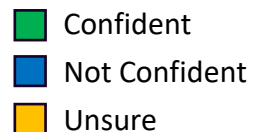
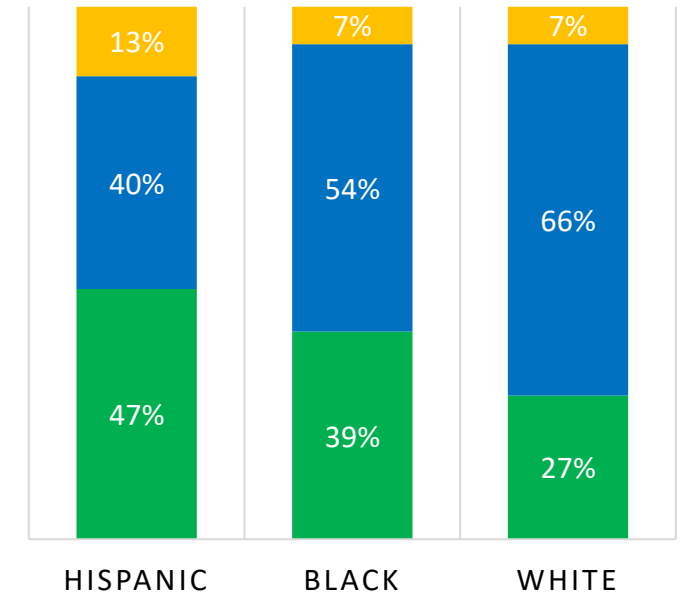
All Respondents



