



**Online Controlled Substances Summit: Public Session
Virtual Public Meeting
July 25, 2024 | 11am-2pm (eastern)**

Transcript

Welcome

Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA

Susan Winckler ([00:00:32](#)):

Good morning and welcome. I am Susan Winckler and I serve as the CEO at the Reagan-Udall Foundation for the FDA. And we are so pleased to be hosting the 2024 Online Controlled Substances Summit today. As we dive into the agenda for the day, I thank our FDA collaborators for their partnership in planning this summit. We hope that at the end of the event, you will have found it informative and engaging. So here's how we'll plan to spend our time together. As noted in the registration, we're gathered to explore the online ecosystem that misuses a variety of technology platforms and capabilities to provide access to controlled substances outside of the legal structure and delivery of healthcare.

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We will hear perspectives from the US Food and Drug Administration, from individuals with real life insight, from researchers and from the technology sector, including social media platforms. Throughout the day, we hope that we will learn from these experts about how the sale and purchase of controlled substances online exacerbates the ongoing public health problem of misuse of these products. That will take us through the next three hours. And again, I thank you for joining us. So I want to turn us as quickly as we can to substance and we kick off that substance with remarks from Dr. Robert Califf who serves as Commissioner of Food and Drugs at FDA. Commissioner Califf, I'm going to turn the virtual stage over to you.

Introductory Remarks

Robert M. Califf, MD, Commissioner of Food and Drugs, FDA

Commissioner Robert Califf ([00:02:04](#)):

Thanks Susan, and I'm glad I'm introduced as providing substance. Often the commissioner has a ceremonial role, but this is obviously a topic that is very important to the FDA to the country and certainly to me as an individual. So on behalf of FDA, I want to welcome you to the Fifth Online Controlled Substances Summit. And I also want to thank the Reagan-Udall Foundation and the FDA planning committee for their efforts in preparing for and convening the summit. A debt of gratitude as well to our speakers, panelists, and attendees for taking the time to participate in what should be an interesting and important set of conversations. As we all know, drug overdose deaths remain a major public health issue in the United States with more than 107,000 reported fatal overdoses in 2023. These are primarily driven by synthetic opioids like illicit fentanyl. Equally problematic is the opioids in

combination with other controlled substances, including benzodiazepines and stimulants such as methamphetamine, as well as emerging substances of concern such as xylazine.

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In response to this evolving crisis in 2022, we announced the FDA's Overdose Prevention Framework, a vision and strategy of creative and effective actions to prevent drug overdoses and reduce deaths. The framework consists of four overarching priorities that align with both the US Department of Health and Human Services Overdose Prevention Strategy and the National Drug Control Strategy. These four priorities are first, supporting primary prevention by eliminating unnecessary initial exposure and inappropriate prolonged prescribing. Second, encouraging harm reduction through innovation and education. Third, advancing development of evidence-based treatments for substance use disorders. And finally, protecting the public from unapproved, diverted or counterfeit drugs presenting overdose risks. So let's move to the focus of the FDA summit. Today's summit addresses the final priority, the illegal online availability of controlled substances. This is an integral part of the FDA's overall efforts to protect the public, including youth from harm associated with drugs that have abuse potential.

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The spread of illegally sold prescription drugs through unsafe websites and social media platforms presents unique challenges for regulators, law enforcement, policymakers, families and clinicians, and others who are working to prevent these dangerous products from harming the American public. While prescription drugs that are controlled substances are an important treatment option for patients who need them, these drugs have a potential for abuse among other risks. These risks are further heightened when prescription drugs are purchased from unknown or unlicensed sources online. Consumers have no assurance that these products are safe and effective. Indeed, these products may actually be contaminated with deadly fentanyl or other dangerous substances. For several years now, this summit has provided a forum for stakeholders committed to preventing the sale of controlled substances through social media, unsafe websites, and other online channels to come together and discuss ways to further their individual and collective efforts to address this issue.

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As we convene for a fifth time, we recognize the importance of including representatives from the public and the private sector, including those from the online ecosystem, academia, regulatory, and other organizations to help navigate these challenges and develop strategic and effective solutions. We also recognize the need to broaden the scope of the summit to meet the moment. I truly believe this year marks a real turning point for our efforts to protect the public. I'm pleased that for the first time ever, the summit includes today's public workshop in addition to tomorrow's closed working session. Online availability of controlled substances is a problem requiring greater public attention and collaboration from all interested groups, particularly given the emergence of rampant misinformation.

[\(00:06:49\)](#):

In a moment, I'll dig a little deeper into this topic, but first I want to highlight a few of our recent activities under the framework as well as how these efforts connect to the themes of today's summit. So first, the overdose reversal agents. Encouraging harm reduction, including broader access to overdose reversal agents goes hand in hand with efforts to address online availability of controlled substances. Let me give you an example of how these efforts intersect. A consumer may purchase what they believe to be prescription Xanax, a benzodiazepine through a social media site, but instead of Xanax, the pills that consumer purchases may be a combination of substances including fentanyl, which could cause an overdose. In such a case, administering an overdose reversal agent such as Naloxone, which rapidly

reverses the effects of opioid overdose could be lifesaving. I'm proud of the FDA's work to facilitate greater access to overdose reversal agents.

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These medications are a critical tool in addressing opioid overdoses. In March of last year, the FDA approved the first branded non-prescription Naloxone nasal spray. We've made great strides since then, and as of today, we've approved a total of two branded and three generic non-prescription naloxone nasal sprays. These approvals have expanded options for lifesaving naloxone to be sold directly to consumers. Furthermore, last May, we expanded the availability of overdose reversal agents by approving the first Nalmefene nasal spray. That action provided another helpful tool to combat the overdose crisis. In addition, we have issues with ADHD and prescription stimulants. Supporting the safe use of prescription stimulants also aligns with our work to reduce both the supply of and demand for a prescription stimulants available online. For instance, a parent who cannot fill their child's Adderall prescription. Whether the medication is in shortage, too expensive due to a copay or inaccessible due to the family's lack of access to medical care may turn to the internet as the last resort.

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The danger is that this parent may not realize that some of the online pharmacies advertising Adderall are not licensed and that a cheaper prescription medication dispensed through this illegitimate online pharmacy may be unsafe and ineffective. This scary reality is one reason that the FDA continues to collaborate with the Drug Enforcement Administration to do all we can to prevent stimulant drug shortages, limit their impact and resolve them as quickly as possible. We recognize the important role that prescription stimulants play in the treatment of attention deficit and hyperactivity disorder or ADHD. And we know the lack of availability of certain medications has been very challenging for patients and their families. More broadly, the FDA has taken steps and will continue to take steps to expand treatment options for ADHD and ensure that patients and clinicians can access the information they need to understand their risks and benefits.

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For example, this past May, we approved a liquid non-stimulant medication clonidine hydrochloride for ADHD in patients six years and older. In May of 2023, we also required a class-wide safety labeling change for certain stimulant medications used to treat ADHD and other disorders to more clearly inform patients, caregivers, and healthcare professionals of risks associated with this prescription medications. Additionally, we supported efforts to better understand the diagnosis and treatment of ADHD in adults.

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Last December, the National Academies of Sciences Engineering and Medicine hosted an FDA funded public workshop on the diagnosis and treatment of ADHD in adults, as well as implications for drug development. We also help patient listening sessions on ADHD this spring, which have helped our staff better understand patient perspectives about their diagnosis and risks and benefits associated with stimulant and non-stimulant treatment for ADHD. Finally, the threat of misinformation. In a few minutes, two of my colleagues, Leigh Verbois, from the Office of Compliance in the Center for Drug Evaluation and Research, and Dan Burke from the Office of Criminal Investigations and the Office of Regulatory Affairs will talk more about the FDA's efforts to protect public health through compliance and enforcement efforts.

[\(00:11:51\)](#):

In my remaining time, I want to focus on an issue that affects not only our efforts in these areas, but in the work we do across the agency. This issue is the abundance of misinformation related to public health and science. Unfortunately, today thanks to the internet and social media, inaccurate information

spreads widely and quickly, making it increasingly difficult for the public to identify verified facts and advice from trusted sources such as the FDA. In particular health misinformation, especially when it comes to online controlled substances, influences consumer behavior and undermines consumer's ability to make informed health decisions, thereby increasing their risks. To counter misinformation and resulting consumer misconceptions, we need to increase public awareness of safety risks, improve education strategies, and make all efforts to reach the right audiences through trusted messengers and by using plain English. As we gather today, one of the issues I hope you'll consider... You will consider how consumers find, confirm and perceive information regarding controlled substances online, including discussion about ways to produce meaningful, measurable public health solutions.

[\(00:13:16\)](#):

In this regard, I'm particularly excited to learn more about Reagan-Udall Foundations misinformation project online purchasing of controlled substances. As well as to hear about the research in this area being conducted by our nonprofit and academic colleagues. Both the growing spread of misinformation and evolving access to legal online control substances are putting consumers at risk. This summit is an important opportunity to think globally about those intertwined issues. Your discussions over the course of the next two days can stimulate the formulation of strategies to change consumer behavior and empower individuals to make better informed decisions when encountering dangerous products. I hope these conversations and resulting collective actions continue beyond the summit. It's only through innovation and collaboration that we'll successfully prevent overdoses, reduce deaths, and shift the trajectory of this crisis.

[\(00:14:16\)](#):

Thanks again for your participation and I hope you have a great and productive summit.

Session 1: Perspectives from the FDA

Presenters

Leigh Verbois, PhD, Director, Office of Drug Security, Integrity, and Response, Office of Compliance, Center for Drug Evaluation and Research, FDA

Dan Burk, Chief, Investigative Services Division, Office of Criminal Investigations, FDA

Susan Winckler ([00:14:23](#)):

Excellent. Thank you so much Dr. Califf for joining us. And it's so helpful to capture the groundwork of what FDA has already been doing and then what we expect to hear in the rest of the session. So we appreciate you investing your time with us this morning and clarifying, just putting out there what the agency is looking for as an outcome of the meeting, we expect to have a good discussion. Thank you. So as we move to our additional speakers, we have one component that I want to share. We've been talking about how today is exploring the misuse of technology platforms to distribute or provide access to controlled substances outside of the legitimate supply chain prescription medications for controlled substances. So this is just a quick reminder of that legitimate supply chain that includes the manufacturer production, the wholesaler distribution, the dispensing through licensed pharmacists and healthcare professional prescribing, and then getting to the patient.

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And today we're talking about the misuse of online platforms to go outside of this structure. So I'll note that was just a grounding, and now we will turn to hear remarks from our two colleagues joining us for this portion from FDA. So as we look for those FDA perspectives, we will hear from Dr. Leigh Verbois, who's director of the Office of Drug Security Integrity and response in Cedar's office of compliance. I'll

turn first to you, Dr. Verbois, and then we will turn to Chief Burke as he follows you. So Lee, would you pick this up and drive us to the next component of our meeting?

Dr. Leigh Verbois ([00:16:11](#)):

Thank you so much, Susan. I really appreciate the introduction. I'd also like to thank those at the Reagan-Udall Foundation and others on my team as well as collaborators that are in the room listening. It's taken a lot to get us here today, and we really appreciate the contributions of everyone making sure that we can have a collective conversation to make sure that we can come to agreements and collaborations on what we think we need to do in this space. So today I'll be speaking about how the US Food and Drug Administration works to protect consumers by reducing the illegal online sales of controlled substances. And we look forward to continued conversations as we move forward in the day, I work within the Center for Drug Evaluation and Research in the Office of Compliance, as Dr. Califf and Susan mentioned. And we have a mission to protect and shield the public from poor quality, unsafe and ineffective drugs through proactive compliance strategies and risk-based enforcement actions.

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And we do this in a number of different ways. Three, specifically. We proactively promote compliance through clear communications and collaborations with all stakeholders, many of you who are in the room. We pursue effective risk-based enforcement actions and we pursue organizational excellence. This includes workplace culture and human resources and business processes to ensure that we are effectively working together. And it's really important that all of these things collaborate and coordinate together to ensure that our mission is really integrated and we work to ensure that we're strategically integrating these strategies across the agency, including in support of FDA's overdose prevention framework. As Dr. Califf mentioned earlier, I want to highlight our office's work and our event today falls under the fourth priority of FDA's overdose prevention framework. And we work to shield the public from poor quality, unsafe, and ineffective drugs through proactive compliance strategies and risk-based enforcement actions to shield the public from unapproved, diverted and counterfeit drugs presenting overdose risks.

([00:18:28](#)):

This is protecting the public is an integral part of our office's work and mission. So for our conversations both today and tomorrow, we're taking a critical look at the availability of controlled substances online and the serious risks associated with them. We'll be talking about this, you'll hear from a number of other speakers that despite the health risks that we're seeing, consumers are still purchasing controlled substances online. And these dangerous and products and this purchasing pattern has serious real health consequences. So these stories are all too familiar across the United States and around the world. While the supply of controlled substances online is growing, we're still seeing escalating demand for these products. And these snapshots that are on this slide show the real life impact of the online availability of controlled substances that have an individual, consumer and community level. As everyone knows, drug overdoses took about 107,000 lives last year, and as the overdose crisis continues to evolve, this is a call for us in this room to take collective action.

([00:19:40](#)):

This is why we have to have these important conversations and discussions to understand how we can be part of the developing solution. So as part of FDA's efforts to address the online availability of controlled substances, FDA issues warning letters to operators of websites that unlawfully sell unapproved and misbranded controlled substances to US consumers. This is one piece of what we do. There are inherent risks to consumers that purchase controlled substances from illegal online sources. These drugs do not carry the same assurances for safety and effectiveness as those subject to FDA

oversight. Dr. Califf mentioned in his opening remarks that often these types of drugs circumvent regulatory safeguards and are contaminated, maybe counterfeit, contain varying amounts of active ingredients or contain different, possibly more harmful ingredients altogether, like fentanyl. So I wanted to exemplify some of our activities. FDA has issued numerous warning letters to online sites, and here's a selection that we recently issued, including one that we issued on Monday to a site that sold unapproved and misbranded opioids, including tramadol and oxycodone.

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We recognize that warning letters are an important tool in FDA's regulatory toolbox, but to address this important public health issue, it's going to take multiple sectors. Essentially, it's going to take a village. So to echo Dr. Califf's words, we recognize the importance of bringing together stakeholders from the public and private sector. And we've done this over a number of years. The events today and tomorrow, we look... In the events today and tomorrow we look forward to hearing from a diverse pool of experts from multiple sectors. This includes the internet ecosystem from government, international bodies, academia and trade and advocacy groups to make sure that we're hearing diverse voices to ensure that we're building those actionable items. So I'd like to talk about what our summits have meant for us, and as we open our fifth summit, it's important to reflect on what we've learned from all of our previous summits.

