Online Controlled Substances Summit The public meeting will begin shortly

Thursday, September 11, 2025 12:30pm - 3:30pm Eastern Time

<u>Funding Disclosure</u>: 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.







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)



12:30pm Welcome & Opening Remarks

12:40pm Evolving Threat

1pm Session 1: Research Updates and Trends

1:30pm Session 2: Human Impact of Online Access to Controlled Substances

2pm Session 3: Strategies for Intervention/Disruption

2:40pm Session 4: Global Perspective

3:15pm Closing Remarks

3:30pm Adjourn





Introductory Remarks

Grace Graham, MPP

Deputy Commissioner for Policy, Legislation, and International Affairs

U.S. Food and Drug Administration





Evolving Threat

Sangeeta Chatterjee, PharmD

Acting Director, Office of Drug Security, Integrity, and Response, CDER Office of Compliance U.S. Food and Drug Administration



2025 Online Controlled Substances Summit

Reducing the Availability of Controlled Substances Online

Sangeeta Vaswani Chatterjee, PharmD

Acting Director

Office of Drug Security, Integrity, and Response

Office of Compliance

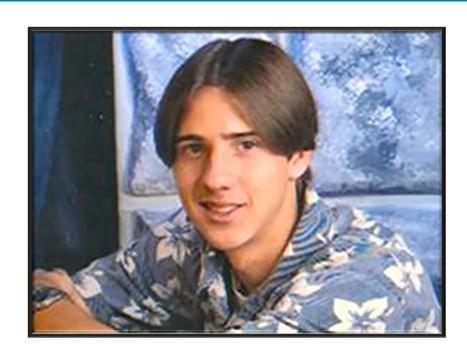
Center for Drug Evaluation and Research

September 11, 2025

www.fda.gov

FDA

Why We Are Here Today: The Human Cost



Ryan Haight died on February 12, 2001, at the age of 18 after buying Vicodin online. This led to the passage of the 2008 Ryan Haight Online Pharmacy Consumer Protection Act, which amended the Controlled Substances Act.



Charlie Ternan died on May 14, 2020, at the age of 22, after ingesting a counterfeit "Percocet" pill that was laced with fentanyl.



CDER Office of Compliance Mission

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



FDA

Easy Online Access to Controlled Substances Threatens U.S. Consumers



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

- Since January 2025, FDA has issued 15
 Warning Letters for the unlawful sale
 of controlled substances to U.S.
 consumers online
- Products cited: Opioids, Benzodiazepines, Schedule II Stimulants
- Often sold without requiring a prescription
- Non-medical and polysubstance use are major concerns

11

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



Identified four recurring themes to ensure

communicate, coordinate, and collaborate

2024 Online CS Summit

Highlighted key themes: Consumer Access, Communications, Partnerships, and Compliance

Focused on the role of registries and registrars

2019 Online Opioid Summit



2023 Online CS Summit

through a holistic approach

that we were able to effectively

12



Online Controlled Substances Summit Participants



- Social media
- Search engines
- Online marketplaces
- Payment processors
- Registries and registrars
- Academia
- International groups
- Federal agencies
- Trade and advocacy

FDA

Examples of Successes

Google Now Deindexing Some Web Pages Based on FDA's Administrative Agency Findings

A new Google policy calls for such deindexing based on administrative agency findings—without a court order—in cases where the agency is "charged with protecting consumers' physical safety from harm by products or services that they consume."

Instagram will send a pop-up about opioid addiction support if you search certain hashtags

Facebook to redirect users searching for opioids to federal crisis help line





2024 Online Controlled Substances Summit Critical Insights FDA



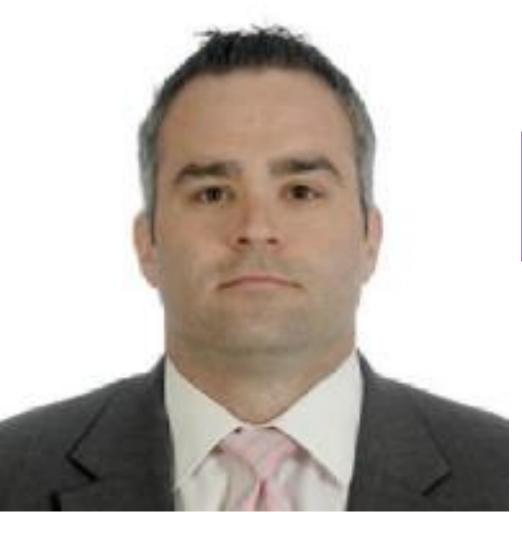
| | Key Themes | Current Challenges | Opportunities for Public Health Intervention |
|-----|--------------------|---|--|
| 4 | Consumer Access | Consumers, including patients, are motivated by disparate needs for CS (medical use, self-medication, and non-medical use) | Develop tailored public health 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 |
| が流れ | 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 |



Collaboration is Essential







Evolving Threat

Jake Ellis

Senior Operations Manager Office of Criminal Investigations U.S. Food and Drug Administration



U.S. Food and Drug Administration Office of Inspections and Investigations Office of Criminal Investigations

Jake Ellis
Senior Operations Manager
September 2025





Investigative Focus

- The FDA Office of Criminal Investigations, Cybercrime Investigations Program, conducts criminal investigations across the entire internet landscape
 - Rogue Online Clear Web Pharmacies
 - Darkweb Marketplace Vendors
 - Social Media Applications
 - Encrypted Chat Applications
- Our Investigative Focus
 - Counterfeit drugs which pose significant overdose risk
 - Synthetic opioids, counterfeit Adderall, counterfeit Xanax
 - Misbranded or adulterated FDA regulated products
 - Foreign unapproved medical products







- Joint Criminal Opioid and Darknet Enforcement (JCODE)
 Operation
 - International Darknet Operation targeting traffickers of counterfeit pills, opioids, and other illicit goods
 - Operations touch the US, Europe, South America, and Asia



























Operation Double OH-7

 FDA – Office of Criminal Investigations operation to combat the emerging threat of synthetic 7-Hydroxymitragynine (7-OH)

Criminal Exploitation

- Online Markets: Sold via high-risk internet pharmacies and dark web marketplaces
- Labeling Fraud: Frequently mislabeled as "natural kratom extract", "all natural", "herbal blend", or "mood enhancer"

Online Activity Analysis Snapshot

• **Reddit**: Online posts mentioning 7-OH have increased exponentially over the last 12 months. Posting in June 2024 saw an estimated 187 mentions of 7-OH, compared to 19,744 mentions in June 2025. Calendar year 2025 has seen an average of 17,622 monthly post mentioning 7-OH.

Questions?



SOM Jake Ellis
Headquarters
301-844-1386
Jacob.ellis@fda.hhs.gov

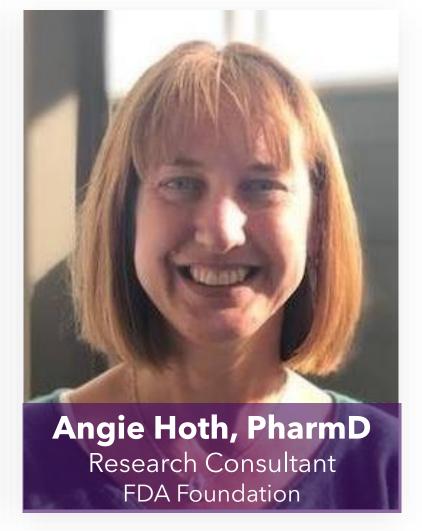


Research Updates & Trends









WHO BUYS COUNTERFEIT MEDS? AND WHY?