By Age

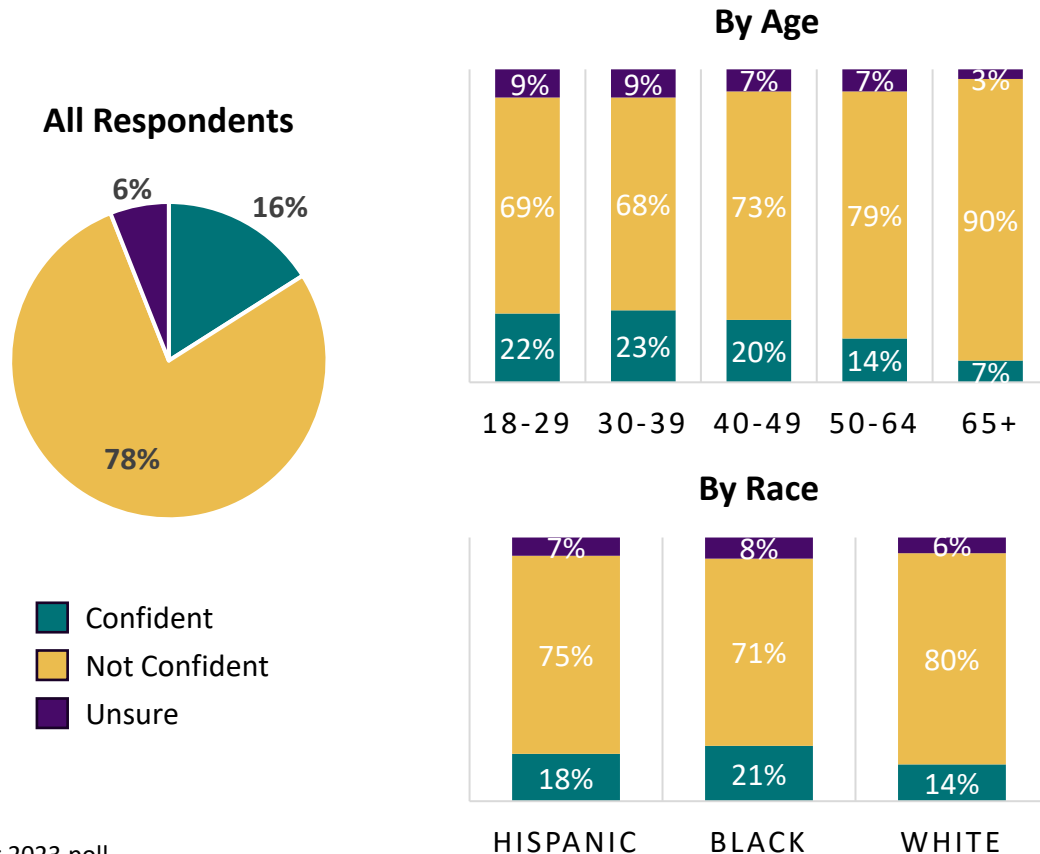


By Race

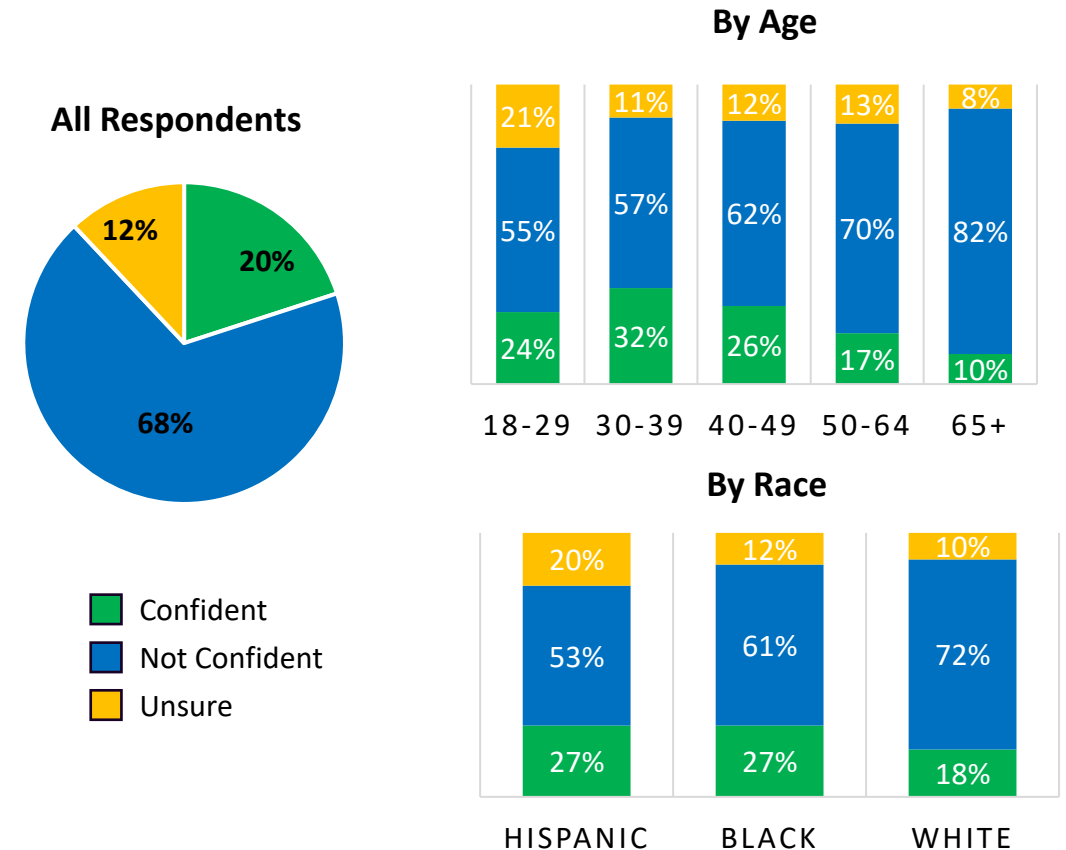


Age & race/ethnicity impact confidence in determining safety

How confident are you that prescription medications obtained online without a prescription **are safe**?



How confident are you that you could tell if prescription medications purchased online **are fake**?



Listening sessions provided additional insights



Motivations for Using Online Channels

- Supply chain issues
- Challenges getting a prescription from a licensed provider
- Cost of the medication
- Convenience

Having to visit multiple pharmacies to find the medication



Verifying Legitimacy

Participants were most likely to check the physical pills or the prescription bottle for any indicators that their medication was, in fact, what they were prescribed to take

- Verification via online searches



Risk Awareness

Not all prescription controlled substances were considered equally risky to obtain online

- Opioids were considered most risky
 - Concerned the opioid could be laced with another substance
- Stimulants viewed as safer to access online
- Less likely to worry about safety if the controlled substance was obtained from a friend or family member



Choosing an Online Channel to Use

- Recommendations from trusted family/friends
- Online reviews
- Knowing the source has many other users
- Advice from social media
 - Using comments on posts as a way to read others' first-hand reviews & experiences
- Patient groups

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Purchasing Controlled Substances Online Without a Prescription



1. Multiple platforms are being used for 1 transaction
2. Online buyers are more likely to be < age 40 and have access to a smartphone, internet and electronic payment systems
3. Recognition of risk is paired with a low confidence in one's ability to evaluate online environments' or medications' safety or legitimacy
4. Despite the low confidence in identifying risk, consumers will still opt for obtaining prescription controlled substances online without a prescription
5. Primary reasons for buying a controlled substance online include supply chain issues, cost, and unable to obtain a prescription from a health care provider

Online Availability of Controlled Substances



Panelists:

- **Kaitlyn Brown, PharmD, DABAT**, America's Poison Centers
- **Sean Fearn**, Drug Enforcement Administration