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Since 2018, these events have laid the groundwork for effective concrete actions from each of our subsequent... Our previous summits. Notably, in last year's summit, we expanded the scope of topics from opioids to all controlled substances. And we identified recurring themes to ensure that we were able to effectively communicate, coordinate, and collaborate with a holistic approach. Through these recurring themes, we identified collaboration, education, barriers to action and continuity. And today we're hoping to navigate challenges collectively identified in previous years to develop a strategic and actionable solution based progress. We'll be taking a closer look at this public health issue through the lens of effective communication and addressing misinformation in ways to empower consumers to take and make safer choices. For this effort to succeed, public discourse and collaboration is essential. And disrupting current trends will require comprehensive solutions designed to change consumer behaviors and protect public health.

[\(00:23:01\)](#):

We're all going to need to use multifaceted strategies to adjust both supply and demand. If we just look at one side, we're not going to be able to bring a public health solution that really addresses this. And we're going to need to recognize that online sale of controlled substances is complex, evolving, and really is a global issue. At the FDA, we use a multidisciplinary approach to address this public health threat. And I'm going to turn it over to Dan Burke in the Office of Criminal Investigation to describe their approach to this public health issue.

Susan Winckler [\(00:23:36\)](#):

So Dr. Verbois, thank you for that grounding. And as we know with many things at the agency, there are collaborative efforts and in fact, the greatest strength comes from those collaborative efforts. So we will turn now to Dan Burke, who is Chief of the Investigative Services Division in the Office of Criminal Investigations at the FDA. Dan, we would welcome the chance to hear your perspectives on enforcement progress, trends and challenges. I'll turn it to you.

Dan Burke [\(00:24:04\)](#):

Well, thank you Susan. And thank you to the Reagan-Udall Foundation for hosting this very important summit. And just a quick hello to Leigh Verbois, who I've enjoyed working with over the years and over many continents, right, Leigh? Her office has been such an outstanding partner within FDA.

[\(00:24:21\)](#):

The numbers of overdose deaths in the United States are staggering and have signaled a true public health crisis. Every day, our first responders encounter persons suffering from addiction, and I think it's a safe bet that all of us know someone who has died or continues the everyday, every minute struggle with chemical dependency. In fact, earlier this month, two of my daughter's coworkers died from a fentanyl overdose. Yet to date, not one mention of their deaths in the news, just whispers among her coworkers. As some states begin to experiment with freedom of self-medication legalization, or decriminalization of drugs, we are in the midst of an addiction crisis, along with a flood of counterfeit drugs and hard to detect analog substances available directly to consumers via the internet.

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All of us here today can play a role to help whether through prevention, education, research, monitoring, or treatment. Enforcement has a role as well. Now, look, we know we can't arrest our way out of this, but cutting sources of supply and holding accountable unscrupulous, greedy, frankly sinister people who profit and prey on addiction is part of the government's overall strategy to combat this problem. Here, you see this greed and callousness firsthand with some internal communications we obtained between online pharmacy operators and customer service personnel. Over the past several years, agents from FDA's Office of Criminal Investigations known to us in FDA as OCI, along with our regulatory partners and other federal, state and local law enforcement agencies are working together in a way that I've not seen in my near 30 years in law enforcement. It is truly an all hands on deck approach. The internet has truly transformed our lives.

[\(00:26:18\)](#):

I started my career right as the internet began to reach inside our homes. Remember that harmonic buzz of a dial-up modem? I do. The first cyber investigations I worked as an agent with US Customs involved the online sale of child pornography. Back then, we were ahead of the criminals who pedaled these horrific images online. Domain names had real subscriber information. IP addresses could be traced to users and payments flowed through financial systems with robust anti-money laundering controls. When I came to FDA in 2005, our team employed those same tools and techniques to investigate and prosecute illegal online pharmacy networks. Yet as cyber criminals have become more sophisticated, our legal tools and investigative resources have lagged and today remain wholly inadequate. On top of that, there's no federal level regulatory system in place for online pharmacies. In fact, an online pharmacy today is regulated as about as much as the medical charlatans pedaling snake oil from covered wagons in the Wild West.

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I have witnessed firsthand over my career our ability to detect and ultimately hold responsible persons profiting from the sale of illicit substances eroded, cryptocurrency, the use of dynamic IP addressing, cloud computing, darknets encryption. All the legitimate tools used to promote secure computing are also used by bad actors who operate globally with impunity. And unlike traditional organized crime, illicit online pharmacy networks are a patchwork of individuals who most likely have never met, a perfect storm feeding this addiction crisis. So now more than ever, we must rely on voluntary compliance in good corporate citizens to ensure online platforms aren't used to harm others. Despite these challenges, OCI and the Cyber Crime Investigations Unit, I know Jake and Sean are on right now, and Nicole, have been working for a number of years to disrupt and dismantle online marketplaces,

vendors, and networks that are manufacturing and selling counterfeit misbranded and unapproved drugs to Americans.

[\(00:28:32\)](#):

And many of these drugs pose a significant risk of overdose. OCI's internet investigative efforts, including a dark web initiative targeting counterfeit drugs, the Operation Wild Wild Web has led to the arrest of 275 individuals, 224 convictions, as well as the seizure of drug counterfeiting tools, counterfeit drugs, and over \$59 million in virtual currencies and other assets. Our cyber agents also monitor the surface web and social media to identify sellers of counterfeit FDA regulated products. Cybercrime agents can swiftly make undercover purchases from online merchants selling pills suspected to be counterfeit or substandard. OCI is also a key member of the Department of Justice's Joint Criminal Opioid and Darknet Enforcement Task Force known as J-CODE. It's a mouthful. J-CODE is part of the all hands on deck approach I mentioned, comprised of many federal law enforcement agencies working together to combat the opioid crisis on the darknet.

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Operation SpecTor depicted in this slide is an example of this cooperative approach. Last year, a case led by OCI received J-CODE's case of the year, dubbed the Undertaker 45 case. It resulted in the seizure of approximately three kilograms of counterfeit pills, \$450,000 in virtual currency and bank accounts, and the arrest of three suspects. The pills were counterfeited to represent FDA approved versions of Oxycontin, Adderall, and Xanax, but found to contain fentanyl, methamphetamine, and alprazolam derivatives. The OCI team selection is a testament to their innovative strategies and collaborative spirit. For every online purchase, a package is sent often through international mail facilities. There, FDA investigators and special agents use sophisticated tools developed by scientists from our forensic chemistry center to rapidly screen suspect products and packaging to assess pharmaceuticals offered for entry. Additionally, OCI works with our foreign counterparts to coordinate international criminal investigations. We have agents posted at Europol and London, and we recently worked with authorities in Kenya and Uganda to target violative shipments of health products encountered via their postal in air cargo in those countries.

[\(00:30:53\)](#):

A recent joint operation in the UK [inaudible 00:30:56] Operation Ancord examined over 900 parcels containing medicines, devices, veterinary products and cosmetics. Importantly, intelligence about online sources of these parcels was shared with OCI's Cyber Unit. I also chair the Permanent Forum on international Pharmaceutical Crime, which is a global working group among foreign agencies that share our unique public health and law enforcement mission. Aim to position our agents to act nimbly to investigate transnational crime. So I'll leave you with a final story from the trenches. This May, OCI along with our federal law enforcement partners, announced the take-down of a major darknet market and the arrest of its owner, Rui-Siang Lin of Taiwan. He used the identity of Pharaoh to operate incognito market. Incognito market was an online drug marketplace that existed on the dark web since October 2020. Since that time, and through its closing in March, incognito market sold more than a hundred million dollars of drugs, including counterfeit versions of FDA approved medicines.

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Incognito Market was designed to foster seamless transactions across the internet and across the world, and incorporated many features of legitimate e-commerce, such as branding, advertising, and customer service. After logging in with a unique username and password, users were able to search thousands of listings for narcotics as well as listings for prescription medication that was advertised as being authentic but was not. For example, in November 2023, an undercover OCI agent received several tablets that

purported to be oxycodone. Testing by FDA's Forensic Chemistry Center, revealed that they were not authentic oxycodone at all, and in fact, were fentanyl pills. In exchange for selling on incognito market, each vendor paid 5% of the purchase price to Lin. To facilitate these financial transactions, Lin operated a bank which allowed its users to deposit cryptocurrency on the site into their own accounts. After a transaction was completed, cryptocurrency from the buyer's account was transferred to the seller's account, less the 5% fee.

[\(00:33:10\)](#):

The bank enabled buyers and sellers to stay anonymous from each other. Well, not really. In March of this year, incognito pulled an exit scam, stealing millions from the bank, and decided to blackmail its vendors saying it would release the purchase records of vendors who refuse to pay to keep the records confidential. You can see here they say, "We got one final little nasty surprise for you all. We have accumulated a list of private messages, transaction info, and other 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. Surprise, surprise. Whether or not you and your customer's info is on that list is totally up to you," they said.

[\(00:33:58\)](#):

"And yes, this is extortion."

[\(00:34:01\)](#):

There really is no honor among thieves. Yet another example of heartlessness are drug additives like Xylazine and medetomidine, which are non-opioid sedatives, and their effects cannot be reversed by naloxone. In 2023, FDA took actions to restrict imports of xylazine, and we are working with other federal and state agencies to identify similar emerging threats. Look, we at FDA and at OCI are ever mindful that persons suffering from addiction are continually victimized, and the crimes that we investigate from substandard, counterfeit, adulterated, tampered with or stolen medical products are greedy and heartless. Any one of us from young to old can fall victim. And I remain hopeful that meetings like this between government and industry will help foster a true spirit of cooperation in his shared goal to protect public health.

[\(00:34:58\)](#):

So with that, Susan, I'll turn it over to you. Thank you.

Susan Winckler [\(00:35:01\)](#):

Excellent. Thanks so much, Dan. It's always helpful to have an illustration of what can be done from the federal government perspective and what has been done, recognizing that as we get further into this meeting, this is not a challenge that we can address solely from an enforcement posture. We need a broader public health approach. So thank you so much to both you, Chief Burke and to Dr. Verbois for providing that FDA overview. We want to turn now to ground us in the impact of this activity on the lives of individuals and families across the nation and across the globe.

Session 2: Perspectives from the Real World

Presenters

Coreen Johnson, Senior Project Coordinator, Young People in Recovery

Chris Wilks, PhD, MPA, Senior Consultant, Health Management Associates

Susan Winckler ([00:35:44](#)):

So our next speakers will share their experiences and what they have learned about the personal impact of this activity because it's one thing to think and talk about the numbers and the financial component, but there is a real public health impact at issue here. So I'm thrilled Coreen Johnson is joining us. Coreen, thank you so much for joining us today to share your perspectives. We're looking forward to hearing more from you. I also have to thank you for your day job in serving as a senior project coordinator at Young People in Recovery. So I'll turn it to you to share some thoughts.

Coreen Johnson ([00:36:28](#)):

Yeah. Thank you so much. Like introduced, my name is Coreen Johnson. I am the senior project coordinator for a nonprofit grassroots organization, Young People in Recovery. YPR envisions a world folks where everyone has the resources and access to those resources that they need to thrive in recovery from drugs and alcohol. So thankful to be here. I think this is an absolutely important topic. As you know, we all are really just in this world, and those of us who are utilizing substances get those substances from any which direction that we can.

([00:37:15](#)):

So the risk, folks. The risk of purchasing substances online. First of all, with any type of illegal substances that we purchase, whether in person meeting in public, finding those substances online, there's legal consequences of course. Most importantly, let's really dive into the health risks and the self-harm risks. Contamination is huge, incorrect dosage, unknown ingredients. And let's look at really the safety concerns that are involved around purchasing substances that we don't see directly from a pharmacist.

([00:38:02](#)):

Safety concerns, so the quality there. Buying controlled substances is illegal. Its potential legal action for us really can hinder our future. Let me tell you, as a person in recovery, myself, being involved in the legal system when I was younger, really paved a path of uncertainty for me and my career. As I am fully in my career now, thankfully, I was able to get over those mountains that I created for myself. But let's keep in mind that criminal charges do follow us.

([00:38:43](#)):

So with the health risks, the contamination of substances, we never know what we are getting, point-blank, unless we see it come directly from a pharmacist. So focusing on substances that are pharmaceutical as well as substances that are illegal. We do not know what is in illegal substances. So when we resort to purchasing substances online over different platforms, and I will talk about those platforms shortly, we are really putting ourselves at risk. And folks, most of us are aware of the overdose epidemic that's happening here in our country. Unregulated dosages increase the risk of overdose. Meaning if we are not, and I say this a lot, getting our substances from a pharmacist, we are increasing our chance of overdose risk. There's also a lack of medical oversight. Making sure that we are communicating with our doctors is so, so, so important. That is going to reduce that risk of harm.

([00:40:15](#)):

So it is my understanding that the dark web marketplaces are pretty easy to access. So I wanted to share just a quick little tidbit. So my son, he is 24 and because I am open with my recovery, he has felt comfortable being open with his substance use and therefore we led him... He led himself rather. But I like to take a part of that into recovery himself. So I spoke to him a little bit about gaining some real world knowledge about accessing substances online. So let me just read to you what he wrote to me.

([00:41:00](#)):

He says, "I think buying drugs online is really scary and it can be laced with anything. And people make up face profiles on these online platforms that you don't really ever know who they are. You could be dealing with the police. You could be dealing with people who have ill intentions. You could be dealing with people that really are just set out to make money and you just never know." He said also, "A lot of people will post online and tell their friends, and that's how one person gets big and that's how minors get involved." He said people also sell it on the black market in large containers and vacuum seal those drugs, and ship them through the different services that one can ship through."

[\(00:41:58\)](#):

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

[\(00:42:41\)](#):

So transactions, typically use cryptocurrencies, for example, Bitcoin, and this helps maintain that anonymity. Again, I think that really personally and professionally, this has a lot to do with shame. If we as a community really look at those risks of scam, of law enforcement, of really increasing our overdose chances, we need to be able to utilize the area of breaking down stigmas so that folks are not feeling ashamed.

[\(00:43:24\)](#):

Social media is another platform. Instagram, Snapchat, WhatsApp, Telegram, and other encrypted messaging apps. These communications happen from the seller to the buyer in a direct form where they can usually then utilize those different messaging apps. Again, the risk here is scamming law enforcement and those different. When I was in my active substance use, Reddit was not available. However, there was Myspace, and I dove into Myspace. I utilized Myspace to meet people in my area that I was seeking substances from. And let me tell you, I put myself in some very unsafe situations. Meeting people in the community that I had no idea who they were. Oftentimes, they did not match their profile picture. So [inaudible 00:44:37] online communities, we really need to be aware of them and the consequences that we are setting ourselves up to face.

[\(00:44:51\)](#):

So speaking of those safer alternatives, because I've really pointed out the risk factor involved here. Focusing on reducing stigma is going to be key to alleviating some of these harsher consequences that folks are facing when purchasing both what they feel are prescription type substances and illegal substances online. Seeking support from healthcare providers or counselors, that's hard to do. We as the community, especially the foundation here that we're speaking for, we all really need to be working on providing a safety net for folks who are using substances. Breaking down those stigmas, meaning changing the language that we're utilizing. One of the biggest terminologies that I hear is the word abuse. If we could just shift that connotation a little bit to utilizing the word use, and person first language, those are two steps that we all as community members, as people in recovery, as allies to recovery and people who are working in this field, just making those two shifts is going to help immensely.