SALEEM ALHABASH

Professor & Associate Chair / Associate Director of Research

Department of Advertising and Public Relations

Center for Anti-Counterfeiting and Product Protection

MICHIGAN STATE UNIVERSITY







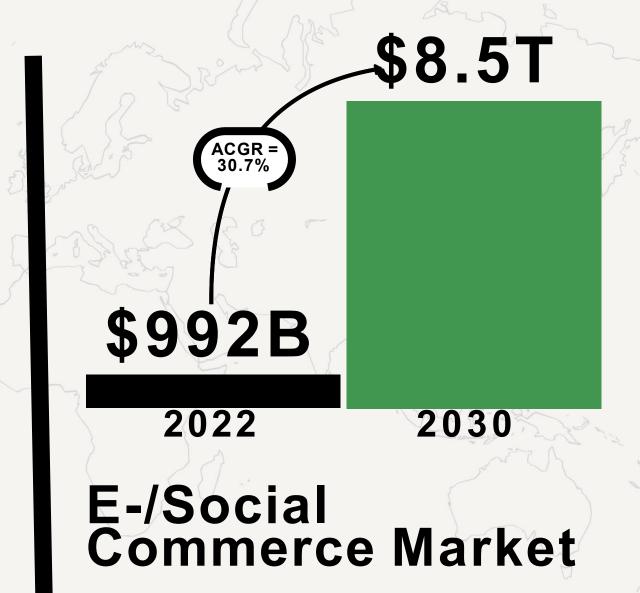
Global Economy















\$200-\$413B annual sales of counterfeit medications



1.5M counterfeit medication units seized by CBP in 2023



50% of all meds sold online are counterfeit & 97% of online pharmacies operate illegally



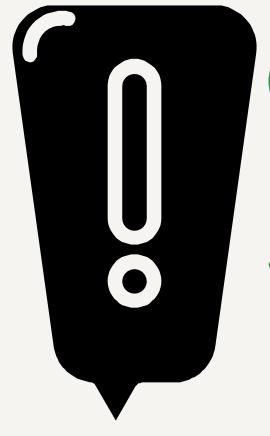
1M deaths annually attributed to counterfeit medications; including 250K children who die from taking fake malaria and pneumonia meds





Law Enforcement

Collaborative efforts among brand owners, law enforcement, and platforms (!) for seizures and take-downs





Supply Chain Complexity

Increasing complexity due to explosive **volume** and **velocity** of counterfeit supply.



Tech Solutions

Identifying counterfeit supply chain and tracking the prevalence of counterfeit products online and offline (e.g., track & trace, smart packaging, blockchain, etc.)

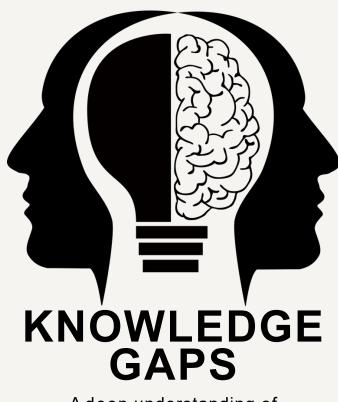


Mission Impossible

Enhanced competence of counterfeiters renders anticounterfeiting efforts near **impossible** to contain



FOCUS ON CONSUMERS



A deep understanding of consumers is necessary for designing and implementing effective consumer education and awareness-raising anticounterfeit campaigns and efforts





RAISE YOUR HAND!



Never have I ever....

request on social media from someone you did not know in real life?

opened a suspicious attachment sent to your email from a stranger?

bought a product from a shady website, e-commerce, or social media platform?

clicked on a suspicious link sent to your email and immediately regretted it?

downloaded/used a 'pirated' piece of content (e.g., movie, song, image)?

shared private information online or with someone you don't know or fully trust?



online risks are EVERYWHERE

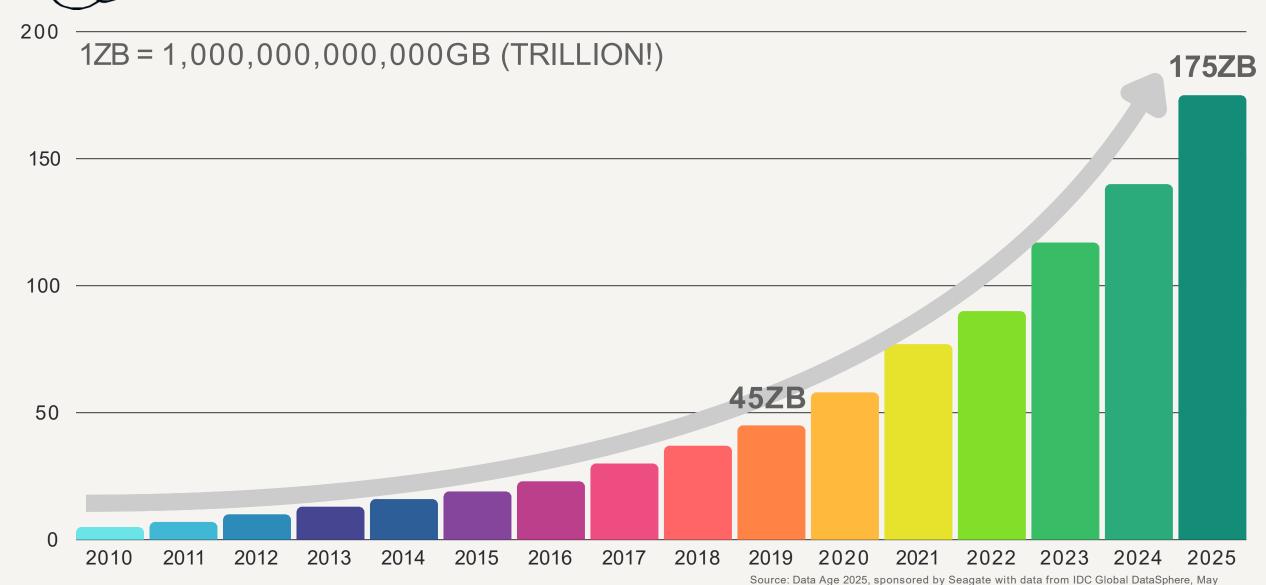


ISITADATA/INFORMATION: PROBLEM?:

ORAPEOPLE : PROBLEM?



DATA AND INFORMATION





DATA AND INFORMATION

To **store** the "entire Global Datasphere on DVDs, then you'd have a stack of single layer Blu-ray Discs that could get you...

to the moon

23



circle earth

222 g

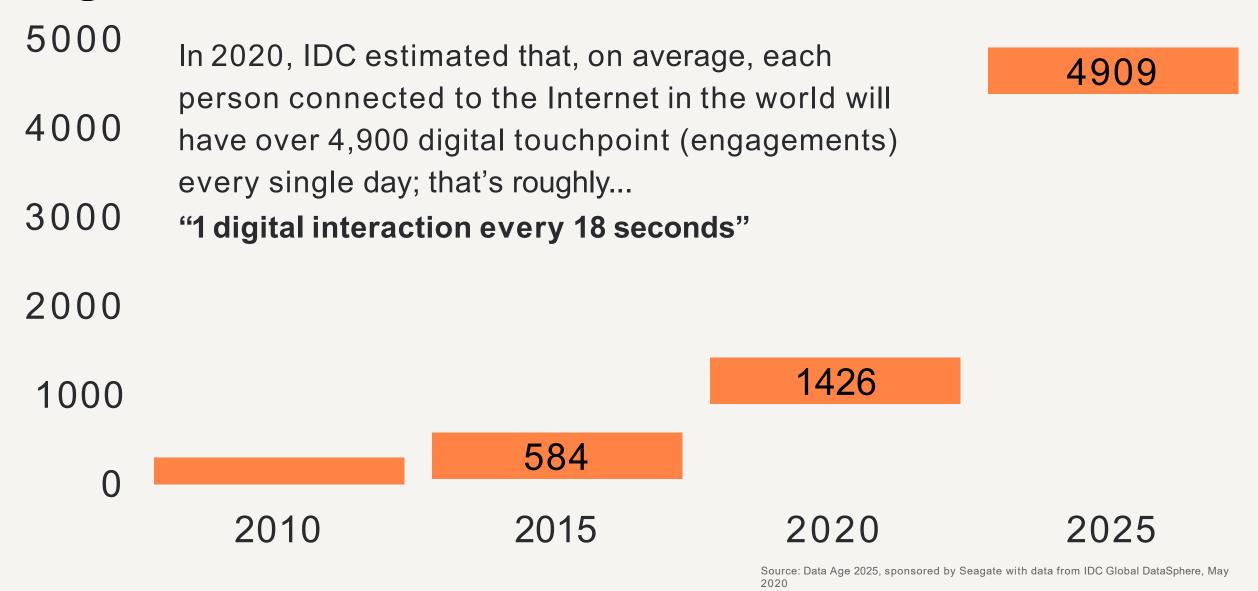


To download all that data... it would take one person 1.8 BILLION years to do it or 81 days if everyone on earth pitched in and worked non-stop!