Going Beyond the Message

Tim Mackey, MAS, PhD
University of California, San Diego

Tim K. Mackey, MAS, PhD
FDA's Fifth Online Controlled Substances Summit
July 25 – 26, 2024

Beyond the Obvious: Developing Strategies for “Digital Prevention” of Online Controlled Substance Sales

 S-3
Research

UC San Diego

VIRTUAL | VIRTUAL

FDA's Fifth Online Controlled Substances Summit

JULY 25 - 26, 2024

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- [Meeting Information](#)

Date: July 25 - 26, 2024

Day1: Thu, Jul 25 11:00 AM - 3:00 PM ET

Day2: Fri, Jul 26 11:00 AM - 4:00 PM ET

Content current as of:

04/01/2024

Regulated Product(s)

Drugs

Attend

[Register for This Event](#)

Attend the public meeting:

Registration through [Reagan-Udall Foundation](#)

The U.S. Food and Drug Administration (FDA), in partnership with the Reagan-Udall Foundation for the FDA, will host the two-day virtual public meeting, "FDA's Fifth Online Controlled Substances Summit." The goal of this summit is to identify innovative solutions to reduce the illegal availability of controlled substances online.

What we know:

**Controlled substances are still sold
all over the Internet, endangering
the public**

WE KNOW ALOT



**SOCIAL MEDIA, FENTANYL & ILLEGAL DRUG SALES:
A REPORT FROM THE COLORADO DEPARTMENT OF LAW**



Overview of the Online Illicit Drug Ecosystem



Analysis of Platform Policies and Practices Applicable to Illicit Substance Transactions