[\(00:46:26\)](#):

And let me point out this last bulletin point, harm reduction. Harm reduction approaches such as there's a hotline out there called Never Use Alone. Folks, if you are going to be purchasing substances from the internet, and again, I'm highly discouraging you from doing that, but please always carry Narcan and

always use that Never Use Alone hotline. They will come up with a safety for you. They will get you support groups and help you engage with those support groups. There's also licensed pharmacies out there. Please, I beg you, utilize those.

[\(00:47:08\)](#):

This is my contact information if you have any questions. YPR offers free recovery support services where we welcome all pathways to recovery. And you do not have to be 100% abstinent from substances to get our free services. So please do reach out. We are all about breaking stigmas. We are all about welcoming anyone. And yes, it does say young, but there is no emphasis on the word young. All age populations are welcome. Again, I just want to say thank you all for your time, for your interest in being here, and really for putting this together. This is such an important topic and education is key. Thank you, Susan.

Susan Winckler [\(00:48:02\)](#):

Coreen, that was so helpful from the reminder to talk about this in use and grounding us in why individuals might not only use these mechanisms, but also inherently trust them for many things and think through and say, "Well, why wouldn't I hear?" So you've given us so much to think about and incorporate into our conversation of as we think about how do we decrease the demand, how do we support the individuals in their use? And then I just do have to say, I am that mom who gives Narcan as a hostess gift because I think that we should all have it in our cars in the glove compartment, just in case one of the things that we hope we never have to use, but we have it available.

[\(00:49:02\)](#):

So we have one additional speaker in this session, and so I want to welcome to the stage now... We'll transition to hear from Dr. Chris Wilks. Dr. Wilks is a senior consultant at Health Management Associates, and she conducted a series of interviews with people in local communities to gain insight into those local perspectives and challenges. So Dr. Wilks, it's hard to follow Coreen, but would you pick that up and help us learn some more in this stage?

Dr. Chris Wilks [\(00:49:35\)](#):

Thank you so much, Susan. Hi again, everyone. Yes, hard to follow Coreen. My name is Chris Wilks. As Susan mentioned, I identify as a black woman. I have brown skin that looks like river stones feel and roasting chestnut smell. I wear glasses over large expressive eyes, and without my glasses, I am unable to complete most activities of daily living. So they're my adaptive equipment. I am wearing a soft pink long sleeve blouse. So in August and September of last year, Leavitt partners supported the Reagan-Udall Foundation for FDA in understanding the landscape around online purchasing of controlled substances. So that's what Coreen was talking about. That's what we've all been talking about today. And we did conduct six interviews and they included individuals who interact directly with known users of controlled substances, or individuals who worked in related fields. So over the next few minutes, I'll share some takeaways from those conversations using de-identified quotes.

[\(00:50:50\)](#):

So just a quick note of where these interviews took place. You can see that we had Utah, Colorado, Minnesota, Michigan, Ohio, and Maryland. So those are where our interviewees were from. So the content of the interviews covered four topics. One was motivation for purchasing control substances online. The second was around the logistics of access. The third was content related to safety. And fourth, were recommended interventions from our interviewees. And make a note that these findings

are not to be generalized, but I think to follow on what Coreen just shared with us, it's a clear indication that this is an issue that's popping up all over our nation and in need of our attention.

[\(00:51:40\)](#):

So first motivations, interviewees explained the possible reasons, and Coreen already mentioned some of these. So I'll just be re-emphasizing and underlining why someone would choose to purchase controlled substances online. One of the reasons is for recreation, demonstrated in the quote, "There are people who are partying who can use and go on with their lives." So these are casual users, people who may be earlier on the addiction continuum who are using online substance for recreation, and their motivation is to get party drugs.

[\(00:52:21\)](#):

Another is to find substances or drugs that they have been given legitimately as demonstrated by the quote, "People are typically pursuing the same drug they were prescribed." So in these scenarios, someone is given a legitimate prescription by a clinician and they were not able to obtain more through the healthcare system, and so they moved to purchasing online, and that's maybe pain medication that's highly regulated or perhaps they lost health insurance coverage and are not able to purchase their prescriptions. A third motivation is around a combination of secrecy, anonymity, stigma, and lowered risk of encountering law enforcement. In the third quote, one of the interviewees suggests, "The people in question here are likely suburbans. Street users don't go to an app." So the implication from this code is that individuals who are buying are, again, in the early part of the cycle of addiction. They're relatively stable and are motivated to purchase online because it's easier to hide their substance use and they can remain anonymous.

[\(00:53:42\)](#):

Other motivations we heard included self-substitution. So a long-time user, an individual who is addicted may be downshifting to a drug or controlled substance that they view as healthier or better from them than the one they previously use. There's medication shortages as a motivation. Also, we heard about favorable side effects from some of our younger people, college students. So someone may want a weight loss side effect that substance might have. And then the other is motivation is a distribution intermediary. So that's from the seller side. So an individual who sells controlled substances may be trying to get a supply that they can then redistribute to their own customers.

[\(00:54:38\)](#):

So this slide is about factors that facilitate online purchases. So the quotes on the slide speak to that. They include the lack of hurdles in online purchasing, it being part of a generational culture and the multi-platform transaction process that makes it hard for to be tracked. So the first quote says, "Buyers don't have to have therapy. There are all these hoops you have to jump through financial or social to get therapy." The implication is that the ease, the convenience and the speed of online purchases are factors that facilitate access and relatedly that the lack of mental health workforce, and the inability of some to obtain legal support for their issues may direct them to purchase online.

[\(00:55:36\)](#):

One interviewee also mentioned that, "Social media is the way kids are interacting, so it's the way they're going to interact around drugs." So social media is in fabric of our current culture. Coreen mentioned this. In this scenario, the culture of interacting online and the know-how that comes with navigating apps and platforms are facilitators of access.

[\(00:56:02\)](#):

Another interviewee notes, "It is rare that a transaction is happening entirely on one platform." So transactions take place across multiple applications or platforms. The initial exchange may occur on one platform, a verification of the buyer and the seller's identity may occur on a second platform. And then the actual exchange of payment using Bitcoin, and the delivery address occurs on a third platform. So that transaction helps to facilitate some secrecy and protection for individuals who are buying and selling, which is another facilitator of access. Others include inconsistent and poorly enforced policies, or workarounds that individuals have found, such as using alternate language to refer to the substances and the people selling them so that they don't get blocked by algorithms. Another facilitator are the algorithms themselves. So if you perform a search on the algorithm, we'll try to bring more of the things to you that you're looking for. And then the encryption is another facilitator that we heard about.

[\(00:57:24\)](#):

Moving on to safety on the next slide. So interviewees talked about safety considerations, and the quotes we share here recognize the distinctions in the kinds of people who are purchasing online and in their different relationships to safety and their safety concerns. One quote reads, "People who are involved in addiction are concerned about the drugs, but they are never concerned about the danger." This quote is about individuals who have moved through the last stages of addiction and may be unable to stop the use of substances without support.

[\(00:58:06\)](#):

So the second quote applies to buyers or individuals who may be concerned about risks and safety, but who inaccurately believe they have taken the appropriate precautions. This quote reads, "Social media provides legitimacy. They're able to use the mechanisms to vet." So because a seller or a plug may be part of your network, or connected to a friend of a friend because they have a photo and a profile and a huge number of followers, a buyer may have a false sense of security around the safety of the substances they're purchasing.

[\(00:58:51\)](#):

The third quote is about another group of potential buyers. It reads, "There are some people who are absolutely unaware of the risks. They're unable to protect themselves because of the easy access." And this third group of individuals who are purchasing are not even aware that there are high risks, that there's a chance of a fentanyl overdose, that the things they're buying may be adulterated. So the discussions from interviewees around safety considerations shows the broad gamut of individuals and what their needs might be.

[\(00:59:32\)](#):

On the next slide, we talk a little bit about interventions from quotes from interviewees. So the first reads, "Even the illicit market, there's a lot of peer-miseducation," and we heard this with previous speakers. The implication is that there's room to get the correct information out there to those who need to hear it or read it from sources they trust. The second quote reads, "The person selling may not know what they're selling. They got a reasonable bulk purchase on the dark net." The implication here is that sellers may need as much education as buyers. We recognize that some sellers don't care, but others do. The final quote here reads, "Always center and focus on the patient or client. Educate them so they're more equipped." This quote, like the other two, seem to suggest that they're gains that we can make from getting the right information out there.

[\(01:00:39\)](#):

Other suggestions from interviewees include increasing harm reduction campaigns. We heard that from Dr. Califf. Educating parents on safety risks, leveraging social media, influencers for education, recommendations about obtaining legitimate access to controlled substances when they're needed,

addressing drug shortages, and aiming information towards people who are buying so that they have the correct information with which to make decisions.

[\(01:01:13\)](#):

Thank you all so much for the opportunity to share some of these perspectives from people who are either working with buyers of substances, or who are in associated fields. And I look forward to hearing the remaining presentations and to the conversations that follow. Back to you, Susan.

Susan Winckler [\(01:01:34\)](#):

Chris, that was so helpful in adding to Coreen's presentation and providing the words, the power of the reflection and the thoughts. And then what helpful recommendations for us to consider in the language that we use, in the speaking that we do, or the messengers who we might use. And addressing some of the broader factors that may drive individuals to seek out other ways to access to controlled substances. So thank you for that in helping us have truly a visualization of the challenge that we're trying to address. So with that, we'll go to our next session, which I would say moves a bit from the qualitative to the quantitative.

Session 3: Online Availability of Controlled Substances: A Snapshot

Presenters

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

Justin Macy, PharmD, JD, Chair of Alliance for Safe Online Pharmacies (ASOP) Global Foundation

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

Reactor Panelists

Kait Brown, PharmD, DABT, Clinical Managing Director, America's Poison Centers

Sean Fearn, Chief, DEA Community Outreach & Prevention Support, Office of Public Affairs

Susan Winckler [\(01:02:29\)](#):

So while we've been focusing on an illustration and the words and the picture, what might drive the use here, we now want to turn to some additional components of research. And particularly, we will be hearing from three different researchers to provide a snapshot about what's happening in the online availability of controlled substances. And then we'll bring in two additional folks and we'll have a moderated panel discussion among those five individuals.

[\(01:03:05\)](#):

So to kick us off, I'm first going to turn to Dr. Murray Aitken, who is executive director at the IQVIA Institute for Human Data Science. Dr. Aitken, I know you are going to talk to us about transactions through illegal online pharmacies, or I think IOP is the abbreviation that we're going to see on your slides. So I'm going to step away so that we can bring you to the stage, and learn from you. I'll turn it to you.

Murray Aitken [\(01:03:36\)](#):

Thank you, Susan. But thank you also for two Reagan-Udall Foundation for this opportunity to discuss this important issue and for the opportunity to share with you some of the research that we've been doing at the IQVIA Institute in collaboration with IE University in Spain and Translucent DataLab. So I'm going to be focused on the perspective that we have on controlled substances that are available to Americans and being provided to them through illegal online pharmacies. And this view is based on

novel advanced analytical modeling that's powered by artificial intelligence. It was originally developed at the IE University in Spain through a grant from the European Research Council, and it's been further developed through a collaboration between Translucent DataLab and the IQVIA Institute for Human Data Science. And I'm pleased to represent both those organizations in this session today.

[\(01:04:47\)](#):

I'm going to give a brief overview of the methodology that has been developed and how this enables us to map the universe of unregistered pharmacies that Americans are ordering controlled substances from. And we can see the volume of drugs that are flowing through this channel. I'll then show some of our snapshot views of what's going on and the impact that these medicines are having on Americans. So to begin with a brief description of the methodology, and basically this is about applying big data techniques and multiple proprietary AI-based algorithms to develop this novel view of IOP activity. And in this case for today, specifically looking at how controlled substances are being accessed through that channel.

[\(01:05:46\)](#):

So I just want to spend a couple of minutes on the methodology with... We have more explanation of this in a report that we put into the public domain last year, but just to briefly orient everyone to what's going on here. First off, this starts with identifying the domains or websites that appear typically in Google searches based on the keywords that people enter that drives traffic to the pharmacies that are included in the National Association of Boards of Pharmacy list of illegal online pharmacies. So that's the starting point to identify the keywords that are typically used in those searches. And of course, those are typically the names of the drugs that people are searching for.

[\(01:06:43\)](#):

There's then a series of iterative steps to scrape the text from these domains to identify links between these domains and others, and to classify the domains as IOPs as appropriate. That data that's generated, can then be used to map the network of the identified IOPs where each pharmacy is a node in the network and a hyperlink from one domain to another is a directional network tie. And by looking at this, we can see the structure of this network of pharmacies. And about 1/3 of all the IOPs are structured around a central cluster with densely tied IOP accounts forming a network around that cluster. The remaining IOPs are part of a vast periphery, composed of loosely linked or even isolated IOPs. So again, our methodology has enabled us to paint the picture of the landscape of these IOPs.

[\(01:07:59\)](#):

Then the second step is to take those domains and use internet traffic analytics data that's obtained from a third party to estimate each domain's monthly visits. So how many people are going to those sites? So there, we know how many people are going to the site, they're searching for something, but we don't know if they're buying. So we have to calculate a conversion rate for each visit. And we do that by placing orders, which I should quickly point out are subsequently canceled. So they're not filled orders, but they are placed orders. And we do that for a sample of sites on a periodic basis. And then we use the difference in the order numbers relative to the number of visits to the site to calculate that conversion factor.

[\(01:08:51\)](#):

And then we apply that based on an algorithm that's trained with conversion rate data for different types of websites and searches. And that gives us the basis for determining the volume of purchases that are going across all the identified IOPs. We then match the names of the drugs or the molecules to IQVIA's National Prescription Audit master data, and then we use a series of calculations to estimate

each drug's sales. So I realize I've given a very simplified high-level view here, but it is one that we have validated where possible, and we have continued to refine this over the past three years.

[\(01:09:39\)](#):

One important caveat, we're only looking at activity occurring in pharmacies through e-commerce domains. So therefore, we're not looking at social media. We're not looking at the dark web, which we know are also active sources for these controlled substances. I should also note, relative to the earlier conversations that we cannot know the source of the drugs that are being provided through the IOPs, whether it's a diverted, falsified, counterfeit, substandard in some way. We only know that the patient is receiving the drug from an online pharmacy that is not registered to do business in the United States.

[\(01:10:22\)](#):

So what are we seeing in terms of current activity and trends? So we have taken a set of specific controlled substances listed here, 38 molecules, and we've extracted the data for those molecules through March of 2024. First, we start with the availability of controlled substances in illegal online pharmacies. So here, we're showing in the light blue bars the total number of active IOPs in each month, so over the past 15 months, it's fluctuated between about 14,000 and 18,000 sites, about 15,000 in March. And of those total IOPs, the dark blue bar shows the number that are selling one or more of those controlled substances I just showed. So that represents about 25% of the total, or three to 4,000 sites. Again, there are different ways to measure these numbers, but this is the consistent way that we're looking at it based on our modeling.