175ZB



DATA AND INFORMATION





DATA AND INFORMATION

and there are a lot of BADACTORS out there!



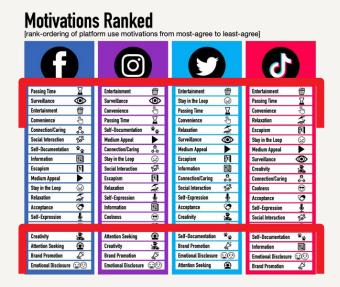




a few observations

With the democratization of the Internet (including social media), platforms are likened to social organisms that evolve beyond their original purpose, ushering 'organisms' that are the sum of human-algorithm interactions

| Convenience | Entertainment | Entertainment | Entertainment |
|---------------------|---------------------|---------------------|---------------------|
| Entertainment | Convenience | Convenience | Convenience |
| Passing Time | Medium Appeal | Photos | Medium Appeal |
| Ivieulum Appeal | rassing time | імеціці і Арреаі | rassing time |
| Photos | Self-Expression | Passing Time | Self-Expression |
| Information Sharing | Information Sharing | Self-Expression | Self-Documentation |
| Self-Expression | Social Interaction | Self-Documentation | Photos |
| Social Interaction | Self-Documentation | Social Interaction | Social Interaction |
| Self-Documentation | Photos | Information Sharing | Information Sharing |









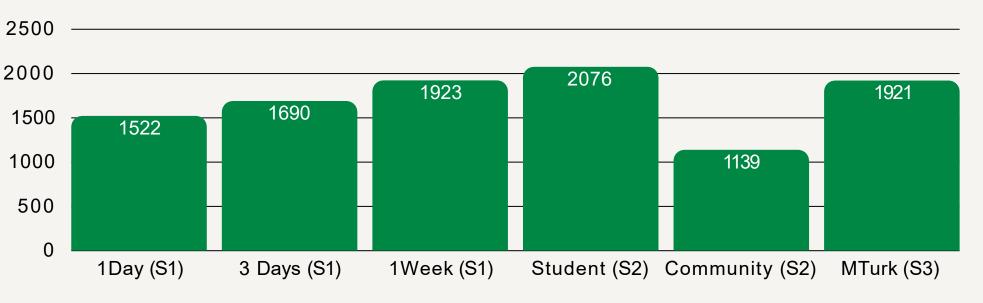
a few observations



Though digital platforms are accessible for free, users place considerable value on their digital presence, thus indicating a deep psychological (and physical) attachment to social and digital media



How much money would you need to give up Facebook?









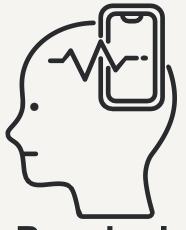
Social and digital media use is...







Habitual/ Ritualistic



Passively Addictive



Psychophysiology and eye-tracking study of organic social media use!

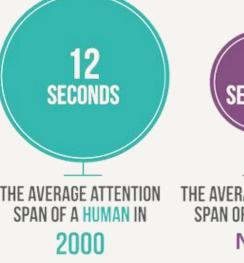


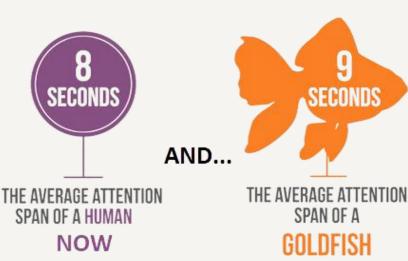


a few observations



On average, participants switched from one segment to another every 10 seconds













10 seconds of heart rate and skin conductance level change prior to pressing the "like" button simulate an "orienting response" or the "What is it?" response, which is automatic, nearly unconscious, and happens over a short period of time (fast).







a few observations



What happens online... does not stay online. In a postdigital world, online behaviors reflect and influence offline behaviors... and when normative perceptions are aligned with risky behaviors, chances are, humans will engage in such risky behaviors









2.02

CONSUMER BEHAVIOR



1.23





INTENTIONS TO CONSUME ALCOHOL

t(139.89) = 5.43, p < .001, Cohen's d = .90









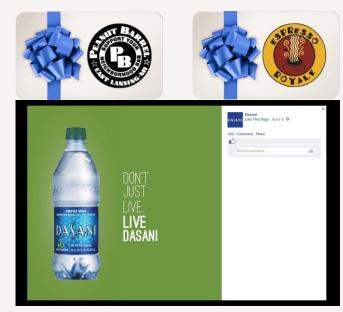








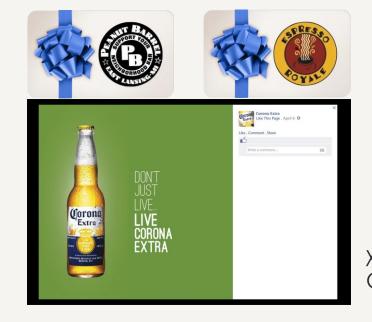






73%





 $\chi 2(1) = 4.20$, p < .05, Cramer's V = .19







a few observations



Risks are everywhere and they manifest themselves in new forms and influences as technology use evolves and deepens into the fabric of our lives.





https://www.vice.com/en/article/man-dies-by-suicide-after-talking-with-ai-chatbot-widow-says/ https://medium.com/@BernardMichaels/ai-got-me-to-file-the-divorce-petition-in-my-abusive-marriage-f0d33e9320d9



RESEARCHAPPROACH SURVEY METHODOLOGY





DESCRIPTIVE ANALYTICS **PREVALENCE**















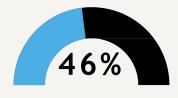






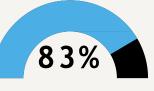






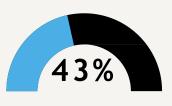


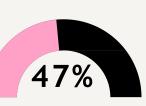


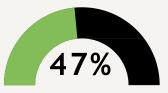














DESCRIPTIVE ANALYTICS **PREVALENCE**















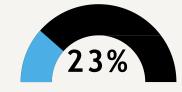








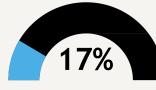


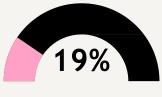




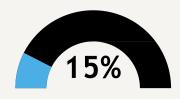


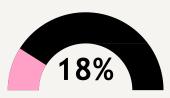
















DESCRIPTIVE ANALYTICS **DEMOGRAPHICS**





NON-DECEPTIVE SFC MED PURCHASE



DECEPTIVE SFC MED PURCHASE







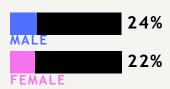




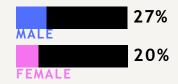


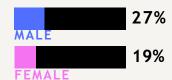


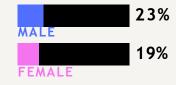










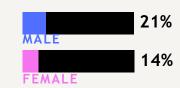




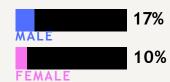














DESCRIPTIVE ANALYTICS **DEMOGRAPHICS**

SFC MED PURCHASE

DECEPTIVE





NON-DECEPTIVE SFC MED PURCHASE



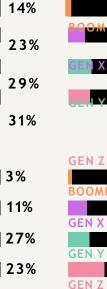


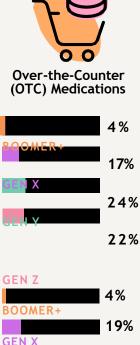


GEN Z

GEN Z

BOOMER+

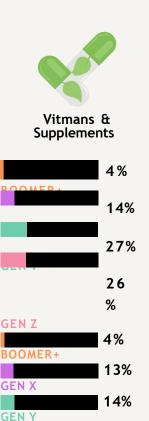




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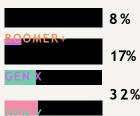
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GEN Z