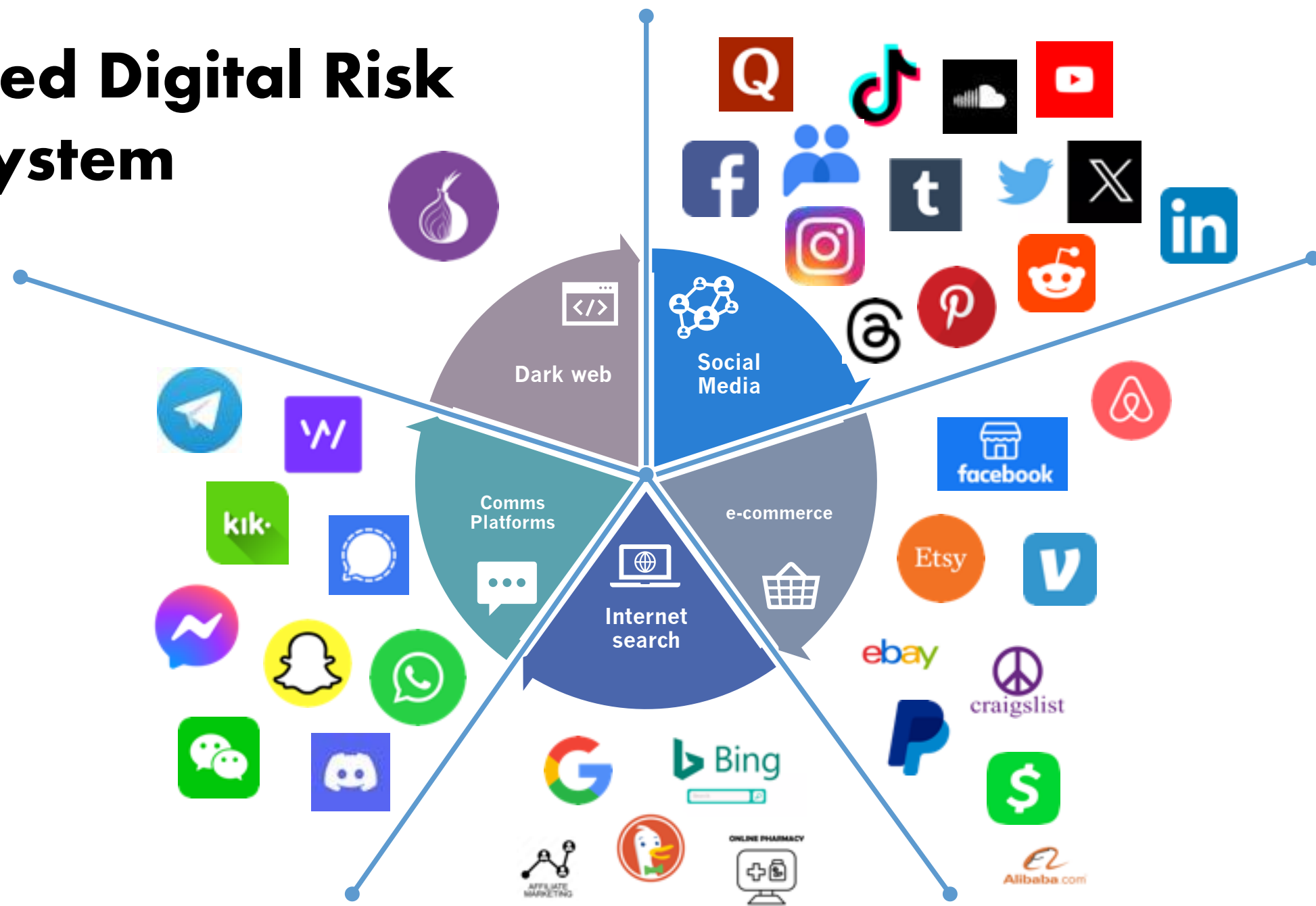


Review of Applicable Federal and State Laws that Impact Sale of Illicit Substances

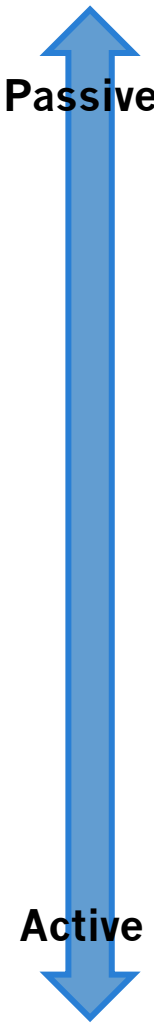


Recommended Actions for Addressing Illicit Substance Sales Online

Shared Digital Risk Ecosystem



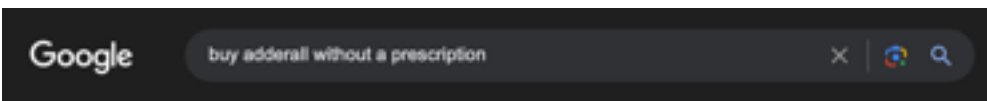
Digital Exposure → Risk



Passive exposure to drug selling content: Users may be exposed simply for engaging in online activity. They might join an online group, follow a certain user, get fed content due to searching for a hashtag, or get a comment or message directly from a drug dealer



Search functions on platforms: Users who actively search for “no prescription” or other terms to find drugs online via search engines, online pharmacies, or search functions on platforms (e.g., social media, messaging apps, etc.)



Appealing marketing and products: Drug dealers may use attractive images, memes, menus and appealing and interesting product features (e.g., different pill shapes, and variety of dyes/party packs),

Online groups and chats: As users get more familiar with the online environment or experiment, they can join dedicated online and encrypted spaces for access to illicit drugs.



What is being done:

Content moderation, law enforcement action, push for platform accountability

SWOT Analysis?

	Strengths	Weaknesses	Opportunities	Threats
Content Moderation	Removes content and limits digital exposure	Few consequences for seller/criminals (aka whack-a-mole)	Sharing signals and building better models?	Inconsistent enforcement, privacy concerns?
Law Enforcement Efforts	Holds sellers accountable and ability to disrupt networks	Length of time and needed resources to prosecute cases	Ability to address more systemic issues (e.g., precursor trade)	Resources, data access, and training
Platform Accountability	Can lead to changes in platform policies and actions. Can change the risk environment	Self-regulation, lack of industry-wide best practices, etc.	Policy change (new legislation, accountability standards), litigation, advocacy	<p>← <i>These are also risks for platforms</i></p> <p>← But maybe nothing gets done!</p>

What needs to be done:

Changing the paradigm to focus on
"whole-of-Internet" digital
prevention against online drug
selling

Key Point #1: Better detection of drug selling "signals"

- **Whole-of-Internet signal surveillance:** Proactive detection of changes to emojis, codewords, marketing and selling tactics, and strategies used to exploit platform features
- **Universal Blacklisting:** Sharing seller information signals across platforms (e.g., registration information, MAC addresses, IPs, other metadata) and applying consistent removal and blocking policies
- **Off-platform? My problem?:** Exploitation of platform features off-platform (e.g., other social media sites, darkweb, etc.) is a platform's problem. Need to understand trends occurring outside your user environment



Key Point #2: How and why do users interact with drug sellers?