[\(01:11:39\)](#):

So how much volume of controlled substances is going through these IOPs? So we convert all our metrics to prescriptions. So obviously in most cases, there is not an actual prescription written by a doctor, but for the sake of simplicity, we talk about them as if they were prescriptions. So what we're showing here, the number of controlled substances, prescriptions we estimate being provided from IOPs, so about 300,000 in January of 2023 and over 750,000 in March of this year. For the 12 months of 2023, the total was about 4.1 million prescriptions. That represents about 2%, just over 2% of the volume that's going through legal pharmacy channels as tracked by IQVIA's National Prescription Audit. Again, we can interpret that number as we wish, but the other takeaway from this chart is just actually to see the fairly significant increase we've seen just in the past three months. We're a little careful not to draw too broad a conclusion until we have a little bit more data around this year, but certainly the overall trend line we're showing here is moving in the wrong direction in terms of that increase.

[\(01:13:11\)](#):

In addition to tracking the volume of controlled substances flowing through the IOPs, we've also done some modeling on the impact that this has on triggering incremental adverse events. And again, I don't have the time to explain the methodology behind this, but it's broadly based on looking at reported adverse events from the FDA's FAERS database and establishing correlations with the relative IOP-sourced volume for each of the molecule that shows up in the FAERS data set. And what we've found is a very high correlation. The greater the relative number of drugs being sourced from IOPs, the higher the level of adverse events. And this of course could be because patient's not under the care of a healthcare professional, they're taking drugs that have not been prescribed for them, or indeed, the drugs are of substandard quality.

[\(01:14:07\)](#):

So we've looked at this for the controlled substances molecules and see that drugs sold through IOPs generate around eight times more adverse drug reactions than those sold through regular pharmacies.

This translates into incremental healthcare costs, about 40 to \$50 million per month or about half a billion dollars annually.

[\(01:14:34\)](#):

Let me quickly show some more aggregate views of the volumes involving controlled substances. Here we're showing the molecules with the highest IOP sales volume based on their average monthly numbers over the past 15 months. So testosterone has by far the highest volume of the molecules I showed previously, over 300,000 monthly prescriptions, followed by Diazepam, Valium, and Alprazolam, Xanax coming third. You can see others at lower level volumes but still significant, and confirming patients are accessing these drugs through these IOPs.

[\(01:15:17\)](#):

We also know the numbers fluctuate month to month, and this can be because there are programs to shut down or disrupt the IOPs as we've heard about, so tackling the supply of drugs, there's also more demand driven programs that are put in place. So here, we're showing the average monthly volume growth from the beginning of '23 until March of this year, some molecules more significant than others. Diazepam Clonazepam both up 20%, morphine up 15%. Also notable to see ketamine down 23% where we know there has been a lot of activity.

[\(01:16:02\)](#):

Being able to look at these monthly volumes and change also lets us see the impact of interventions by the FDA or DEA or others. So here, we're looking at the trends since the introduction of the One Pill Can Kill initiative from DEA that launched in September, 2021. And you can see here the trends in the volume of IOP sales for controlled substances, that's the dark blue line, for all other drugs in light blue, and then specifically for fentanyl, which again, we know is a big focus of this initiative where we're tracking here an 80% reduction in the volume of fentanyl IOP sales through the end of February.

[\(01:16:51\)](#):

So there's many factors of course at play. I hope that this is helpful to just give a snapshot of what we're seeing from our novel approach to monitoring this and estimating the volume that's flowing through these IOPs. And with that, I'll turn it back to you, Susan. Thank you.

Susan Winckler [\(01:17:12\)](#):

Excellent. Thanks so much, Murray. It's so interesting to see the data and the fluctuations in that, and we'll welcome you back after the next two presenters for a bit of discussion about that, so thank you so much for sharing that insight. I want to turn to our second presenter in this session who is Dr. Justin Macy, who serves as the chair of the Alliance for Safe Online Pharmacies Global Foundation, and as director of innovation for the National Association of Boards of Pharmacy. Dr. Macy, we are so interested in hearing what you've learned about consumer perspectives and the use of online pharmacies, so we'll turn it to you.

Dr. Justin Macy [\(01:17:56\)](#):

Thank you so much, Susan, and thanks everyone for having us here today as well. So yes, I'm here today wearing two hats. First, the ASOP Global Foundation and as well as the National Association of Boards of Pharmacy, so just by way of background, I'll give some information on both of these organizations.

[\(01:18:13\)](#):

Aesop has two actual organizations, so maybe this is a two point fiver. So you've got Aesop Global. They're a nonprofit. They do a lot of the advocacy work, education, and ultimately, they're trying to

ensure the safe access to medication and combating illegal online drug sellers, generally speaking. Aesop Global Foundation is a charitable 501(c)(3), more dedicated to research, not part of advocacy, also trying to educate and create education programs and research on the same topic. So some natural corollary there. I'm the chair of the Aesop Global Foundation and that's who I'm representing today.

[\(01:18:52\)](#):

Likewise, I'm also with the National Association of Boards of Pharmacy. It looks like as far as the NABP or the National Association of Boards of Pharmacy goes, we are the nonprofit that represents the state regulators. So sometimes there's some confusion about who exactly or representing or what our role is. We facilitate things across state lines for those state regulators to help them in their practice of regulating the actual profession of pharmacy as well as the supply chain in general. Generally speaking, as you can imagine, 51 jurisdictions. It probably doesn't make a lot of sense individually to tackle the internet, so for a long time now, since '99, we've been involved here.

[\(01:19:34\)](#):

So I'm going to go ahead and give some more information here at this point. So at a high level, we estimate that there's about 40,000 active illegal online pharmacies. You saw from Murray a slight difference in those numbers. That's more of a difference in our calculations and definitions. When we think of an active illegal online pharmacy, we think of the broader definition that we use for our not recommended list, which includes anyone selling or facilitating the sale of medication, prescription-only medication.

[\(01:20:01\)](#):

And they usually have to violate one of the big three. One, no prescription required. 95% over the last 10 years that we looked at that as a study didn't require a prescription, selling drugs that are not approved or have the appropriate market authorization in the US, and lastly, selling without the appropriate licensure that's required to facilitate those sales. 54% of those websites that are on the not recommended list, which confusingly, also around 40,000 websites on the not recommended list, not all of those are active. 54% of those websites sell controlled substances at our time of review. Again, we look at different controlled substances than Murray, so our numbers and conversations that we've had previously actually are very aligned in these cases.

[\(01:20:47\)](#):

And then we estimate that about 20 illegal online pharmacies go live globally every day. That's retrospectively calculated based on the domain names being created.

[\(01:20:56\)](#):

ASOP Global Foundation has done research about consumer sentiment, specifically a 1500 person survey in 2023. Likewise, there are previous surveys so we have some longitudinal data as well. From the most recent survey, 54% of Americans have previously purchased from an online pharmacy. Of those, 85% currently use an online pharmacy to fill at least one prescription, 61 use it for the majority, or rather most, and 71% of them started in the last one to three years. So our takeaway from this is not only is there a growing trend to buy things online, generally speaking, but also pharmaceuticals, but during COVID, it probably increased dramatically, and it's pretty sticky. Once you get there, you're likely going to continue.

[\(01:21:42\)](#):

Big baseline question, why buy drugs online? And I think we've covered this a little bit already, but cost and convenience. That is from our representative sample also completely aligned here as well. Likewise, you also have drug shortages or products being out of stock. And to piggyback on some former IQVIA

data as well in talking about COVID, we talked specifically here about telehealth visits and the increase of those telehealth visits for mental health disorders. And so you can see that visits for ADHD, of which controlled substances are the primary modality for therapy, rose by 21% during COVID.

[\(01:22:19\)](#):

And you can see that data compared to other things like depression, hypertension, diabetes, HIV, AIDS, pretty simple. If it's something that doesn't need to be seen in person or you could diagnose over a phone call rather than something where you're primarily doing qualitative discussions for that diagnosis, you saw a large spike in online prescribing for those products during COVID, specifically ADHD products, 9.4% increase in those prescriptions. A separate report showed an increase by about 15% during that same period of time, so we all are aligned in the relative change to it. Overall, for all mental health disorders, you've got about a 7.6 increase in 2020 and 5.5 in 2021.

[\(01:23:10\)](#):

So why does this matter? Ultimately, this matters because generally speaking, this has an impact across the board. So last month, this is a telehealth provider that FDA and CDC put out a warning for or an alert for last month that was indicted. This indictment actually charges the corporate executives with the possibility of 20 years in prison for criminal charges. And I will flag, this is not the type of scenario where we would typically think of them, someone we would qualify as a not recommended list. They were licensed, they had pharmacies, they had providers, but the actual fulfillment of these services was fraudulent, or at least alleged was fraudulent. They allegedly weren't engaged in full patient evaluations. They had tactics that were deceptive on social media and other systems.

[\(01:24:11\)](#):

So this is even a scenario where you have a licensed actor. At the time, they were accredited, not by NABP but they were accredited for the social media advertising that took place and existed, and they infiltrated that system. So if you're thinking about this from a consumer perspective, this checks all the boxes, it has all the safety precautions but still ended up being a problem. This warning specifically was intended to a flag to other healthcare providers, that between 30 and 50,000 patients of this telemedicine firm may be needing to get into care of some sort. Some of them may have legitimate diagnoses and needs. Some of them may not based on the alleged crime that may or may not have occurred. Ultimately, at the end of the day, this is the exact thing. If we can't get this part of it right, then it's really hard to do the rest.

[\(01:25:03\)](#):

It's really easy for me to say this as a Monday morning quarterbacking, so I wanted to show this slide here that we actually generated and created in 2022 and provided, ultimately showing the risks that ended up being similar here, the first being that a lot of these telemedicine startups that came about during COVID were pushing controlled substances. They used subscription-based models, which also means as a result that it has more regulators who are invested in this issue, which as mentioned by Lee earlier, it's going to take a village. Having subscription models and different components of it just means there's more authority for that village as well. Primarily use social media advertising very, very aggressively, and had lots and lots of publicly available complaints. When we published this, there was a congressional investigation, a DEA investigation, Department of Justice investigation and an FDC investigation into different entities that were included here. And we weren't the only ones. You can see all of these headlines that actually existed from 2022, but you'll notice that indictment went out last month, and so this problem persisted for that amount of time and existed on that area.

[\(01:26:15\)](#):

So when we're talking about shooting back to consumer sentiment and why these things matter, consumers are going to the internet and they think that 54% of all the websites that are offering care have been approved by the FDA or our members, the state regulators. That number is even higher for those who have actually used online pharmacies previously. We know that is obviously not true. 44% of Americans believe that online pharmacies do not need a prescription from a healthcare provider. That's in part as well because of some of that advertising that we've seen. We've seen telemedicine firms advertise, no prescription required, right? And in theory, if doing it legally and compliantly, they're issuing a prescription as part of their patient consultation and their intake before actually handing off that prescription to a pharmacy, but that still is probably increasing consumer confusion about what's going on in this process. As we've talked to several, quite frankly, consumers on our end that have had that same confusion.

[\(01:27:13\)](#):

And then lastly here, 47% of Americans believe that whatever they see on that first page of search engine results is verified and is allowed to do that. Again, if we talk specifically to people who have bought from online pharmacies before, 61%. So always, you're seeing an increase, and as that's becoming a higher number, that becomes dangerously scary to us.

[\(01:27:36\)](#):

So as far as what we've seen as trends as well, when we're thinking about the harms, if we ask people, have you directly had an experience or someone in your immediate direct family had an experience with harmful, counterfeit or substandard medication? 24%, one in four. That's a seven-point increase since 2021, so about a third increase.

[\(01:27:58\)](#):

If we contrast that to another question we ask, describing whether or not purchasing medication online is too risky or risky at all, you see that 43% people say that it's not, which is actually a 12% increase. So people are experiencing more adverse events and simultaneously believing that it's safer and safer than it has been historically.

[\(01:28:21\)](#):

A couple of other notes here, we have put up the Bad Meds campaign that's put in partnership with ASOP Global Foundation as well as NAAP. You can see Danny Trejo came in and really helped out in putting this together. This PSA is available. I wanted to share that the DEA has also made statements specifically about cartels utilizing technology platforms as part of their actual operations and requesting assistance. And I wanted to leave just with the idea that overall, this probably isn't going away, whether it's creative criminals using Eventbrite, not something I would've immediately thought of, or it's rolling stone covering this, or the surgeon general asking for warning labels. This is probably going to be a reoccurring problem. We've been at each online opioid summit, or previous opioid summit, now controlled substance summit. Historically, we think this is going to likely continue, and so we're desperately seeking that help. Thank you.

Susan Winckler [\(01:29:23\)](#):

Justin, so helpful to help us understand consumer perception about the facilities, or facilities thereof, but to think more about the licensure status and understanding. And even though we had some different definitions, there's some consistency in the numbers, so thank you for that component. I want to turn to our third presenter and then we'll come back for the broader conversation.

[\(01:29:50\)](#):

So our third presentation is coming to us from Dr. Angela Hoth, who is a research consultant here at the Reagan-Udall Foundation for the FDA, and she's going to provide us a fuller picture about how confident Americans are in making online purchases of controlled substances. So Dr. Hoth, we'll turn it to you.

Dr. Angie Hoth ([01:30:15](#)):

Well, thank you for the introduction, and I am excited to present the data collected by the foundation, and this was definitely a team effort. So to better understand the purchase of controlled substances online and through social media, the Reagan-Udall Foundation conducted a landscape assessment that included an in-depth literature search and social media evaluation. This preliminary research then informed design of questions posed in two omnibus polls and two virtual listening sessions. We aspire to answer three main questions. What is the current environment for purchasing controlled substances online? Who is making these purchases? And what motivates consumers to use online sources for controlled substances instead of obtaining these medications through licensed pharmacies?

([01:31:08](#)):

Today, I'm going to share with you the key findings from the social media evaluation, online polls and listening sessions. I'll then conclude with the main takeaways from the landscape analysis as a whole.

([01:31:20](#)):

So you heard a little bit already about the social media landscape. So one of our major findings was that consumers will begin transactions on one platform and then move to a second or third encrypted platform to finalize their purchase. Buyers using social media were generally under the age of 35 and able to complete purchases by having access to a smartphone, a good internet connection, and a payment method compatible with electronic purchases. Buyers also tended to be recreational drug users or individuals who had a legitimate prescription for a controlled substance at one time, but then lost access. Motivations for purchasing controlled substances via social media include recreational use, self-medication for either previously diagnosed or self-diagnosed conditions, weight loss as a side effect of stimulant medications, self-tapering by substituting a prescription controlled substance for a street drug, or purchasing for resale to peers.