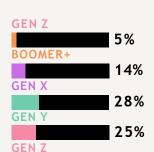


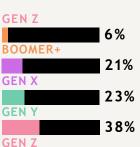
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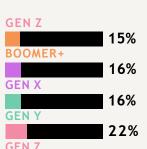




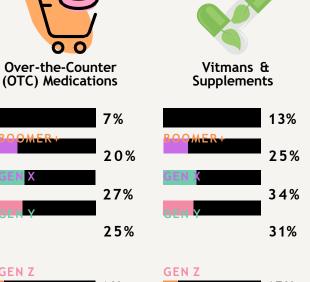


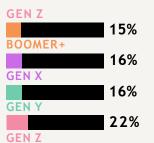














DESCRIPTIVE ANALYTICS PSYCHOGRAPHICS

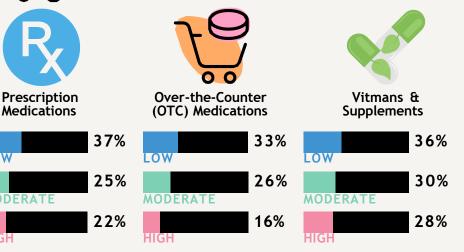




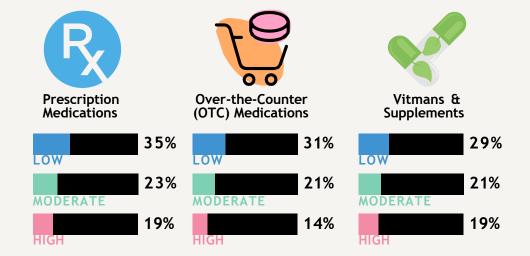
LOW

MODERATE

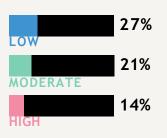
NON-DECEPTIVE SFC MED PURCHASE

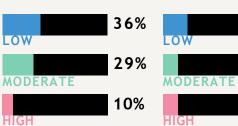








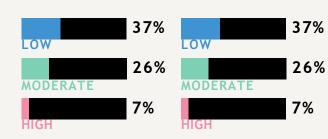


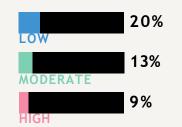


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14%

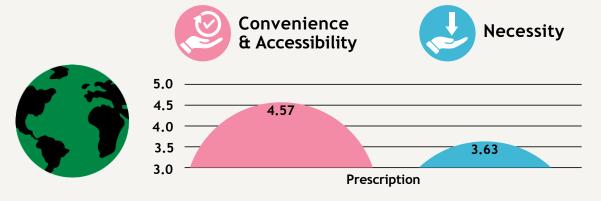
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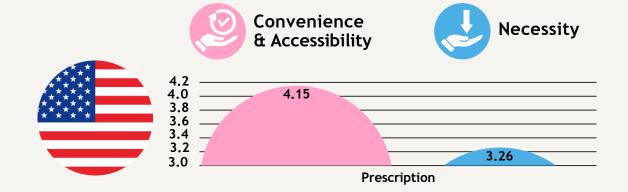


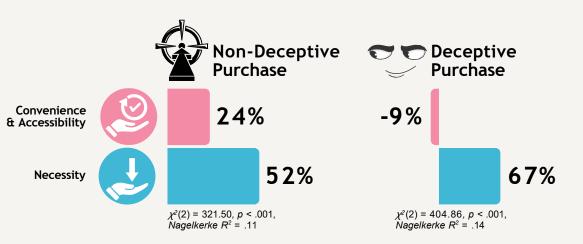


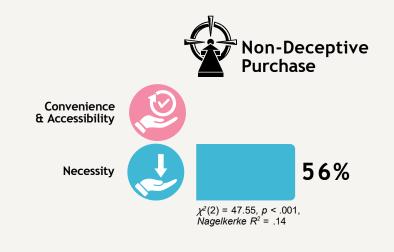


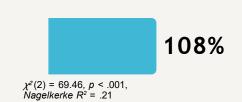
DESCRIPTIVE ANALYTICS **MOTIVATIONS**











Deceptive

Purchase

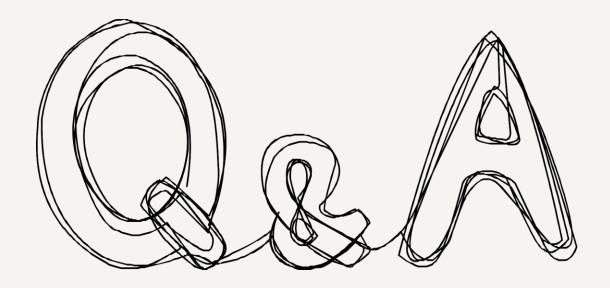


ACTIONABLE INSIGHTS



Consumers – globally and in the US – are gravitating toward online marketplaces to buy different kinds of medications, with demographic and psychographic individual differences that come at play.

Though the convenience of buying medications online is valid, the availability of counterfeit medications increases the risks associated with this behavior, especially that convenience motives are not the chief drivers of this behavior... instead, it's the necessity of getting medications when they're not available or consumers have limited access to them.



LET'S KEEP THE CONVERSATION GOING!

EMAIL <u>sa@msu.edu</u>

WEBSITE WWW.A-CAPP.MSU.EDU

Online Controlled Substance Purchases: Consumer and Patient Trends

John B. Hertig, PharmD, MS, CPPS, FASHP, FFIP



Internet Medicine Sales:

• Why Do Consumers Go Online?







CONVENIENCE



ACCESS

Contributing Trends

- Historic Shift to Buying Medicine Online
 - 52% of U.S. adults have used an online pharmacy
 - A 10% increase compared to 2021, and 17% increase from 2020
- A rise in patient harm
 - 24% of Americans who have purchased medicine online report receiving harmful, counterfeit, or substandard products
- Policy has normalized remote access (for now)
 - U.S. telemedicine flexibilities that allow Schedule II–V prescribing via telehealth without a prior in-person exam remain in effect through Dec 31, 2025, with DEA/HHS pursuing longer-term rules
- Shortages and access gaps push consumers online
 - Persistent stimulant supply disruptions (e.g., mixed amphetamine salts/"Adderall") have led many patients to look beyond local pharmacies
- Sales channels keep shifting
 - Increasingly use of social media/encrypted messaging and crypto payments

Social Media Threat



Contents lists available at ScienceDirect

Health policy

journal homepage: www.elsevier.com/locate/healthpol



Purchase of prescription medicines via social media: A survey-based study of prevalence, risk perceptions, and motivations

Charlotte Moureaud a,1,*, John Hertig b,2, Yao Dong c,3, Iago S. Muraro c,4, Saleem Alhabash c

^a AbbVie, 1 N. Waukegan Road, North Chicago, IL 60064, United States

^b Butler University, 4600 Sunset Ave, Indianapolis, IN 46208, United States

^c Michigan State University, 404 Wilson Road, East Lansing, MI 48824-1212, United States