SUBSTANCE USE & MISUSE
https://doi.org/10.1080/10832094.2024.2010007



ORIGINAL ARTICLE

Is This Safe? Examining Safety Assessments of Illicit Drug Purchasing on Social Media Using Conjoint Analysis

Michael Robert Haupt^{1,2}, Raphael Cuomo^{3,4}, Maryling Cu⁵ and Tim K. Mackey^{1,2,4}

¹Department of Cognitive Science, University of California San Diego, CA, USA; ²Global Health Policy & Data Institute, San Diego, CA, USA; ³Department of Anesthesiology, University of California, San Diego School of Medicine, San Diego, CA, USA; ⁴Global Health Program, Department of Anthropology, University of California, San Diego, CA, USA; ⁵S-B Research LLC, San Diego, CA, USA

ABSTRACT

Background: Illicit substance sales facilitated by social media platforms are a growing public health issue given recent increases in overdose deaths, including an alarming rise in cases of fentanyl poisoning. However, little is known about how online users evaluate what features of social media posts convey safety, which can influence their intent to source illicit substances. **Objectives:** This study adapts conjoint analysis which assessed how attributes of social media posts (i.e., features) influence safety evaluations of mock posts selling illicit substances. 440 participants were recruited online for self-reporting use or purchase of controlled substances or prescription medicines recreationally. The following attributes were tested: drug packaging, drug offerings, profile photo of seller, payment info provided, and use of emojis. Results: Packaging was ranked the most important attribute (Average Importance =43.68, Offering=14.84, Profile=13.86, Payment=14.11, Emoji=13.41), with posts that displayed drugs in pill bottles assessed as the most safe. Attribute levels for advertising multiple drugs, having a blank profile photo, including payment information, and including emojis also ranked higher in perceived safety. Rankings were consistent across tested demographic factors (i.e., gender, age, and income). Survey results show that online pharmacies were most likely to be perceived as safe for purchasing drugs and medications. Additionally, those who were younger in age, had higher income, and identified as female were more likely to purchase from a greater number of platforms. **Conclusions:** These findings can assist in developing more precise content moderation for platforms seeking to address this ongoing threat to public safety.

KEYWORDS

Online drug purchasing; controlled substances; drug dealing; social media; online content moderation; conjoint analysis

Introduction

The US has been experiencing a rapidly escalating public health crisis over the past decade concerning drug-related overdoses and deaths. Between 2010 and 2017, the opioid-involved overdose death rate rose from 21,888 to 47,600, and by 2019 increased again to 49,860 (National Institute on Drug Abuse, 2023). Between 2013 and 2019, the death rate for synthetic opioids, such as fentanyl, increased by a staggering 1040% (3105–36,359 deaths), reflecting a new chapter in the crisis characterized by the dangers associated with counterfeit products and other illicit drugs laced with fentanyl (Mattison et al., 2021). While not as prevalent as natural and synthetic opioids, deaths due to the involvement of other drugs such as psychostimulants (e.g., methamphetamine) and the non-medical use of prescription psychoactive drugs have been rising as well (Bonnie et al., 2017; Mackey et al., 2013). The COVID-19 pandemic also had a major impact on public drug use: since the beginning of the pandemic the US experienced a dramatic increase of over 20,000 additional

drug-related deaths from the previous year, resulting in the largest single-year percentage increase on record since 1999 (Baumgartner & Radley, 2021).

While multiple factors have contributed to the opioid crisis (see Humphreys et al., 2022 for review of causes), the increased use of social networking sites (SNS) further exacerbates this issue by providing convenient and accessible spaces for conducting drug sale transactions. In fact, drug transactions on SNS have been documented extensively by research and investigative reporting detecting illegal opioid sales and prescription drug dealing across several platforms such as Twitter, Facebook, Discord, Instagram, and TikTok (Fuller et al., 2024). See the following papers for a review of transactions across platforms and drugs types, and factors influencing online purchasing (Constone, 2018; Demant et al., 2020; Dwoskin, 2018; Hu et al., 2021; Lapowsky, 2018; Lytinen et al., 2018; Mackey et al., 2017; Mackey & Kalyanum, 2017; Mackey et al., 2018; Moyle et al., 2019; Oksanen et al., 2020a, 2020b; Petersen et al., 2021; Rutherford et al., 2022; Tika, 2018; van der Sanden et al., 2022; Whelan et al., 2023; Yang & Lu, 2017). Additional

- **What is Appealing?:** What features of drug selling are appealing/misleading? Incorporate these into signal detection and content moderation.
- **Construct Digital Personas:** Develop personas for different types of controlled substance seeking and purchasing behavior