([01:32:27](#)):

We then conducted two online polls to further learn about consumer knowledge and perceptions, and how they weighed risks and benefits when purchasing controlled substances online. The majority of respondents recognized the risks of buying medication online without a current prescription, but this was paired with a low confidence in their ability to evaluate a medication or an online environment's safety or legitimacy. Almost three-fourths of respondents thought it was somewhat or very risky to buy medication without a current prescription, and nearly the same percentage reported that buying a controlled substance online without a current prescription was even riskier.

([01:33:06](#)):

68 to 75% of respondents were not confident that the medication purchased online would contain the right ingredients or correct dosage amount, or if they could tell whether the medication was fake. Over half were also not confident that they could determine whether an online pharmacy was licensed.

([01:33:27](#)):

Some poll respondents would buy or consider buying a controlled substance without a prescription, even if they did not trust the online source. The top reasons provided included they were doing so because they were unable to obtain a prescription from a healthcare provider, they were unable to

afford the medication, or they were unable to fill the medication at a local licensed pharmacy. Convenience was also a factor for those respondents under the age of 40.

[\(01:33:56\)](#):

Age was the strongest indicator of the likelihood to consider online sources for medication without a current prescription. Looking at the blue portions of the bars, you can see that Americans under 40, and particularly those aged 30 to 39, were more likely to consider getting any prescription medication and a controlled substance online without a current prescription.

[\(01:34:17\)](#):

Respondents under 40, represented by the gold bars, had lower perceptions of risk compared to their older counterparts when considering the level of risk associated with purchasing any prescription medication or a controlled substance online, and were more likely to believe that it was neither more nor less risky to buy a controlled substance online as compared to non-scheduled drugs.

[\(01:34:44\)](#):

Next to age, race, and ethnicity also drove behaviors and perceptions of risk. Again, looking at the blue portions of the bars, you'll see that non-White respondents showed higher rates of buying or considering to buy prescription medications or controlled substances online without a prescription. Perceptions of risk also differed. White respondents were more likely to consider purchasing any prescription medication online as risky compared to non-White respondents. Black respondents considered purchasing a controlled substance online as riskier than respondents identifying as White or Hispanic.

[\(01:35:24\)](#):

Age and race and ethnicity also influenced confidence and judgment. In data not shown here, 89% of poll respondents considered it to be somewhat or very risky to buy a prescription medication from an unlicensed pharmacy. We also asked how confident they were in being able to tell if an online pharmacy was licensed. Looking at the green sections of the bars, consumers under the age of 50 and non-White respondents reported more confidence in being able to identify legitimate online pharmacies.

[\(01:35:57\)](#):

Similar patterns were seen when consumers were asked how confident they were that the medications obtained online were safe or whether they could determine whether a medication was fake. Though most of the respondents were not confident in their abilities, a higher proportion of respondents who were under the age of 50 and identified as Black or Hispanic expressed confidence in their abilities to make these determinations.

[\(01:36:22\)](#):

Finally, we hosted listening sessions to gain further insight into how consumers weigh risk and benefit when it comes to purchasing a controlled substance online without a prescription. These sessions confirmed some of the findings from the social media evaluation and polls, and provided additional insights into consumer perceptions and behaviors. Motivations were the same those mentioned earlier, and a number of participants reported having to visit multiple pharmacies in order to find the medication that they were prescribed, which they thought could then drive them to search online.

[\(01:36:57\)](#):

Participants did not perceive the online purchase of all prescription-controlled substances to be equally risky. Stimulants such as Adderall were considered to be a safer purchase. And to ensure that they received the correct medication or dosage, participants said that they would make sure that the medication they purchased online looked like what they had been previously taking, or they would

search online for verification by matching the medication to a picture or to tablet or capsule markings. And when asked how they would select a site for purchasing prescription medications online, most would turn to family and friends for recommendations. They would also use online reviews and consider advice from groups on social media.

[\(01:37:45\)](#):

So in conclusion, from the landscape analysis, we found that multiple platforms are being used for one transaction. Online buyers were more likely to be under the age of 40 and have access to a smartphone, internet and electronic payment systems. Recognition of risk is paired with a low confidence in one's ability to evaluate an online environment or a medication's safety or legitimate, but despite this low confidence in identifying risks, consumers would still opt for obtaining prescription-controlled substances online without a prescription, for the primary reasons of not being able to access the medication due to supply chain issues, cost, and being unable to obtain a prescription from a healthcare provider. Thank you.

Susan Winckler [\(01:38:34\)](#):

Dr. Hoth, thanks so much for that overview of the research and helping us further dig into this question, and how does this happen? And I'm so intrigued and hope that as we move to the reactor panel, we'll discuss a little bit about the, "Even though it may be risky, I'll still use it," and so what are some of the intersections of those drivers and the realities? So with that, let's turn to our discussion.

[\(01:39:02\)](#):

So for the second half here, we're going to add two new voices to our conversation, and particularly Dr. Kaitlyn Brown and Director Sean Fearn's will be joining us as reactor panelists to help us explore the information we just heard and contribute to a collective discussion. So I'll ask Dr. Brown, clinical managing director at America's Poison Centers, and Sean Fearn's, chief of the Drug Enforcement Administration's Community Outreach and Prevention Support in the Office of Public Affairs to come on camera, as well as all of our speakers for this session, so welcoming back, Murray, Angie, and Justin.

[\(01:39:44\)](#):

So let me first say to the voices that we haven't yet heard, Dr. Brown, help us think through those presentations that we just worked through. What did you hear and what would you like to underscore, or are there questions that you'd want to ask of Justin, Murray or Angie?

Dr. Kait Brown [\(01:40:06\)](#):

Thanks, Susan. Yes, so listening to those presentations was incredibly insightful. Hearing the amount of consumers that are turning to online pharmacies, the types of controlled substances that are being acquired through these online pharmacies, and just how many nefarious players there are in that online pharmacy market, and the disparity in consumers being able to identify safe online pharmacies that are legitimate and licensed. And even the gray area that Justin mentioned with litigation over the perception of having a pharmacy that's gone through all the licensed channels and still coming up with issues.

[\(01:40:49\)](#):

One of the things that comes to my mind is thinking about raising consumer awareness and education, I guess, how can we put these data into action? It was really great to see Murray's slides show the One Pill Can Kill campaign and that effect on fentanyl searches specifically, and what that showed me, you didn't really see a dip in overall controlled substances, but fentanyl. So how can we better make the

public aware that other online controlled substances or non-controlled substances may contain dangerous, unlabeled substances? And I'll put that out to anyone on the panel.

Susan Winckler ([01:41:33](#)):

Yeah. So Kate, it is actually a great... Sean, would you like to pick that up and tell us a little bit more about One Pill Can Kill. Kaitlyn, thanks for helping me with my job and the transition there. It was perfect.

Sean Fearn ([01:41:48](#)):

What a setup. Susan, good afternoon and thank you very much for the invitation. My compliments to you and the entire Reagan-Udall Foundation team. Dr. Brown is absolutely right. What DEA has been saying with the One Pill Can Kill awareness campaign is that while fentanyl is our number one focus at DEA, both with the Sinaloa and the Jalisco cartels, any substance can include fentanyl. And so an individual, a consumer who thinks they're buying a legitimate stimulant pharmaceutical substance online, that might not be real if you're not getting that from your licensed doctor through your licensed pharmacy. And that's ultimately the easy call to action that we have, and I would say in response to Dr. Brown and to Murray and Justin and Angie, this is incredibly helpful, good data, and every single individual who's joining the Reagan-Udall Foundation in this meeting today needs to help get your data out there to help bridge public health and public safety.

Susan Winckler ([01:43:00](#)):

Sean, that's helpful, and it strikes me, it's actually resonating with some of the questions that we are seeing. As you noted, the One Pill Can Kill, I think Murray connected that too, we saw a decrease in fentanyl, but we also need to help folks understand that it can be in anything. And what I wanted to note in some of the Q&A we've seen, while we are talking about controlled substances, so these are drugs that we know and we classify in a certain way have a risk of abuse and misuse, there's risk with other components as well. But we focus on these because they're... I guess I should turn to the researchers. I think we see more sale and the illegal access in the controlled substances space. I just want to confirm with the... I know that's what DEA looks at, but Murray, Justin, Angie, just to confirm that, right? It's the premise of the meeting but I need to confirm it with you.

Murray Aitken ([01:44:08](#)):

Well, I would say absolutely, it's the premise of the meeting and clearly controlled substances are a category of their own, but they're not necessarily, they're not the bulk of the drugs that are being accessed through illegal online pharmacies. So there's a lot of hormones of one type or another that are not controlled substances but which we see flowing through these channels, for example, and of course, the obesity drugs have ticked up dramatically in terms of their flow we can see from our modeling data through IOPs as well. So I definitely wouldn't want to leave the impression that IOPs are all about controlled substances, even though clearly, this group of molecules that are controlled poses proportionately greater risk of harm and so on. But this is a broader story. I also think, by the way, in solving the issue, being able to talk about different types of medicines. And recognizing there's different motivations for different types of medicines from the patient perspective is probably a useful way to get some traction rather than trying to solve everything all at once.

Susan Winckler ([01:45:30](#)):

Really helpful. And I think even also instructive, particularly with the anti-obesity products, likely somewhat access and shortage dynamics, which are part of what we see in the controlled substance space.

Murray Aitken ([01:45:48](#)):

Yep.

Susan Winckler ([01:45:48](#)):

So helpful information as we concentrate our conversations today related to controlled substances. Justin, I saw you unmute. So I want to give you the chance to jump in here.

Dr. Justin Macy ([01:46:00](#)):

Yeah. I would say the controlled substance probably aren't the majority of drugs that are sold online.

Susan Winckler ([01:46:04](#)):

Yeah.

Dr. Justin Macy ([01:46:04](#)):

They're the minority, probably. However, they probably have the lowest therapeutic index or they pose the greatest risk of harm across the board. I do think that which controlled substances as well falls in line here too. One thing that I'll flag though is that just because a drug is being advertised as not being a controlled substance, doesn't mean it doesn't contain a controlled substance, right? So if we're thinking about pills that are going to be used, or tablets that are going to be used for weight loss, for example, sibutramine, pulled off the market in the US, it's a controlled substance still probably in a collection of those, historically. And if you look at tainted supplement data along those lines, you've seen that historically show up in them from FDA warning letters and the like as well.

Susan Winckler ([01:46:49](#)):

Yeah. That's an important reminder. And I was struck as we thought here in hearing the data that Angie presented about the many... There's misuse of a lot of technology here to, I guess in a way, take activity that perhaps used to happen physically on a street corner to now happen virtually in the online environment. And it's not just a street corner, but we have to think about that in a different way. So any thoughts about the multiple platform dynamic that Angie shared? Yes, Sean, go ahead.

Sean Fearn ([01:47:40](#)):

Susan, thank you. I would simply reiterate that there is no safe pharmaceutical substance sold on social media sites. And that's part of DEA's message to the public that if you think you're buying a Xanax or an Adderall or an OxyContin through any social media platform, I'm not going to single out any one of them, but if you find that you're going to try and buy it on that social media platform, you are buying something that is not legitimate, that could contain a fentanyl or other substance and has the potential to kill you.

([01:48:14](#)):

And the other thing that Angie's data, the data from the Reagan-Udall Foundation really emphasizes is the age discrepancy between the risk perceptions.

Susan Winckler ([01:48:24](#)):

Yeah.

Sean Fearn ([01:48:25](#)):

Young people live online today. It's one thing that the 40, 50, 60- year olds are going to say, "Yeah, I know not to buy online at a site that's not legitimate." But, again, young people think they're impervious and they'll go... And therefore, efforts to educate young people about the risks of going to social media for substances, whether they think they're legitimate or they're seeking an uncontrolled substance, that's really, really important.

Susan Winckler ([01:48:58](#)):

That's a good reminder as well as helping us think through the messengers who might be most powerful there, right? With a couple of teenagers in my house, I know there's some things that I should say and there's some things that I should distinctly not say, but they need to hear-

Sean Fearn ([01:49:14](#)):

Right. Yeah.

Susan Winckler ([01:49:14](#)):

... and it has to come from someone else. Which then, Kait, I want to turn back to you a little bit only because I would love for us to hear a little bit more about... We know some of the roles of the other players around our squares here, but tell us a little bit about the role of the poison centers and your collaboration and where do the poison centers come into the conversation?

Dr. Kait Brown ([01:49:40](#)):

Right. Yeah, thank you for asking that. So from America's Poison Centers, we are the association for our 55 member poison centers that serve the United States and territories. And over the past year, we've been working closely with our partners at FDA as well as DEA to help facilitate more surveillance about these types of falsified products that may be in the marketplace. So one of the ways that we recognize that we can improve public safety is by acknowledging that these products are in communities. And the National Poison Data System, which receives cases in near real time from poison centers across the country, is a great way to be able to see what anomalies are being detected. And part of that initiative involves really educating our specialists at the poison centers about these products. That's a big step, making sure they're able to ask the right questions and talk to healthcare providers and the public alike to be able to recognize a case that may involve one of these products with acquiring a drug online being one of those, right?

([01:50:45](#)):

And then additionally, we're also trying to bolster our education efforts. So we have a large network of poison centers and educators across the country. So we can really get into communities and impact the knowledge in communities. And then another portion of this is also trying to facilitate information sharing between organizations. FDA becomes aware of a known falsified product problem, DEA becomes aware, our regional poison centers become aware, and we need to better integrate and facilitate that information so we can protect public safety. So the poison centers are there 24/7. They're free service, and they're responding to clinical emergencies, but they are also able to help send signals to protect the greater public health. And that's really what we're trying to do with our partners.

Susan Winckler ([01:51:34](#)):

Right. And I was struck as I heard... If I heard correctly, I think I heard Murray, Justin, and Angie give rather startling numbers about the number of consumers who are using these mechanisms to access medications through the system, which then becomes important for your members to be thinking about that as a source of medications versus just what we may think of as a traditional brick and mortar or even a mail order pharmacy that is legitimately licensed.

Dr. Kait Brown ([01:52:10](#)):

Right. And sometimes our centers do even receive questions about patients who are trying to identify a product or a pill that they have because maybe their prescription bottle fell over and they had a loose pill. But now we know it's an important question to ask. Well, seeing these data, right? That people are trying to identify the pills to verify if they're safe and the right thing, that's another question that our specialists need to add to that layer is was this obtained from an online pharmacy? Because we can't be sure in our identification in that case, right? So really important insights coming from all partners on this call.

Susan Winckler ([01:52:44](#)):

Absolutely. And, Justin, there's a question that I was seeing about when you have... Well, I think it's two part. How do we think about the legitimate versus the illegitimate? And how do the legitimate players avoid becoming suppliers to the illegitimate supply chain? Talk to us a bit about that.

Dr. Justin Macy ([01:53:09](#)):

Yeah. I think it's really important when you're thinking about the illegal pharmacies, especially the stereotypical ones. They're not part of the US supply chain, typically. Often they're diverted products. They're coming from somewhere else. They're substandard or counterfeit, but they're unapproved, things like that. That's typically the case. It's just a completely different divorce supply chain in those instances, or it could be approved in another country to different standards.