Controlled Substances and Social Media

- 1,002 participants, with 730 reviewed (met inclusion/exclusion criteria)
 - Mean age 38.0 (SD 11.5)
 - 63.7% male, 35.4% female
 - Insurance coverage: 85.8%.
 - Social media use: 52.0% spend 1–2 hours/day; 29.4% spend 3–4 hours/day
- Purchases online in the past 12 months (% of the full sample)
 - Narcotics (e.g., oxycodone, hydrocodone, fentanyl, etc.): 54.6%
 - Stimulants (e.g., Adderall®, Ritalin®): 52.0%
 - Sedatives (e.g., Xanax®, Valium®, Ativan®): 29.6%

Contemporary Consumer Considerations

- A series of macro-level forces are driving the growth and sophistication of illegal online drug sellers:
 - Tariffs and Trade Frictions: Increased costs create incentives for counterfeiters to exploit price disparities.
 - Insurance Loss & Underinsurance: Patients unable to afford legitimate medications are pushed toward cheaper, unregulated options.
 - Artificial Intelligence: Enables rapid creation of fake websites, SEO manipulation, and automated consumer engagement via chatbots.
 - Social Commerce & Influencer Ads: Bypasses traditional pharmacy guardrails to market directly to consumers.
 - **Shortages:** in high-profile drugs create lucrative opportunities for counterfeiters.
 - Cross-Border Importation: Leverages foreign jurisdictional shields to evade enforcement.
 - Modern Payment & Logistics: Crypto, peer-to-peer transfers, and micro-fulfillment networks facilitate illegal transactions.

Key Takeaways

- Continued increase in e-commerce/online controlled substance purchasing
 - Online pharmacies can be a safe (and potentially cost-effective)
 alternative to traditional "brick-and-mortar" pharmacies, but must be
 thoroughly vetted
- Educated consumers take less risks; more education is needed
 - "Where do you get your medication?"
- A global issue resulting in serious negative impact on public health and patient safety, especially with controlled substances

The Future...



References

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- HHS Telehealth Policy explainer. Federal Register telehealth.hhs.gov
- NABP (2024–2025 Annual Report). 40,000+ "Not Recommended" websites and consumer tools (safe.pharmacy)
- NABPFDA. Internet Pharmacy Warning Letters (ongoing enforcement against illegal online pharmacies). U.S. Food and Drug Administration
- DEA. One Pill Can Kill (2025 update). Seizure data on fentanyl-laced counterfeit pills resembling common controlled meds. DEACDC Media Advisory (Oct 2, 2024)
- ASHP Shortage Detail: Mixed Amphetamine Salts (2025). Continuing backorders/allocations affecting access
- Global Initiative Against Transnational Organized Crime (2025). \$1.7B darknet drug sales (context on online drug market dynamics)



Angie Hoth, PharmD, MPH Reagan-Udall Foundation for the FDA



Online Purchase of Controlled Substances through Social Media



Project Overview

> To better understand the purchase of controlled substances, we conducted an observational assessment of social media interactions related to the selling and/or purchasing of controlled substances (opioids, stimulants, and benzodiazepines), including where and how sales are advertised, initiated, and conducted.

Methods & Data Collection

- Identified Platforms: Chosen based on popularity, purpose of site, and research on sites where purchases may occur
- > Search terms
- > Update of social media scan conducted in 2023

Substances of Interest

Searches included drug name, brand name, and 3+ slang terms identified through preliminary research.

| Туре | Name | Brand Name | Slang & Search Terms |
|----------------------|-----------------|---|---|
| Stimulants | Amphetamine | Adderall® | addies, addera11, addieplug, bennies, black beauties, buyaddies, crosses, hearts, la turnaround, speed, truck drivers, uppers |
| | Methylphenidate | Ritalin® | Kiddy coke, poor man's coke, coke junior, jif, study buddies |
| Opioids | Hydromorphone | Dilaudid | d, dillies, footballs, juice, smack |
| | Hydrocodone | Lortab [®] , Norco [®] , Vicodin [®] | bananas, dro, fluff, hydros, tabs, vikes, v-itamin, watson-387, 357s |
| | Fentanyl | Actiq [®] , Sublimaze [®] | apache, china girl, china white, dance fever, friend, goodfella, jackpot, murder 8, tango and cash, tnt |
| | Oxycodone | Oxycontin®, Percocet® | 30s, as, berries, blues, blueberries, hillbilly heroin, ms, o.c., oxy, oxycet, oxycotton, ozone, roxy, ercs, greenies, kickers, m-30s, percs, rims, tires, wheels, 512s |
| | Oxymorphone | Opana® | biscuits, blue heaven, mrs. o, o bomb, octagons, stop signs |
| Benzo- diazepines | Alprazolam | Xanax [®] | bars, benzos, blues, chill pills, downers, nerve pills, planks, tranks, ladders, school bus, xans, xannybars, xanplug, zanies, sellingxans |
| | Clonazepam | Klonopin® | k, k-pin, pin, super valium |
| | Diazepam | Valium [®] | eggs, jellies, moggies, vallies |

Substances of Interest

Searches included, when possible, popular drug-based emojis.



Common Emoji Codes



Key Takeaways





Safety

Safety of product is not typically discussed in advertisements or during public interactions

Some strategies may increase perceived safety

- Sellers titled "drugstore" or "pharmacy"
- Mixing of legitimate ads with illicit content



Motivations

Common motivations for purchasing online

- Fast, discreet delivery
- No prescription required
- Ease of access
- Urgent need

Some users also cited taking control of their health as a reason for bypassing traditional medical channels



Platform Functions

Policies on all platforms restrict the purchase or sale of controlled substances - policies have changed since 2023

- Consumers & sellers are very savvy to create workarounds to new policies
- "It takes a network to defeat a network"

Search functions may facilitate or block access to sales information



Purchasing

Purchasers typically use social media to identify sellers and then move to a third-party platform for transaction

Payment details are rarely disclosed in posts

Conclusions



- ➤ Despite platform policies prohibiting the sale of controlled substances via social media platforms, users can still locate sellers through creative search terms, indirect links, and third-party platforms.
- > Common motivations for purchase through social media include fast, discreet access without prescriptions, while safety information and purchase details are often vague or absent.
- ➤ Massive amounts of information and constantly evolving terminology make assessment and regulation difficult. Searches are often limited by platform algorithms, location, and more.
- ➤ Missed opportunity for harm reduction messaging to be pushed to people who search for drug-related terms that helps them understand risks and mitigation strategies. Some platforms offer warning or safety statements, but general harm reduction information is limited.

Human Impact of Online Access to Controlled Substances





Jennifer FrinkFamily Representative

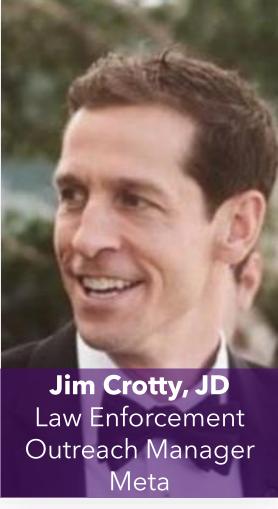


Ed TernanPresident & Co-Founder
Song for Charlie

Strategies for Intervention & Disruption











Global Perspective









Strengthening the security of the medicines supply chain

Carrie Harney
United States Pharmacopeia



USP's enduring mission



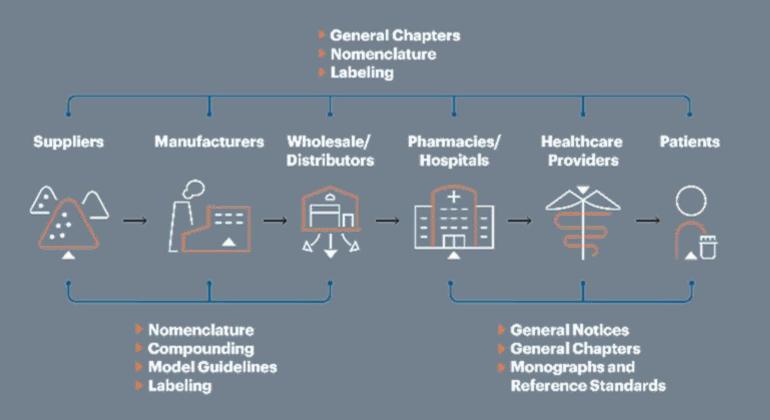
To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines, dietary supplements, and food ingredients.