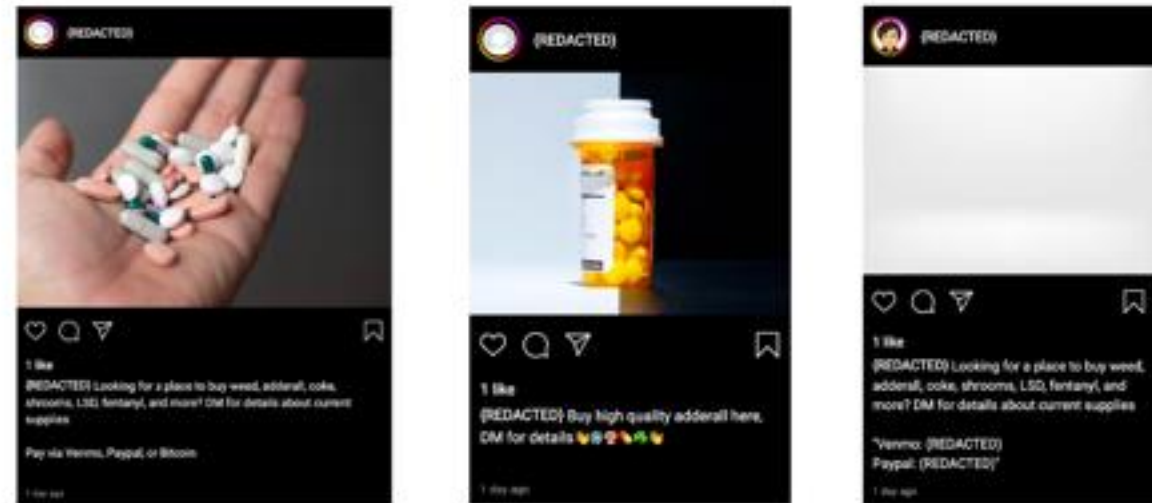
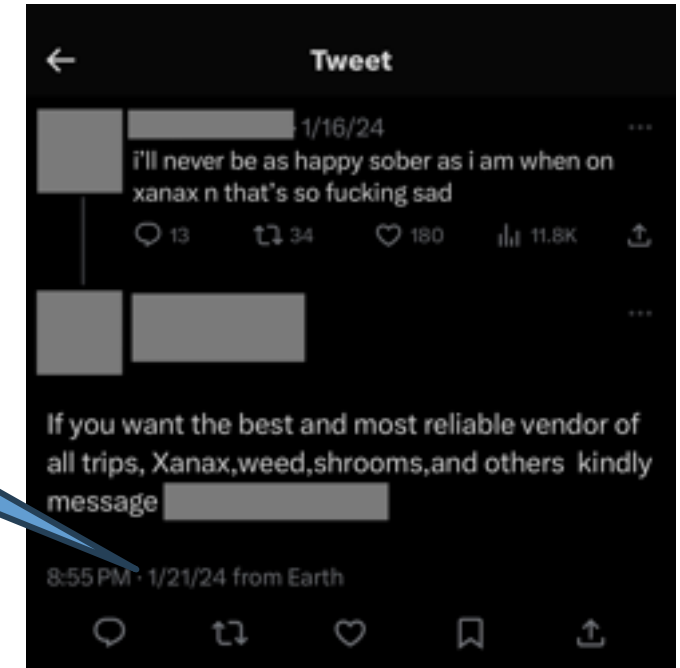


Figure 1. Example social media posts for conjoint exercise (left) packaging = pill in hand, offerings = multiple, profile = none, payment info = included, emojis = none; (center) packaging = official, offerings = adderall only, profile = none, payment info = none, emojis = included; (right) packaging = blank, offerings = multiple, profile = animated human face, payment info = included, emojis = none.

Key Point #3: Developing digital prevention as good as drug selling

- Digital drug dealers target users: We have observed drug dealers "slide" into user discussions about substance use and targeting vulnerable populations (e.g., youth)
- Where is the counter messaging?: Drug dealers regularly posts sales offers and drug availability, *where is the targeted education and messaging to these same users/groups?*
- We need precision-based digital prevention as good as targeted ads: Platforms are experts at precision marketing, we need to spend the same time, \$\$\$, and precision in removing €S content and replacing with health promotion and education

Where's the health promotion?



CONTACT INFORMATION

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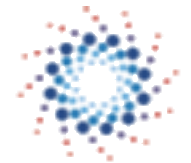


@tkmackey

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Challenge.gov
Government Challenges, Your Solutions



Going Beyond the Message

Erin Stack, MS
Comagine Health

Insights From Young People About Trusted Messengers & Communication Strategies for Fentanyl and Pill Use Prevention

Erin Stack, MS

Director, Research and Evaluation |
Research & Evaluation Team

Comagine
Health

Online Controlled Substances Summit | 7/25/2024



DATA COLLECTION PURPOSE

To better understand youth and young adults' awareness, beliefs, and behaviors related to fentanyl and counterfeit pills.

ONLINE SURVEY



- 897 young people, ages 15-25 in Oregon
- 54% female, 64% White, 15% Hispanic or Latino

INTERVIEWS



- 21 young people with lifetime non-Rx pill use
- 43% female, 48% multiracial

What did participants share?