([01:53:32](#)):

The one thing I will flag though is what we have seen in our work on DSCSA or the Drug Supply Chain Security Act is making sure that if you are a pharmacy, buying from a authorized wholesaler who's able to do that so you're not buying from someone upstream that may be actually just an illegal online pharmacy player in the illegitimate supply chain, finding out a new way to monetize in bulk, which we've definitely seen those instances. Those things have happened into the domestic supply chain as well through those carryovers. And if you were to ask me if it was likely to be the same actors who were doing it directly to patients as doing it directly to pharmacies, my answer would be, of course, right? No evidence to support it. 100%, no, it's true, right? So as far as the other side of it, if you're a wholesaler and you're thinking about it downstream, less of an issue typically as long as you're selling to legitimate pharmacies and things like that.

Susan Winckler ([01:54:25](#)):

Okay. That's helpful. And, Sean, I thought you raised a hand. So I want to turn to you. And then Angie, Justin, and, Murray, I'm going to come back to each of you quickly to highlight one part of your presentation that you hope everybody heard. Sean.

Sean Fearn ([01:54:43](#)):

Susan, I will be very quick just to respond to your prompt about how we can help prevent the legitimate pharmaceuticals from becoming part of the black market problem. And that's prescription drug take back. Obviously, DEA does Prescription Drug Take Back twice a year. The next one is Saturday, October 26th in 2024, but every day should be take back day. And everybody on this call that's supporting the Reagan-Udall Foundation can help get that word out that when someone has finished with their medication, they dispose of it properly to help keep it from being diverted. Thanks.

Susan Winckler ([01:55:21](#)):

That's a great call out, Sean, and important, right? As we think about in such a daunting problem, and we know a lot of things need to be done, what are some things that each of us as individuals can do to help make sure that we don't, in any way, accidentally contribute to the problem? So, Angie, what do you want to highlight from... And it actually can be what you shared or what you heard someone else share. I'll let you do either.

Dr. Angie Hoth ([01:55:49](#)):

Okay. I think what really struck me is from one of our listening sessions that people found stimulants to be less risky to buy online, and then how to identify whether their medication is fake or legitimate. I think that is really room for education and countering misinformation.

Susan Winckler ([01:56:16](#)):

That's a great point, Angie, that some of the illegitimate product will look really good and still be dangerous, but there's also probably some that won't, and might that be a way to help us distinguish. Justin, what do you want to highlight or underscore?

Dr. Justin Macy ([01:56:38](#)):

Just for consumer information from our end, from an AP, safe.pharmacy. It's really easy to remember as far as a website goes. It has a drug disposal site on it that if you put in a zip code, you can find every drug disposal site that's registered, right? Various things like that. If you put in a website, it'll tell you if it's been accredited by us or whether it's on our not recommended list or whether we don't have any information about it yet. Things like that. Those tools exist and they exist for a reason. We'd like people to leverage these or to get the message out there and help on them. And anything we can do, we're happy to help support.

Susan Winckler ([01:57:09](#)):

Great. And, Justin, to confirm, it's safe.pharmacy?

Dr. Justin Macy ([01:57:13](#)):

That's it. Yep.

Susan Winckler ([01:57:14](#)):

All right. And, Murray, last word before we turn to... We're actually next going to talk about messengers, which I think is going to be so informed by the thoughts that the six of you just shared. So, Murray, what do you want to highlight?

Murray Aitken ([01:57:29](#)):

So my highlight is there are new capabilities that enable us to watch and monitor what's going on, to see the trends, to see the impact of interventions, that decline in fentanyl that we're observing. By the way, we should celebrate some part of that. It's not over, but let's acknowledge the great progress that has been achieved there. But the point is we can apply some modeling and some analytics to this so that we're not entirely in the dark as to what's going on.

Susan Winckler ([01:58:09](#)):

That's a really good point that we should just underscore in all of this when we're talking about research, right? It helps us understand that there are many interventions that need to be made at many points in the system. But then we should also evaluate the impact-

Murray Aitken ([01:58:29](#)):

Right.

Susan Winckler ([01:58:29](#)):

... and focus the resources, and then see... Then I imagine this will also evolve. And so-

Murray Aitken ([01:58:35](#)):

Yeah.

Susan Winckler ([01:58:35](#)):

... track the evolution so that we can help individuals protect themselves and better understand the environment.

Murray Aitken ([01:58:47](#)):

[inaudible 01:58:48].

Susan Winckler ([01:58:49](#)):

What a really informative... You can tell, I'm excited about all the information that you've shared. So appreciate you investing your time with us today and the work that you do day to day. So thank you so much for helping us with the data that helps us better recognize the complexity of the problem and the impact of intervention.

Session 4: Going Beyond the Message

Presenters

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

Erin Stack, MS, Director of Research and Evaluation, Comagine Health

Susan Winckler ([01:59:14](#)):

So with that, I will turn to... I previewed and said we need to talk about messengers next. And so we're going to be bringing two individuals to our stage to talk about message delivery, audiences, and the critical role of providing credible information. And particularly, let's talk about that importance of who is

delivering the message and how that might change for varied audiences. So I'll turn first to Dr. Tim Mackey, who is a professor at the University of California, San Diego. But I think, Dr. Mackey, you're actually joining us from around the world today, if I'm correct. So we'll turn it to you. Thanks so much for joining us.

Dr. Tim Mackey ([02:00:01](#)):

Thanks for having me, Susan. But it's been a great conference so far, and I've really enjoyed the other presentations. I'll get right into the presentation that I'll be focusing on, which is going beyond the obvious in developing strategies for digital prevention of online controlled substance sales. So as mentioned by the other speakers, particularly Dr. [inaudible 02:00:21], we've been through this process of having these online controlled substance summits a number of times and we've made a lot of progress. We've gone from a point of view of trying to understand the problem to understanding who the stakeholders are, to identifying some four areas where we really need to focus on, and now we're at the point where we can talk about creative ideas to address the issue. So it's really exciting to see the progress that we've made over this time and to really get to some substantive issues around digital prevention on these different platforms. And because the internet is so diverse, of course, a lot of those interventions have to be tailored to the particular features of those different forms of access and risk.

([02:01:08](#)):

So what I'll be talking about today is three components, what we know, what we're doing, and what we can do in the future to advance this component of digital prevention of online controlled substance sales. And unfortunately, today what we know is that controlled substance sales are still occurring all over the internet and continue to endanger the public. Just like any public health challenge, a lot of times what we start with is trying to understand the scope of the problem, the characteristics, and aspects of risk.

([02:01:41](#)):

And so this is a report. I'm just going to highlight that we co-authored with the Colorado Attorney General's Office, where we focused on what the risks associated with social media and online controlled substances were. So we provide here an overview of the whole ecosystem and analysis of platform policies and practices that are applicable to substance sales online, and, of course, the federal and state regulatory environment of how that's changing because of all the challenges we've seen over the time of these stakeholder engagements, which started off around controlled substance sales online, but have moved into fentanyl and other substances like xylazine that we talked about before. And then the report also closed with a few recommendations of how we could address the issue from a multi-stakeholder perspective.

([02:02:32](#)):

So again, just like any public health issue, we actually have quite a bit of research and quite a bit of data, understanding the scope of the problem. And now what we have to get into is the more proactive aspects of really trying to change the risk environment for consumers online.

([02:02:49](#)):

So the other thing that's really important that a number of speakers have already talked about is that few of these transactions occur on a single platform. So the important thing to recognize is that we all live in a shared digital risk ecosystem, which includes social media platforms, e-commerce platforms, the internet index websites that have been discussed a lot in this meeting, communication platforms, and, of course, the dark web. And so this is the holistic view of the risk environment that any user could be exposed to. And in order to really address the issue from a complete perspective, we have to have

consistent policy and consistent application of patient safety components across all of these elements of the internet. Because if we do robust enforcement or robust prevention in one space, those drug sales can just go to another space. And indeed, transactions occur over multiple platforms. So if you don't address all of the platforms at the same time, you're really only addressing a partial part of the issue.

[\(02:03:53\)](#):

We also know that digital exposure, meaning exposure to drug selling content, can lead to different forms of risk. And those risks can come from passive to active forms of sourcing drugs online. For example, people may be simply searching for information online that's not drug related or may join an online group. But because of the algorithms or the terms they're using, they may actually get surfaced up content that is from a drug dealer, even though they're not searching for that information. So that passive exposure can be very dangerous for people when it comes to substance use initiation. Also, people may search more actively for no prescription online pharmacies to find sellers that are actively engaged in selling drugs.

[\(02:04:40\)](#):

Other things that happen in this space is that drug dealers often use attractive images, memes, and menus, including things about party pills and party packs to make their products more attractive than other products that are available. And there's a lot of actual innovation, unfortunately, that goes on in this space with drug sellers. And then, of course, there are spaces where users arguably know what they're getting into. They're going to online groups and chats where they have to validate that they're a user or even validate to their identity, and they know that these are active online drug selling marketplaces. So we have different levels of exposure to this content, but also different levels of risk. And we have to understand that in the continuum of this digital risk environment, there are different behaviors that are going on.

[\(02:05:29\)](#):

So what is being done? Some of the things I'll just focus on, and we can do a quick analysis on content moderation, law enforcement action, and a push for platform accountability. So some of the strengths, weaknesses, opportunities, and threats of each of these areas is, of course, content moderation limits digital exposure because it removes content that can be harmful to consumers. But it has weaknesses because there's not really many actual consequences for sellers when their content is removed. So the opportunities are to share signals and build better models on how to detect these sellers and more effectively take that content down. Law enforcement efforts have the ability to disrupt networks in a very holistic way. But because of the length of time and resources you need to prosecute cases, this can be a barrier. And another thing that is an opportunity here is the ability to address more systemic issues such as the precursor trade, which is really about the supply chain component of this problem.

[\(02:06:31\)](#):

And then platform accountability. When platforms change their policies or more actively enforce their policies, they can actually change the risk environment. And that's an amazing transformation that can happen in this space that we're seeing over time. Of course, self-regulation is one weakness and a lack of wide best practices across the industry. There are opportunities and threats in both of these spaces, including policy change, new accountability standards, and advocacy in this space that can be seen as both opportunities and threats depending on which stakeholder you're mentioning. But I think the greatest threat of all of this is that we just don't get much done over this time, and that's something we can't afford to do at this point.

[\(02:07:14\)](#):

So what needs to be done or some of the things that we can focus on moving forward is a whole of internet digital prevention approach to online controlled substance selling. And some three key points I wanted to mention of things we could potentially work on is more proactive detection of signals or things that drug sellers use to sell products online across all of the internet and sharing that intelligence across different platforms, different stakeholders, and different patient advocacy groups. So for example, really doing more dynamic tracking of changes to emojis, code words, marketing and selling tactics that we see change on a month to month basis, and then the general strategies that are used to exploit these different platform features, which are different for each platform.

[\(02:08:02\)](#):

The idea that we could do some form of universal blacklisting where we could share seller information across platforms, some of it public information, some of it information that platforms may have on their own, such as MAC addresses or IP addresses, and then applying very consistent removal and blocking policies so that it really prevents this content from surfacing up to consumers.

[\(02:08:23\)](#):

And then another thing I think that's very important for platforms is understanding that when a drug transaction may occur off a platform, it's still a platform's problem if their platform is being exploited in any way to facilitate that transaction. So a lot of times these transactions are occurring on an encrypted communication application, but the marketing of that seller is happening on a public platform or a public post or comment. And so this is an example, some of the research that we've done, looking at the interactions of drug sellers and their activity across multiple platforms.

[\(02:08:57\)](#):

Another thing we need to do is really understand how and why do users interact with drug sellers. And so this is a study where we constructed drug selling ads and we asked people which ones they found to be more trustworthy. And wanted to really understand the consumer dynamics of why people interact with drug selling content and what their perception is of it. And from here, we know that people have some misperceptions about whether drugs can be sold online illegally or not, and whether if a drug seller is providing a pill bottle where they trust that information more than a different type of image. And then other things like not knowing that perhaps you cannot buy multiple drugs from one particular seller. And from here, we can construct different digital personas to do more precise targeted interventions towards different types of online users instead of just doing a campaign wide or a whole approach, but really looking at it from an individual perspective.

[\(02:09:56\)](#):

And finally, I think what we really need to focus on is developing digital prevention that's as good as drug selling. And what I mean here is that drug dealers often slide into user discussions and tell them about drug availability. So here's an example of a tweet where it says, "I'll never be as happy sober as I am when I'm on Xanax." And then the response from one user is that they have drugs available. So what's missing here is any type of health promotion or prevention to remove this content and then to replace it with harm reduction discussion or anything related to, again, prevention. And there are a lot of great prevention messages out there tailored for different groups such as Song For Charlie. So we really need to spend as much money as we do on precision marketing on removing controlled substances content online and replacing it with health promotion and education. And counter messaging will be very important, I think, in this next phase of addressing this issue. I just want to thank the organizers, and look forward to any discussion we have later on. Thank you.

Susan Winckler [\(02:11:12\)](#):

Excellent. Thanks so much. I'm struck by the point... I think we're going to come back to this quite a bit that we should develop digital prevention that's as good as drug selling. That just puts it right out there. Thanks so much, Tim, for joining us.

[\(02:11:28\)](#):

We have one additional speaker in this section. And so for that, I am going to turn to Dr. Erin Stack, who is director of research and evaluation at Comagine Health. And we're looking forward to hearing your survey results from research in Oregon. I welcome you to the virtual stage, and we're excited to hear from you.

Erin Stack [\(02:11:49\)](#):

Great. Thanks, Susan. Hi, everyone. As mentioned, my name is Erin Stack, and I'm the research and evaluation director at Comagine Health. I'm based in Portland, Oregon. And today I'm going to share information collected from young people about who they trust to tell them about the dangers of fentanyl and counterfeit pills and what information they want to know to help them stay safe. We collected survey and interview data last year from young people, ages 15 to 25, to help us better understand their awareness beliefs and behaviors related to fentanyl and counterfeit pills. The information I'm sharing today comes from the data collected from 897 people completing online surveys and 21 people interviewed. We collected a lot of information from participants during that data collection effort. Today I'm really going to be focusing on messaging.

[\(02:12:41\)](#):

So where and from who are young people currently getting information about fentanyl and counterfeit pills? So that's the current information sources. And then where and from who they would like to get information about fentanyl and counterfeit pills? So that's the trusted information sources. And then what recommendations they have for sharing information? So that sharing information including information content and format. So most frequently, participants indicated getting information about fentanyl and counterfeit pills from the internet, generally, and then from friends and acquaintances. Acquaintances could be thought of as friends of friends or online connections. Less frequently, participants noted teachers, parents, TikTok, TV, and Instagram as places where they're currently getting information.