USP's standards today



More than 9,000 USP standards provide quality benchmarks across the supply chain in over 140 countries



- Establish and disseminate public <u>Documentary Standards</u> for the quality, purity, identity, strength, and labeling of medicines, dietary supplements and foods
- Provide physical <u>Reference Standards</u> to support tests and assays in USP compendia
- Educate producers, practitioners, and others seeking <u>information on quality</u> and USP standards

Illegal online sellers bypass patient protections



At any given time, there are an estimated 30,000-40,000 illegal online pharmacies in operation globally.

 Products sold by illegal online drugs sellers often contain little or no active ingredients; are manufactured in unsafe conditions; contain dangerous ingredients; and/or are controlled substances



The APEC Supply Chain Security Toolkit





- USP APEC Center of Excellence on Supply Chain Security
- APEC Dialogue on Supply Chain Security
- ▶ APEC Supply Chain Toolkit

Toolkit to combat illegal internet sales of medical products



- Summarizes the scope of the illegal drug seller problem
- Provides definitions of key terms
- Makes recommendations to combat illegal internal medical product sales
- Provides public education resource materials
- Ongoing trainings to support implementation of best practices and recommendations



Internet sales toolkit recommendations



- 1. Develop and deliver **targeted public awareness campaigns** to educate patients and healthcare professionals about the threat of illegal online medical product sellers and how to purchase medicines safely.
- 2. Strengthen laws and policies to protect patients from S&F medical products purchased online. Include education on online pharmacies in educational curriculum for healthcare professionals.
- 3. Distinguish safe, legally operating online pharmacies from illegal online medical product sellers.
- 4. Establish Model Voluntary Protocols for Internet commerce companies.
- 5. Participate fully in INTERPOL's <u>Operation Pangea</u> and other cooperative international activities, including the World Health Organization Member State Mechanism on S&F Medical Products and MEDICRIME Convention.
- 6. Establish effective NRA, customs, and law enforcement coordination to remove illegal online medical product sellers.
- 7. Ensure active participation by NRAs, law enforcement, and other government officials to take a leadership role in preventing the manufacture and distribution of S&F medical products
- 8. Involve all stakeholders in creating solutions, including NRAs, law enforcement, customs officials, NGOs, manufacturers, distribution companies and Internet commerce companies, patients, and healthcare professionals.
- 9. The activities under the Internet Sales Toolkit should be closely **aligned and coordinated with activities of the APEC Supply Chain Integrity Centers of Excellence** under the direction of the APEC Supply Chain Steering Committee.

Thank You



The standard of trust



Controlled Substances Virtual Summit

Global Rapid Interdiction of Dangerous Substances (GRIDS) Programme

Vladimir Kostic





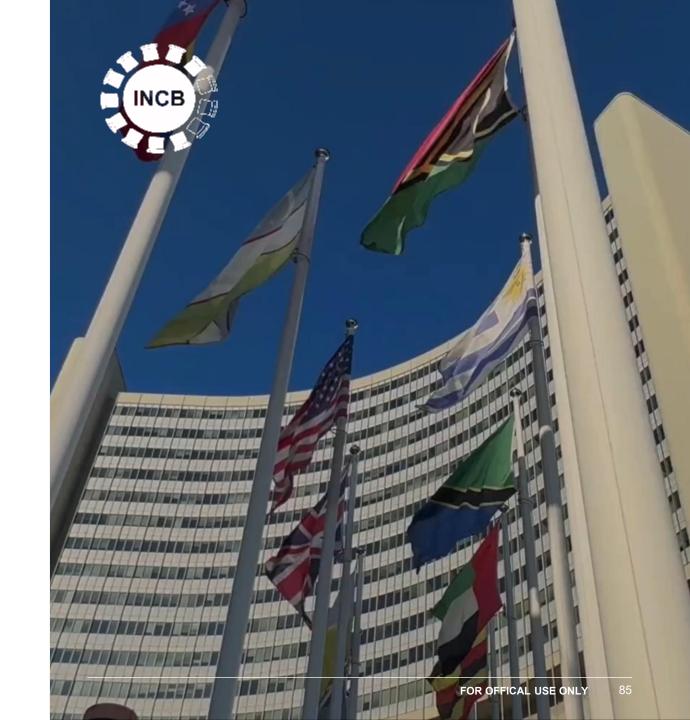
International Narcotics Control Board

Established under the 1961 Treaty

The International Narcotics Control Board (INCB) is a **UN treaty-mandated body** established in **1961**. Based in **Vienna**.

INCB ensures the availability of **adequate supplies** of narcotic drugs, psychotropic substances, and precursor chemicals for:

- · Legitimate medical use
- Scientific purposes
- Industrial applications
- INCB works to prevent the diversion of these substances for illegitimate purposes.





GRIDS | Information Exchange for Actionable Intelligence

INCB Locations with International Operational Partners CARICOM, Interpol, OCO, UPU & WCO

GRIDS footprint in 9* locations dedicated to increasing tool access, capabilities and trafficking outcomes

GRIDS Cyber Communications Centre (GC3) hosts IONICS suite of state-of-the art targeting tools (IONICS, GRIDS, SNOOP)