**Current
Information
Sources**



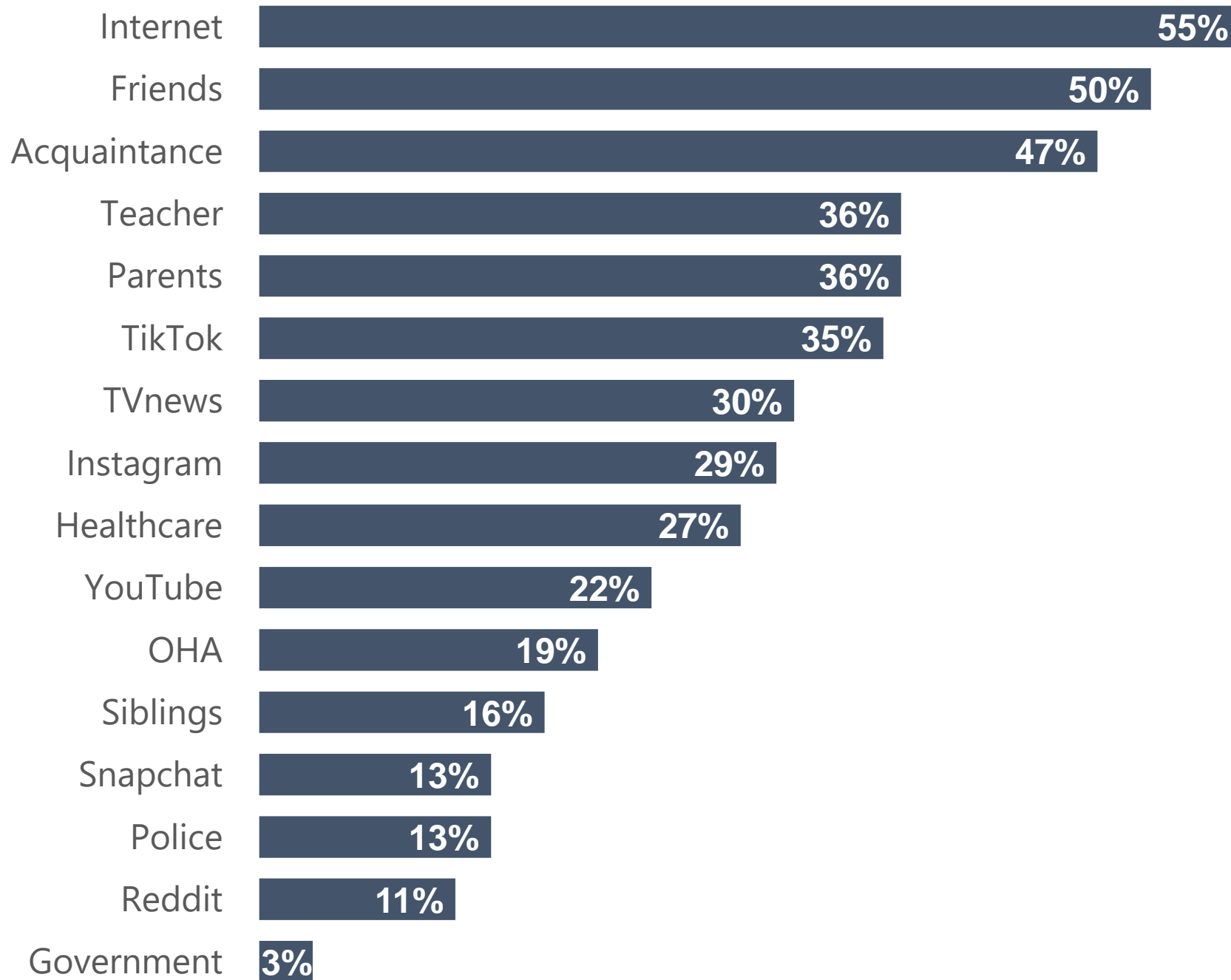
**Trusted
Information
Sources**



**Information
Content &
Format**

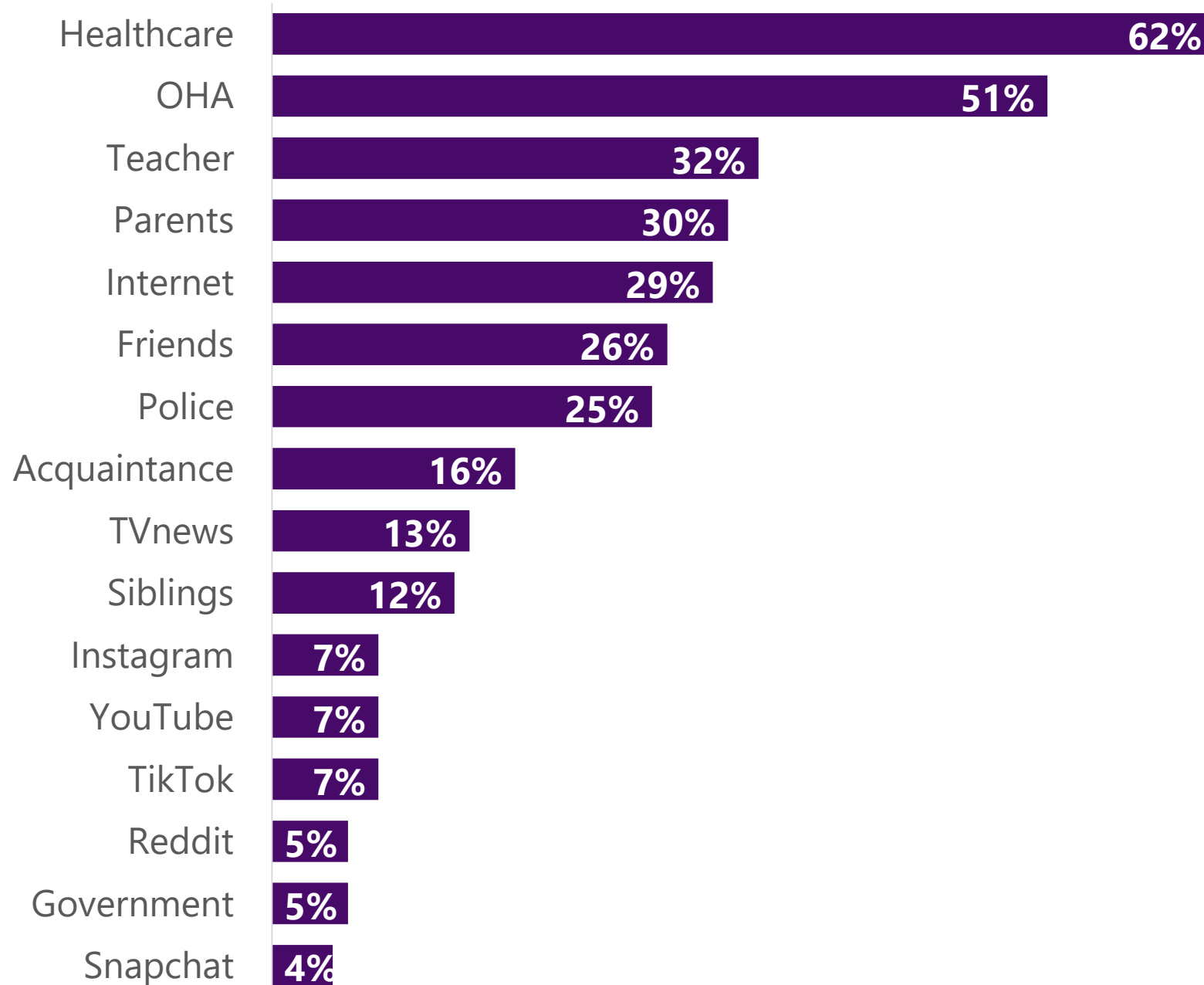


Current Information Sources





Trusted Information Sources





Trusted Information Sources

“ You want someone with education specifically on the topic. For me, that would go to doctors who specifically work with clients who are addicted, maybe even MAT [Medication Assisted Treatment] professionals who know a lot and work first-hand with addicts every day.”



Information Content

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 effect of fentanyl on the body
- »»» Statistics on overdose rates and fentanyl prevalence
- »»» Overdose response training
- »»» Debunking common misconceptions



Information Content



“ I’d like to know the forms in which fentanyl comes in so I can be more aware.”



“ Just the facts, **not a fear-based** approach, but just like: ‘This is the effect of it, and this is the statistics that we have found.’”



“ Adding a layer of education, not only on what fentanyl is, how to respond to overdose, and what healthcare is actually helpful.”



Information Format

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, Narcan access

They recommended content that was:

- »»» Tailored to youth populations
- »»» Quick and easily digestible
- »»» Nonjudgmental
- »»» Harm reduction focused rather than abstinence based

Closing

- Young people are open and interested in learning more about fentanyl, pills, and ways to stay safe
- Top selected trusted sources include healthcare providers and state health authorities
- Young people recommend quick, non-judgmental, health promotion and harm reduction-focused messaging available via social media

Thank you!

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- Mary Gray, PhD
- Soomin Shin, MA



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- State Opioid Response Grant (SAMHSA and OHA)

**Scan the QR
code for
more
information:**



Perspectives from the Tech Sector

Panelists:

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



Closing Remarks

Marta Sokolowska, PhD

Deputy Center Director for Substance Use and
Behavioral Health
Center for Drug Evaluation and Research
U.S. Food and Drug Administration



Online Controlled Substances Summit

Thank you for attending!

The public meeting recording, transcript, and other materials will be available next week at reaganudall.org



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