[\(02:13:29\)](#):

Important to note that healthcare and government agencies, including the state government agency or state health authority, and my state, the Oregon Health Authority listed on this slide as OHA, those entities are pretty low on this list around where people are currently getting information. So you'll see healthcare providers were selected by 27% of participants. And then the Oregon Health Authority is listed there in the lower half selected by 19 participants. And then government generally was there way at the bottom. Only 3% of individuals said that they were getting information about fentanyl or counterfeit pills from the government.

[\(02:14:05\)](#):

When we compared those numbers to where and from who people would like to receive information about fentanyl and counterfeit pills or who they would trust to provide information, these numbers really change. So healthcare providers and the state health authority jump up on the list to the top two. Teachers and parents also float towards the top. This is really highlighting the mismatch between where people are getting information and where they want to get information. Social media entities and government were selected with the least frequency. So you see those starting with Instagram, YouTube, and TikTok at 7%. They were selected with least frequency, but there may be opportunities to partner

and to use social media as a mode of communication while trusted sources are promoted as the deliverers of the message. And I'm going to talk about that a little bit more.

[\(02:14:59\)](#):

As I mentioned, participants shared frequently that they wanted to hear from healthcare experts, specifically people working directly with people with substance use disorder and people with lived and living experience of drug use. So here's a quote to highlight that. I'm going to read using the participant's words, not necessarily words that I would use. So this person said, "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 professionals who know a lot and work firsthand with addicts every day." And MAT, in this instance, stands for Medication Assisted Treatment.

[\(02:15:38\)](#):

So information participants were interested and varied, most likely depending on an individual's experience of substance use, but there were topics that came up frequently that people wanted to know more about. So individuals were especially interested in the forms that fentanyl comes in and what it can be mixed into so they can build up ways to stay safe. There's also quite a bit of interest in short and long-term effects of fentanyl and other drugs on the body. Also, people were very interested in knowing the facts and statistics. Often folks were really interested in very localized information to get a better understanding of how drug use and overdose were impacting their direct community and fentanyl's presence in the local drug supply. So people really had this framing of wanting to know local information so that they could connect with their community.

[\(02:16:26\)](#):

In addition, people noted overdose response training information, including how to identify an overdose and how to respond. So participants or respondents were often very compassionate, really wanting to be helpful, help their friends, help their community, and wanting to know more about what they can do to help.

[\(02:16:43\)](#):

And then finally, here you'll see individuals wanted to know more about the myths and debunking misconceptions. It's following this overall idea of not knowing what information to trust and feeling a bit overwhelmed about the information they are currently receiving. And specifically, I'm just going to share a couple quotes from participants about what they want to know. One participant said, "I'd like to know the forms in which fentanyl comes in so I can be more aware." Another participant said, "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.'" And then the final quote I'll share, this person said, "Adding a layer of education, not only on what fentanyl is, but how to respond to overdose and what healthcare is actually helpful."

[\(02:17:28\)](#):

Participants most often suggested messaging be shared on social media in short content [inaudible 02:17:34]. Some folks did note billboards for information sharing, that they may not always have access to a phone or the internet. Recommendations for formatting content, included tailoring for different age groups and settings, specifically tailoring to populations that are pretty small. So even the age group that we talked to, the 15 to 25, individuals noted that was probably too big of a range and messaging should be really in smaller chunks of age categories. Individuals wanted this information to be quick, easily digestible. Individuals noted having it be nonjudgmental. So avoiding stigmatizing drug use and people who use drugs, but focus on health and community promotions and ways that they can stay safe and they can keep their community safe and their friends. They also wanted more information to be a harm reduction focus instead of only focusing on non-use options.

[\(02:18:27\)](#):

Overall, we learned that young people are really interested and they want to know about fentanyl and pills, and they want to be able to stay safe and keep their friends safe. They shared some specific trusted sources to deliver that information, specifically healthcare providers and state health authorities, and they want the health promotion and harm reduction information and messaging to be where they are, which is social media, and they want it to be quick and nonjudgmental. So based on this information, we encourage strategizing across public health, healthcare, and social media to effectively develop, deliver, and promote messaging that share specific community and health promotion messaging.

[\(02:19:03\)](#):

Thanks, everyone. I just want to shout out all the partners on this work, my colleagues at Comagine Health, our great partnership with Oregon Health and Science University, and our Oregon Health Authority partners. And I'll share, here's a QR code if you want more information. Thank you.

Session 5: Perspectives from the Tech Sector

Panelists

Amanda Plisner, JD, Senior Manager, Proactive Trust and Safety Operations, Snap Inc.

Ernest Voyard, JD, Director, Public Policy, Meta

Susan Winckler [\(02:19:19\)](#):

Fabulous. Thank you so much, Erin. I think your presentation combined with Tim's gives us so much to think about and have as we all think about what it is that we can do, what are the powerful messages. And what I am so inspired by is that the youth who you spoke to, although a wide range, said, "We want to be safe and we want to keep our friends safe. And so how might we do that?" So thank you for sharing your insights. Tim, thank you for sharing yours. I don't know how this has happened, but somehow we are two hours and 24 minutes into our program, and about to turn to the final session. So let's do that. In this final session of today's summit, we are going to hear from representatives of the technology sector about their efforts to prevent the misuse of their services in accessing controlled substances outside of the healthcare system.

[\(02:20:18\)](#):

As our panelists join, I have a regret to note that our representative from Google, Dr. Megan Jones Bell is no longer available to participate in today's session. But I know from conversations we've had before that we are about to have a very productive discussion.

[\(02:20:34\)](#):

So our participants today represent only one component of the technology ecosystem, but we're so thankful that the players in the social space are willing to speak to this challenging topic. And we hope that in the future, we'll have voices from other components of the technology ecosystem, including search engines in the transactional or payment voice. But let's turn to our leaders who are doing important work in this space and who have joined us today.

[\(02:21:01\)](#):

I'm going to turn first to Amanda Plisner. Amanda, if you would tell us a little bit about your role as senior manager for trust and safety operations at Snap, and what actions or programs Snap has been pursuing to protect against the misuse of your services. And I'll note, we might also benefit from some framing about the basic reach and function of Snap Inc. Some of our attendees, I'm going to guess are

more familiar or we have children who are incredibly familiar, but we would benefit from that grounding. Would you pick it up?

Amanda Plisner ([02:21:38](#)):

Absolutely. Thank you, Susan. And thank you to everyone at the FDA who played a role in bringing us together today to continue this important work. As you said, Susan, I'm Amanda Plisner, and I lead Snap's Proactive Safety Operations team, which encompasses our proactive detection, investigations, law enforcement referrals, and third-party intelligence work.

([02:21:57](#)):

Before I dig into some of the things that we're doing to combat the exploitation of our platform by criminals seeking to sell drugs, I'm going to take your cue and provide a truncated version of what I call Snapchat 101.

([02:22:10](#)):

Snapchat was created 12 plus years ago now with the idea that it would be a platform that our community could use to connect and have fun with their friends and family. It was specifically designed to bring people closer to those who matter most to them in real life, and to allow them to communicate in a way that's most similar to the way that they would communicate in real life.

([02:22:28](#)):

This is reflected in specific design decisions, like the fact that when you open the app, it opens to our camera where users can then capture routine moments in their daily lives and share them with their real friends. The emphasis on facilitating connections among real friends rather than meeting new people or connecting with strangers is also why there's no public friend lists and why even our over 18 users, by default, can only communicate with friends or people in their contact book.

([02:22:57](#)):

As far as the reach, more than 800 million people, including 90% of 13 to 24-year-olds in the United States, come to Snapchat each month. And we work hard to make sure that the time that Snapchatters are spending on the platform as is as enjoyable and safe as possible. So to that end, combating the fentanyl epidemic and anti-drug work more broadly has been a priority for us for years now.

([02:23:21](#)):

We approach the problem holistically with teams across Snap working to prevent both the sale and purchase of drugs by educating our community and making the platform hostile to drug sellers. We believe education is a really powerful tool, as we've heard from other participants as well. So this is an area where we have done and continue to do a lot of work.

([02:23:43](#)):

For example, we have a dedicated in-app portal called Heads Up, which shows educational content from experts about the dangers of fentanyl, addiction, and substance abuse to users who search for drug terms in the app. Our expert partners in that content include the Center for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, the Community Anti-Drug Coalitions of America, Truth Initiative, and the Safe Project.

([02:24:10](#)):

Since the launch of that feature of Heads Up, over two and a half million Snapchatters have been proactively served expert content from these organizations. We have also done a special series on fentanyl with Good Luck America, which is our original new show. And we partner with Song for Charlie,

a leading fentanyl awareness organization you heard mentioned just a few minutes ago to run PSAs as well.

[\(02:24:33\)](#):

Now pivoting to some of our efforts to remove bad actors and deter drug sellers from exploiting our platform. This really starts with our policies, which prohibit the use of Snapchat to buy, sell, or facilitate the sale of illicit drugs. However, while we do have simple and intuitive ways for our community to report violations to us, we don't rely on that to identify drug content. Instead, we use a combination of keyword-based detection, computer vision and machine learning to detect that content. We now detect 94% of illicit drug content before our user reports it to us.

[\(02:25:08\)](#):

In addition, because we know the drug dealers often first connect with users on another platform, something we also heard a little bit about just now. We partner with intelligence experts to detect bad actors who advertise on other platforms, but indicate that they plan to continue the conversation, continue communicating on Snap. This allows us to proactively find those users and remove them from our platform. We also engage directly with those other platforms to share signals that help us to intervene in that cross-platform abuse and also to benefit from one another's learnings since we really are and should be in this work together.

[\(02:25:46\)](#):

And one other key component of our work, I want to be sure to mention, is the effective support that we provide for law enforcement and their efforts to take action against illegal activity, including that which might be occurring on our platform. We're dedicated to quickly responding to law enforcement inquiries that we receive, and we also hold the annual law enforcement summits, which are intended to reinforce for law enforcement how they can work with Snap to support their investigations.

[\(02:26:10\)](#):

I want to make sure I'm conscientious of time, so I'll wrap up now just by adding that while we're proud of the work that we do in the space, but we're also very much aware that there continues to be more for us to do both individually and in coordination with partners across industries and across sectors. So we are committed to continuing to do this work and continue the fight.

Susan Winckler [\(02:26:30\)](#):

Amanda, that was so helpful from... If I can recap a bit of your tour there. Right? You had the component of sharing information, so proactively communicating with your users. And then in the enforcing it. Right? Not only having a policy that says, "No. You can't engage in illegal activity." But then accepting the reports, looking for the activity, taking action on it, and then collaborating with others. So really helpful just to kind of understand all that whole continuum that we see in the Snap piece.

[\(02:27:09\)](#):

So let me turn then to Ernest Vyard. Would you provide the same framing but from your role as director of public policy at Meta? And we probably need the same component of remind us about Meta and your reach.

Ernest Vyard [\(02:27:27\)](#):

Oh, no. Great. And I'll go through a bit of that. Thanks, Susan. Great seeing you again. And first thing I want to do is I really want to acknowledge as I get into our policies at Meta. I want to acknowledge that families and communities around the US and really around the world are struggling with the opioid crisis

and that this epidemic really affects every part of our society, and that we must all work together to respond from governments, to the private sector, healthcare systems, to civil society organizations, we must all do our part to combat this crisis, which is why Meta is proud to participate in forums like this with the Reagan-Udall Foundation and the FDA. So thanks you again for inviting us.

[\(02:28:04\)](#):

So a little bit about Meta and a little bit about our efforts in this space. And these are a few of the things that we're doing in this space. We use our policies and technology to really remove this content, to improve our detecting of this content, and to make getting help easier.

[\(02:28:20\)](#):

At Meta, one of the things we've been doing is strengthening our community standards, which outline our policies and are developed in collaboration with our internal teams and external experts. Our community standards make it clear that we prohibit content, whether it's paid content or organic content or content on our common solutions like Facebook Marketplace, that promotes the buying or selling of illicit drugs. And we do our best to remove that content whenever we find it.

[\(02:28:48\)](#):

And from non-medical drugs, we also have policies that remove the content if it admits to the personal use of non-medical drugs without a reference to recovery, treatment or other assistance to combat usage. We also make a lot of efforts to remove accounts that repeatedly violate these policies or otherwise dedicated to drug sales.

[\(02:29:14\)](#):

We are deeply invested in detecting and removing content that violates these policies before people may see it or report it. And in taking action to prevent the misuse of our platforms whenever we see that our policies have been violated. For example, we build products with ways to report that problematic content to us, and then we take steps to make it harder to find this kind of stuff. And we use our technology to try to detect it and remove it proactively whenever we can.

[\(02:29:42\)](#):

At Meta, we really believe that the power that technology can and must be harness to combat this crisis. Across all platforms, people come together through our products to provide vital support, whether it's communities for people who are helping loved ones recover, health professionals who are sharing treatment information or organizations that are combating the stigma that prevents many from seeking help.

[\(02:30:07\)](#):

We support organizations on the front lines who are using technology and social media to bolster their efforts in fighting this crisis that's scourging communities. And similar to Snap, we also provide educational resources. If people try to search for content on our platforms, including directing them to SAMHSA's national helpline because we really want to make finding the vital resources for treatment easier. And just as we do when we are confronting other harms on platform, we work closely with partners across the industry to collaborate on best ways to prevent illicit drug use from proliferating. And I want to mention particularly in this platform, and similar to Snap, in addition to collaborating with industry, we also collaborate with law enforcement, which I think is really important to mention.

[\(02:30:53\)](#):

We routinely respond to legal requests and work closely with law enforcement and emergency responders to help keep people safe on our platform. We proactively cooperate with law enforcement authorities to help combat the sale and distribution of illicit drugs. When we identify a credible threat,

we reach out to law enforcement, and we do that though in accordance with our terms of service and applicable law.

[\(02:31:17\)](#):

And was mentioned earlier, I want to mention some of our collaborative efforts to get better at detecting this content. We're working with several other partners, including Snap, to identify patterns and signs of illicit drug content. And Tim mentioned that earlier in his conversations how important that is. Through this program, we identified novel ways to detect illicit drug content at scale on our platform, and we routinely share these signals back with Snap so that we can independently evaluate these signals and remove drug violating content across our platforms.

[\(02:31:51\)](#):

This work strengthens our ability to find and remove this kind of content from both of our platforms. And as this program develops, we're hoping to engage additional companies to work together and tackle this industry-wide issue. Being cognizant of time, I'll stop there.

Susan Winckler [\(02:32:07\)](#):

So Ernest, that's really helpful and I think hit some of the same components about the detecting, the removing and the proactive education or reaching out and sharing resources. And then I think if I had my word cloud for the piece that keeps emerging here. It's about we heard collaboration a lot. Right?

[\(02:32:31\)](#):

In collaboration with the tech sector, with the public sector and law enforcement, you each mentioned. And then a bit, I would imagine you have some collaborations on community-based organizations as well. Can you share some thoughts about what works in these collaborations?

[\(02:32:52\)](#):

And Ernest, I'll turn to you first and then to you Amanda. So Ernest, any thoughts about if you would emphasize anything in those collaborations, either about them and then what makes them work?