GRIDS provides systems access across all <u>Govt Law &</u>

<u>Regulatory Enforcement</u>

<u>Agencies, INTERPOL, OCO,</u>

<u>Caricom, UPU, & WCO</u>



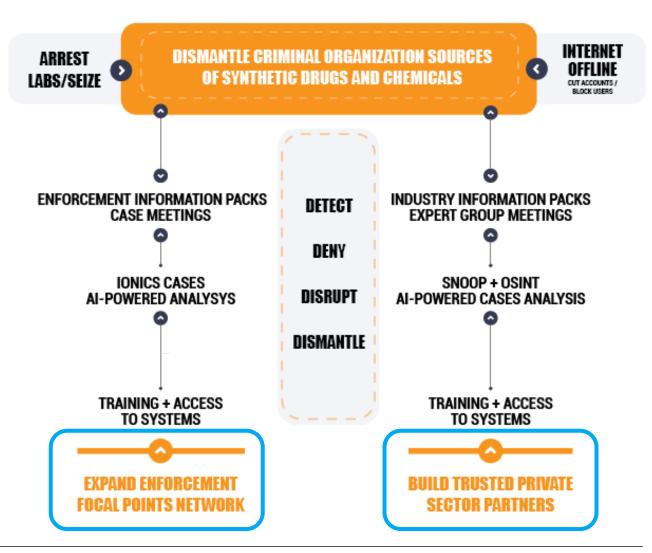


GRIDS | Operational Approach to Dismantle Sources of Drugs

Provide Actionable Intelligence & Advanced Technologies

INCB GRIDS APPROACH

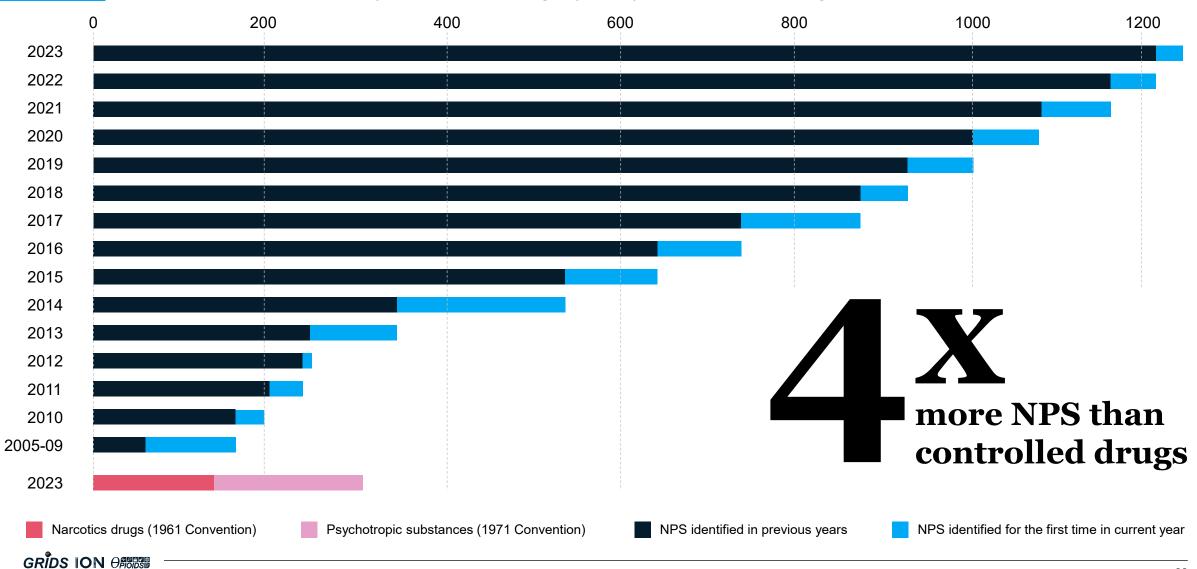
- Exchange information across all national law and regulatory enforcement agencies
- Prioritize transnational organized crime, cyber crime related & border security
- Prioritize detecting/ interdicting deadliest drugs fentanyls and its precursors- dismantling the source transnational criminal networks
- Develop, operate & train LE on next generation information sharing technologies as the UN hub for national & international partners
- Build effective public-private partnerships that dismantle online transnational criminal networks





Global | Trends on Synthetic Drugs & Chemicals

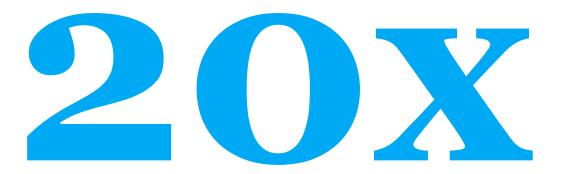
Number of internationally controlled drugs (2023) and NPS at the global level, 2005–2023





Trends in Synthetic Drugs and Chemicals

2010-2022Global Seizures of "Pharmaceutical" Opioids



Higher Volume of Seized OPIOIDS

Source: UNODC World Drug Report 2024 https://www.unodc.org/unodc/en/data-and-analysis/wdr2024-drug-market-trends.html



Global | IONICS Live Data on Synthetic Drugs & Chemicals

Emerging Synthetics Trafficked as Suspected Pharmaceutical Products





Figure 1. Photographs of falsified "accordance" tables containing etantiazepyne in New Zealand in 2022 (left, IONICS# 54739) and in Slovenia 2021 (right).



Figure 4. Unconfirmed OSINT report of powder sold as alprazolam noted in the USA in 2021 (left) and of various fulsified alprazolam tablets preportedly containing bromazolam in the USA in 2023



Finotograph 3: Tablets with isotonitazene identified in Canada to Documber 1019



Photograph 4: Tablets with trotonitazine identified in Canada in February 2020



Figure 8. Pregabalin consignments from Bangladesh to Qatar (IONICS # 29941), clearly showing production numbers (General Directorate of Druas Enforcement of the Ministry of Interior of Qatar)



GRÎDS ION OFFICIOSE



Tools

Information Exchange and Actionable Intelligence

















3

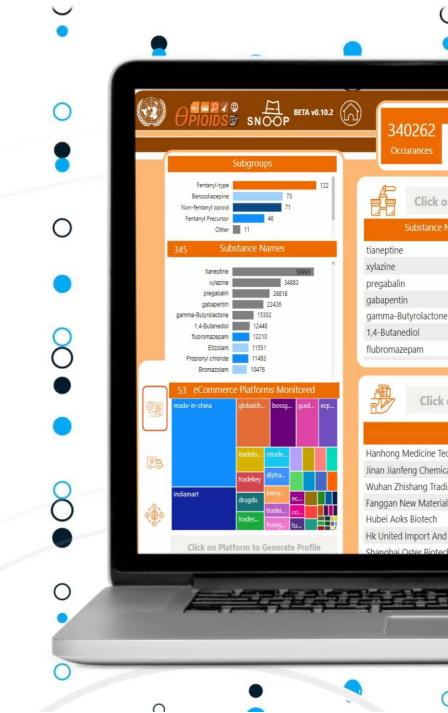
IONICS COMMUNICATIONS SUITE

- IONICS for smart mobile devices
- Provides a suite of targeting tools
- Transforming information into actionable intelligence

SNOOP

Scanning of next-generation opioids on online platforms.

- Monitors the global B2B e-commerce of synthetic opioids, fentanyls, and related chemicals by wholesale distributors.
- Focuses on chemical names, CAS identifiers, and InChiKey.
- Links suspicious online markets across multiple platforms and flags highrisk "companies."
- Exports **consolidated account details of "companies"** (seller, emails, phone numbers/WeChat/WhatsApp, sender and financial data).



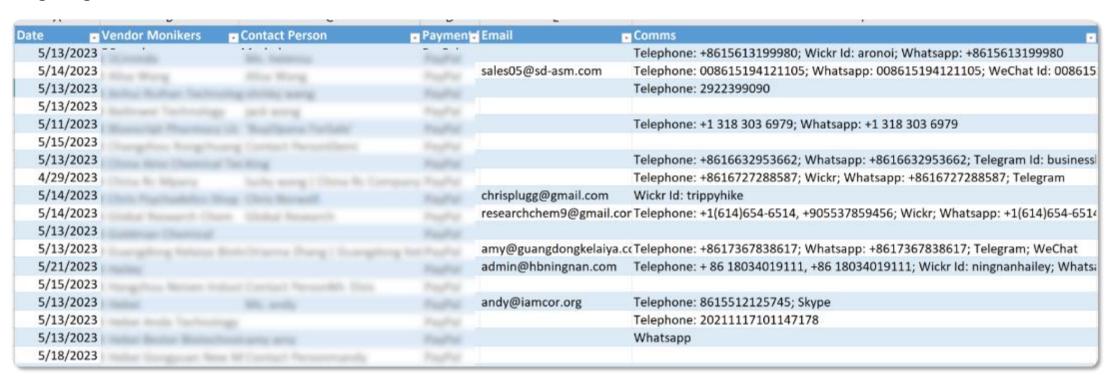




GRIDS

Providing Officers with State-of-the-Art Tech Tools

Export Company Contact Details, 3rd Party Accounts, Emails, Encrypted CommunicationsAddressing Cross-Platform Exploitation via Targeting Centres





GRIDS | Building Public-Private Partnerships

Addressing Novel Opioids, Chemicals & Equipment Sales





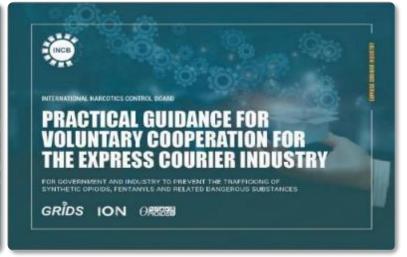
- 25 UN international events hosted for practical cooperation with "4M" industry since 2018
- Experts from Governments, international organizations and the private sector

INTERNATIONAL MARCOFICE CONTROL BOARD

PRACTICAL GUIDANCE FOR
VOLUNTARY COOPERATION FOR
FREIGHT FORWARD INDUSTRY

PGIR GOVERNMENT AND INDUSTRY TO PRIEVENT THE TRAFFICKING
OF SYNTHETIC OPPOSITE, FEMTANNIS AND RELATED DANGEROUS
SAUBSTANCES

GRÎDS ION CARSON

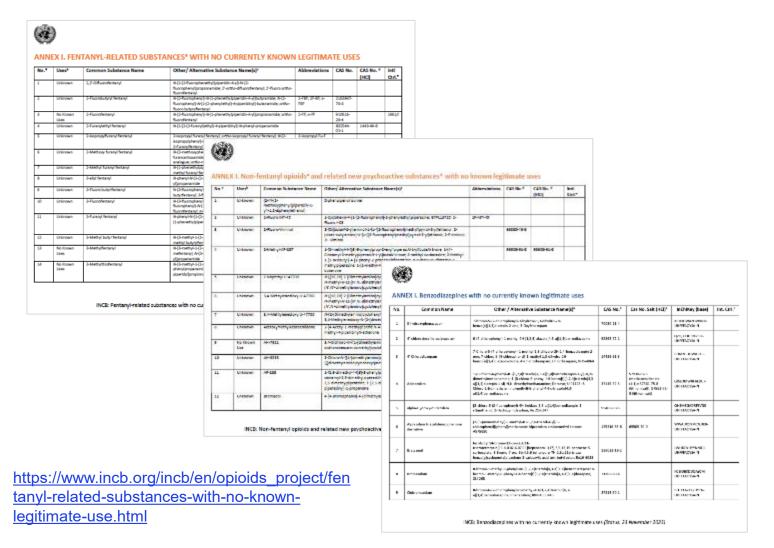


- Over 300 technical recommendations since 2018
- Practical and promising practices compiled & disseminated



GRIDS

Access to Real-Time Communications & Targeting



Does the substance have ANY legitimate use?

153 fentanyl-related substances with **no legitimate uses** in circulation

69 non-fentanyls opioids identified with **no legitimate uses** in circulation

Includes pre-precursors

37 benzodiazepines with **no legitimate uses** in circulation



GRIDS | Building Public-Private Partnerships

Tech against Trafficking



Online Controlled Substances Virtual Summit 2025 Session 4: Global Perspective

Use of digital surveillance tools to search for irregular online sales The EPINET experience in Brazil

Laila Sofia Mouawad
Technical Officer
International Cooperation



Challenge

- Massive expansion of e-commerce
- Volume and anonymity of online transactions
- Lack of harmonized global regulations
- Proliferation of counterfeit and substandard products
- ➤ Illegal products frequently advertised and sold on social media platforms and online marketplaces. The use of encrypted messaging apps and cryptocurrency for transactions further complicates surveillance and enforcement actions



EPINET: Overview

- ➤ Technical cooperation project ANVISA and the United Nations Development Program (UNDP)
- ➤ Hiring of a especialized private company to develop the digital surveillance tool (EPINET)
- ➤ Monitoring online sales e-commerce in Brazil through up to 800 keywords



EPINET: Overview

- > Searches based on models of Artificial Intelligence (AI), using several factors, URLs and contents to classify signals and threats
- Companies covered: All Brazilian websites and e-commerce platforms
- Contract signed in 2021 effective from November 2021 to December 2024 (pilot project)
- Ongoing internal process to rehire the tool



EPINET: Overview

Drugs, supplements, medical devices, unauthorized products (Regularly updated based on observed trends)

Keywords selection

Definition of criteria

Additionally needed for detection/exclusion

Signals captured sent to the first validation step (automated) -Results are "possible threats"

Searches

Confirmation

Possible threats are submitted to a second validation step (automated and/or human) Warning letters automatically sent, requesting the takedown

Takedown

Monitoring

The software regularly checks whether the advertisement was removed and generates effectiveness data





EPINET: Numbers of the pilot project

+128.000.000 Signals captured

+920.000 Potential threats detected

+220.000 Warning letters issued

+98% Takedowns





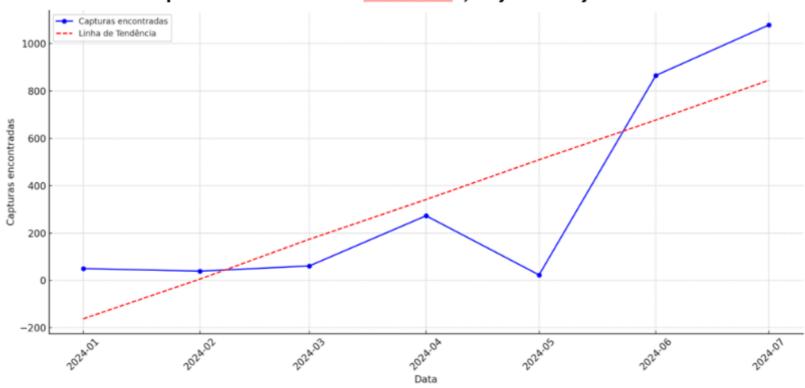
EPINET: Potential

- Deep/Darkweb investigations are possible, including monitoring malicious forums, onion pages, and malicious Telegram/WhatsApp groups
- Controlled substance example: Vyvanse (Lisdexamfetamine): 6-months investigation detected 54.771 mentions
- Modus Operandi: prescription falsification, direct sales, lotters, including digital marketing strategies



EPINET

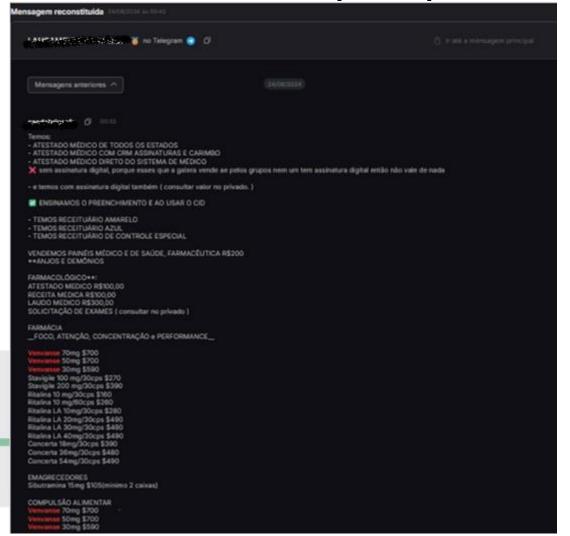
Capturas associadas à "Venvanse", de janeiro a julho de 2024



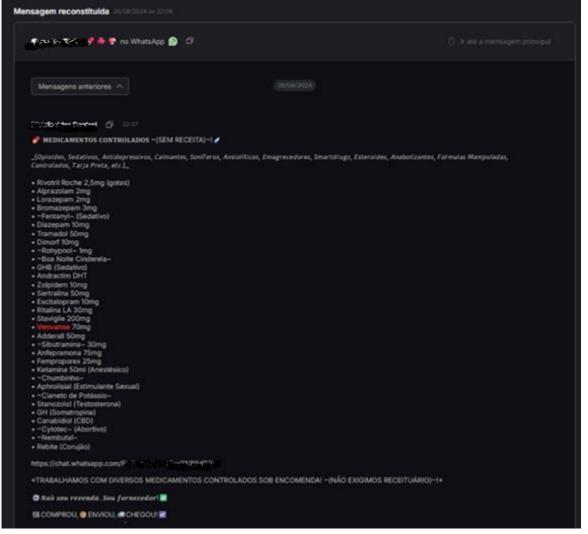


EPINET

Advertisement of prescription sale



Advertisement of drug direct sale



Global Perspectives for regulatory authorities

- > Investments on advanced digital surveillance tools
- > Strengthening international cooperation
- ➤ Enhancement of public awareness about the dangers of purchasing medicines from unverified sources
- Collaboration with internet service providers, payment processors, and tech companies are also essential in dismantling online networks that facilitate the illegal drug trade.



THANK YOU

Laila Sofia Mouawad

Brazilian Health Regulatory Agency (Anvisa)

https://www.gov.br/anvisa/pt-br/english





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

Sangeeta Chatterjee, PharmD

Acting Director, Office of Drug Security, Integrity, and Response, CDER Office of Compliance

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



REAGAN-UDALL

FOUNDATION FOR THE FDA