Ernest Voyard [\(02:33:06\)](#):

Yeah. You're right. And we really have focused on collaboration in this space. I mean, this issue really needs all of us across sectors and society to work together. We've long supported organizations on the ground fighting this crisis. And we think that partnering with experts really maximizes our impact and it reduces the stigma, helps raise awareness, helps connect people with resources, and it'll help stop attempts to violate our policies.

[\(02:33:32\)](#):

A couple of highlights I can mention in groups we've worked with and I think things that have worked include working with Mobilize Recovery, which we actually supported since its inception in 2019. And actually the organization was initially incubated as a pilot project under 2019 Facebook Community Leadership program, which was a fellowship to support and fund extraordinary community leaders with the effort of creating real world impact. In 2023, actually, we co-host and Mobilize Recovery DC, which was a summit that brought together more than 600 individuals in recovery from families, advocates, and policymakers from around the country to fight the opioid crisis and overdoses and support recovery.

[\(02:34:19\)](#):

This year, we're actually also supporting the Mobilize Recovery bus tour. It's a Mobilize Recovery bus tour across America and has a plan to stop in 15 cities nationwide to highlight their recovery experiences unique to different regions throughout America. And hopefully we'll see some of you out there.

[\(02:34:37\)](#):

We've also partnered with the Partnership to End Addiction, which is a non-profit leading to transform how the nation addresses addiction with campaigns to help connect parents and guardians and young people with educational resources on prevention and recovery. And according to the Partnership to End Addiction, in the second half of 2023, our campaign reached more than 10 million people with recovery resources in both English and Spanish across our platforms, and it drove about 35,000 people to their risk assessment tools, which help members identify risk factors specific to their loved ones and provide personalized guidance on how to address these risks.

[\(02:35:17\)](#):

Also mentioned earlier in the call was Song For Charlie, and we've been working with them to help support their public awareness campaigns that alert young people and their parents about the dangers of counterfeit pills and fentanyl. And as I mentioned before, I think we both mentioned the fact that if people are searching for content on our platforms, we send them to the SAMHSA National Helpline because really want to make finding these resources easier.

[\(02:35:43\)](#):

And the final thing I want to mention, something that occurred recently, and by recently, I mean about two weeks ago, is that alongside Snap and X, with the help of the US State Department and UNODC, we launched the alliance to prevent online drug harms, which we're also calling the Prevent Alliance.

[\(02:36:01\)](#):

And this public-private partnership is a goal, we plan to harness what all of us have learned and bring it together for a stronger response to the opioid crisis. With the Prevent Alliance, we're working to develop a voluntary framework to lay out how tech companies can share our successful strategies to effectively combat online-related drug harms.

[\(02:36:22\)](#):

In this adversarial environment, we really think that being able to build on one another's successes will enable all of us to move faster to disrupt bad actors. And second, we're hoping to work across industries to prioritize public education, both online and offline, to raise awareness about the dangers of synthetic drugs. We think that by providing reliable information and fostering an open dialogue, we'll be able to empower individuals to make informed decisions and seek help when needed.

[\(02:36:51\)](#):

And then finally, we're hoping to share best practices for the types of campaigns and tools that we're using. We think that these efforts won't only focus on overdose prevention, but also on supporting and offering support to those who are searching for treatment options and ensuring that help is accessible to all those who need it. So I will move on from there.

Susan Winckler [\(02:37:17\)](#):

Ernest, what a number of collaborations, and I want to underscore a piece that we at the foundation have learned and many in this community know, but how important it is to hear the voice of the individual and listen to that and then incorporate it into the activity. So the bus tour that you mentioned and the components very helpful. And then so excited about the recent partnership and that collaboration there.

[\(02:37:48\)](#):

Amanda, would you want to underscore? I feel like, Ernest, if we'd allowed him to have slides, would've had about 11 things there and some of them intersected with Snap. Right? So what would you want to underscore as we talk about collaborations and what works?

Amanda Plisner ([02:38:06](#)):

Yes. So as you know, there is a lot of intersection between the work that Meta is doing and the work that Snap's doing, which is great. That's what we want to see. The platforms banding together to do the right thing, to leverage our respective resources to make an impact.

([02:38:22](#)):

I really can't overemphasize the importance of collaboration and addressing complex, multifactorial problems like the sale of drugs. We at Snap certainly know it's not a problem we can solve alone and we feel privileged to be able to do the work alongside a number of strong partners across industries, across sectors.

([02:38:40](#)):

I briefly talked a little bit about the collaborations that support some of our in-app resources, but we also engage in cross-sector collaborations geared toward raising awareness in other ways. For example, several years ago, we began working with the ad council to develop a national public awareness campaign about the dangers of fentanyl.

([02:38:56](#)):

The campaign now includes other platforms as well and is focused on getting educational materials out to teens, young adults and their caregivers and meeting them where they are. Also, as Ernest mentioned, we recently partnered in the Alliance to Prevent Drug Harms. That being I think a unique experience or unique opportunity to have this public-private partnership to focus not only on disrupting illicit online drug activity, but also the awareness raising and educational components.

([02:39:34](#)):

And what I think really makes a difference and what makes these collaborations so valuable is the exponential impact that we're able to have when diverse stakeholders with varied backgrounds, varied areas of expertise come together in furtherance of that shared goal. Together we're able to do way more than any of us would be able to do on our own.

Susan Winckler ([02:39:55](#)):

And I think inherently we think about that as we're considering collaboration that it's a force multiplier, but I don't know that we always underscore that. So Amanda, I appreciate you raising, facilitating all of that, making sure that we're thinking about the collaboration and how that lets us do more is important, and then helps with the ecosystem and what we're trying to share here.

([02:40:26](#)):

So we have time for another question. So I'm going to do one more, and then I would say also if there's anything that you want to underscore in what you've already said, it never hurts to emphasize and highlight that. But let's do the question. This has to do with the pace of technology change, particularly in communications and facilitating interaction, which I have to say there is such benefit from your platform that it's also helpful that you're addressing this component where there's the misuse of the platform.

([02:41:01](#)):

But we've also seen a lot of change in technology. In our prep call, I mentioned to you that my rising high schooler can't believe that her older brother couldn't use ChatGPT to help him with his English. That's just a technology change. We don't let her do it either, but it's a technology change that she thinks is amazing.

[\(02:41:22\)](#):

What technology changes or challenges, what should we be thinking about that might present new challenges or new opportunities as we're thinking about addressing the misuse of your services to facilitate illegal access? Is there something on the horizon that we should be thinking about? Amanda, I'll turn to you first.

Amanda Plisner [\(02:41:47\)](#):

Sure. The challenge or one of the challenges that we should be thinking about, and I wouldn't necessarily call it a new challenge, is how we'll keep up with the inevitable evolution in the way that drug sellers operate online. We heard this discussed a little bit earlier, but at its core this is a financially motivated crime. And those engaged in it are highly incentivized to be persistent.

[\(02:42:08\)](#):

So we'll have to continue to work just as hard, just as long, and with just as much persistence as the bad actors who we're combating are. We also need to be careful not to have blinders on that allow new trends to evade us while we're focused on the problems that we're already familiar with and hard at work to address. I've mentioned this already, but I'll say it again to underscore it as you say, Susan, that we'll always have more work to do and we need to continue to do it well. And with the same degree of enthusiasm and commitment that we have been. We really can't take our foot off the gas if we want to keep up in advance beyond the drug sellers who we're up against.

Susan Winckler [\(02:42:53\)](#):

Right. And that's maybe a piece that we have not said enough about today, but we should remember that this is a financial. Right? There's financial benefit in the illegal activity, and so they're incentivized to as much as we are all incentivized to say, "We need to engage and shut this down." They're incentivized to find a way around what we might do. So keeping our eye on that and continuing to do the research.

[\(02:43:27\)](#):

Ernest, I'll turn to you for the same thing. We now are reminded we have to keep track of all the new ways that bad actors will try to defeat our collaboration and the work that we do to prevent their activity. What would you raise as new challenges or new opportunities and what would you highlight?

Ernest Voyard [\(02:43:47\)](#):

Yeah. I mean, I wish I could predict the changes that are on the horizon, and that's one of the challenges that we have. But what I do know is that at Meta, and I'm sure at Snap and across that we're going to continue to continue invest in technologies to keep the illicit drugs and sales off our platforms. We're going to keep working on raising awareness. We're going to keep working on increasing education to combat the dangers of drug misuse. And we're going to keep working at connecting people with help and resources.

[\(02:44:17\)](#):

Now we can't lose sight of the fact that this challenge is bigger than any single platform, is bigger than any single industry, and that we need to continue to collaborate with each other, with governments,

with other organizations, health experts, researchers, and our peers at other tech companies to tackle these issues.

[\(02:44:33\)](#):

I mean, I'll sound like a broken record, but I'm really excited about the Prevent Alliance and I'm excited that we signed on. And I really think that that's where the future is. That as we work together, it'll strengthen our ability to really respond to this crisis. And that's probably where I would focus is that we need to keep working together.

Susan Winckler [\(02:44:50\)](#):

Yeah. That's fabulous. And a good reminder of that resource. And I want to make sure I got it. It's the Prevent Alliance?

Ernest Voyard [\(02:45:00\)](#):

Prevent Alliance is our shortened term for it. Yeah.

Susan Winckler [\(02:45:01\)](#):

That's right. It was longer. Give me the longer one again, because it involves both your organizations. Right?

Ernest Voyard [\(02:45:06\)](#):

Yeah.

Susan Winckler [\(02:45:06\)](#):

Yeah.

Ernest Voyard [\(02:45:07\)](#):

Yes. It's the Alliance to Prevent Online Drug Harms, and it's currently Snap, Meta and X.

Susan Winckler [\(02:45:13\)](#):

Excellent. So the Alliance to Prevent Online Drug Harms really helpful and I so appreciate both of you joining us today to talk through and help us understand what you are doing, what works, where the collaborations are helpful, and the efforts that you're taking to work with each other in the tech sector, to work with the public sector, to work with other organizations in the private sector.

[\(02:45:46\)](#):

This part is giving me hope because you're doing work and you recognize that there's a challenge and are taking efforts to improve the environment and keep your platform safe and productive and not the street corners that we were talking about earlier.

[\(02:46:08\)](#):

So thank you for the work that you do today and for... Well, I guess we've already laid out, there's going to be work to do tomorrow and to keep pace with the illegal actors and to try and keep their activity off the platforms. And then I do have to say, you have both perfected your sound bites so well that we're going to be able to turn to our FDA partner like two minutes early, which never happens in these meetings.

[\(02:46:39\)](#):

So we really appreciate both of you investing your time today and to helping us think through what you're doing, what works well, and then for sure the Prevent Alliance, we'll make sure that folks can see that in the chat. So thank you for your efforts and for joining us today.

Ernest Voyard [\(02:47:00\)](#):

Thank you.

Amanda Plisner [\(02:47:02\)](#):

Thank you. Bye-bye.

Closing Remarks

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

Susan Winckler [\(02:47:05\)](#):

And so let me say it is now time to think and reflect on what we've been hearing about for the last two hours and 52 minutes to think through what we've learned about the environment for the online sale of controlled substances, the impact, what we're seeing in the research.

[\(02:47:27\)](#):

And so I want to close out today's meeting by turning to Dr. Marta Sokolowska, the Deputy Center Director for Substance Use and Behavioral Health in the Center for Drug Evaluation and Research at FDA.

[\(02:47:42\)](#):

Marta, that's where you set the strategic leadership for the center's work related to controlled substances and substance use. I think it's an understatement to note that we've had a robust conversation and learning today. As we turn to close out the public meeting, what would you share as final thoughts and takeaways and things that we should be considering?

Dr. Marta Sokolowska [\(02:48:06\)](#):

So first of all, let me say big thank you to everyone for making this insightful and interesting workshop. We have learned a lot. We've heard a lot throughout the last few hours. And in the next few minutes, I wanted to just summarize some of the key messages that we've heard from our presenters and panelists.

[\(02:48:32\)](#):

So my first takeaway in this summit is that it provided an opportunity to hear a wide range of perspective, which is so critical when we are trying to address this broad problem.

[\(02:48:45\)](#):

In our opening remarks and first session, we've heard about the work that FDA is doing to protect the public from unapproved, diverted, or counterfeit drugs presenting overdose risks. In our real world session, we've heard the perspectives of people with lived experiences and professionals in the healthcare and social work fields.

[\(02:49:08\)](#):

Our speakers emphasized the different kinds of risks associated with purchasing controlled substances online. They also highlighted the importance of understanding the different motivations for why people might purchase online, pursue the online purchases of controlled substances. And the facilitators then make these purchases far too easy. It's critical we understand those if we really want to address those issues.

[\(02:49:36\)](#):

In our third session, we've heard a snapshot of a data on growth in illicit online pharmacies and the analysis on websites selling prescription medications online without licenses. We also heard about perceptions and behaviors from American consumers who are purchasing controlled substances online and examples of strategies to help consumers make safer choices such as take-back days.

[\(02:50:05\)](#):

In our fourth session, we've heard about importance of matching the right message with the right messengers, and it's so critical. We also heard a proposal for a whole-of-internet approach to digital prevention as well as research on strategies for tailoring the messaging in terms of information and format.

[\(02:50:28\)](#):

And in our fifth session, we've heard perspective from the tech sector about critical role of partnership and collaboration between platforms, including new effort with the United Nations Office on Drug and Crimes.

[\(02:50:43\)](#):

So throughout these sessions, there are a few common threats. First, any controlled substances online from any platform other than a licensed pharmacy can be dangerous. Simply put, consumers don't know what they are purchasing no matter how it's advertised.

[\(02:51:06\)](#):

Second solutions, it's not as simple as telling consumers not to purchase controlled substances online. We need to do more and we need to emphasize the importance of collaboration across the different sectors. And this work that you have done so far, Susan and others from RUF, FDA, the panelists, presenters and public, it's going to help us to get that.

[\(02:51:32\)](#):

So with that, on behalf of FDA, I wanted to thank everyone for all your great work so far and the input that you have made to help us do the solutions.

Susan Winckler [\(02:51:44\)](#):

Marta, thank you so much. In working with your colleagues to say that we should have this kind of public discussion of this challenge and to go through, and have that discussion of the day. So we appreciate you recapping, you recapped the day so well that we have a good sense of where it is and what it is that we need to do moving forward.

[\(02:52:14\)](#):

And so with that, I will say I want to thank everyone who joined us. Thank every one of our speakers. Each of you contributed something to this informative dialogue and helping us understand more about the issue so that we can do more to address the issue.

[\(02:52:34\)](#):

We hope that today's discussion answered many of your questions on the sale and purchase of controlled substances online, its potential risks and what the future direction and collaboration might take between both public and private stakeholders. But I think the bottom line here is we still have much to do in this arena. Each of us can do something and collectively, we can do more.

[\(02:52:59\)](#):

Thank you for joining us today, and I hope that you have a productive rest of your day. Take care.